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**The Re-Interpretation of the Professional Responsibilities of
Pharmacists**

Kenneth Mullan

**Thesis submitted for the degree of Doctor of Philosophy
University of Glasgow**

October 2001

Abstract

From a distinguished profession, highly trained in the manufacture and compounding of medicinal drug products, exercising absolute autonomy in health care practice, and with a central role in national health care provision, the pharmacy profession had, by the end of the twentieth century, spiralled into the role of a limited distributor of pre-prepared medicinal drug products, and despite retaining a graduate status, with little or no independence of judgement.

Extensive analysis undertaken by the pharmacy profession has resulted in agreement that pharmacists needed to adopt some sort of new or "extended" role. That role should be one which builds upon the existing expertise of the pharmacist in relation to drugs and drug therapy but which would see the pharmacist becoming more actively and directly involved in patient care. As a result, pharmacy is now expanding into new areas beyond those traditionally expected of the profession and, it is now accepted that the term 'pharmaceutical care' is appropriate to define pharmacy's new mission.

The aspirations of the profession towards a recognition of its contribution to health care, the role of the pharmacist within the health care team, and the ability of the profession to adapt, and re-evaluate its benefit to drug therapy, developed in a cohesive and structured manner over a period of three decades, has necessitated a parallel acknowledgement by the judiciary of the relevance of that role.

An analysis of judicial attitudes in the United States of America towards pharmacist responsibility has shown distinct patterns or trends. Early cases set the standards for pharmacists at a high professional level. The courts later restricted liability to technical inaccuracy in prescription processing. More recently, the judiciary is recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions. A legislative gloss to these developments has been provided in the United States of America by the enactment of legislation which seeks to recognise professional roles, enhance pharmacy practice standards, and improve the outcome of drug therapy for patients, by bettering patient compliance with drug regimes.

There is a current expectation, particularly on the part of the public, but also on the part of health care policy makers, that pharmacists have a responsibility to detect problems with prescribed medications, and that to fail in this responsibility is a direct threat to the public health. The new expectations of drug therapy and the parallel anticipations of the participants in drug therapy have created a new duty on the part of the pharmacist, to intervene and promote the patient's best interests.

In this thesis, it is argued that this perspective is a reasonable one. Pharmacists ought to detect and prevent problems with drug therapy. The public should be disappointed if a profession, a government-sanctioned monopoly, has the ability to improve the public health but fails to do so. In turn, courts (and a legislature) that refuse to recognise expanded responsibilities for pharmacists, and that fail to impose corresponding expanded liabilities for the failure to meet a responsibility, are perpetuating an outdated view of pharmacy practice based on an incomplete understanding of the medication use system. There are solid policy reasons for

imposing a higher standard for pharmacists that includes, but goes beyond, mere technical accuracy in order processing. In turn, there are limits to what pharmacists can reasonably be expected to do, and a legal system exploring the subject of expanded pharmacist responsibility should be aware of those limits.

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An Historical Review of the Role and Functions of the Pharmacist in the Health Care System

Purpose

This chapter seeks to review, historically, the functions and roles of the pharmacist in the health care system. It seeks to show the significant changes which have occurred in those roles over time due to factors largely outside the control of the pharmacy profession. It will conclude by determining the position of the pharmacy profession in the health care system as it exists in the latter part of the twentieth century.

Early History

The early history of pharmacy is necessarily linked with the early history of medicine. Disease and its treatment were a mystery to the very early civilisations. It has been argued that it must have been a shocking mystery to early man coming with such force and lack of explanation that he thought to counteract these supernatural forces with magic (Singer and Underwood 1962, Cowen 1962 and Gerrard 1965).

It is possible to trace the history of pharmacy back to biblical times and beyond (Sonnedecker 1976, Matthews 1962, Poynter 1965, Palmer, 1986). The Book of Ecclesiastics states:

"The physician is worthy of honour and his skill is to be admired. With medicines he doth heal a man and take away his pain and of such medicines doth the apothecary makke a healing ointment"

This quotation demonstrates that the current division of labour within health care between medical practitioners and pharmacists was recognised at an early stage. The division was inspired by the early physicians who were anxious to retain for themselves the twin roles of diagnosis and treatment and who could see the advantages of allowing their assistants to prepare medicines - a role which they regarded as menial. Whilst this division may not have been explicitly recognised it has been argued that pharmacists have been struggling since to maintain the integrity of the profession in light of this perceived division (Brushwood 1988). As we shall see, the enactment of legislation for the pharmacy profession has often proved to be the battleground where this question of integrity has been fought. The intent of the legislation was often to defeat the claims of others to be recognised as members of the growing profession of pharmacy rather than the promotion of the aims of the profession itself (Holloway 1991).

The early developments in the history of pharmacy and the debt which pharmacy owes to early civilisations have been well documented (Trease 1964, Sonnedecker 1976, Mez-Mangold 1971, Clark 1961). In the river valleys of the Nile Tigris and Euphrates, medicine was seen as an integral part of religious ideology - healing being regarded as a purification or catharsis of the divine punishment of illness (Cowen 1962). Sonnedecker (1976:4 and 479) in describing this development indicates that the early Greek word *Pharmakon*:

"developed from that of a charm or magic agency, exerted by means of plants with healing but also with poisoning effect to that of a remedy without any collateral significance. Often the designation was restricted to purgatives in a real as well as a figurative sense."

As well as using this appeal to "magic" early civilisations including those of Babylonia-Assyria, Mesopotamia, ancient Egypt and early Greece were also well aware of the positive qualities of a number of natural occurring substances including vegetable and mineral drugs which together with other substances could be prepared to formulate healing drugs. It has been indicated that whilst it was clear that the Babylonian-Assyrians recognised a separate group of preparers of medicine their true function in health care has not generally been known (Thompson 1962).

Much more is known about the development of medicine in the ancient Egyptian society due to the fact that Egyptians wrote down many of the quantitative contents of their preparations and the uses to which they could be put and examples of these and the tools and instruments used in the formulation of such products have been discovered. Despite this it remains unclear whether a separate role developed for pharmacists. Sonnedecker (1976:10-11) refers to the conflicting evidence given by Jonckheere (1955) and Sigerist (1955). Sigerist was of the belief that ancient Egypt had no pharmacist - the physician compounding for himself from his own or centrally located stores of ingredients or delegating the task to his servants while Jonckheere was of the opinion that two groups of pharmacy personnel existed, both specialist-functionaries and technical servants. The debate is important to the extent that it is intended to explore the development of a separate role for the profession of pharmacy. At this stage, what was clear was that the use of formulated and prepared drug products was well recognised as being beneficial to the expansion of a well developed health care system.

The development of health care continued and indeed expanded through the Greek, Roman and Arabian periods. The developments in Greece were tied in with their theory of basing culture on individuality. The emergence of philosophy and of a variety of schools of thought on the subject

brought with it the development of the notion of a rational explanation of nature and its phenomena . Such rational explanation extended to the practice of medicine. Aristotle, Pythagoras (Ackernecht 1982:52), proponents of a four element theory of explanation of nature and its phenomena, were responsible for the belief that pharmacy - the choosing of specific naturally occurring substances and their compounding into healing preparations - had to be influenced by astrology in the same way that most happenings on earth could be influenced by the gods through the planets (Sonnedecker 1976:14-15, Ackerknecht 1982, Singer and Underwood 1962 and Clark 1961).

Hippocrates extended the notion of the four element theory to a parallel concept of four humours. Harmony or disharmony of these humours was the main cause of health or sickness. Nature would provide the healing power for any sickness but there was to be no reason why drugs naturally occurring in nature could not be employed to assist in that process. Again, however, the notion of individuality, as espoused generally by the Greeks, was to the fore in the Hippocratic tradition of medical treatment. Each individual was to be treated as an individual and peculiar unit.

Hippocratic theories were extended throughout the Greek civilisation, with, at times, a greater emphasis being placed on the use of drugs. Ackerknecht (1982:66) gives a chronological table of a variety of medical sects. At the same time as Hippocrates was propounding his four humour theory, the Greeks still maintained an expertise in the use of medicinal plants. Foremost amongst these experts was Dioscorides whose classification of plants and their use in medicine resulted in the publication of early treatises on materia medica which are held to be classic texts in the development of pharmacy (Sonnedecker 1976, Mez-Gold 1971 and Ackerknecht 1982, Trease

1964).

The contribution of the Greek era lies essentially in the advancement of the knowledge of drugs, the refinement of techniques and the development of scientific medical thought and practice. Greek tradition spilled over into Roman society, The Hippocratic tradition had been continued through the development of the Alexandrian School (Mez-Mangold 1971 and Ackerknecht 1982). At this stage many Greek physicians moved to Rome and other parts of the expanding Roman Empire (Trease 1964:7). Indeed many of the best known practitioners of medicine in Greek society, including Dioscorides and Galen, were to be found in Rome and were to find like minds there, although there was an initial opposition to them. Ackerknecht (1982:69) argues that the firm establishment of Greek traditions in medicine in Rome was brought about by the influence of Asclepiades in the last century before the birth of Christ. The Romans were quite content to utilise Greek expertise in the practice of medicine preferring to devote their own labours to the development of expertise in the areas of law, government, architecture and war. Before the arrival of the Greek tradition in medicine, the Romans were prepared to rely on religion and superstition as the main source of remedy for disease and illness although they had made indirect contributions to health care in a number of other ways e.g. sewage, water supplies, bathing and heating for the home (Trease 1964 and Ackerknecht 1982). The Greek influence led to an improvement in the status of medicine in Roman society.

The work of Galen provides a prime example of the influence of the Greeks in Roman medicine. He was prepared to accept the Hippocratic tradition of the four humours but was also prepared to state that if specific diseases could be attributed to imbalances within the humours (Hippocratic harmony and disharmony) then drugs could be classified which would counteract the specific

imbalances, arranged according to the number of qualities which they were stated to have. "Simples" were described as having one quality, "composites" had several qualities whilst "entities" did not have one or more specific qualities but were effective through their whole substance (Sonnedecker 1976:19 and Mez-ManGold 1971). Galen was aware of the dangers of adulteration of drugs and kept stocks of drugs, obtained from all parts of the known world, for himself (Trease 1964:10)

Galen's contribution was to bring an order to the classification of medicinal products and their application to medical treatment. Galenic physicians prepared these products themselves although there had emerged a group of preparers of medicines who specialised in the compounding of medicines. The physician maintained his primary role in medical treatment by remaining in charge of the application of the prepared medicines and for ensuring that they were properly compounded. These preparers of medicines were given a variety of names in Greece including *pharmakopoli*, *rhizotomoi* and *seplasiarii*. It has been argued that the fact that so many groups of preparers of medicines existed is evidence that there was no real separation or distinction of specialities between practitioners of medicine and pharmacists at the height of the Greek developments (Sonnedecker 1976:20). On the other hand, it is possible to argue that some physicians were prepared to hand over the function of gathering and compounding medicinal products and that this is an early recognition of a role for such an expert within health care.

The aspirations of the Romans in the field of war led to the invasion of a variety of countries throughout Europe and beyond. It was natural that when conquered, these countries would be subjected to Roman influences and traditions. Many Greek physicians, including Dioscorides,

were in fact employed as army surgeons in a well organised system of army health care and their experience in the practice of medicine followed the Roman armies in their conquests.

The Roman invasion of Britain ensured that the Greco-Roman influence over medicine reached this country. There is a strong argument that the Roman invasion of Great Britain was the main source of inspiration for the development of health care techniques in the Anglo-Saxon, Norman and Medieval periods although distinct specialisation may not yet have commenced (Matthews 1962, Trease 1964). It is known that trade existed between Britain and Rome - the Romans being anxious to export the rich ore and mineral deposits to home and were keen to ensure that the drugs and other items used by Galen and other Greco-Roman physicians were available in Britain (Trease 1965:35). Although there remains little direct evidence of the Greco-Roman tradition in medicine (Matthews 1962:1), it may be surmised that, as the Roman armies had a well-developed health care system and army surgeons and physicians trained in the Galenic way and given the continued two-way trade, the tradition was well founded and its influences remain.

The Roman Empire began to break up around the fourth and fifth centuries A.D.. The weakening of the Empire led to its successful invasion by a number of different groups. The refounding of Byzantium under the name of Constantinople led to that area becoming the main centre of drug trade. Trease (1964:12), Sonnedecker (1976:23) and Mez-Mangold (1971:39-49) describe the importance of Constantinople for the continued development of medicine and the fact that the banishment of Nestorius from Constantinople led to the development of a Greco-Roman tradition in the Arabic countries and in the Arabic language. The followers of Nestorius continued with their tradition of translating the works of Plato, Aristotle, Hippocrates, Galen and Dioscorides and developing the ideas contained in their works.

That tradition expanded with the successful invasion of a number of countries and the establishment of an Arabian Empire. Arabian medicine, developed in line with an emerging intellectualism, although based on the works of Plato, Aristotle, Hippocrates, Galen and Dioscorides, began to flourish in its own right. A number of prominent Arabian physicians and authors are mentioned by Sonnedecker (1976:23-26), Trease (1964:14-15) and Mez-Mangold (1971:12). Their works, although concerned to continue traditional authority and dogma, made significant contributions on four main fronts - formulas and compendiums, herbals and texts on materia medica, treatises on toxicology and diet and drug therapy (Sonnedecker, *ibid*).

Arabian medicine made significant contributions to the practice of modern pharmacy (Sonnedecker 1976 and Mez-Mangold 1971). The contributions lay in the areas of pharmaceuticals - the introduction and refinement of evaporation, filtration and distillation techniques - and the description of a number of significant drug products. These developments combined with an increased awareness of the requirement of official responsibility for public health led directly to the establishment of the first health care system where pharmacy was recognised as a distinctive profession capable of making its own significant contributions. Specialist apothecary shops emerged which were subject to inspection and regulation and dispensaries were attached to emerging hospitals. The profession of pharmacy had come to be recognised as involving a recognition of the distinctive elements of the materia medica and compounding medications according to the prescriptions of physicians. It is easy to recognise how the development of those dual functions made such a contribution to the practice of modern pharmacy.

The period which followed the break up of the Roman Empire throughout Europe is often referred to as the Dark Ages. This period saw a decline in the ordered practice of medicine with resultant destructive epidemics (Trease 1964:12). The practice of medicine by lay persons once again became based on superstition, magic and folklore. The orthodox practice of medicine fell into the hands of the Church. This was largely due to the fact that the invading forces were anxious to put an end to the development of culture. All study was therefore restricted to the safe haven of the Church. As a result any systematic study of medicine was also restricted to the realm of the Church and became known as Monastic Medicine.

The fact that there was systematic study did not necessarily mean that such study was scientific. Monastic Medicine placed a heavy reliance on faith as the principal method whereby illness could be cured (Sonnedecker 1976, Trease 1964 and Clark 1961). Whilst having to rely on accounts of the ancient works and treatises on medicine due to the unavailability of copies of the manuscripts themselves and whilst certain ancient manuscripts were of little use in that they could not be translated, Monastic Medicine did, nonetheless, produce some medical treatises principally concerned with the treatment of certain illnesses and diseases. At the same time, however, a trend developed to rely on the growing expertise provided by the Greco-Arabic tradition.

That trend was developing in depth at the School of Salerno founded in or around the 8th Century (Sonnedecker 1976, Trease 1964 and Singer and Underwood 1962) and reaching its zenith in the 11th to 13th Centuries. The development of the Arabic influence in the School was increased by the arrival there of Constantine who had undertaken significant Latin translations of Arabic manuscripts. This new knowledge when combined with existing copies of the ancient Roman and

Greek works allowed the scientific study of medicine to re-emerge from the shadow of the Dark Ages.

As has been said, a number of significant texts emerged from the School of Salerno some of which had a direct relevance to the continued development of the pharmacy profession. That development continued when the invention of the printing process allowed for the wide dissemination of pharmaceutical works. At the same time the store of knowledge on medical and related matters was being added to by the recommencement of study of philosophy and science even in the wake of uninformed opposition to such learning (Sonnedecker 1976:33). That development was eventually to lead to the establishment of Universities and other Schools of Learning.

In the meantime, a significant event in the history of the profession was taking place in Germany. At the court of Frederick II was a court apothecary, Michael Scot, who was also involved in the translation into Latin of the main Arabic works of medicine and pharmacy. In or around 1240, Frederick II, no doubt due to the influence of Scot at his court, issued an edict which was to have a profound effect on the development of the pharmacy profession (Sonnedecker 1976, Trease 1964 and Smith 1986).

Three regulations contained in the edict were of specific significance:

- (1) The separation of the pharmacy profession from the medical profession;
- (2) Official supervision of pharmaceutical practice;

- (3) Obligation by oath to prepare drugs reliably, according to skilled art, and in a uniform, suitable quality.

Sonnedecker (1976:35) suggests that this edict must mean that a well developed system of public pharmacies must have existed by that time. The origin of these pharmacies is unclear. However it is likely that they developed either from monastic dispensaries or from stores in which the trade with drugs had become specialised. The monastic dispensaries were open to the public and eventually were taken over as private concerns - the forerunner to the modern pharmacy practice.

Two other minor regulations of Frederick II's edict are worthy of mention:

- (4) The limitation of the number of pharmacies within a designated geographic and political entity;
- (5) The fixing of the prices of drugs by the government.

It has been correctly suggested that these two regulations have a more profound effect on the development of the practice of pharmacy within European countries than on other Anglo-Saxon countries, including the United States of America (Smith, 1986:4).

The development of the pharmacy profession in Europe was to continue along the basis provided for in Frederick II's edict. The role of the pharmacist as an established and distinct member of the health care team was established by that edict. For example, Trease (1964:47) refers to the fact that by the middle of the thirteenth century the profession of pharmacy was strictly controlled by

legislation in Sicily. What was to continue that development in Europe was not controversy over the role that the pharmacist was to play within the health care team - a question, as will be seen, which was to dominate the development of the pharmacy profession within Britain - but rather the continuing changes within the nature of drugs themselves and their effect on the treatment of illness and disease.

The particular conclusion which might be drawn at this stage of the discussion of roles and functions is that by the time of the edict of Frederick II, a separate role for the pharmacy profession had been recognised. That separation of function was almost unique to the European Countries. It would be quite some time before a similar division of labour was officially recognised within Britain.

Developments within Britain

In Britain similar invasions were taking place in the wake of the evacuation of the Romans. As a result, there was little amalgamation of groups within the country until the Norman invasion in the 11th century. It has been suggested that a direct consequence of the delayed amalgamation of groups of peoples was a parallel delay in the development of professions in general and the health care professions in particular (Smith, 1986:4-5 and Sonnedecker, 1976:100). This, as we have seen, was the opposite of developments which were taking place in the rest of Europe.

During the early part of the Middle Ages in Britain, prior to the eventual amalgamation of the various tribes and groups within Britain, the practice of medicine once again reverted to a practice based on superstition and magic whether practised by lay persons or by the Church.

Monastic Medicine, based on the development of that mode of practice throughout the rest of Europe, did flourish for a time and several texts, including herbals, based on the classic Greco-Roman practitioners were published towards the end of the Middle Ages (Matthews 1962:10-27). It is well recognised that pharmacy work was carried out in the hospitals attached to monasteries, mainly compounding (Trease, 1964:40).

However Trease (1964:42) is of the opinion that the development of pharmacy monastic medicine was relatively unimportant. No separate profession of apothecary had emerged or was likely to emerge. Rather the function of physician, apothecary and surgeon were carried out by the same person. In Trease's view the real origins of pharmacy lay in the growing development of a trading community. Trade with Continental Europe had continued from Roman times and began to take on a greater significance after the Norman invasion and the Crusades.

Trading and the Guild System

Those returning to Britain from Europe and beyond brought with them a thirst for knowledge and culture available in other countries. There was a recognition that Britain had not emerged from the Dark Ages in the same way as its European counterparts. In addition there was a requirement for the importation of delicacies and luxuries which had been found on Continental Europe. To begin with, this involved mainly the importation of wine but soon other commodities were being introduced under the headings of "mercery" and "spicery". Although there are some difficulties over the definition of the term spicery, it appeared to include materials, mainly of vegetable origin, often from the East or countries bordering the Mediterranean and of high value in relation to their weight (Trease, 1964:43-44 and Sonnedecker 1976:100). Spicery certainly included drugs

and medicines.

Spicery in Britain was dealt with by traders known as Spicers and Pepperers. Original traders in spice were to be found at the Mediterranean seaboard where they were known as pevriers and epiciers. Because of the increase in trade between the Mediterranean area and Britain these traders were soon established in London. It would appear that the essential difference between Spicers and Pepperers was that the latter were importers and wholesalers of spicery while the former were retailers who sold their stock in trade from booths at fairs or, eventually, in permanent shops. Trease (1964: 44-45) is able to date the development of the twin trades of Spicer and Pepperer from the fact that surnames deriving from the terms had begun to emerge in the 12th century and that Guilds representing those trades had also been mentioned in historical records of the time. Matthews (1962:31) points to the fact that the Guild of Pepperers are recorded in 1180 as having been fined for the establishment of a Guild without royal licence.

The Guild System

The development of increased trade brought with it a parallel development of the Guild System as traders and merchants began to take on an increasing importance. Guilds or Gilds were well known throughout the rest of Europe and traders dealing there could see the advantages of collective organisation to achieve common goals (Matthews 1962:29-33). As well as seeking to protect commercial concerns, the Guilds had also an important religious dimension. Indeed it has been argued that, initially, the primary concern of the Guilds was the development of their religious and charitable functions - including the provision of funds for burial rites and masses - and that the trend towards the protection of trade and commercial interests only developed later

(Gerrard 1965:1 and Trease 1964:61).

That trend developed as those members of the same trade tended to live within the same locality in London, initially and, eventually, in other provincial towns. To begin with the guilds were known as merchants' guilds but when these were deemed incapable of protecting commercial interests they were overtaken by new craft guilds. Each craft guild usually had three levels of membership - apprentices, journeymen and master craftsmen. Guilds attempted to guard their reputation and membership from non-qualified outsiders by introducing forms of examinations or other tests which would ensure that only those with the requisite knowledge and skill within the craft would become master craftsmen. The Guilds made significant contributions to the development of London and other towns in which they were organised (Matthews 1962:29-30). Trease (1964:55-56) mentions a number of Spicers who were Mayors or other officials of a number of towns in England.

Spicers and Pepperers Guilds

Both the Spicers and the Pepperers, as important traders and merchants, formed their own Guilds as part of the ongoing process of the development of Guilds to protect trade and commercial interests. Some Spicers began to specialise in the dispensing and compounding of medicines and began to take on the mantle of **Apothecary** although this term was often used interchangeably with that of Spicer. This specialisation was due in part to the friction which arose due to the restriction in practice which was imposed by certain of the Guilds (Matthews 1962:32). The Spicers also maintained close links with the Grocers - known as merchants selling by weight but in reality another form of Pepperer. The Guild of Grocers contained many foreign merchants

trading in spices and drugs. The Pepperers in turn maintained their organised status but all three groups quickly realised that their commercial interests were frequently overlapping and that some sort of collective organisation was inevitable. The first attempt at this was probably the formation of the Fraternity of St Anthony in 1349 - the use of the name of a Patron Saint reflecting the religious dimension to the formation of the Guilds mentioned above. The Fraternity contained most of the major Spicers and Pepperers of the time.

The formation of this Fraternity had more to do with an attempt to rectify a major business failure than to unify a number of forms of trader. Although the distinct trades of Grocer, Spicer and Pepperer continued for some time, the establishment of the Fraternity of St Anthony had set a trend which was to continue.

It is interesting to note that there was little overlap between the role of the three types of trader mentioned so far and Physicians. Physicians were keen to protect their own interests and establish a position in society which would reflect their growing professional status (Gerrard, 1965:2 and Singer and Underwood 1962:78-84). The training of physicians by this stage was mainly by learning through apprenticeship and not through formal education and registration even though two Universities had already been established in Britain. The main reason for this lack of friction between the physicians and the traders probably lies in the fact that the former were mainly drawn from an ecclesiastical background and sold their services principally to the rich (Trease, 1964:70).

Apothecaries mainly involved themselves with the practice of pharmacy and became more and more specialised in that function. Trease (1964:70) points to an inventory which was taken of an

apothecary's shop which took place in 1415 which showed that, by that date, a specialised pharmacy practice existed which included aspects of pharmaceuticals.

In 1428 the trend towards amalgamation of the traders continued with the formation of the Company of Grocers. In essence the formation of this Company was simply a change of name for the Pepperers. However the Apothecaries were granted certain guild benefits within the Company and continued as members of it. It has been suggested (Gerrard 1965:2) that junior membership of the Company of Grocers and subjection to its disciplinary procedures was to provide the first inklings of unhappiness on the part of the apothecaries with their position and role in the health care system.

"By the middle of the 14th century these merchant guilds had grown so powerful that there was increasing competition between them. Each was over-running the other by trading in as many different types of commodities as it could; or it had come to an arrangement to maintain prices or spheres of influence - in modern terms, the formation of cartels."

However it was to be the relationship between the apothecaries and the physicians and, more importantly, the frictions caused by it which was to dominate the development of the pharmacy profession over the next few centuries.

Apothecaries and Physicians

By the end of the 15th century, an open conflict between the apothecaries, now specialised practitioners of pharmacy, and the physicians began to emerge. The apothecaries were involved in the practice of medicine as well as in the preparation and dispensing of drugs (Sonnedecker

1976:100) and it was this drift into the spheres traditionally occupied by physicians which was to cause conflict. Henry VIII, who it is suggested (Matthews 1962:35), practised pharmacy himself, attempted to resolve this conflict by issuing a regulation in 1511 which sought to delineate the functions of the physician and apothecary.

The physicians actively sought the passing of the regulation in order to maintain their status as the primary practitioners of medicine. They had perceived that the apothecaries, amongst others, were a threat to this privileged position and sought to negate that risk. It is interesting to note that this was the first stage at which there was an attempt at legal regulation of the health care system. It should also be noted that the purpose behind the early legislation for the general regulation of health care was often the protection of interests and positions. That is a theme which will be returned to again and again.

The regulation, often referred to as the first Medical Act, specified that no person could practise medicine or surgery in London or within 7 miles of it unless he had been examined, approved and admitted by the Bishop of London or the Dean of St Paul's. The latter were to be assisted in the examining process by four doctors or other experts in surgery and physic. The fact that the two principal examiners were clerics emphasises the strong ecclesiastical connection with the practise of medicine. This regulatory protection restricted the practice of medicine to the physicians.

This process, by the physicians, of restriction of the right to practice and the maintenance of a privileged position within the health care system continued through the early half of the 16th century. The College of Physicians was founded in 1518 and by 1540 had used their increased authority and status to claim and be granted the right to regulate the apothecaries' practice. This

was achieved by obtaining the authority to **"search, view and see the apothecary wares, drugs and stuffs"**.

However it was clear that the apothecaries were continuing to practise medicine. Gerrard (1965:2) suggests two main reasons for this. Firstly, there were relatively few physicians who in any case tended to be found in the larger towns. Hence there was a real need for the separate practice of medicine in the countryside. Secondly, the physicians charged large fees for the diagnosis of an illness and the writing of a prescription. When the prescription was presented to the apothecary for dispensing, a further fee was payable. As a result, only the very rich could afford to be treated by the physicians. Whilst this fact suited the physicians' ambitions it had the net effect of ensuring that the poor sought out the apothecaries for their treatment. The apothecaries would diagnose free of charge and seek payment for the dispensing of a cure.

This reality concerning health care practice resulted in the relatively swift passing of a new Medical Act in 1543. This Act gave the right of:

"every person being the King's subject having knowledge and experience of the nature of herbs, roots and waters to use and minister, according to their cunning, experience and knowledge".

The effect of this legislation was to acknowledge the position of the apothecaries, and others, as preparers of medicinal products and to give them the right to administer those products without the regulatory requirement of examination and licensing. Sonnedecker (1976:102) notes the generality of the requirement for expertise in the subject-matter and adds that the concession to those with this expertise related only to medicinal products for external application. However the

most important conclusion which he makes about the passing of the Medical Act of 1543 was that the official recognition of a branch of medicine which dealt with the preparation and administration of medicinal products fuelled the aspirations of the apothecaries.

The Growth of the Apothecaries

Throughout the latter half of the 16th century, the apothecaries continued to develop their role within the health care scheme. During this period certain of the Grocers were continuing to practise as apothecaries but a new class of apothecaries had emerged who regarded themselves as the trained preparers of medicines (Matthews 1962:37). This grouping sought to use its influence to promote their own interests and positions. In particular they were anxious to gain independent recognition through the granting of Guild status or something similar.

In 1607, King James I granted particular advantages to the apothecaries as a section of the Grocers' Company (Sonnedecker 1976:102). This was not sufficient for a growing number of influential individuals who wished to have complete independence from the Grocers. Amongst these were Sir Theodore Turquet De Mayerne and Gideon De Laune, physician and apothecary to James I. Their influence with the King brought about the introduction in December 1617 of a Charter establishing a separate City Guild titled the "**Master, Wardens, and Society of the Art and Mystery of the Apothecaries of the City of London.**"

Sonnedecker (1976:102, drawing on Thompson (1929), Underwood (1963) and Copeman (1967)), Matthews (1962:41-45) and Trease (1964:110) describe the Charter and new Guild in depth. The Charter acknowledged the important role which had been played in the development

of the Society of Apothecaries by Theodore de Mayerne and another physician Henry Atkins, both of whom were well known to the King. The main reason given for the enactment of the Charter was the fact that there existed a group of unskilled and ignorant practitioners without the knowledge or instruction of the apothecaries who were engaged in the production and compounding of corrupt medicinal products. This conduct was seen to be injurious both to those treated by these practitioners, naturally enough, and to the professions of apothecary and physician. The solution was seen to lie in the separation of physicians and apothecaries.

The apothecaries were organised into a Society of Apothecaries, were given a Hall for meetings, a governing body was organised and full rules and regulations for the running of the Society were drawn up. Links were to be maintained with the physicians by calling on the President and other officials of the College of Physicians for advice on the content of the Apothecaries' Society's ordinances regarding medicines and compositions.

The remainder of the Charter is taken up with the descriptions of the privileges and rights which the apothecaries were to enjoy in the future. Like the physicians before them, they were to enjoy exclusivity of practice within geographical boundaries surrounding London. The right to keep an apothecary's shop or warehouse within seven miles of London was restricted to existing or future members of the Society of Apothecaries. Existing members were named in the first Charter to the Society. Future membership depended on apprenticeship and examination.

Details were given in the Charter of the types of compounds which could only be prepared or sold by apothecaries. It therefore became unlawful for grocers or others to prepare or sell such products. The apothecaries were given the right to inspect the premises of any person who

claimed to practice as an apothecary, including those who were not members of the Society, for the purpose of testing their knowledge and of scrutinising their products. The Act made it clear, however, that the physicians were to retain all existing rights and privileges. Any person not meeting the required standards could be fined and have their products destroyed.

The Grocers protested strongly against this infringement of their own practices and the elevation of the status of the apothecaries but to no avail. Sonnedecker (1976:102) indicates that the main reason why King James I confirmed the separation by ordering that the Charter granting status to the apothecaries be enroled in the City of London's records and the apprentices of the Society of Apothecaries be admitted to the Freedom of the City in April 1618 was that he saw the Grocers as being mere tradesmen who had no professional skill. This confirms the view that the main reason behind the grant of the Charter was the abolition of unprofessional and dangerous practice. The apothecaries continued to demonstrate their expertise in the both the manufacture and dispensing of medicinal products by opening, in 1623, their own manufacturing laboratory for the production of galenic and chemical medicines. Although the primary reason given for this development was the prevention of the introduction of adulterated drug products by others, this function grew in importance for the apothecaries throughout the seventeenth and eighteenth centuries. The first manufacturing laboratory became a commercial company in 1682 and this and other apothecary companies came to be regarded as an important source of reliable medicinal drug products.

The Physicians and the Apothecaries

During the latter half of the seventeenth century the relationship between the apothecaries with their newly granted status and the physicians whose position within the health care system had already been well established took on a new dimension. Matthews (1962:112) reiterates the earlier findings that, at this time, there were very few physicians, who mostly lived in the London area and charged heavily for their services. He points to the fact that, in London at least, both the physician and the apothecary would attend the patient. The physician would prepare a prescription or "Bill" for the apothecary to dispense. Problems remained however for the patient without the boundaries of London or who could not afford to pay the large fees of the physician. It is accepted that the apothecary continued to practise medicine, in addition to maintaining their shops, primarily for those who could not afford or had no physical access to a physician.

The Great Plague of 1665-1666 reinforced this view of the apothecary as medical practitioner. During the early period of the plague many physicians died and those who survived fled to the sanctuary of the countryside. Treatment of the plague victims was left largely in the hands of the apothecaries who appear to have responded readily to the task (Whittet 1965 quoted in Sonnedecker 1976:103). Matthews (1962:112) refers to an entry in the Journal of St Bartholomew's Hospital dated 23rd December 1665 which records the payment of a gratuity to an apothecary who attended patients in the hospital **"the physicians having absented themselves from the hospital during the existence of the Plague."** These heroic efforts were undertaken despite the fact that the apothecaries lost many of their own number. Trease (1964:132) points out that the records indicate that 33 of 85 apothecaries known to be in London during the plague died of its effects. In addition the names of 114 apothecaries disappeared from the records at this time - the assumption being that they died of the plague either in London or elsewhere in

England.

The endeavours of the apothecaries during the plague years when compared with the efforts of the physicians elevated the former in the minds of the general public. As a result the apothecaries continued to be accepted as the legitimate practitioners of medicine. They had been so regarded for quite some time in the provincial areas of England. The effect of the plague years was to extend that social approbation to London.

It might be thought that all of this would not meet with the approval of the physicians. Such proved to be the case. The physicians had recognised the growing threat of the apothecaries for some time. It has already been noted that the charging of high fees for dispensing medicinal products had led patients directly to the apothecaries' shops. The continuing movement of the apothecaries into the practice of medicine was having a further detrimental effect on the physicians' position. Open conflict was the inevitable outcome.

The first skirmish in that conflict was the decision by the physicians to open dispensaries in London towards the end of the seventeenth century. The first of these dispensaries was opened in the College of Physicians in 1696. The physicians' dispensaries charged less, basing the fee on the net cost of the drug itself and the labour involved in its preparation (Gerrard 1965:3). The physicians also began to claim charitable intent in treating the poor for nothing and reinforced these claims and others, for example that the apothecary was incompetent and neglectful, through the issue of pamphlets and other materials (Bayles 1940:473). The apothecaries, shocked at the effect of the tactics being employed against them, responded with allegations of their own concerning physicians' arrogance, ignorance of medicines and uncharitable profits (Matthews

1964:114 and Bayles 1940:473).

The College of Physicians sought to bring the conflict with the apothecaries to an end by taking an action in the courts. In 1703 a case was brought by the College of Physicians against an apothecary called William Rose. The College alleged that Rose had contravened the provisions of the Medical Act of 1542/3 by prescribing medicines for a John Seale - "a poor Butcher" - without a prescription from a physician and that such behaviour amounted to unlawful medical practice. The Court of Queen's Bench agreed and fined Rose. It appears that the jury in the case were hesitant about bringing in a guilty verdict and on that basis the Society of Apothecaries decided to bring an appeal (Bayles 1940:8). On appeal the House of Lords found for Rose on the basis that it was in the public interest for apothecaries to add to their traditional functions of compounding and selling medicines the function of giving medical advice (Journal of the House of Lords March 15 1703-04 and Wall 1940:10).

It is generally accepted (Sonnedecker 1976:104, Matthews 1962:114-115 and Trease 1964:181) that the net effect of the decision in the Rose case was that the majority of apothecaries turned their attentions to the practice of medicine or surgery and away from the maintenance of their shops. The shops were not abandoned altogether but rather were left in the hands of the apothecary's assistants. Matthews (1962) demonstrates that, by the latter half of the eighteenth century, almost all trained apothecaries became medical practitioners rather than druggists. Gerrard (1965:3) and Trease (1964:169) points out that the new found freedom to practice medicine did not bring with it the automatic right to charge for medical advice. The apothecary turned medical practitioner could only charge for the medicinal products which they provided.

The assistants of the apothecary who were left with responsibility for the running of the shop while the apothecary visited his patients were either apprentices of the apothecary or were "druggists" - members of the Grocers Company who received their name by virtue of their former trade in spices and drugs. Matthews (1962:67) describes the druggists as follows:

"The wider spread of chemicals as well as the influx of drugs, hitherto unfamiliar, from the newly opened-up countries added complexity to the trade of the wholesaler who had formerly stocked drugs and chemicals as "grocery". Some men now began to think that there was sufficient trade to be obtained in these commodities and that concentration upon the apothecaries' demands would yield greater profit. The men who did this styled themselves, or were so styled by others, as "drugmen" or "drugsters" and towards the end of the 18th century they became known as "druggists" or "chemists and druggists".

These dispensing assistants acquired expert knowledge themselves particularly in relation to the materia medica of the day (Trease 1964:167, Matthews 1962:61-111 and Gerrard 1965:3) which allowed them to leave their apothecary masters and open their own shops. Trease (ibid) describes how one shop in Derby, still in existence as a pharmacy today, was owned by apothecaries from 1675 until 1751, by a partnership of an apothecary and surgeon until 1764 and thereafter by a druggist. The chemists and druggists were encouraged in this regard by the physicians who were still anxious to curtail the practitioner activities of the apothecaries. The apothecaries, in turn, saw these new developments as a major threat to their traditional functions of dispensing and compounding medicinal products. This was despite the fact that they had largely abandoned these functions in favour of the practice of medicine. Despite encroaching on the monopoly of the physicians they were anxious that their own monopoly should not be threatened.

In 1794 the apothecaries formed the "General Pharmaceutical Association of Great Britain". The

idea behind this association was to restrict to apothecaries the dispensing and sale of medicines (Matthews 1962:117). It attempted to introduce legislation which would seek to guarantee their threatened monopoly. Their lack of success in this regard resulted in the dispersal of the Association soon after its formation (Gerrard (1965:3 and Matthews 1962:118).

The disputes between the apothecaries who had moved into the practice of medicine, the physicians whose monopoly they sought to break and the chemists and druggists who wished to wrest the monopoly over the sale and dispensing of medicines from the apothecaries continued during the early part of the nineteenth century. The apothecaries wished to reform the practice of medicine through the training and registration of medical practitioners including the control of the pharmacy profession. That latter aspiration was opposed by the chemists and druggists who saw themselves as the practitioners of pharmacy and the rightful administrators of that profession. The physicians who had most of their ground swept from under them by the decision in the Rose case were anxious to protect whatever position they could.

Legislation concerning the imposition of tax on certain drugs and glassware prompted the apothecaries into action. There was a growing realisation on the part of the apothecaries that they would have to yield some ground to the newly organised chemists and druggists (Gerrard 1965:4, Earles 1991:S2 and Matthews 1962:119). The concessions were contained in the Apothecaries Act of 1815. To an extent it could be argued that this legislation satisfied the requirements of both the apothecaries and the chemists and druggists.

The Act gave powers to the Society of Apothecaries to control the professional standards and medical education in England and Wales (Sonnedecker 1975:104). The Act recognised that the

physicians would continue to practice medicine and imposed an obligation on the apothecary to dispense and prepare medicines as directed by a physician. That right and the right to inspect the shops and drugs of an apothecary, retained by the Society of Apothecaries under the legislation, was not exercisable against the chemists and druggists. Further the apothecaries were subject to rigid examination, qualification and admittance procedures.

In addition to the specific legislative provision (Clause III) which restricted the application of the provisions of the Act to the apothecary, a further provision (Clause XXVIII) exempted the chemists and druggists from the strict legislative requirements:

"nothing in this Act will extend, or be construed to extend, to prejudice, or in any way to affect the Trade or Business of a Chemist and Druggist, in the buying, preparing, compounding, dispensing, and vending of Drugs, Medicines and Medicinable Compounds, wholesale and retail;"

Any person who had carried on such a trade or business prior to the passing of the Act could continue to do so. The Apothecaries Act in general and Clause XXVIII in particular were exactly what the chemists and druggists wished to see. Matthews (1962:115-116) describes the effect of the legislation on the chemists and druggists as follows:

"It was thus recognised that the chemist and druggist had already established himself as a supplier of medicines, both by wholesale and retail. In fact, the Act was almost a charter for him; he had no qualification, such as the physician, no prescribed training or apprenticeship such as the apothecary or surgeon, no real standard by which his goods or dispensing was to be checked,...The chemist and druggist was therefore free of any inspection and could carry on his business without any kind of oversight, either by the College of Physicians or by the Society of Apothecaries."

This amounted to a notable victory for the chemists and druggists and had the secondary effect of

moving the apothecaries further towards the practice of medicine - leaving the practice of pharmacy in the hands of the chemists and druggists.

The Pharmaceutical Society of Great Britain

The recognition of the status of the chemist and druggist as preparers and dispensers of drugs and medicines and thus the right group to organise the pharmacy profession was, initially, an informal one. Gerrard (1965:5) points out that while the chemists and druggists might have won some sort of concession from the apothecaries and physicians, other considerations had to be carefully weighed up.

"They had no permanent organisation, there was no uniform of education, or training, or registration and, even more important, there was no legal protection of their status. Furthermore, both the physicians and the apothecaries were extremely dubious about their skill and knowledge. Adulteration, often with poisonous substances, was not uncommon and, although the chemists and druggists were not really responsible, they often were blamed for it."

The first step in the process, designed to protect the newly won status and recognition of the chemists and druggists, was to retain the committee - the "Druggists Association" - which had been so successful in lobbying to gain their exemption from the provisions of the Apothecaries Act of 1815 to maintain a close examination of any future legislation which would have a harmful effect on their activities. Examples of the role of this Committee include the support given to a proposed Sale of Poisons Bill in 1819 and the opposition to Medicine Stamp legislation in the late 1920s. In order to effectively air their grievances concerning this latter legislation the Druggists Association formed themselves into the **"General Association of Chemists and Druggists"**. This organisation was shortlived and once its function of opposing

the legislation had been achieved it was disbanded (Earles 1991:S2 and Matthews 1962:120).

The formation of these committees had convinced some prominent chemists and druggists of the value of having a body to organise the practice of pharmacy, protect the interests of chemists and druggists and promote and advance the profession through the establishment of appropriate training, qualification and admission requirements. Foremost among these prominent members of the profession were Jacob Bell (Holloway 1991:1-29), William Allen, Robert Farmer, George Walter Smith and George Baxter. The catalyst for the development of a body along the lines envisaged by these men was, again, the introduction of legislation which could have detrimental effects on the trade activities of the chemists and druggists.

A Bill "**to amend the Laws relating to the Medical Profession in Great Britain and Ireland**" was introduced into the House of Commons on 5 February 1841 by Benjamin Hawes following a public enquiry into the medical profession in 1939. The Bill was designed to introduce reforms to all sections of the medical profession including chemists and druggists. The net effect for the latter would be the introduction of education and regulation requirements together with the publication of a national Pharmacopoeia designed to ensure uniform and authoritative dispensing. Holloway (1991:89) summarises the reaction of the chemists and druggists to the proposed reforms:

"If the Bill became law, their business would be ruined. Any chemist who recommended ten grains of rhubarb, or strapped a cut finger, or explained to a customer the usual mode of taking a medicine would be liable to a penalty of £20 and to summary imprisonment (or a ruinous law suit) for non-payment. Chemists and druggists would be placed under the jurisdiction of a governing body, in which they were not represented, but, in the election of which, their chief competitors, the apothecaries or general practitioners, would have the largest number of votes."

Holloway is of the belief that Hawes may have been duped by the apothecaries into proposing a scheme which would have the chemists and druggists under the control of the apothecaries. Meetings of small groups of chemists and druggists were arranged to formulate plans to oppose the proposed legislation. These meetings, held initially in London, elected a General Committee made up of the representatives of the main wholesale and retail chemists and druggists.

Earles (1991:S3) suggests that the success of these preliminary meetings owed much to the development of improved communication systems in England and Wales and, more importantly, by the emergence of a dominant personality to lead the chemists and druggists in their legislative struggles. That personality was Jacob Bell. Holloway (1991:1-29) describes Bell's background in depth. He was the son of a Quaker pharmacist, was a partner in his father's prominent business and was well known at the time as a wealthy socialite who patronised science, literature and the arts alike.

The General Committee succeeded, through intense lobbying and petitioning, in their initial aims of opposing the Hawes Bill and indeed a subsequent Bill introduced by him designed, again, to reform the medical profession. However it was quickly realised that the profession of chemist and druggist would continue to come under pressure unless adequately organised and regulated. An example of the continuing pressure came soon after the successful opposition of the Hawes' legislation.

The Society of Apothecaries brought an action against a chemist and druggist for practising as an

apothecary without their licence contrary to the Apothecaries Act 1815. The chemist and druggist was allegedly involved in counter prescribing. In the lower court he admitted that he had attended patients, advised them and furnished them with medicines. The Lower Court held that despite this evidence, the chemist should be protected by the exemption clause (Clause XXVIII) of the 1815 Act. The decision was reversed on appeal where the Court of Queen's Bench (11 L.J.Q.B. 156) held that the administering of medicines amounted to practice as a medical practitioner and could not be protected by Clause XXVIII.

Jacob Bell and his influential colleagues were certain that the answer to the problems of the chemists and druggists lay in the formation of a body which would continue to advance the pharmacy profession. On April 15th 1841, at a meeting held in the Crown and Anchor Tavern in London a resolution was proposed:

"that for the purpose of protecting the permanent interests, and increasing the respectability of Chemists and Druggists, an Association be now formed under the title of the Pharmaceutical Society of Great Britain." (Holloway 1991:92)

The resolution was immediately adopted and for the first time the chemists and druggists had an organisation which, although born out of adversity and with specific aims and objectives, had the chance to become the permanent, representative organisation of the pharmacy profession.

The existing Committee made up the first Council of the Society and this Committee drew up the initial laws and constitution of the Society. These laws and constitution were adopted in June 1841. Jacob Bell did not hold office immediately in the Society but spent much of his time expanding the membership, particularly in the provinces (Holloway 1991:93-97 and Matthews 1962:125). At the same time it was realised by Bell and others that the education of members of

the pharmacy profession had to be closely monitored. Regulations were quickly formulated for examinations for admittance to the qualification of pharmaceutical chemist. The first candidates for examination were admitted in 1842 (Matthews 1962:125) and a School of Pharmacy was formed in the same year. The success of the Society to date prompted its founders to petition the Queen for a Charter of Incorporation.

Due largely to the efforts of William Allen, the first President of the Pharmaceutical Society, a royal Charter was granted to the Society on 18th February 1843. The Charter detailed the objects of the Society. These were:

"for the purposes of advancing chemistry and pharmacy, and providing a uniform system of education of those who should practise the same: also for the protection of those who carry on the business of chemists and druggists: and that it is intended also to provide a fund for the relief of distressed members and associates of the Society and of their widows and orphans." (Matthews 1962:127)

The Charter outlined in detail the requirements for membership, provisions for examination, regulations for the administration of the Society, the Constitution of the Society and bye-laws for its administration and day-to-day running (Gerrard 1965:5-7 and Holloway 1991:139-141. The powers granted for the regulation of the education and admission of members were seen as being particularly important.

Despite these extremely important advances for the pharmacy profession, Jacob Bell and others were not yet satisfied that the profession was properly protected. Although the idea of the Society was generally well received certain opposition to the notion of organisation and collectivism

continued to appear. This would eventually manifest itself in a split between those chemists and druggists who wished to practise and develop the profession of pharmacy by maintaining membership of the Society and those who wished to continue selling drugs largely as wholesalers. In addition to these concerns, it was felt necessary to continue to monitor legislation which was likely to have adverse effects on the Society's members. However, at the heart of the dissatisfaction felt by Bell and others was the fact that membership of the Society was not compulsory for those who practised pharmacy.

Bell believed that the best way to achieve this degree of protection was for the Society to promote its own legislation in Parliament. Attempts were made at proposing legislation for the regulation of the pharmacy profession, most of which foundered or were abandoned at an early stage (Holloway 1991:148-151) although the Society was still instrumental in opposing legislation such as the Medical Reform Bill of 1844 which was seen to be prejudicial to their interests.

As a result, Jacob Bell resolved that the only method of ensuring the introduction of appropriate legislation was to have a member of the Society returned as an MP. Bell was elected as MP for St Albans in 1850 though not without a certain controversy (Holloway 1991:151-163 and Earles 1991:S5). Once elected, Bell proceeded to introduce a Pharmacy Bill which was enacted as the Pharmacy Act 1852. This Act - for regulating the Qualifications of Pharmaceutical Chemists - confirmed the Charter and bye-laws of the Pharmaceutical Society, established procedures for the carrying out of the statutory obligations of the Society and set up a system for the registration of chemists and druggists. Admission to the Register, which was to be maintained by the Society, was conditional upon the award of a Certificate of Qualification, obtainable after examination from Examiners appointed by the Society. The Act established two Examining Boards for these

purposes - one in England and Wales and one in Scotland. Clause XII of the Act restricted the use of the titles of Pharmaceutical Chemist or Pharmaceutist to those registered as members of the Pharmaceutical Society. Finally the Act prevented existing medical practitioners from becoming registered with the Society. The net effect of this clause - Clause XI - was to end the dual purpose practitioner who both practised medicine and maintained a shop.

The grant of the Royal Charter of Incorporation, the influence exercised in the passing of the Pharmacy Act 1852 and the introduction of relevant pharmacy journals increased greatly the status of the Pharmaceutical Society. This growing status was reinforced when the Society was asked to assist in the development of a British Pharmacopoeia which appeared under that title in 1864 (Gerrard 1965:8, Matthews 1962:133 and Holloway 1991:188-189).

The Pharmacy Act 1868

However the 1852 legislation, as eventually enacted, did not match the hopes of its promoters. It certainly did not ensure that the practice of pharmacy would be limited to those who were examined and registered by the Pharmaceutical Society (Earles 1991:S6). Over two thirds of all chemists and druggists were not members of the Pharmaceutical Society. As has already been stated, those who opposed membership were mainly chemists and druggists who were interested in selling drugs as wholesalers. The members of the Society were those chemists and druggists who were interested in developing the profession of pharmacy and saw their profession as involving the compounding and dispensing of medicinal products.

The wholesale chemists and druggists formed their own Society in 1861 - the United Society of

Chemists and Druggists. It was made clear from the outset that the purpose of this Society was to be the protection of the trade and business interests of its members. For the next seven years the United Society and the Pharmaceutical Society claimed to control the development of the pharmacy profession.

In 1863 the General Medical Council introduced a plan to bring the education, examination and practice of pharmacy under the control of the General Medical Council. This proposal, which was eventually abandoned, prompted both Societies to consider their own proposals for the development of pharmacy in the future. Bills were drafted by both Societies and sponsors for them were sought in the House of Commons. Although initial support was weak (Holloway 1991:209-231), a compromise was reached between the Societies and a Bill which recognised the interests of both groups was presented in 1867 and became law as the Pharmacy Act 1868.

The 1868 Act began by requiring that in future it would be unlawful for any person to sell or keep open shop for retailing, dispensing or compounding poisons - a schedule in the Act listed the articles to be defined as poisons - or to use the titles "Chemist and/or Druggist" or "Pharmacist" or "Dispensing Chemist" unless that person was a pharmaceutical chemist or chemist and druggist within the meaning of the Act and was duly registered under the Act. A Register of Pharmaceutical Chemists and Chemists and Druggists and Assistants was to be maintained by the Pharmaceutical Society. Entry to the Register was confined to Pharmaceutical Chemists and to those already in the business as Chemists and Druggists, subject to a certification that they were so in business and to a certification that he was suitable to be registered. Thereafter entry to the register would be subject to examination with the Pharmaceutical society as the examining body. Chemists and Druggists in business prior to the passing of the Act were eligible for election as

members of the Pharmaceutical Society and up to seven members of this new class of members could be elected as members of the Council of the Pharmaceutical Society.

The 1868 Act could be described as a successful compromise for the two sides of the pharmacy profession. The Pharmaceutical Society succeeded in bringing the qualifications and registration of the Chemists and Druggists under their control and in confirming their role as the principal administrators of the pharmacy profession. The Chemists and Druggists succeeded in breaking through what they saw as the elitism of the Pharmaceutical Society and in promoting and protecting their own interests. Despite this Holloway (1991:239) indicates that the wording of the Act was to cause trouble for half a century.

There were difficulties initially with the maintenance of the registers under the Act, the restriction on the use of titles contained in the legislation, the articles contained in the lists of poisons contained in the schedule, the admission of women to the profession and the exemptions contained in the legislation concerning apothecaries and other medical practitioners - which was to lead to amendments of the legislation.

These difficulties and others led to a period of drift and depression in the pharmacy profession (Holloway 1991:255 and Earles 1991:S11). That period also saw an increase in the development of the proprietary medicine trade and retailing by co-operatives, department stores and pharmacy chains owned by limited companies. These retailers often used the title "Chemist". This development was resisted by the Pharmaceutical Society who wished to protect the professional status granted by the 1868 Pharmacy Act.

Matters came to a head in the case of the *Pharmaceutical Society v The London and Provincial Supply Association* ((1880) 5 App. Cases 857). The Pharmaceutical Society had originally brought an action against a sole proprietor of a retail business, not registered under the 1868 Act, for the sale of a scheduled poison. The sole proprietor admitted his wrong, paid his fine and immediately converted his business into a limited liability company, the London and Provincial Supply Association, with a qualified chemist and druggist as a shareholder, and argued that the company would not be liable for any future violations of the legislation. The Pharmaceutical Society took the case as far as the House of Lords who decided that limited liability companies might use the titles contained in the 1868 Act without penalty.

The decision in the case did not fully resolve the issue of the use of titles by limited liability companies and this issue was set to concern the pharmacy profession for at least 20 more years. In the meantime, the 1868 Pharmacy act was to be amended again to deal with the problem of the class of membership of the Pharmaceutical Society afforded by the Act to the Chemists and Druggists. It might be remembered that Articles 18 and 19 of the 1868 had restricted the class of membership available to those Chemists and Druggists who had entered the register by passing the "Minor" examination. These members were classified as Associates while Full membership was reserved for those Pharmaceutical Chemists who had passed the "Major" examination. The Pharmacy Acts Amendment Act 1898 changed this position by making all Chemists and Druggists eligible for election to full membership of the Pharmaceutical Society. Other amendments were also made to the constitution of the Society which were to make it more representative of all aspects of the pharmacy profession.

The Mid-Twentieth Century

In the meantime the row over the use of pharmaceutical titles by limited companies was continuing to simmer. Following the decision in the London and Provincial Supply Association Ltd case, retailers such as Jesse Boot began to use various titles for their business and to organise associations for the protection of their business interests. This, combined with their aggressive selling tactics, alarmed the Pharmaceutical Society who recognised a danger to the integrity of the profession. The problem was only resolved by the passing of the Pharmacy Act 1908.

Under this Act, corporate bodies could use the title of "Chemist and Druggist" provided that a pharmacist was appointed as a qualified superintendent to control and manage all aspects of the company's dealings in poisons. The superintendent also had to be a member of the Board of Directors of the company. The titles "Pharmaceutical Chemist", "Pharmaceutist" and "Pharmacist" were restricted to the existing pharmaceutical chemists, including the former chemists and druggists.

Section 4 of the 1908 Act extended the Pharmaceutical Society's powers in relation to the education of those training for the pharmacy profession. The Society could make bye-laws in relation to courses of study and examinations which were required of candidates seeking registration as pharmaceutical chemists and chemists and druggists.

The Act also contained amendments to the previous legislative provisions relating to poisons - a matter which had been concerning the Pharmaceutical Society for some time (Earles 1991:S12-S13 and Holloway 1991:284-294).

It is possible to argue that, by the early part of the twentieth century, the pharmacy profession, after a period of turbulence, was beginning to resolve the major issues which had concerned it. The Pharmaceutical Society had established itself as the principal regulator and administrator of particular aspects of the pharmacy profession, including training, education, registration and admission. The apothecaries had long since moved into the role of general medical practitioners. The wholesale chemists - now pharmaceutical companies - were relatively content with their position in the pharmaceutical scheme and the retail limited companies had seen their position secured by the passage of the 1908 Act.

However the Pharmaceutical Society had not yet been able to limit all the functions of dispensing and compounding to those who were registered under the pharmacy legislation. Our review of that legislation has shown that pharmacy had more often been linked to the control of poisons than to the functions of compounding and dispensing (Earles 1991:S13). The catalyst for placing control over those functions came with the passage of the National Insurance legislation.

The Pharmaceutical Society was able to convince the promoters of this legislation that the pharmacist was the correct person to directly supervise the dispensing of national insurance prescriptions and that, as such, all contracts for the dispensing of such prescriptions should be restricted to those in business as pharmaceutical chemists. This development ensured that the principal functions for pharmacists after the passing of the National Health Insurance Act 1911 would be dispensing and compounding (Matthews 1962:138-139 and Earles 1991:S13) although dispensing by doctors would only cease completely after the national health legislation was extended to all in 1948.

The extension and development of the pharmacist's role following the passage of the national insurance legislation had the incidental effect of bringing into question the role and powers of the Pharmaceutical Society in relation to the trading and employment conditions of its members. In a friendly action, (*Jenkin v The Pharmaceutical Society* ([1921] 1 Ch 392)), brought to determine this question, the High Court indicated that the expenditure of the funds of the Pharmaceutical Society in the formation of an industrial council committee for the regulation of the trading and employment conditions of its members would have the effect of turning the Society into a Trade Union. Such a course of action would be contrary to the objects of the Society as contained in its Charter. The net effect of this decision was the formation of an association for the express purpose of protecting the interests of employee pharmacists. This was known initially as the Retail Pharmacists Union, then the National Pharmaceutical Union and is in existence now as the National Pharmaceutical Association (Blyth 1992).

The Pharmaceutical Society was now in a position to devote its attention to the development of the discipline of pharmacy. The period from 1920 saw the formation of a number of local associations and organisations to advance and promote pharmaceutical science (Earles 1991:S14, Matthews 1962:148-153 and Holloway 1991:376-378). In addition, it was proposed to have an annual meeting of the delegates of these associations to discuss developments in the science of pharmacy - a compromise was eventually reached with the existing British Pharmaceutical Conference to continue the annual meetings under that name. The Pharmaceutical society was also instrumental during this period in developing journals, a Codex and revisions to the British Pharmacopoeia. Pharmacological laboratories were also opened to deal with the requirements of the Therapeutic Substances Act 1925 in relation to the control of certain substances.

During this period it was also thought necessary to consider amendments to the poisons legislation. Earles (1991:S15) argues that it was the developments within medicine and science which prompted the possibility of review. At the same time several prominent members of the Pharmaceutical Society saw the possibility of a review of the poisons legislation as an opportunity to review the pharmacy profession (Holloway 1991:381-388). A draft Bill on poisons and pharmacy was published in 1930 which, after certain discussions and delays, became the Pharmacy and Poisons Act 1933. Earles (1991:S16) outlines the main reasons why the Pharmaceutical Society eventually supported the legislation:

"The no-opposition policy was supported by the argument that the proposed legislation, although associating the legal practice of pharmacy with the supply of poisons, established the Pharmaceutical Society as the controlling body of British pharmacy and provided it with the unchallengeable right to represent all persons on the professional registers."

Under the 1933 Act membership of the Pharmaceutical Society became compulsory. The distinction between registration and membership was abolished. Every person registered as a pharmacist became, by virtue of that registration, a member of the Pharmaceutical Society. Annual fees for membership became payable in addition to the registration fee. A Statutory Committee was established with the power to supervise the functions and activities of registered pharmacists be they individuals or companies. The Pharmaceutical Society was given the power to enforce the provisions of the Act. These supervisory and enforcement powers included the disciplinary power to remove names from the Register and inspect premises through inspectors appointed for that purpose. In addition to these provisions relating specifically to pharmacy a great deal of the Act was taken up with provisions relating to poisons.

The Late Twentieth Century

The 1933 legislation reinforced the position of the Pharmaceutical Society in relation to the pharmacy profession in Britain. Pharmacy was recognised as a discipline concerned with dispensing and compounding, the control of drugs products and medicines and the advancement of the science of pharmacy and pharmacology. The Pharmaceutical Society was seen as a self-governing body which had control over its own affairs and was the principal regulator and administrator of the members of the pharmacy profession.

Over the next thirty years the pivotal position of the pharmacy profession and the Pharmaceutical Society would be strengthened by a number of pieces of legislation. Following the passage of the 1933 Act, the Council of the Pharmaceutical Society established a Committee to enquire into the future of pharmacy. When its report was published in 1941, it placed a strong emphasis on the discipline of pharmacy as opposed to its commercial aspects (Earles 1991:S16). The Report also emphasised the requirement for a Code of Ethics for the profession.

In 1941, the Pharmacy and Medicines Act was passed which made some minor amendments to the scheme governing the advertisement of remedies for a list of specific diseases. As has already been stated, the passing of the 1946 National Health Insurance Act ensured that the pharmacist's primary function within the health care scheme was the dispensing of medical prescriptions. The Pharmaceutical Society was anxious to ensure that the training of pharmacists should be carefully controlled and its 1941 Committee of Enquiry had recommended minimum standards of entry. By the 1950s these would become three years of academic study leading to the award of a pharmaceutical chemist diploma or a degree (Holloway 1991:412). By the late 1960s the minimum requirement for registration as a pharmacist would become an approved degree in

pharmacy followed by a period of supervised practical experience.

The 1953 Pharmacy Act abolished the existing register of chemists and druggists and instead established a new Register of Pharmaceutical Chemists.

By this time it was felt that concentration of the existing Charter of Incorporation and the existing legislation was necessary. A Supplemental Charter was granted on November 19th 1953. This Charter recognised the new developments in the profession of pharmacy and the movement away from the earlier ideas by having as a principal objective the maintenance of the honour and the safeguarding and promotion of the interests of the members in the exercise of the profession of pharmacy. In 1954 a new Pharmacy Act was passed to consolidate the existing legislation which was now spread over a long period of time. The new Act also made certain changes in the classification of membership of the Pharmaceutical Society.

The Pharmaceutical Society would also be closely involved in monitoring legislation on the control of drugs and medicinal products and were always anxious to ensure that the pharmacist was considered to have the appropriate expertise in the control of medicines. A number of pieces of legislation culminating in the Medicines Act of 1968 confirmed that role for the pharmacist and the pharmacy profession (Earles 1991:S17).

So by the middle of the twentieth century, the position of the professional pharmacist within the health care system had been well established. He was well educated and received expert training in the dispensing and compounding functions and in the control of medicines and drug products. He was a member of a self-governing Society who supervised his work and promoted his

interests and the interests of the pharmacy profession and discipline in general. He had professional status and was regarded as an essential provider within the health care team.

Conclusion

This chapter has sought to review, historically, the functions and roles of the pharmacist in the health care system. It has been seen that the pharmacy profession has a long and intricate history and that the roles and functions of the pharmacist have changed and have been refined to cope with greater changes within the health care system as a whole. The historical development of the pharmacy profession has been dependent upon the historical development of other members of the health care team - in particular the general medical practitioner - and the evolution of a drug development and distribution system.

It was concluded that by the middle of the twentieth century, the pharmacist's role within the health care system was crucial - a professional recognised as having essential expertise and knowledge and without whom the health care plan would not be complete. Yet within thirty years that position and role would be questioned and doubted even by pharmacists themselves. The next chapter will seek to review the particular circumstances which forced the pharmacy profession to change their perspective and adopt a position which was distinct from the one which they had earlier readily assumed.

The Assumption of Particular Roles and Functions by the Pharmacist in the Health Care System in the late Twentieth Century

Purpose

This chapter will review the reasons why the pharmacist was to adopt particular functions and roles within the health care system in the late twentieth century. It seeks to show that the principal reasons why the community pharmacist was to become a dispenser of medicines and drug products prescribed by medical practitioners were the advent of the National Health Service and the spectacular growth of the international research-based pharmaceutical industry (Nuffield 1986:18 and Reekie and Weber 1979:1). It will be seen that the period from the 1940s to the 1980s saw the National Health Service changing radically the provision of health care within the United Kingdom. In a parallel and almost as a corollary to the birth of the NHS, the evolution of the pharmaceutical industry had the most significant technological and scientific impact on the practice of medicine within the National Health Service structure.

It will be concluded that these two determinants forced community pharmacy into accepting certain roles and functions as providers of health care - roles and functions which by the end of the period concerned would be questioned and doubted even by the profession itself.

The Development of the National Health Service

Eckstein (1958:161) quotes an anonymous member of the House of Lords who when speaking during the debates on the National Health Service Bill stated that the National Health Service:

"is not the product of any single party or any single Government. It is in fact the outcome of a concerted effort, extending over a long period of years and involving doctors, laymen and Government, to improve the efficiency of our medical services and to make them more easily accessible to the public..... Responsible people were advocating a much wider and more comprehensive service long before this."

This quotation summarises well the history of the National Health Service. The post-war Labour government and its Minister of Health, Aneurin Bevan, is rightly commended (Foot:1973) for the implementation of the legislation which has formed the roots of the present day arrangements. However it is impossible not to look back further in history to trace the influences and motivation for what the then Minister of Health, Mr Henry Willink, when introducing a White Paper (398 H.C. Deb. col 428, 16 March 1944) on the health service to the House of Commons, described as:

"...the biggest single advance ever made in this country in the sphere of public health."

Some commentators (Eckstein 1958:10-19 and Webster 1988:1-10) trace the history of the National Health Service back as far the eighteenth and even the seventeenth centuries. To the extent that much of the Poor Law and Public Health legislation was enacted during that century and that many of the "voluntary" hospitals i.e. those which were built and financed by, largely, religious philanthropists to provide medical services to the poor (and which were still the nucleus of the hospital system at the time of the formation of the National Health Service), these commentators are correct (Grimes 1991:iii-iv and Hodgkinson 1967). However the starting point for most other commentators would be the introduction of proposals for a National Health Insurance scheme by Lloyd George in 1911 (Pater 1981:2, Klein 1989:3 and Grimes 1991:6-46). It will be seen that while the legislation - the National Health Insurance Act 1911 - which

implemented these proposals ensured that a large percentage of the population would have some access to medical care, it was the problems associated with the administration and running of the scheme which would lead to a consensus view by the late 1930s that change would have to come about.

In relation to pharmacy, the National Health Insurance Act 1911 has already been referred to in chapter one of this work. It was concluded there that the main effect of the legislation for pharmacists was that their principal functions would become dispensing and compounding. It is a logical development of the thesis that this chapter seeks to show that the completion of the national health service scheme **and** the development of a pharmaceutical industry had the principal effects of ensuring that the main function of pharmacists would become that of dispensing and that the role of compounding would largely disappear.

The scheme introduced by the National Health Insurance legislation was designed to provide minimum medical care. The plan was restricted both in terms of the range of services which were to be provided and the numbers and class of persons who would be covered. Section 1 of the Act provided medical benefits for manual workers or non-manual workers whose incomes were less than a fixed monetary limit. The initial qualification level of income was set at £160. This ensured that 11.5 million people, amounting to some 27.4% of the population, were initially covered by the scheme (Webster 1988:11 quoting Eder 1982 and Gilbert 1970). Those who were excluded from the scheme included the unemployed dependants of those already covered, self-employed persons and those whose income exceeded the strict limits (Eckstein 1958:20).

By the outbreak of the second world war, with an increase in the income level for qualification,

the numbers covered by the scheme had increased to 20.3 million people amounting to some 43% of the population. Although they appear to have been indifferent participants in the scheme to begin with, due to the arguments with the government over the capitation fee, Webster (1988:11) again reports that by 1938, 90% of active general practitioners were taking some part in the national health insurance plan.

Section 3 of the Act made it clear that the funds for the provision of the benefits conferred by the Act were to be derived from contributions made by the insured themselves or their employers and contributions made centrally from Parliament in the ratio of seven-ninths from individual contributions and two-ninths from public moneys. Different contribution rates were established for employed and voluntary contributors with provision being made for the alteration of those rates in relation to particular groups and at particular times.

The range of benefits conferred by the Act were outlined in Section 8. The principal benefit was the provision of medical treatment and attendance, including the provision of medicines and medical and surgical appliances. Other benefits included treatment in a sanatorium for particular illnesses, periodical payments whilst rendered incapable of work by some specific disease or by bodily or mental disablement to be called "sickness benefit", "disablement benefit" where the incapability for work lasted beyond twenty-six weeks and maternity and other benefits.

Eckstein (1958:20 quoting from Levy 1944) indicates that the sickness benefit payments were so low that they appeared to be designed for no discernible purpose at all, amounting initially to a payment of some 15 shillings per week which would have a negligible effect on any household income. So too Webster (1988:11) agrees that the inadequacy of these cash benefits placed an

enormous burden on families when, at the time of sickness, they could least afford it.

Medical attendance and treatment without payment would be available from the insured's chosen panel of general practitioners established by those responsible for the administration of the scheme. Medical attendance and treatment included drugs and medicine. A range of additional benefits, financial and medical including dental and ophthalmic treatment, hospital and convalescent care and home nursing (described by Eckstein 1958:27 as being indispensable to adequate medical coverage) were only available under certain specified conditions.

While the National Health Insurance scheme had the obvious advantages of introducing a large percentage of the population to a range, albeit a limited range, of medical benefits, the scheme ran into a number of administrative and other difficulties which would ultimately ensure that change was necessary. The consensus was that change would involve a radical new structure rather than an overhaul to improve the existing structure. What, then were the problems?

The system of delivering the two types of benefits described above - the provision of general practitioner services and the payment of cash benefits - was provided under two types of administrative arrangements set out in Sections 14 and 15 of the Act. Under Section 15, the scheme for the payment of sickness and other benefits was entrusted to a number of "Approved Societies". Eckstein (1958:22-23) describes at length how the arrangements for the use of such societies came about and the problems which inevitably resulted.

A large number of voluntary medical insurance associations had been in existence prior to the proposal for the introduction of a national health insurance scheme. Initially these voluntary

associations objected to the introduction of any new plan for health insurance and received substantial and influential support for their cause. Eckstein describes the eventual administrative structure for the payment of sickness benefits as:

"... the price Lloyd George had to pay for his legislative "miracle". The potential opposing forces...went along with the Chancellor's scheme when it became clear that they would not be displaced by it, but would indeed, become the administrative agents for the national insurance system" (Eckstein 1958:23)

Approved Societies thus became any group which wished to administer national health insurance and which satisfied conditions laid down under the eventual enacting legislation. These requirements were laid down in Section 23 of the Act. National health insurance affairs were to be operated on a non-profit basis and control of these affairs was to be exercised on a democratic basis by the members of the society. Approval to function under the national health insurance scheme had also to be obtained from the Minister. Such ministerial approval was generally dependent upon the successful fulfilment of the criteria concerning profits and control as outlined in Sections 27-41 of the Act.

As a result of the concessions to the voluntary associations, the Approved Societies which came to administer the scheme eventually numbered 7,000 in total and could be anything from Industrial Insurance or Life Insurance Company to a lawn tennis club with varying numbers of members. Eckstein is able to conclude that:

"Health Insurance was not to be administered by a cumbersome public bureaucracy but by the insured themselves and therefore on a highly decentralized basis. The principle of self-administration was to be carried to its ultimate extreme; not only were the insured to control the administrative units to which they belonged, but they were also to choose what units to belong to. The aim was, unmistakably, to pass

off National Health Insurance as a voluntary thrift movement by steering as clear as possible of normal bureaucratic machinery." (Eckstein 1958:22-23)

As indicated above, the Approved Societies would only be responsible for the administration of sickness and other benefits. Under Section 15 of the Act, the general practitioner services were administered by Insurance Committees which were made up of local doctors, pharmacists and local authority representatives.

This expanse of this administrative machinery was bound to lead to practical difficulties. To begin with, many of the societies benefitted both financially and politically despite the expectation contained within the legislation and enacted through the criteria for approval as an Approved Society that profit and undemocratic control should be left out of the equation. Secondly, the range of "additional" medical services available was diverse. Because these services were not available as of right, their provision was dependent upon the capability of the approved society to pay for them. Unfair, inequitable and limited distribution of the additional services was the result. The figures are described by Eckstein (1958:27). By 1939 4,834 societies out of 7,000 provided dental treatment to 11,800,000 members out of 17,000,000; 4,821 societies supplied ophthalmic services to 10,000,000 members and 2,603 financed stays in convalescent homes for 10,800,000 of the insured. The final statistic is probably the most damning. Only 1,600,000 people had hospital benefit of any kind.

Restricting the care of the insured to the competence of the ordinary general practitioner ensured that the range of medical benefits obtained was basic. Hospital and specialist treatment was excluded and the quality of the treatment obtained from the general practitioner was low.

Webster (1988:11) indicates that certain workers received half of their dental and ophthalmic treatment while others did not receive any such benefits. Klein (1989:3) quotes from the Political and Economic Planning survey of health care undertaken in 1937:

"It is disturbing to find that large numbers of general practitioners being taught at great trouble and expense to use modern diagnostic equipment, to know the available resources".

Problems also existed with the range and distribution of hospital services although Eckstein (1958:34) notes that by the time the 1946 Health Service Act was passed, a striking volume of hospital services was being provided by local authorities. Early on, a dual system for the provision of hospital services had existed which had led to difficulties and conflicts. Services were provided by both the voluntary and municipal sectors who competed against each other and when necessary abrogated specific responsibility for patient care by transferring patients from one type of hospital to the other (Klein 1989:3).

The public hospitals were obliged to treat those patients who required treatment providing that the institution could supply that form of treatment, and charges were made on the basis of ability to pay. In the last resort treatment was free for those who could not afford it. The voluntary hospital sector had been introduced with this latter ambition in mind - payment for treatment coming from the charitable donations of philanthropists. However as we shall see, the viability of the voluntary sector on the basis of voluntary donation had largely disappeared by the mid 1930s and they too came to rely on payment from the patient as the basis of their financial future.

Eckstein (1958:44-83) summarises the problems associated with the condition of medicine which

led directly to the socialisation of medical services. Most of these problems were associated with the provision of hospital services and with the supply of other medical services.

To begin with there were significant shortages in the physical facilities available and in the skill of the practitioners within those facilities. Eckstein disputes a number of the official figures available as a reliable indicator of the extent of the shortfall but is nonetheless of the view that a serious shortfall in the number of hospital beds did exist and that there were serious difficulties with the adequacy of the equipment which was available. He is also clear that the adequate provision of beds and equipment is worthless if there are not adequately trained staff to service them. This latter problem compounded the predicament concerning the lack of physical resources.

Basically there were not enough medical practitioners and those who were in the profession were not sufficiently well trained. The lack of numbers of medical practitioners could be put down to the fact of bias in the social selection process. For some time, the medical profession was not held in the same social regard as the other professions. Medicine in the early days was regarded more as a trade than a specialty leading to suggestions that it was only fit for tradesmen. When rigorous medical training (and professional discipline) were introduced, the training was so time-consuming and costly that further discrimination was the net effect.

The lack of specialism in the medical profession could be put down to a number of factors foremost amongst which was the possibility of a lack of sustained, adequate income following lengthy and costly training. Specialists tended to be found in the voluntary as opposed to the municipal hospital sector where the title of consultant gave them a degree of prestige and

professional recognition without the attendant (financial) trappings of success - the award of title of consultant was unpaid and honorary.

This forced a number of practitioners to remain among the ranks of general practitioners and led to a shortage of skilled medical practitioners. This, in turn, led to the dual consequences of a geographical maldistribution of specialists - they went where the financial and professional rewards were the highest - and to the provision of most medical services, including surgical procedures, by general practitioners whose qualifications and capability for the position went largely unchecked (Klein 1989:3).

The geographical maldistribution of available facilities and manpower is identified by Eckstein as the second major fault associated with the condition of medicine prior to the introduction of the National Health Service. As we have already noted, specialists tended to go to the areas of the country where the population was located who could afford to pay for their services. Eckstein (1958:59) quotes from Sir Ernest Lock Carling and T S McIntosh (Carling & McIntosh 1945), the surveyors of the North-Western Area on this particular problem:

"The chief determining factor is not whether there is enough work to keep a specialist busy but whether there is enough private practice to make it worth his while to settle in the place concerned;"

Such irregular geographical distribution of medical services was not restricted to specialists. The provision of general practitioner services was also affected. General practitioners were located in upper-middle class towns where they could achieve a substantial income with the least amount of work. This class dominated nature of the practice of medicine was also reflected in the fact that

working-class medical practitioners, relying totally on those who were medically insured and those organisations and societies to whom he was contracted, did not earn the same substantial level of income nor professional status as most of his fellow professionals.

The third problem associated with the condition of medicine in the late nineteenth and early twentieth centuries was the uneconomic use of the services due to disorganisation. Eckstein (1959:62-63) believes that the problem of irrational organization was the most serious fault with the pre-Health Service medical system.

To begin with, the organizational problems were founded on the fact that most of the hospitals, both public and voluntary, were extremely small. On the voluntary side, this was due to the fact that charitable donations, which were the basis of their foundation and establishment could only allow for the creation of smaller institutions. Similar shortage of resources on the part of local authorities affected the size of the establishments which it could create. The problem concerning size was exacerbated by the organization of the services available within the hospitals. Many of the hospitals provided general medical services but equally others concerned themselves solely with the treatment of certain illnesses, mainly infectious diseases.

The duality of the hospital system led to its own problems (Eckstein 1958:66-67). As has already been noted, there was little collaboration between the voluntary and public hospital systems. The voluntary hospitals enjoyed the greater amount of prestige based on the fact that they dealt with spectacular, acute short-stay cases, attracted the greater number of medical specialists and that almost all the teaching hospitals were voluntary hospitals (Webster 1988:2-7). The public related the voluntary system to the better forms of treatment.

"The inescapable conclusion is that Britain had no hospital "system" at all before the Appointed Day. There were, at best, two badly coordinated hospital patterns, each consisting of a large number of equally poorly coordinated parts." (Eckstein 1958:71)

A further difficulty related to finance. We have already noted that the voluntary hospital sector developed serious financial problems by the mid 1930s. Similar quandaries affected the public sector. Equally the lack of finance affected the members of the medical profession to the extent that the vast majority of young medical practitioners was impecunious.

The final problem associated with the condition of medicine prior to the establishment of the National Health Service identified by Eckstein was the existence of unsatisfactory clinical conditions - that is that general medical practice fell short of acceptable scientific standards (1958:78). While this problem was not confined to the practice of medicine in Great Britain, it was not helped by the lack of willingness on the part of the medical practitioners to move away from single-handed practice to large group practice.

The combined effect of all of the problems described above was a growing collective awareness that change was necessary. Following the end of the First World War - when the problems with the provision of medical services described above were greatly exacerbated - a number of reports were published which were designed to address the issue of the state of the provision of health services.

The Interim Report on the Future Provision of Medical and Allied Services

The first of these reports was produced as a direct result of the formation of the Ministry of Health in 1919. At an early stage the Minister of Health created a Consultative Council on Medical and Allied Services under the chairmanship of Lord Dawson (Webster 1988:18-19; Klein 1989:4-5; Eckstein 1958:114-115). This council was asked to:

"...consider and make recommendations as to the scheme or schemes requisite for the systemised provision of such forms of medical and allied services as should...be available for the inhabitants of a given area."

Its first report, published in 1920 (Great Britain 1920), emphasised three main difficulties with the existing services - firstly, that the existing structure of medicine denied the nation of the benefits of medical learning; secondly, that the structure of medicine had not maintained pace with the development of scientific knowledge and that the basis of the structure, based on distributive theories, was obsolete (Eckstein 1958:115). The report advocated remedying these difficulties by the development of a new organisational structure which would distribute services according to community needs.

At the heart of that organisation would be the domiciliary services - general practitioner, pharmacist, nurse, midwife, health visitor - but the integrated provision of services also required primary health centres, secondary health centres, supplementary services and teaching hospitals (Pater 1981:8-9). In addition to outlining the details of these services, the Report also concluded that voluntary hospitals should be maintained; research should be encouraged; a proper and efficient system of medical records should be maintained and a new system of administration of these services should be introduced. Domiciliary services would be paid for out of the existing insurance schemes and charges should be made for hospital services (Eckstein 1958:119). The

report of the Dawson Committee was never implemented although it has been suggested that, so comprehensive was the report, the founding of the National Health Service in 1946 was merely the deferred execution of the report.

Voluntary Hospitals Committee

The publication of the Dawson Report nonetheless began a process whereby aspects of the existing provision of medical services would be looked at critically. It has already been noted above that one of the major difficulties with the existing structure was the dual provision of hospital services in both the voluntary and public sector and that both sectors, but especially the voluntary, were experiencing great financial difficulties. In January 1921, the Minister of Health appointed a further Committee under the chairmanship of Lord Cave to appraise the financial circumstances of the voluntary hospitals and to recommend changes in their financial structure (Great Britain 1921).

The Committee recommended that some funding should come from the public purse but that this assistance should be confined so that the purpose and function of the voluntary hospital sector should not be frustrated. Grants were to be awarded but the voluntary sector was also recommended to ensure that their accounting and administrative machinery be improved. It was also encouraged to set up a contributory system whereby employees and employers should make payments towards hospital care (Pater 1981:12-13).

The eventual implementation of the recommendations of the Cave Committee, although not as extensive as originally formulated, had the effect of turning around the fortunes of the voluntary

hospital sector. However additional problems within the hospital system as a whole - not the least the difficulties associated with coordination and cooperation between the two sectors - remained and had to be considered further. Pater (1981:14-15) report that, in October 1926, when Neville Chamberlain was Minister of Health, he set off a major debate by suggesting in a speech that there should be closer collaboration between the two sectors and that one method of arriving at this ideal would be the establishment of a central authority for the development of hospital policy. *The Times* indignantly dismissed the idea by suggesting that it would be impossible to find a better system of hospital administration than in the voluntary sector.

That debate continued throughout the latter half of 1927 both within the Commons and in the pages of *The Times*. The pressure and controversy culminated in the introduction of the Local Government Bill in 1928 which included provisions relating to the removal of responsibility for the administration of the public hospitals to public health authorities. When the legislation was eventually enacted in 1929, Section 13 required local authorities to consult with voluntary hospitals when an extension of hospital services was being proposed. While the concept of this provision was to introduce greater cooperation between the voluntary and public sectors, no real cooperation ever actually took place. (Pater 1981:16 and Webster 1988:20).

The Royal Commission on National Health Insurance

The Royal Commission on National Health Insurance was appointed on 11 July 1924 and was asked to report:

"what, if any, alterations, extensions and developments should be made in regard to

the scope of the scheme and the administrative, financial and medical arrangements set up under it." (Great Britain 1926)

The Commission, chaired by Lord Lawrence and made up of members with wide knowledge of administrative matters, began its work on 17 July 1924. During 1924 and 1925 it published a great deal of evidence which represented a memorandum handed in by Government Departments and other representative bodies. By the end of February 1926, a Majority and Minority Report were published (Great Britain 1926).

Levy (1944:24-25) indicates that the Royal Commission was not the first enquiry into the workings of the scheme. A Committee under the chairmanship of Sir Claud Schuster had sat in 1913-1914 and had looked at the workings of the Approved Societies and a second enquiry dealing with the financing and administration of the Societies had sat in 1916. Levy also reports that the Royal Commission's workings had two distinct aspects - it did review very closely the various arrangements made by the existing legislation for the different benefits approved under the scheme but did not make any systematic review of the administrative system on which National Health Insurance had been based in order to test its effectiveness in its first year.

The Report did contain evidence as to necessary changes in the existing scheme but did not necessarily recommend those changes. The first difficulty was the inequality in benefit which was apparent in the system. However the Commission thought this to be a good thing implying that freedom of choice of Society meant that the member ultimately benefited by choosing a Society which offered the benefits which he desired (Levy 1944:26). Levy also reports that the Commission did not look into the methods whereby members were attracted to particular

Societies or the different methods of financial and other administration which pertained to different Societies.

Evidence to the Royal Commission also showed that democratic representation and control by members was a fiction. This showed that the deficiencies in the Approved Society scheme which had existed prior to the passing of the 1911 Act had not gone away. The Societies were more or less commercial ventures and the Majority Report advocated their continuance. By 1924-25, it was evident that the stated aim of the 1911 Act to bring about the organisation of genuine mutual and associative administration had failed (Levy 1944:28).

The Minority Report emphasised two points of criticism about the Approved Societies - that they were a complete hindrance to the development of a complete public health policy and that the intentions of Parliament as to their control had not been realised. The Minority Report advocated the abolition of the Approved Societies as agencies for the distribution of cash benefits and their replacement by Local Authorities (Levy 1944:28).

On the question of the development of a national health service, the Commission concluded, without specifically recommending, that:

"...the ultimate solution will lie, we think, in the direction of divorcing the medical service entirely from the health activities as a service to be supported from the general public funds." (Great Britain 1926)

The Reform Programme of the British Medical Association

The British Medical Association (BMA) made its first foray into the reform of the medical services by the publication of a report in 1938 - *A General Medical Service for the Nation* (BMA 1930). This report undertook a review of the existing relationship between the general practitioner services provided under the national insurance scheme and those other services for which the local authorities were responsible. The conclusion was that refinements were needed. At the heart of the proposals for improvement were four underlying principles - firstly, that the medical service system should be directed as much to the achievement of positive health as much as the relief of sickness; secondly that each individual should be provided with the medical services of a general practitioner whom they had chosen themselves; thirdly that consultants and specialists be available to everyone and finally that there should be closer coordination of the variety of parts of the medical structure by the development and implementation of a planned national health policy (Eckstein 1958:116 and Scott, Cooper and Seuffert 1950:xvi)).

The BMA was in favour of an expansion of the national health insurance scheme so that the dependents of the working population were also covered, together with the statutory guarantee of additional benefits. Greater cooperation between the voluntary and municipal hospital sectors would be ensured by the reorganisation of the local government structure which would deal with health administration (Klein 1989:5).

The initial reforms of the BMA have been described as conservative when compared with the detail of the earlier Dawson Report. It is thought by Eckstein (1958:117-118) that the Dawson report advocated a series of long-term measures while the BMA's document merely fiddled at the edges of the existing system. The importance of the report lies in the fact that the BMA felt sufficiently incited to act in the first place and begin a process which was to lead it to suggest

further reforms. In between those further developments, the Socialists were to produce their own proposals for change.

The Socialist Medical Association

By the early 1930s the socialist attitude towards the provision of medical services had altered greatly, from a purely ideological perspective, from the earlier pronouncements on the subject by the Fabians. The official policy of the Labour Party on the provision of medical services was formulated by the Socialist Medical Association which outlined its main agenda in 1933 (Klein 1989:5).

The basis of their proposed structure was that medical services were to be provided free of charge to everyone; that the personnel involved in the provision of such services should be full-time and salaried; that general practice should move towards a group-oriented practice with full coordination of all medical functions; the basis of the organisation of the provision of services would be the large general hospital and the health centre and finally, that all medical services would be managed by local authorities following reorganisation of the local government structure.

As noted above, the proposals put forward by the Socialist Medical Association were eventually to become the official policy of the Labour Party on the provision of medical services and the reform of the health care system. As such, they occupied a pivotal position within the structure whereby the formation of the National Health Service was to come about.

The British Medical Association's Medical Planning Commission

The outbreak of the Second World War had the effect of stimulating into action many of those who had for some time been outlining in theory what form the proposed reforms of the health service should take. On 21 September 1939 the Ministry of Health, continuing a process, begun in 1938, whereby civil servants within the Ministry had already started to look at the future of the health services, issued a memorandum outlining an option whereby the hospitals could be administered by the Ministry of Health as a National Hospital Service. Earlier papers in this series had advocated the extension of the National Health Insurance scheme and the gradual development of local authority services (Webster 1988:21-22). Klein concludes that this exchange of papers and ideas by civil servants:

"set out most of the main assumptions, issues and factors that shaped the discussions over the next six years..." (Klein 1989:7-9)

Civil servants had begun to take the initiative in developing policy options, placing an emphasis on practical solutions which would initiate change through agreement, particularly agreement with the medical profession. Such change would be managed through the development of existing organisations rather than by introducing new institutions. However certain fundamental changes would be necessary. The Approved Societies who were responsible for the administration of the national insurance scheme would be excluded from the new system.

Official Labour Party policy on the issue, as described above, was made clear to the Ministry of Health in February 1941 (Webster 1988:25). Importantly, the British Medical Association turned

to the subject once again. Klein indicates that the civil servants had recognised that the support and cooperation of the medical profession was the key to the implementation of successful change. As such the BMA's revised proposals would be crucial.

The BMA's 1930 paper, as described above, was revised and reissued in 1938 (BMA 1938). Soon afterwards, after realising that this thinking on the subject may be out-of-date and contrary to its interests, the BMA convened a Medical Planning Commission to study the wartime developments and their effect on the country's medical services. This Commission, which consisted of 73 members, produced an interim report on the subject in June 1942 (Grimes 1991:74-79 and Scott, Cooper and Seuffart 1950: xvi).

The overall ethos of the Draft Interim Report of the Commission was to

"render available to every individual all necessary medical services, both general and specialist, and both domiciliary and institutional." (Medical Planning Commission, 1942a: para III)

In order to achieve these aims, the Commission advocated the central planning of medical services by public authority; the organisation of general practice in health centres and the arrangement of hospitals on a regional basis (Eckstein 1958:119, Pater 1981:39 and Scott, Cooper and Seuffart 1950 xvi-xviii). The Commission did not indicate how the professional services would be paid for although the members did oppose the idea of a salaried medical service. Nor did it indicate the extent of the proposed coverage of the scheme or whether the scheme should be financed centrally or by a combination of central funds and insurance contributions.

"Despite these reservations and unresolved questions, it was clear that the commission wanted nothing less than a unified, centrally planned, public medical service based on a new system of general practice, a regionalised hospital service and governmental control either through the Ministry or a medical corporation".
(Eckstein 1958:120)

The proposals of the Medical Planning Commission were largely accepted by the medical profession itself (Pater 1981:40). Eckstein (1958:131) indicates that the shortcomings of the existing medical services had been shockingly brought to light by the early years of the war and this drove the profession to abandon their own corporate interests and concentrate on the objective needs of the medical system. Their fever for reform however was soon muted by the proposals for reform which were eventually produced by the Government.

The Regional Hospital Surveys

An announcement was made in October 1941 by the Minister of Health that he intended to initiate a survey of hospital services in England and Wales. The objects of the survey were to obtain information about the hospital facilities; assess the adequacy of those facilities and provide advice on the manner in which the existing facilities could be coordinated and expanded (Scott, Cooper and Seuffart 1950:xviii).

The results of the surveys, which were comprehensive in the extent of their coverage, showed that ten hospital beds per one thousand of the population, as well as a further five per one thousand for the mentally ill, were needed. This meant that the existing provision needed supplementing by 40%. In addition the existing hospitals needed regrouping. Improvements were

needed in the numbers and location of teaching hospitals and the provision and distribution of specialists and consultants. The surveys also noted a lack of cooperation and co-ordination between the voluntary and municipal hospitals and strongly criticised the lack of treatment for the chronically-ill (Scott, Cooper and Seuffart 1950:xix).

Plans for a National Health Service 1942-1946

1 Social insurance and allied services: Report (Great Britain 1942)

Eckstein (1958:134) indicates that the report of the Committee on Social Insurance and Allied Services, chaired by Sir William Beveridge is usually recognised as the most important factor leading to the formation of the National Health Service. Pater (1981:43) puts its influence down to the fact that the schemes which had been produced until then had lacked the appropriate sense of urgency, energy and indeed, reality - qualities which the final report of the Beveridge Committee had in abundance.

Sir William Beveridge had been appointed in June 1941 to head up a group of senior civil servants from the government departments involved in the administration of cash benefits and pensions. The terms of reference were:

"to undertake, with special reference to the inter-relation of the schemes of social

insurance, a survey of the existing national schemes of social insurance and allied services, including workmen's compensation, and to make recommendations".
(Great Britain 1942)

The Committee took evidence from a wide range of organisations. During the course of its work, the personal influence of the chairman became so obvious that this, and the fact that certain decisions concerning policy would arise, led to the final report, published in December 1942, bearing the name of Beveridge himself (Webster 1988:35, Pater 1981:43 and Grimes 1991:81).

The pharmacy profession made known its views to Beveridge through the submission of a joint memorandum of the Pharmaceutical Society of Great Britain and the National Pharmaceutical Union. This memorandum emphasised that pharmacy was a distinct calling comparable in status with medicine and dentistry and which only pharmacists were competent to practise. Failure to recognise the position of pharmacy and to make use of the services of pharmacists would result in a lack of efficiency and the uneconomical use of medical supplies. In addition to the pharmacist's specialised knowledge of medicines, his training was such as to allow him to deal with many questions which would arise in connection with the health services. As such, the health services would benefit from the appointment of pharmacists, both to administrative posts in the central, regional and local authorities and from their employment as practitioners. The memorandum urged the Committee to take advantage of pharmacists in planning developments for the new health services (Pharmaceutical Journal: June 27 1942 p.222).

The recommendations of the Beveridge Committee - for the provision of a single universal social security scheme administered by a new Ministry of Social Security - contained in the published report were based on three assumptions introduced in Part VI of the Report. The three

assumptions were based on provision for children's allowances (A), comprehensive health and rehabilitation services (B) and of maintenance of employment (C). Of these, the second (Assumption B) assumed the greatest significance for the development of a National Health Service. This assumption was that a comprehensive health service available to all would be provided. Pater (1981:44) in discussing the rationale behind Beveridge's view that a comprehensive national health service was one essential factor in a satisfactory system of social security, identifies three elements behind his thinking. The first was that it was logical, in a system where high benefits were payable during sickness, to have a scheme whereby the level of sickness would be reduced. The second reason was allied to the first, that for the same reason of reducing liability to pay sickness benefits, early diagnosis and treatment were essential. Finally the health service was necessary to guarantee that cautious certification, necessary to control the payment of benefits, would take place.

It has been noted (Eckstein 1958:134) that the Beveridge Report, while large on constructive ideas, was short on detail, particularly on how the new comprehensive scheme was to be financed. Webster (1988:35-36) points to Beveridge's own change of views on this subject. At an early stage in the deliberations of the committee, he was of the view that a medical service without any charge was correct. The possibility of a charge might prevent individuals applying for treatment. In addition, if the policy view was that the provision of health care treatment was a matter of national rather than individual interest, it should be provided free of charge in the same manner as the provision of police and defence services. The fact that access to the service would be determined by a doctor would prevent frivolous use of the free services.

By the time the final report had been produced, these views had been somewhat modified. By this

stage, the main emphasis was on the principle of contributory insurance with the Insurance Fund making major grants towards the funding of the medical service in return for a larger voice in the administration of that service. In addition, there might be the possibility of "hotel" charges for hospital patients, further charges for other subsidiary services and for dental and optical appliances (Beveridge Report: paras 426-439).

All the main commentators are agreed that the absence of detail could not detract from the overall importance of the Beveridge report in the development of a National Health Service. Webster (1988:35), Pater (1981:45) and Grimes (1991:89-90) indicate that the Report quickly captured the public imagination. Copies of the Report and summaries of it sold rapidly and in numbers. The result was that the Government was faced with a warmly accepted commitment to the provision of a National Health Service which would be difficult to ignore (Klein 1989:7). Eckstein (1958:134) states that the significance of the Report lies partly in the fact that it placed policy concerning the provision of medical treatment in the context of social policy thereby turning the Government's attention away from the hospitals and forward to the planning of the administrative details of the comprehensive national health service.

It was clear that following the publication of the Report, the Government would have to come up with some sort of plans for the introduction of a scheme for a general medical service and the reaction of the Government forms the next significant step in the road towards the introduction of the National Health Service, to be examined below. Equally important, though, would be the reaction of the medical profession to the proposals introduced by the Beveridge Report.

The reaction of the medical profession to the proposals has been described as conservative (Pater

1981:49). Their concerns related to the principle of a full-time salaried general practice and the fact that patients would not be paying for services in any way. Administratively, the medical profession preferred a national corporation with a medical advisory committee together with the reform of local government to provide an effective regional administration of the health service. Lastly, the medical profession were concerned about the timing of the implementation of the proposals. The absence of so many members of the profession in service in the armed forces led many to believe that the decision to introduce a comprehensive health service should be delayed. However, despite these initial misgivings, by February 1943, the British Medical Journal (British Medical Journal 1943) was recommending the introduction of the Beveridge Report and was indicating that the medical profession would agree to the introduction of a scheme for a comprehensive medical service provided its character, terms and conditions of service were negotiated with the medical profession (Cartwright 1977:173). At the same time, the Government announced the outcome of its deliberations on Beveridge's proposals.

Webster (1988:39-40) reports that the question of the Government's commitment to the implementation of the Beveridge proposals was inseparable from the broader issue of the priorities for post-war reconstruction. As such the Beveridge proposals had to be considered initially by the Reconstruction Priorities Committee which itself had been restructured as a result of the publication of the Beveridge Report. In this Committee, there was no disagreement concerning the need for the introduction of a comprehensive health service thereby leaving the way open for a full discussion of the issues in Parliament.

The Beveridge Report was debated in the House of Commons between the 16th and 18th February 1943. Eckstein (1958:135) states that the fact that the Government statement on the

proposals by Sir John Anderson, was read to the House, contrary to parliamentary custom is indicative of the importance which the Government attached to the Beveridge proposals despite their initial statement being described as provisional. In brief the Government accepted the principle of Assumption B and the concept of a comprehensive medical service not directly linked to social security seeing the proposals as being the culmination of a long series of efforts, including its own ideas for hospital reform and the Medical Planning Commission's draft interim report (Pater 1981:45). The approach was cautious however with indications that no obligations would be placed on patient or doctor and that there would be no threat to the voluntary hospital sector or professional interests (Webster 1988:40).

During the debates following the pronouncement of the statement of the health service, there were calls for more urgent action and for the immediate establishment of a Ministry of Social Security. In further debates in the House of Lords, there was a series of criticisms of the proposals contained in the Beveridge Report and the of the Government's reaction to them in the Lower House. These criticisms related to the handing over of control of hospitals to local authorities, the administrative arrangements for health centres and the possible introduction of a medical council representing the interests of the profession (Pater 1981:46-47). However the Government line was again to endorse, in principle, the policy behind the Beveridge Report, making it clear that the details of control and funding had yet to be worked out.

The pharmacy profession's immediate reaction to the publication of the Beveridge Committee Report was to realise that it would involve fundamental changes to the practice of the profession and to advocate a unified plan which would follow the proposals which had already been put forward before the Committee through the submission of the joint memorandum.

(Pharmaceutical Journal 29 May 1943 page 196). After some time for reflection further ideas as to how the pharmacy profession might participate in a national health service were put forward by the President of the Society (Pharmaceutical Journal 26 June 1943 page 230). These ideas reflected the view that the existing facilities in pharmacy could adequately provide for the public what was needed under a national health service but that particular administrative arrangements would have to be introduced to ensure compliance with appropriate standards.

Following the initial announcements in Parliament, the Minister of Health began a series of discussions with a variety of interest groups including the representatives of voluntary hospitals, local authorities and the medical profession. Webster (1988:40) indicated that the impetus for these meetings was the sense of realism which had been introduced into the debate by the Parliamentary announcements in February 1943. Each group was sent details of the principles on which the Government proposed to act. Pater (1981:52) outlines these principles in full while Webster (1988:45-50) and Pater (1981:55-69) comment in detail on the nature and form which the discussions took. The proposals include the idea that the health service should be comprehensive and available to all but not necessarily on a compulsory basis. The service was to be free (subject to the possibility of charges for inpatient treatment and for some appliances) and patients were to have a free choice of doctor and comprehensive use of voluntary hospitals. Beveridge's rationale relating to the need for efficient certification and prevention of illness to avoid liabilities on the social insurance funds was included as a proposal. The new service was to be administered locally with an significant input from the medical profession whose terms and conditions of employment would be a matter for a new central medical board. The existing arrangements for the administration and management of voluntary hospitals were to be maintained subject to certain minor changes relating to nurses' pay and medical appointments.

Finally and importantly, general medical services would be based in health centres.

All the groups were told that the discussions were non-committal and that there would be room for further consultation with their members at a later stage. Pater (1981:56) comments that the discussions with the local authority representatives were friendly and fairly constructive, probably because the local authority representatives were conversant with the language of government.

"The same could not be said of the discussions with the voluntary hospitals and the doctors, where suspicion and mistrust surfaced very soon"

The basis of the mistrust on the part of the voluntary hospitals was their perception that rather than amounting to a partnership with the local authorities the proposals amounted to the domination of the voluntary hospitals by the local authorities. Drawing on their own previous, poor, experience of the relationship with the local authorities the voluntary hospital representatives decided to come up with their own proposals. These were discussed with the Government representatives during a further series of meetings until a consensus of sorts was reached (Pater 1981:58-59).

Pater (1981:61) reports that the basis of the medical profession's distrust was the fact that its opinion had largely been ignored by the Ministry of Health who, in the past, had not shown any large degree of interest in the development of a comprehensive national health service. As such the initial discussions took place in a guarded, even critical, atmosphere. A long series of negotiations, accompanied by lengthy debate (Eckstein 1958:140-143) within the medical

profession itself, the latter prompted by the leaking of certain Ministry of Health proposals to the press (Cartwright 1977:173), resulted in a certain degree of stalemate. The Ministry confirmed that they would give full weight to the views of the medical profession and that nothing in the discussions so far would bind anyone. The developments in relation to the medical profession were closely monitored in the pharmaceutical press (Pharmaceutical Journal 11 September 1943 page 100). The initial discussions having been completed in a somewhat fraught atmosphere, the Government sought to bring its policies into the open through the publication of a White Paper.

In the interim a number of other groups asked to see officials of the Ministry in order to express their views. These included pharmacists. Pater (1981:74) reports that representatives of the pharmacy profession were seen by Ministry officials. The pharmacy representatives were keen to see a greater professionalisation of their role. In their view, an adequate pharmacy service could be provided through the continuance of the chemist shop. However they sought some degree of protection from the possibility of competition from the proposed local authority employed pharmacists. In addition they approved of the idea of a central body which would have the role of co-ordinating local professional committees, setting standards, defining terms of service and regulating the entry of new recruits. Having made their representations, they too were prepared to await the publication of the White Paper.

2 The White Paper

Although the White Paper *A National Health Service* (Great Britain 1944) was eventually published in February 1944, drafts had been in existence since July of the previous year. The proposals in these drafts were considered first by the Reconstruction Priorities Committee and the

War Cabinet during the following months. Amendments were made before the final draft was approved on 4 February 1944 by the Reconstruction Priorities Committee and on 9th February 1944 by the War Cabinet.

The overall basis of the White Paper was the provision of a comprehensive public health service. Detailed administrative arrangements for the provision of such a service were outlined and may be summarised as follows:

Structure of the Service

(i) Central Central responsibility to Parliament would lie with the Minister of Health.

At the side of the Minister there would be a professional and expert advisory body called the Central Health Services Council

(ii) Local Local responsibility would be based on the county and county borough councils.

Areas suitable for hospital organisation would be designated by the Minister after consultation with local interests.

The county and county borough councils in each area would combine to form a joint authority to administer the hospital, consultant and allied services.

At the side of each new joint authority would be a consultative body called the Local Health Services Council.

Each joint authority would also prepare and submit for Ministerial approval an area plan for securing a comprehensive health service in its area.

County and county borough councils would also be responsible for the local clinic and other services in accordance with the area plan.

(iii) General Medical Practice Everyone would be free to choose a doctor

Medical practice would be a combination of group and separate practice.

Grouped practice would be conducted normally through specially equipped and publicly provided Health Centres.

General practice would be organised centrally under the responsible Health Ministers. The main terms and conditions of the doctor's participation would be centrally settled and much of the day to day administration would be the responsibility of Central Medical Boards.

The role of the Board, composed mainly of doctors, would be to oversee that the distribution of general practitioners would be on an equitable basis, by refusing, if necessary, consent to enter into practice in certain areas.

It was not proposed that there should be a universal salaried system for doctors in the new service. Doctors in the Health centres would be remunerated by salary or equivalent; doctors in separate practice would be paid by capitation fee.

It was not proposed to prohibit doctors in public practice from engaging also in private practice for any patients who still wanted that.

Compensation would be paid to any doctor who lost the value of their practice.

Arrangements for the supply of drugs and medical appliances would be considered and discussed with appropriate bodies.

(iv) Hospitals

A proposal was put forward for the formation of Joint Hospital Authorities composed of representatives of both the local authorities and professional consultative bodies.

These authorities would prepare plans for the provision of comprehensive hospital services in their respective areas.

The independence of the voluntary hospitals was to be guaranteed by allowing them to remain outside the scheme. Should they choose to join the scheme, they would receive specific sums of money for the services which they provided.

The Joint Hospital Authorities were also to be responsible for the provision of adequate numbers of specialists and special services such as clinics, home nursing and health visiting.

The pharmacy profession's immediate reaction was to express disappointment that the Government remained broadly satisfied with the drug supply system under the existing National Health Insurance scheme given that the joint memorandum to the Beveridge Committee had outlined details of the profession's suggestions for improvement in that system. Any proposal for only minor changes in the existing system would be met with vigorous opposition (Pharmaceutical Journal 26 February page 83).

The medical profession's reaction to the proposals has been described by Pater (1981:83) and Grimes (1991:101-102) as suspicious, rapidly becoming critical. Eckstein (1958:143) is of the view that their initial fears related more to what they perceived to be hidden in the Paper rather than what had actually been proposed.

Their tactics thereafter were to delay the implementation of the proposals. A questionnaire was produced to ascertain the views of the profession as a whole. The idea of the questionnaire was welcomed by the pharmacy press who hoped that the debate within that profession would be as vigorous and as detailed (Pharmaceutical Journal 18 March 1944 page 111).

The BMA questionnaire produced some surprising results. The profession welcomed the idea of a free health service for the entire population, the establishment of a Central Medical Board, the idea of group practice in health centres and the abolition of the sale of practices but rejected the White Paper overall (Eckstein 1958:148, Pater 1981:87-90).

The White Paper was positively welcomed in Parliament during debates which took place on 16 March 1944. The pharmacy profession's reaction to these debates was less enthusiastic. The concerns related mainly to the fact that the debates revolved around two points relating to the fear of regimentation of doctors and the fear that voluntary hospitals would be liquidated if the proposals as they stood were implemented (Pharmaceutical Journal 25 March 1944 page 130).

By the end of April 1944, a Memorandum had been produced by the Joint Committee of the Pharmaceutical Society, the National Pharmaceutical Union and the Pharmaceutical Standing Committee for Scotland. The Committee proposed that pharmaceutical bodies be established at national, regional and local level. At national level a Central Pharmacy Board at the same level of the Central Medical Board was proposed. An Area Pharmacy Board was proposed at the level of the new Joint Authorities and at the level of county and county borough councils, a local Pharmacy Board was proposed as an expert body which would be available for consultation and advice on pharmaceutical matters. In addition, the Committee invited debate on the type of health centre which it was proposed to set up and the level of remuneration for the pharmaceutical service both of which would be affected by the structure of the administrative machinery (Pharmaceutical Journal 29 April 1944 page 173).

The next step for the medical profession was to produce, in May 1944, a Report for the Annual Representative Meeting which eventually took place in December of that year, having been postponed as a result of the war. The Report began by indicating that:

"There is suspicion, not without basis, that these proposals found their first

inspiration in a desire to control an independent profession in order to control medical certification and so the outgoing of a social security fund. Health is not mainly a question of medical services ... It is inclined to suspect that the inspiration of the Government's document is political rather than medical." (BMA 1944)

The BMA proposed that the central body should be concerned with all civilian health and medical functions of central government and exclusively with those; that the central body should be advised by a statutory body, predominantly medical in nature; that this statutory body should play a prominent and effective part in advising on ministerial policy on health and medical services and on the means of achieving positive health; that the medical members of the Central Health Services Council should be elected by the medical profession and should hold office for three years and that the Council should not be concerned with terms and conditions of service but that such terms and conditions should be negotiated directly between the Minister and the medical profession with a permanent agreed machinery being established for this purpose.

The pharmacy profession had some sympathy with the medical profession's general view and with the more detailed practical plans which the Report put forward (Pharmaceutical Journal 20 May 1944 page 206). However by June 24 1944, the pharmaceutical press was expressing concern that any proposed disturbances suffered by the medical profession were bound to affect pharmacy given the inevitable close links between the two professions.

Negotiations with the medical profession were postponed pending the outcome of the December meeting of the Annual Conference (Pharmaceutical Journal 10 June 1944 page 236). As such, almost a year had passed since the publication of the White Paper without there being any official response from the medical profession. Pater (1981:90) states that the meeting firmly endorsed the

British Medical Association Council's criticism of the proposals outlined in the White Paper (Pharmaceutical Journal 16 December 1944 page 244). The net result was that the Government had to reopen negotiations not only with the medical profession but with the voluntary hospitals and the local authorities who were equally dissatisfied with aspects of the proposals (Klein 1989:14-15). In a parallel way, the Government entered into discussions with those other groups who would be affected by the introduction of the scheme including pharmacists and others (Pharmaceutical Journal 10 February, page 78, 17 March page 139 and 21 April 1945, page 200).

Pater (1981:98) indicates that the Ministry of Health's proposals for pharmaceutical services were that they should remain such as they had been under the National Health Insurance scheme but that they should be received by the entire population. Contracts should be between the pharmacist and a local committee which should have pharmacy representatives amongst its members. Dispensing services might be provided in health centres but there should be no compulsion to use them. At further meetings, the pharmacists pushed for further representation in planning and administration at local level and the right to have all hospital and clinic dispensing done by them or under their supervision. Further they demanded more control over the opening of new pharmacies and for an assurance that all dispensing in pharmacies should be under the pharmacist's direct and personal supervision. Further assurances were sought relating to gifts or rewards for pharmacists' services.

The pharmacy profession produced a detailed response to the White Paper which included details of changes which had been discussed with the Government in late April 1945. The memorandum welcomed the proposal to introduce a National Health Service. It emphasised that the new service

provided an opportunity of putting pharmacy in its rightful position among the health services and called for a fundamentally new approach to every aspect of the provision of medicines and the utilisation of the pharmacist. The proposals had two general principles. The first was that where pharmaceutical questions were involved, effective pharmaceutical advice and direction must be available. The second was that the experience of thirty years' working of the National Insurance Acts must be the foundation of the new service. The memorandum also re-emphasised the requirement for a central pharmaceutical body and made clear that remuneration must be adequate to ensure that the service was self-supporting (Pharmaceutical Journal 28 April 1945 page 207).

As a direct consequence of this involved round of negotiations and meetings, Henry Willink, the Minister of Health prepared a report of the progress which had been made to date. In the meantime a draft Bill had been prepared and was in circulation. Willink's report was considered in cabinet (Webster 1988:74 and Grimes 1991:113) but in view of the impending election, it was felt that it would not be appropriate to publish the report. Developments now awaited the outcome of the general election.

3 The Labour Party in Government

The victory for the Labour Party in the general election of 1945 brought Aneurin Bevan to the Ministry of Health. Following an initial settling-in period, Bevan conducted a number of meetings with the interested groups while formulating his own proposals on how the scheme should be introduced. These proposals were discussed at length in the Cabinet during the months of November and December 1945. By early December the Minister was able to outline to the

Cabinet proposals for the introduction of a national health service and was able to ask for authority to prepare a Bill for consideration (Pater 1981:114-115 and Grimes 1991:138).

Early in January 1946, a further paper with an outline scheme which followed closely the recommendations contained in the 1944 White Paper (Pater 1981:117) was produced for the Cabinet and sent to a number of interested parties including representatives of the medical profession and the pharmacists. The policy of Mr Bevan of inviting deputations to see him in order to inform them of his decisions was derided by the pharmacy profession who could see no benefit in such intransigence (Pharmaceutical Journal 2 March 1946 page 137).

A draft Bill was introduced to the Cabinet on 1 March and approved by it on 8 March. The National Health Service Bill, described by Webster (1988:94) as "more of a product of metamorphosis than spontaneous generation" was published on 20 March 1946.

Accompanying the Bill was a White Paper which summarised the details of the implementation and administration of the new comprehensive health service (Great Britain 1946). The service would be operated through three main levels - the Minister, acting through new regional and county boroughs, who would be responsible for the provision of hospital and specialist services; counties and county boroughs who would be responsible for health centres, clinics and domiciliary services and executive councils, made up of professional and lay members appointed by the local authorities and the Ministry which would be responsible for the general practitioner services of doctor, dentist and pharmacist.

The Minister would have a statutory duty to provide hospital and specialist services although the

administration of these would be through the regional boards. All hospital property and equipment would be owned by the Ministry. There were to be between 16 and 20 regional boards whose membership would be determined by the Minister and who, in turn, would appoint hospital management committees. The proposal was that Boards would devise and administer the service under the direction of the Minister and the hospital management committees would concern themselves with day-to-day management. Consultants and specialists would be full or part-time and beds would be provided on either a public, free or private basis.

General practitioner services would centre around the formation of health centres provided by local authorities but where the doctors (and dentists and pharmacists) would work under a contract with executive councils. All doctors would be free to join the service if they wished and they could continue to have private patients. All patients would have freedom of choice of doctor. Doctors would be paid by a combination of fixed part-salary and capitation fees. Distribution of doctors would be determined by a medical practices committee who would have responsibility for consenting to entrance or removal to a particular general practice area. The sale of practices would be prohibited but compensation would be paid instead. In addition to health centres, local authorities would also be responsible for the provision of clinics and other services including home nursing and midwifery, home helps, health visitors, ambulances and vaccination and immunisation.

Most of the cost of the new scheme would fall on the Exchequer with certain contributions coming from the National Insurance fund. The local authority services would be paid for from the rates with the assistance of a grant from the Exchequer.

The reaction of the pharmacy profession to the publication of the Bill was to comment critically that the director of the service must be relieved of all other duties and be left free to concentrate on the day to day problems of running the service so great would be the responsibilities associated with that task. Having said that, there was an approval of the general principle embodied in the Bill and of the particular evidence that the pharmaceutical service was to be provided by pharmacists. Some concern was expressed about the detail of the administrative arrangements associated with the new service. The press noted that the biggest effect which the Bill would have on the practice of pharmacy would be to increase significantly the volume of dispensing. As such, clear attention would have to be paid to the planning and implementation of the service (Pharmaceutical Journal 30 March 1946 page 199). The Bill's contents were considered in detail by a joint meeting of representatives of the Pharmaceutical Society, the National Pharmaceutical Union and the Pharmaceutical Committees on 9 April 1946 (Pharmaceutical Journal 13 April 1946 page 236). The result of the meeting was a belief that from a pharmaceutical point of view, the Bill gave the pharmacy profession a fair deal (Pharmaceutical Journal 20 April 1946 page 258).

The National Health Services Bill went through its Parliamentary stages between 20 March and 6 November 1946. Despite discussion and debate at every stage (Pater 1981:119-136, Webster 1988:94-102, Pharmaceutical Journal 11 May, page 297, 1 June, page 352 and 22 June 1946, page 396) its passage through Parliament has been described as smooth, patient steering by a Government committed to a firm but conciliatory line on the legislation (Webster 1988:103). Because the new scheme would lead to such radical changes in the provision of health services, it was not due to come into operation until the "Appointed Day", the 5th of July 1948. In the interim, opposition to the contents of the legislation continued and conflict with the medical

profession seemed to be inevitable (Webster 1988:107-108 and Grimes 1991:183). The difficulty for the Government was that they still needed to enact detailed regulations to complete the scheme and establish an effective administration to run it both of which would require the collaboration of the medical and pharmacy profession. The pharmacy profession's concerns for the content of the regulations were noted at the end of the passage of the Bill through the House of Commons (Pharmaceutical Journal 27 July, page 40 and 3 August 1946, page 65).

The "inevitable conflict" between the medical profession and the Government has been described in detail by Webster (1988:107-120), Cartwright (1977:174-180) Pater (1981:139-164) and Grimes (1989:183-207). Both sides in the argument - the Ministry represented by Bevan and the medical profession in the guise of the British Medical Association - stood firm in their differences of view on aspects of the proposed system. In particular Bevan was clear that there would be no significant amendments to the legislation as enacted although he was prepared to concede a number of points during negotiations. Those concessions were not enough for the BMA and the conflict escalated to the point where the BMA held a plebiscite of members the result of which indicated that the vast majority of doctors disapproved of the legislation as enacted. As a result of mediation by Lord Moran, Bevan announced to the House of Commons that he was prepared to introduce an amending Bill to satisfy some of the criticisms of the medical profession. The proposed Bill which was eventually enacted as the National Health Service (Amendment) Act 1949, was sufficient to satisfy the medical profession who eventually resolved to enter the new service. This measure did not affect the practice of pharmacy at all (Pharmaceutical Journal 21 May 1949 page 373).

On the pharmacy side, a Pharmaceutical Committee Conference on Negotiations took place on

July 17 1947 (Pharmaceutical Journal 26 July 1947 page 59). It was agreed that the Joint Contractors Committee of National Pharmaceutical Union with full executive powers should be the negotiating body. Meetings took place with the Ministry in October 1947. Further discussions continued until the end of the year although the pharmaceutical press was not in a position to report much progress in its end of year review (Pharmaceutical Journal 27 December 1947 page 461).

In late March 1948, the first set of Regulations governing the general medical and pharmaceutical services of the National Health Service was published. The National Health Service (General Medical and Pharmaceutical Services) Regulations 1948 (SI 1948 No. 506) were the first official statement of the proposed arrangements for the supply of drugs, medicines and prescribed appliances to persons receiving general medical services.

Participation in the scheme was dependent upon inclusion in a Pharmaceutical List which would be prepared by the Executive Councils. Applications for inclusion in the list would be made on a specified form similar to that which was already in existence. The Executive Councils would also be responsible for the preparation of schemes for testing the quality and amount of drugs to be supplied and for ensuring the adequate supply of such materials. In addition, the Minister would also arrange for the preparation of a "Drug Tariff" which would include the prices on the basis of which the payment of drugs would be calculated; the method of calculating the payment for containers; the dispensing or other fees payable in respect of the supply of drugs and the standards of quality for drugs and appliances.

The Fourth Schedule to the General Medical and Pharmaceutical Services Regulations set out

the terms of service for chemists participating in the scheme. Any pharmacist participating within the scheme was under an obligation to dispense any lawful prescription which was presented to him and to supply any drug in a suitable container. All drugs which were supplied were to be of the grade or quality outlined in the Drug Tariff. Dispensing was to take place at premises which were included in the Council's list and were to be open at appropriate times. Dispensing of certain medications was to be carried out directly by the pharmacist himself or by someone else under their direct supervision. Special rules were also introduced regarding the maintenance of records and forms for the supply of medicines were also introduced. Payment was to be made according to the rates specified in the Drug Tariff by the submission of prescription forms to the local Executive Council.

The pharmacy profession's first reaction to the publication of these detailed regulations relating to its position within the new health service was generally favourable (Pharmaceutical Journal 27 March 1948 page 211). Attention now focused on the adequacy of the terms for remuneration of pharmacists, particularly in relation to the level of the dispensing fee. By the end of May 1948, the National Pharmaceutical Union circulated what appeared to be the final offer from the Ministry of the terms for the new service. These were not well received by the profession and in June a series of contractors' conferences took place, as a result of which an amended offer was made (Pharmaceutical Journal 12, page 407 & 19 June 1948, page 423). The amended offer was not completely satisfactory but the National Pharmaceutical Union could not advise pharmacists to stay outside the scheme. The result of this frantic series of last-minute negotiations meant that it was not until the end of June 1948 that full information was sent to pharmacists of the arrangements for their remuneration and invitations issued for application for inclusion in the pharmaceutical list (Pharmaceutical Journal 26 June 1948, page 439). In many ways this is

remarkable given the close proximity of "Appointed Day" of 5 July 1948 for the commencement of the new service.

Two days before the commencement of the new service, the pharmaceutical press was eagerly awaiting the changes which it would bring, particularly the increase in the number and level of prescriptions which would be dispensed (Pharmaceutical Journal 3 July 1948). Within one week of the introduction of the national health service, the pharmacy profession was able to comment that the predicted increase in the numbers of prescriptions to be dispensed had become reality (Pharmaceutical Journal 17 July 1948, page 37). A further review undertaken after one month confirmed that the greatest single change for the practice of pharmacy brought about by the introduction of the national health service was the heavy increase in the number of prescriptions presented for dispensing (Pharmaceutical Journal 14 August 1948, page 102). After two months, this trend was continuing and other significant changes relating to childrens' medicines, pricing prescriptions, proprieties, quantities ordered, late service and health centres were noted (Pharmaceutical Journal 28 August 1948, page 133). After six and twelve months the propensity towards an increase in the volume of dispensed prescriptions was noted again and the pharmacy profession was able to conclude that this confirmed the important fact that pharmacists were carrying out the dispensing for practically the whole population and were undertaking the duties for which they were primarily trained (Pharmaceutical Journal 15 January, page 39 and 23 July 1949, page 65). The new arrangement were largely preferred by pharmacists to those which existed before the implementation of the new service. However this enthusiasm was qualified by the finding that the preference for the new system emanated from a dissatisfaction with what had gone before.

The actual system whereby pharmaceutical services were to be provided within the new National Health Service was relatively straightforward for the 16,800 chemists who contracted to supply medicines. Having obtained a health service prescription, the patient would go to the shop of a pharmacist working within the scheme. The pharmacist would dispense the drug product, charge the patient a fee per item and then send the prescription form to a Pricing Bureau. The Bureau would pay the rest of the Bill in accordance with a National Drug Tariff which lists the basic wholesale price of all drugs and medicines. The Bureau would add on every prescription a dispensing fee, an on-cost allowance, representing the usual commercial mark-up over the wholesale price and a container allowance (Holloway 1991:344).

Before considering the actual impact of the introduction of the National Health Service on the provision of medicinal products to patients, it is appropriate to note that as a corollary to the birth of the NHS, the evolution of the pharmaceutical industry had the most significant technological and scientific impact on the practice of medicine within the National Health Service structure. It is worth beginning with the early history of the industry to show how significant its impact was on the development of the National Health service and vice versa.

The Growth of the Pharmaceutical Industry and Its Relationship to the National Health Service

i The Early Development

It has been suggested that the modern pharmaceutical industry - as a direct outcome of the advancement in pharmacological knowledge - is relatively new dating from 1935 (Davies 1967:1 and Cooper 1966:1). However despite that clear fact, it is also true to say that the modern era owes much to pharmacological developments in the late eighteenth and nineteenth centuries.

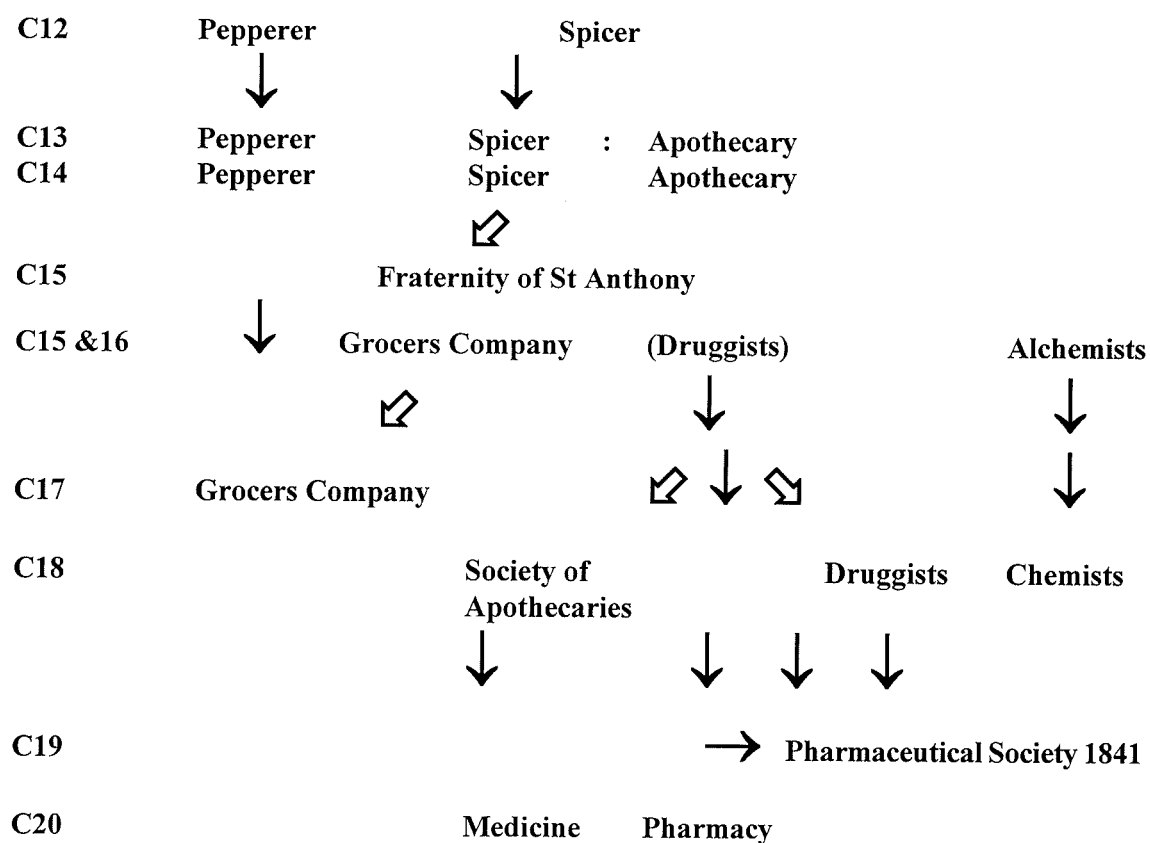
Weatherall (1986a:634) notes the increase in scientific activity which took place in Paris at the end of the eighteenth and the beginning of the nineteenth centuries. He refers to the activities of Lavoisier, Orfila, Magendie, Pelletier and Caventou. By 1806, this activity had spread to Germany and had led to the isolation of morphine from opium by Serturner (Weatherall 1986a:634 and Chetley 1990:18). In Paris Pelletier and Caventou had adapted Serturner's methods and succeeded in isolating a number of alkaloids - emetine, quinine, strychnine, brucine, veratrine, colchicine, cinchonine, atropine and codeine from natural sources between 1817 and 1821 (Weatherall and Chetley *supra*).

In 1824 a chemical laboratory was set up in Germany by Emmanuel Merck which was designed to produce bulk, superior amounts of the newly discovered alkaloids (Cooper 1966:2). To a certain extent this development, whereby processors or makers of medicines established companies which both retailed medical products directly to the public through retail shops and supplied other retailers as immediate wholesalers, mirrored what was taking place in England where large pharmaceutical companies began to appear.

In the first chapter of this thesis, it was noted that the modern pharmacy profession emerged from the movement of Spicers to the role of Apothecaries, their further sub-division into Druggists and their amalgamation with those Chemists who had evolved from Alchemists. In the seventeenth and eighteenth centuries there had been a shift in emphasis from pharmacy to medicine amongst many of the apothecaries leading to the formation of the modern medical profession (Reekie and Weber 1979:3). Absent from that discussion had been the fate of those retailing Chemists and Druggists who had no interest in the practice of pharmacy and did not join their colleagues from the Apothecaries who together formed the Royal Pharmaceutical Society of Great Britain and

thus the modern pharmacy profession.

Poynter (1965:12) uses the following diagram to illustrate the evolution of the apothecary, pharmacist and pharmaceutical manufacturer in the United Kingdom:



Those chemists and druggists who did not have an interest in the practice of pharmacy developed into wholesalers and ultimately into manufacturers. Reekie and Weber (1979:4) and Chetley (1990:18) indicate that this led directly to the formation of some of today's familiar names in the pharmaceutical industry including Allen & Hanbury and May and Baker. It is important to note that in 1867 the London Wholesale Drug and Chemical Protection Society was formed which became the Drug Club in 1891. It will be seen below that these organisations were the forerunner of the Association of the British Pharmaceutical Industry which today represents the interests of those companies in Britain producing prescription medicines. Similarly in 1896 the Proprietary Articles Trade Association was formed which was the forerunner of the Proprietary Association of Great Britain the association which today represents the interests of the manufacturers of non-prescription medicines.

However Liebenau (1990:725) indicates that among the United Kingdom companies, unlike their European counterparts, there was little commitment to pharmaceutical investigation or product development. Many companies did not follow the European example of establishing laboratories relying on the importation of already developed products. Those companies which did establish laboratories did not integrate them into their existing businesses. Although there was some change with the establishment, towards the end of the nineteenth century, of the Wellcome Physiological Research Laboratories, Liebenau (1990:726) is able to conclude that by the time of the outbreak of the first world:

"... the major British pharmaceutical firms were relying on cartel, convention, and licensing agreements with German and Swiss companies to be able to offer new products ... the industry was, in business terms, reasonably stable but unable to supply the domestic market with many of the products that had so changed the industry. There were no major industrial laboratories for product development, and British companies ... seemed incapable of doing much else."

Meanwhile the major developments were continuing in Europe. Chetley (1990:18) and Weatherall (1986a:636) notes that the successful synthesis of an organic compound from inorganic material led scientists such as A.W. Hofmann and W.H. Perkin to work on the possibility of the **creation** of substances. Hoffman had been responsible for the synthesis aniline and Perkin had discovered the first synthetic coal tar dye. This led directly to the link between chemistry and microbiology from which, in turn, the synthetic dye industry developed through companies such as Bayer and Hoechst in Germany. This industry was the basis of the evolution of a number of important pharmaceutical products by the end of the nineteenth century. Chetley (*supra*) indicates that antipryine for fever had been produced by Hoechst in 1883 with Bayer introducing phenacetin for fever and pain in 1888. Very soon afterwards Felix Hoffmann, a

chemist in Bayer's laboratory, made the major breakthrough in the development of aspirin.

One of the next concerns for the chemical industry was the development of products which could cure disease. Already the work of Louis Pasteur, Robert Koch and Joseph Lister had shown - through the development of the germ theory of disease - that there could be success in the prevention of disease through the use of vaccines and antiseptics in surgery (Weatherall 1986b, Cooper 1966:4 and Chetley 1990:19). The solution was finally found through the work of Paul Ehrlich. Ehrlich came to work with Robert Koch and became the Director of the State Institute for Serum Research and Serum Testing (Weatherall 1986b).

His initial work involved stain cells and micro-organisms with chemical dyes. Later after some other work (Weatherall 1986c:770-771) he observed that the bacteria were sometimes killed by some of the dyes. He realised that if the dyes would attach themselves to diseased bacteria without damaging whole body tissues or cells then the contribution to the treatment of disease would be significant.

When the organism which caused syphilis was recognised, Ehrlich sought to identify an arsenic compound which would kill the organism. In 1904 he succeeded, describing his discovery of Salvarsan (arsphenamine) as a "magic bullet", an antibody which could aim within the body on its own. This method was different to, and a considerable advancement on, the use of vaccines which stimulated the immune system of the body to fight disease and earned Ehrlich the Nobel Prize for Medicine in 1908 (Midgley 1988:361, Reekie & Weber 1979:5, Chetley 1990:19, Cooper 1966:5 and Weatherall 1986c).

ii The Association of Manufacturers of British Proprietaries and the Wholesale Drug Trade Association

Despite this significant breakthrough, there would be no further major developments for another twenty-five years. In the meantime there were some significant developments in the United Kingdom in relation to the formation of a trade association for the manufacturers of proprietary medicines. It has already been noted above that in 1896 the Proprietary Articles Trade Association was formed by William Samuel Glyn-Jones for the purpose of the establishment of resale price maintenance. In 1899 Glyn-Jones was also responsible for the formation of the Chemists' Defence Association for the purpose of regulating the pharmacy profession and for ensuring the right of chemists to dispense (Holloway 1994:M2). It was also noted that the London Wholesale Drug and Chemical Protection Society had been formed in 1867 and the Drug Club in 1891.

Glyn-Jones addressed a meeting of all of the representatives of the leading manufacturers of proprietary medicines on 2 June 1919 about the Government's proposals to introduce a Bill relating to Patent Medicines. As a result of his remarks a new group called the Association of Manufacturers of British Proprietaries was formed with membership open to the owners of British owned or manufactured proprietary medicines, appliances and foods. The initial objects of the Association were:

- (1) To promote the co-operation between British subjects engaged in the manufacture of proprietary articles and foods sold by the Drug Trade;**
- (b) To make representations to government departments or other public bodies at home or abroad;**
- (c) To secure mutual support and co-operation in dealing with any demands as**

to wages and working conditions affecting common interests of the industry;

- (d) To initiate, support, or oppose legislation concerning any matters connected with the industry;**
- (e) To take whatever action may be necessary to protect British Industry and enable it to compete in the markets of the world;**
- (f) To affiliate with any other organised body or bodies in the British Empire having objects similar to those of the Association. (Holloway 1994:M2)**

The AMPB spent most of its first seven years of existence negotiating with Government over the possibility of the introduction of proprietary medicines legislation. When the possibility of this initially ran out in 1926, the Association changed its name to the Proprietary Association of Great Britain. Under this title the Association continued in its role of regulating the proprietary medicines industry in Great Britain (Holloway 1994:M6). It is still performing this function today.

The Drug Club which was the successor to the London Wholesale Drug and Chemical Protection Society, joined the Chemists' Supply Association in 1930 to form the Wholesale Drug Trade Association. This development had a significant impact on the formation of the Association of the British Pharmaceutical Industry which today represents the interests of the companies in Great Britain which produce prescription medicines (Lang 1974).

iii The Pharmaceutical Industry From 1935

The important work of Ehrlich which led to the development of chemicals which could be tailored to destroy the micro-organisms which caused disease has already been noted. The impact while extremely significant did not take full effect until the mid 1930s with the work of Gerhard

Domagk. Although Alexander Fleming had discovered penicillin in 1928, his lack of chemical support meant that he was unable to develop it (Weatherall 1987b:113).

Domagk was the Director of the Eberfeld research department of the Bayer Company. In 1935 he published a paper in which he outlined details of experiments in which he injected mice with a virulent strain of streptococcus. Those mice which had been injected with solutions of a red dye, coal-tar called Prontosil were cured while those which were not died within a few days. Domagk believed sufficiently in his discovery to try it out on his daughter who was suffering from septicaemia (Davies 1967:1-2, Weatherall 1987a:28, Cooper 1966:5, Chetley 1990:19 and Midgley 1988:359). This significant discovery led to what has been described as the "therapeutic revolution" (Reekie and Weber 1979:5)

The significant constituent of the red dye was soon discovered to be sulphanilamide. This had actually been discovered in 1908 by the Louis Pasteur Institute in France when its germ-killing properties were not recognised. While this had obvious commercial implications for Bayer who believed that they had a patent on the dye, it did not prevent the revolution from growing. Prontosil had been an immediate clinical success. The new processes initially centred around the isolation of sulphanilamide and soon some 5000 members of the sulphonamide family had been synthesised and tested among them sulphathiazole, sulphadiazine, sulphamerazine and sulphapyridine - the famous M & B 693 from May & Baker's Ltd in 1938 which was twice to save the life of Winston Churchill during the war (Weatherall 1987a:28, Reekie and Weber 1979:5, Cooper 1966:5-6 and Davies 1967:2).

The onset of the Second World War began the period when development of antibiotics was the

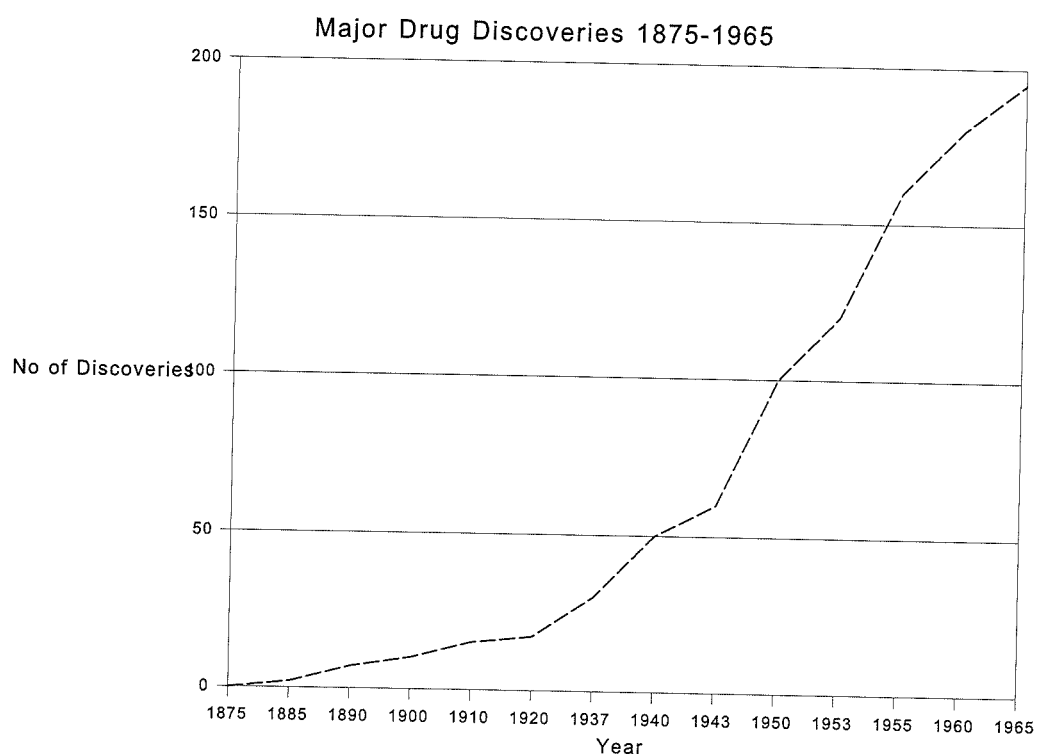
priority. At the heart of that development were Howard Florey and Ernst Chain. Although, as we have already noted, the preparatory work had been undertaken by Alexander Fleming in 1928 when he observed the constraint of the growth on a culture when a spore of the genus *Penicillium* mould settled on it, he found it difficult to produce the antibiotic in ample volume for it to be of clinical value. Florey and Chain were able to prepare solid penicillin. They produced enough penicillin to show its competence in destroying bacteria and the fact that it was non-toxic (Weatherall 1987b:113, Reekie and Weber 1979:5, Cooper 1966:5-6, Chetley 1990:19 and Davies 1967:3).

Some attempt at developing the new discovery on a commercial scale was made in the United Kingdom through the collaboration of the major United Kingdom pharmaceutical companies but the demands of the war were such that effective investigation of bulk methods of manufacture was not possible. The focus switched therefore to the United States of America where the commercial possibilities of penicillin were initially exploited to the full (Davies 1967:4-5, Weatherall 1987b:115 and Chetley 1990:19).

The next significant development related to the limitations of penicillin. Penicillin's anti-bacterial effects are achieved by a hindrance of the synthesis of the cell walls of certain types of bacteria (Cooper 1966:6). The difficulty was that it was discriminate in this effect, only attacking structures which were peculiar to certain organisms. It was inevitable that research would turn to the development of antibiotics which would overcome this limitation. The "therapeutic revolution" took off in earnest (Reekie and Weber 1979:5).

Streptomycin was developed by Waksman in 1943 and the post-war period ("the golden age of

drug discovery") saw the development of a wide range of new drug products from laboratories and from a rapidly developing industry. In discussing the speed of innovation in the new industry Cooper (1966:7) has produced the following graph:



iv The Pharmaceutical Industry and the National Health Service

Into the midst of these developments came the National Health Service in the United Kingdom. Although the pharmaceutical industry in this country was slow to respond to the growing

demands of this new user of its products, foreign companies were quick to grasp the opportunity to take over existing, well-known United Kingdom companies and form new multi-national concerns ready to exploit the new opportunities (Lienenau 1990:727). The new companies were soon to be involved in the large-scale production of innovative, complex drug products necessitating high levels of purity, consistency, stability and efficacy. Reekie and Weber describe the relationship between the rapid development of the new industry as described above and the establishment of the National Health Service as resulting in:

"... a tremendous expansion in the output of the industry, by existing members, by entrants from other industries and by immigrant subsidiaries bringing with them discoveries unique to themselves." (1979:6)

The Table below, taken from the Guillebaud Enquiry (Great Britain 1956:161) demonstrates the immediate impact of the National Health Service on the volume and cost of prescribing in England and Wales and shows the dramatic effect which the new service had.

Year	Number of Prescriptions	Total Cost of Prescriptions
1948 July to December	83,725,810	£11,309,300
1949	202,011,412	30,331,303
1950	217,144,505	34,804,535
1951	227,693,920	41,662,354
1952	215,999,629	43,768,599

1953	219,756,904	44,700,965
1954	218,712,815	45,969,621

A similar impact was noted in Scotland (Guillebaud 1956:164). This large-scale growth in the number of prescriptions dispensed had a dramatic effect on the work of the pharmacist. The Nuffield Enquiry (Nuffield 1986:19) reports that after the introduction of the National Health Service the pharmacist spent less time acting as the first point of contact for the patient and sold fewer over-the-counter medicines. As a corollary the amount of time devoted to dispensing and the income to be derived from it increased significantly. The Enquiry noted that in 1937 the income obtained from the dispensing of 65 million prescriptions represented about 10 per cent of the total income of the 13000 pharmacies in the United Kingdom. By 1984 the income from the dispensing of almost 400 million prescriptions by 12000 pharmacies had risen to 70% of the total turnover.

The provision of pharmaceutical services within a national health service funded from the Exchequer soon put a strain, described as "frightening" (Webster 1988:222) on the estimated funds available for such services. The estimates for 1948/1949 were short by £53 million and for 1949/1950 by £98 million. The National Health Service expenditure on drugs as a percentage of the total National Health Service cost quickly rose from 7.9 to 10.6 (Cooper 1966:8).

Several attempts were made to reduce the cost of the pharmaceutical services. Foremost among these efforts was the introduction of the prescription charge which was designed both to have a deterrent effect and to raise monies directly for the Revenue and the education of both patients

and doctors in the sensible and efficient use of the services (Great Britain 1959).

The proposal for the introduction of the prescription charge was first mooted in October 1949 after the Minister of Health had undertaken his own review of the first twelve months of the service. By that stage 187 million prescriptions at an average cost of 2s. 9d. each had been dispensed representing close to one-tenth of the total cost of the service and financial estimates for the second year of the service had been predicting a large increase in the running costs of the service. The initial call for a prescription charge was opposed by the pharmacy profession who wrote to the Minister outlining the reasons why the proposal would fail to achieve the anticipated result (Pharmaceutical Journal 31 December 1949). Enabling legislative provisions - through Section 16 of the National Health Service (Amendment) Act 1949 - were put onto the statute books.

However it was not until 1952 that the prescription charge was finally introduced. Early in the year, the Chancellor of the Exchequer had announced that the cost of the National Health Service would need to be kept within a limit of £400 million. One way in which that target might be brought about would be to introduce a charge of 1s. per prescription which would bring in some £12 million per year (Pharmaceutical Journal 2 February 1952, page 74). The proposed charge was opposed by the pharmacy profession both on the general issue of the equity of a levy in a scheme which was meant to be free and on the specific issue of the administrative arrangements for the collection of the fees from patients (Pharmaceutical Journal 9 February 1952, page 86). Despite this the National Health Service (Charges for Drugs and Appliances) Regulations 1952 (1952 No. 102) were made on 23rd May 1952 and came into force on 1 June 1952.

The pharmacy profession, in attacking the iniquity of the introduction of a levy in what was meant to be a "free" national health service, predicted that it would lead to a reduction in the overall numbers of prescriptions which would be dispensed and would increase the amount of administration which a pharmacist would have to undertake in relation to dispensing medical prescriptions. In turn this might mean that no effective financial savings might be made (Pharmaceutical Journal 31 May 1952, page 374). A week later the pharmacy press was reporting that there did not appear to be significant opposition from the public to the imposition of the levy although it was also quick to point out that any full effect would not be apparent for a further week or two (Pharmaceutical Journal 7 June 1952, page 406). At the end of year review, the Pharmaceutical Journal was able to show that the fears of an initial drop in the volume of prescriptions dispensed had become reality but also that the figures for prescriptions dispensed had quickly returned to normal (Pharmaceutical Journal 27 December 1952, page 446).

When the efforts to educate both patients and doctors in the sensible use of the new services failed it was decided to turn attention to the question of the prices charged to the NHS by the pharmaceutical companies. Webster (*supra*) indicates that the basis for this was the emergence of evidence that the reasons for the increase in the drugs bill were the emergence of new and expensive drugs and an increased reliance on proprietary rather than standard preparations. The use of proprietary drugs had increased from 5% of all prescription drugs at the beginning of the new service to 75% some 14 years later. Public Accounts Committee Reports were indicating that pharmaceutical companies were making profits far in excess of what was considered appropriate for government contracts.

To deal with the problem the Government initially thought that it might invoke the Defence Regulations to force the pharmaceutical companies to give information and to impose prices. When this suggestion was dismissed as being too radical in practice, the Treasury began discussions with the Association of the British Pharmaceutical Industry to investigate the cost of basic drugs and the profits of companies involved in compounding and wholesaling. The result of this investigation was indecisive and the Government decided instead to consider the proposals of the joint Committee of the Central and Scottish Health Services Councils which had introduced a classification of drugs in use (Webster 1988:224-225). This committee's proposals included the suggestion that there should be two classes of drug - those of no known therapeutic value and those which were advertised direct to the public - which should not be available under NHS prescription. The remaining proprietary drug products were acceptable to the committee subject to satisfactory arrangements for price being made between the Health Department and the manufacturers. Satisfactory arrangements as to price would lead to a certain degree of conflict between the Ministry of Health and the pharmaceutical companies for a period of time.

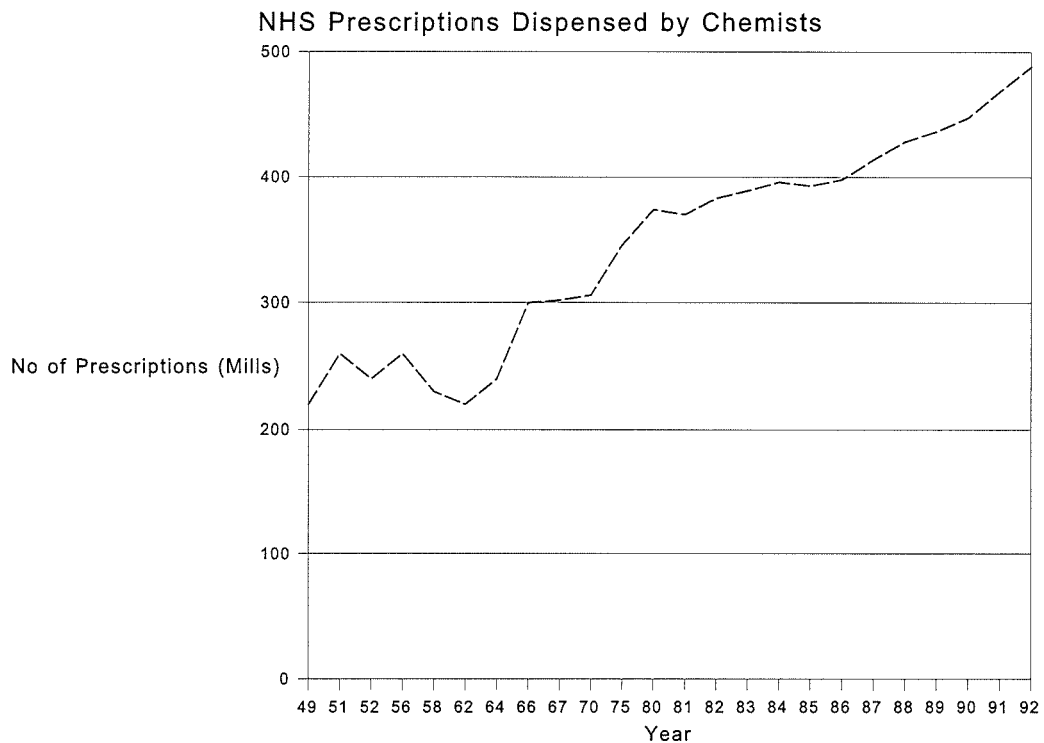
Initially the Government had two suggestions for a satisfactory arrangement - a price no higher than that paid for an average equivalent drug product or an equitable price according to the actual cost of manufacture - while realising that the pharmaceutical companies would be strongly opposed to the first and have problems with the second on the basis that it would be difficult to come up with a formula to satisfy all requirements. Other alternatives were looked at including the possibility of doctors having a free choice over the prescription of any drug product but with patients paying the full cost of any such prescribed drug which did not appear on an approved list and the proposal to introduce statutory registration of new proprietary medicines (Webster 1988:225).

In the meantime, on the advice of a specialist group, the Government's Home Affairs Committee abandoned its favoured short-term policy of creating a standard-equivalent pricing scheme and reverted to the tactic of investigating the pricing of individual drugs and the profits of individual companies. This led directly to negotiations with individual companies concerning the lowering of profits on some of their products, the blacklisting of certain drug products and the formulation by the Association of the British Pharmaceutical Industry, the body which represented the interests of the pharmaceutical companies, of their own proposals for satisfactory prices. Reluctant negotiations continued to take place between the ABPI and the Ministry of Health over a period of time (June 1954 to December 1956) with the Ministry and Treasury themselves favouring different options for an acceptable scheme (Webster 1988:226-227). Eventually the view of the Ministry which favoured a price formula to be applied to all drug products, a scheme which was acceptable to the pharmaceutical companies themselves, was accepted by the Treasury as the more viable option. As a result the Voluntary Price Regulation Scheme was introduced in April 1957. Webster (1988:227) reports that, in reality, this scheme added little to the Treasury funds and gave no more control over the ever increasing drugs bill.

By the middle of the 1960s - and despite the impact of the thalidomide disaster (Chetley 1990:20-21) - the pattern established following the rapid development of the pharmaceutical industry and the increase in the numbers of prescriptions being dispensed under the National Health Service schemes was continuing. The Sainsbury Committee, established to examine the relationship of the pharmaceutical industry with the National Health Service, was able to note the increasing numbers of prescriptions being dispensed under the National Health Service, the effect that this growth was having on the pharmaceutical industry in the United Kingdom and the

growing reliance by the pharmacy profession on this growth as the major element of their income (Great Britain 1967). That pattern has been maintained through to the 1990s.

The following graph shows the continued growth in the number of prescriptions dispensed since the inception of the National Health Service (ABPI 1993:52).



In addition the reliance which was placed on this volume of dispensing by pharmacists has already been noted. By 1984 the income from the dispensing of almost 400 million prescriptions by 12000 pharmacies had risen to 70% of the total turnover. It is equally clear that by the mid 1980s the nature of the dispensing function had changed. The Nuffield Enquiry (Nuffield

1986:20) noted the succession of scientific discoveries and developments which had increased the part played by medicines in therapy. The Enquiry also noted that modern medicines were more effective, more complex and more sophisticated in usage. The compounding function had passed from the pharmacist in the dispensary to the pharmaceutical industry. The net result was that:

"Most medicines are now available made up by the manufacturer in tablet, capsule, ointment, cream or liquid. It is thus rarely necessary for the community pharmacist to compound a medicine extemporaneously in response to a doctor's prescription ... From being the person who himself compounded the medicines prescribed, the pharmacist's role in dispensing is now largely that of checking what is done by others ..."

Conclusion

This chapter has sought to review the reasons why the pharmacist was to adopt particular functions and roles within the health care system in the late twentieth century. It has shown that the principal reasons why the community pharmacist has become a dispenser of pre-packaged, pre-labelled medicines and drug products prescribed by medical practitioners was the advent of the National Health Service and the spectacular growth of the international research-based pharmaceutical industry.

The history of the National Health Service has been reviewed and it can be seen that the period from the 1940s to the 1980s saw the National Health Service changing radically the provision of health care within the United Kingdom. In a parallel and almost as a corollary to the birth of the NHS, the evolution of the pharmaceutical industry had the most significant technological and scientific impact on the practice of medicine within the National Health Service structure.

It can be concluded that these two determinants have forced community pharmacy into accepting and relying on certain roles and functions as providers of health care. What the next chapter will explore is to show how those roles and functions would be questioned and doubted even by the profession itself.

Time For A Change?

Purpose

Chapter one of this thesis reviewed, historically, the functions and roles of the pharmacist in the health care system. It was seen that the pharmacy profession has a long and intricate history and that the roles and functions of the pharmacist have changed and have been refined to cope with greater changes within the health care system as a whole. The historical development of the pharmacy profession has been dependent upon the historical development of other members of the health care team - in particular the general medical practitioner - and the evolution of a drug development and distribution system. It was concluded that by the middle of the twentieth century, the pharmacist's role within the health care system was crucial - a professional recognised as having essential expertise and knowledge and without whom the health care plan would not be complete.

Chapter two analysed the reasons why the pharmacist was to adopt particular functions and roles within the health care system in the late twentieth century. It has been shown that the principal reasons why the community pharmacist has become a dispenser of pre-packaged, pre-labelled medicines and drug products prescribed by medical practitioners was the advent of the National Health Service and the spectacular growth of the international research-based pharmaceutical industry.

It was concluded that these two determinants have forced community pharmacy into accepting and relying on certain roles and functions as providers of health care. What this chapter will do

is to show how those roles and functions would be questioned and doubted by many, even by the profession itself. First, an analysis will be provided of some work undertaken by a number of *sociologists* who began the discussion by questioning the professionalisation of pharmacy. This will be followed by an examination of how this criticism prompted the *pharmacy profession* itself to examine its future role and conduct and how the *medical profession* responded to these developments. Finally it will be seen how the *government* has taken up the issue as part of its own, ongoing investigation of the delivery of pharmaceutical services.

It will be possible therefore to conclude that everyone would appear to be agreed that pharmacists need to adopt some sort of new or "extended" role but are undecided precisely what that role should be. However there is general agreement that the role should be one which builds upon the existing expertise of the pharmacist in relation to drugs and drug therapy (the basis of their technical training) but which would see the pharmacist becoming more actively and directly involved in patient care. Current research on the role of the pharmacist in patient care in the United States of America is confirming that pharmacy should expand into new areas beyond those traditionally expected of the profession. While that development is being welcomed, it is also recognised that it is not without problems and conflicts.

One of these problems concerns the potential for increased liability for pharmacists based on such an expansion. A trend may be developing whereby the courts seem to be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. The recognition of an expanded duty by the courts in the United States has been augmented by the imposition of legislative duties requiring pharmacists to continue to screen prescriptions for potential problems, counsel patients about proper drug use and potential adverse effects and

maintain extensive documentation regarding a patient's medical condition and drug therapy. The implications of these recent developments in the United States are fairly clear and the consequences could be equally significant for pharmacy in the United Kingdom should it follow the same path.

The Debate Begins

The substantial debate concerning a potential change in role and function for the pharmacist began through an analysis of the profession by sociologists.

Typical of this analysis is an article by McCormack (1956:308). She believed that the pharmacy profession was one worthy of study as it had become a "marginal" profession. She describes this marginality as being of degree rather than of kind:

"Its structure is sufficiently undefined so that it may attract persons who are marginal in the social structure and who impose the concomitants of the ambiguous status on the occupation. Its functions are sufficiently unclear that the problems of acquiring sanction and legitimacy persist."

The principal reason why the pharmacy profession was marginal was its incorporation of the conflicting goals of business and profession. The pharmacist's role could be regarded as unstable to the extent that it was beset by the cross-pressures of the business and professional worlds. Although these pressures were not particularly distinctive of the pharmacy profession the particular intensity of the confrontation in pharmacy could be explained by the rapid economic and technological developments of the previous thirty years.

Pharmacists had hitherto been regarded as entrepreneurs working in a small retail business. The growth of chain stores and the development of large-scale retail enterprises had endangered the status of the pharmacist as a businessman. This was likely to lead to the situation where the pharmacist would be forced to choose to become a salaried employee rather than be self-employed. The major rebuttal to the trend had been the move towards professionalisation by means of formal training. The development of multi-year university degree programmes was important in the projection of the pharmacist as a professional scientist with a distinct understanding of the principles and methods upon which pharmacy depended.

This development might be viewed by some of those entering the pharmacy profession as welcome in that the loss of entrepreneurial opportunity would free them from demands which interfere with the true practice of pharmacy. Employment in a large pharmaceutical company or a hospital or a university would be the more attractive possibility. Others, who wish to go into business for themselves, would suffer the most from the current developments, in that the objectives of the pharmacy profession would always be at odds with the pecuniary goals of a business (1956:309). In conclusion, the marginality of the profession was likely to continue for some time.

McCormack's ideas on marginality were developed by Denzin and Mettlin (1968) who sought to analyse pharmacy as an occupation which had taken on some of the characteristics of a profession. They found that pharmacists, *inter alia*, had failed to abide by the professional requirement of non-advertising, that they had failed to recruit into the profession individuals who were committed to the goals of that profession, that they had failed to accumulate a systematic

body of scientific knowledge required for their professional role, that they had failed to hold together a cohesive social organisation exercising strict control over its members, and finally and conclusively that pharmacists were more oriented towards the drug product (its sale, promotion etc) rather than towards providing a professional service to individuals. This led the authors to conclude that pharmacy was an incomplete or marginal profession i.e. they have taken on some of the characteristics of a profession but have failed to shrug off the marginality associated with professions which still contain elements of an occupation.

The profession had not however failed totally. It had developed a systematic code of ethics, it had established definite institutions for transmitting its body of knowledge, it had set up recruitment policies and it did have specialised skills to offer. Certain parts of the profession, in particular the hospital pharmacist, were more professional than others such as the retail pharmacist who probably represented the most non-professional aspects of the profession. Retail pharmacists rarely abided by the professional maxim of no advertising and, more importantly, subordinated the professional goal to personal goals. The fact that the retail pharmacist does sell non-professional items was of no consequence to him/her (1968:377).

The authors are further of the view that the main reason why pharmacy does not cross the line of marginality was its failure to gain control over the social object which merited the development of its professional qualities in the first place. The profession had not developed an ideology to constrain the way in which its members viewed the drug. Viewing the drug as a product to be sold rather than a service to be provided forces the pharmacist to violate some of the fundamental rules of being a professional. The pharmacist becomes an agency through which the drug might be obtained rather than an individual health care professional who provides a service.

"The public sees very little service being provided, and objects to paying a fee to someone for counting out pills and typing a label. No longer is their service visible to the public which demands "specialised intellectual study and training" from professions." (1968:378)

A second reason why pharmacy remained a marginal profession was that it recruited a large number of students who subscribed to the non-professional qualities of the occupation rather than the professional ones. Part of the reason for this is the profession's own failure to decide what its own dominant values should be. Thirdly, the variety of organisations which directed the efforts and activities of the pharmacy profession (in the United States of America at least) had been ineffective in representing and controlling the profession as a whole. Fourthly, the pharmacist had attempted to develop a mandate which revolved around an image which claimed superior knowledge about drugs, their distribution, their chemical composition and their therapeutic side-effects and had failed to maintain it in the eyes of other health care professionals, particularly the medical profession.

The quotation from Denzin and Mettlin regarding the typing of labels and the counting of pills was reflected in the later views of Klass (1975:132). After discussing the historical development of the pharmacy profession, Klass had the following to say about the pharmacist's current role and his/her qualifications for it:

"But in light of these lengthening, highly sophisticated courses in dispensing what indeed has happened to the duties required of a qualified pharmacist in today's pharmacy or drugstore? No longer does he exclusively and expertly mix ingredients for a prescription. No longer does he manufacture his own tinctures or make ointments or creams. His task simply stated, has become counting, measuring,

recording and accounting. Almost invariably, now, the prescription states the single name of a preparation, pre-packaged by the manufacturer in the commonly prescribed quantity and dosage. All that is required of the pharmacist is that he check the prescription against a possible error in dosage by the prescriber, take from his shelf the correct package, or count into a container the prescribed number of pills, write or type a label, record the prescription, now numbered to correspond with the number on the label.

Even when the procedure is rhetorically elaborated ... in order to justify a prescription fee ... is there real need for a full four-year programme of study to perform [this]." (1975:134)

When the intervention of the medical profession in the debate is examined further in this chapter, it shall be seen that their attitudes reflect many of those outlined above.

The following year, Webb (1976:81) in an analysis of the communication between pharmacist and customer also examined some of the features characteristic of retail pharmacy. She agreed with Denzin and Mettlin's assessment that the incongruity associated with operating as a professional pharmacist on the one hand and a business person on the other has never been resolved by the pharmacy profession. The resulting problems of role and status were particularly evident in the relationship between the pharmacy and medical professions. While those problems were not of recent origin they had been exacerbated by a perception within the pharmacy profession that its members were under-used in terms of the training which they had received. As a result they have attempted to expand their role but have not precisely defined what form that expanded role should take:

" ... suggestions appear to centre around the idea of the pharmacist playing a more active and direct role in patient care, that is becoming more 'patient-oriented'." (1976:82)

It would seem only natural that the pharmacy profession would not take such criticism lightly. Pharmacists hardly see themselves as routine technicians counting pills and typing labels. As a result, a major debate about the role which the pharmacist should take within the health care profession has emerged and it began in earnest with the publication of the Nuffield Enquiry Report.

Nuffield Foundation Committee of Inquiry into Pharmacy

In October 1983 a Committee of Inquiry was appointed by the Nuffield Foundation (Nuffield 1986) with the following terms of reference:

"To consider the present and future structure of the practice of pharmacy in its several branches and its potential contribution to health care and to review the education and training of pharmacists accordingly." (Nuffield 1986)

The Committee had been appointed against the background of a substantial change in the nature and type of work undertaken by the pharmacy profession and the feeling that an independent inquiry into the practice of pharmacy and its contribution to health care was required. The membership of the Committee reflected pharmacy in all of its divisions and also contained representatives of the medical profession, family practitioner committees, local health authorities and consumers' associations. The Committee issued an open invitation to submit evidence which was sent to all of the pharmaceutical organisations as well as to those concerned with medicine, nursing, education and to government departments. In response, the Committee received over two hundred submissions. It also held a number of oral hearings of evidence and undertook a number of visits to relevant institutions.

The Final Report of the Committee began with an analysis of the pharmacy profession as it was then constituted. It then examined the three main branches of the profession - community, hospital and industrial - in more detail before scrutinising the provision of education and training. Finally the report examined the role of the Pharmaceutical Society of Great Britain and completed by making a number of conclusions and recommendations. For present purposes, given that this thesis centres on the roles of community pharmacists, concentration will be on the Committee's observations on community pharmacy.

The Committee noted that the community pharmacy was characterised by the high street shop where prescriptions were dispensed and medicines sold. It also recorded that there were few pharmacies which confined themselves to the dispensing of prescribed medicines but were also involved in the retail of other goods and commodities. The Committee also noted that a number of the multiple or chain pharmacies such as Boots had diversified into a range of household and leisure goods and the fact that certain supermarket chains had decided to include a pharmacy in their larger stores. On the statistical front, the Committee observed that the number of pharmacies had been falling between 1940 and 1980. The Committee also reviewed the legal requirements for the provision of pharmacies and pharmaceutical services in the United Kingdom and analysed how pharmacists were remunerated.

On the important question of the change in the roles and functions of pharmacists, the Committee observed that the 1986 role of the community pharmacist as primarily a dispenser of doctors' prescriptions arose overwhelmingly from the introduction of the National Health Service. This had led to the increase - already examined in chapter two of this thesis - of the number of

prescriptions dispensed annually from 246 million in 1950 to 395 million in 1984. The Committee also noted that over the same period, there had been an equally radical change in the nature of dispensing. By 1986 the pharmacist would rarely be called upon to compound a medicine extemporaneously but would largely dispense pre-manufactured and pre-packed medicines from the pharmaceutical industry.

"The dispensing process now consists of interpreting, and if necessary clarifying, the prescriber's requirement on the prescription form; assembling and labelling the medicine; and handing it over with any necessary instructions to the patient or his agent. From being the person who himself compounded the medicines prescribed, the pharmacist's role in dispensing is now largely of checking what is done by others - that the prescription is legible and not inappropriate; that what is prescribed has been accurately assembled; and that the patient is informed of the way in which the medicine is to be used." (Nuffield 1986:20)

The Committee observed one possible impact of this development on the image and status of the pharmacy profession:

"There are those, both within the profession and outside, who would say that this has represented a steady but substantial diminution in the professional role of the community pharmacist." (Nuffield 1986:22)

The Committee thus concluded that in the work which they were undertaking in 1986, pharmacists were not utilising the education which they had received. As such, they agreed with the views that pharmacists could undertake a wider role with greater responsibilities. In considering what that role might possibly be, the Committee made a number of predictions for the immediate future:

- (1) The discovery and development of new drugs would continue which would be more

effective in their use with equivalent introduction of new delivery systems. Developments in biotechnology would supplement and possibly supplant the use of existing medications.

- (2) The cost of treatment would continue to rise and the resultant pressure on resources would force governments to reduce expenditure in a number of different ways including the transfer of treatment from hospitals into the community.
- (3) The proportion of elderly in the community would increase; the resultant increase in the number of ailments and consumption of drugs and the parallel need for specialised attention for the elderly would also place pressure on resources.
- (4) The use of information processing facilities would increase.
- (5) The exploitation of the potential of the new treatments would lead to increasing co-operation between the health care professions.
- (6) Individual consumers would wish to have a greater say in health care, would seek further information and would demand more choice. There might be an increasing likelihood that individuals would require the health care professional to justify him/herself and not to take advice which had been given on trust. (Nuffield 1986:23-24)

The Committee then went on to consider what would be the likely effect of these predictions on

the pharmacist and his/her future role and function. The Committee's recommendations were as follows:

- (1) Dispensing would continue to be an important activity within pharmacies but the pharmacist's future professional role should be seen in terms of greater collaboration with other health care professionals, particularly general practitioners and greater involvement with members of the public.
- (2) Systematic arrangements would be needed to enable community pharmacists to co-operate with general practitioners to increase the effectiveness and reduce the costs of prescribing.
- (3) While it would be an expensive use of resources to stipulate that the pharmacist must advise every patient on how to use medicines, it would be appropriate to promote the personal involvement of pharmacists in giving advice on the taking of medicines which should be concentrated on those most likely to benefit from it. Wherever drugs formed an important part of treatment or therapy, it would be likely that both the patient and the National Health service would benefit from a more active involvement of the pharmacist. Particular groups, such as the elderly, would be encouraged to register with a single pharmacy.
- (4) Pharmacists could help in the treatment of certain patients at home and in the provision of pharmaceutical services to nursing homes and other establishments.

- (5) There could be a role for pharmacists in health education in co-operation with other health care professionals.
- (6) The professionalisation of pharmacists would not be compromised by the fact that they are also involved in the retail trade. However it was noted that commercial pressures had tended to frustrate hopes of those who wished to develop interprofessional co-operation in health centres. The part of a pharmacist's premises which provided NHS pharmacy services should be immediately distinguishable from the parts devoted to other retail activities. There should be adequate accommodation for confidential consultation.
- (7) The system for remunerating pharmacists under the NHS contract acted counter to the pharmacist's professional role and would need to be changed. The NHS contract should continue to be with the pharmacy owner who need not be a pharmacist; payments under the contract in respect of prescriptions dispensed should be reduced and separate payments should be made for other professional activities. The NHS contract should specify the range of services to be provided and the means by which this is done, including the degree of supervision exercised by a pharmacist, should be a matter of professional conduct.
- (8) The law should continue to require pharmacies to be under the personal control of a pharmacist which requirement could be satisfied if the pharmacist could be contacted during a temporary absence. The handling of medicines whose sale is restricted to pharmacies should be a matter of professional practice rather than detailed in statute. There would be some scope for the transfer from the Prescription Only Medicine (POM)

to the Pharmacy (P) category and although the General Sale List (GSL) should remain, the pharmacist should not be given a monopoly.

- (9) The Royal Pharmaceutical Society should give guidance on the exercise of professional responsibilities but the determination of these should be for the pharmacist. The Society should also give careful and earnest consideration to the degree of supervision needed in the dispensing of prescriptions. (1986:131-133)

The Reaction of the Pharmacy Profession to the Nuffield Committee Report

As might be expected, the response of the pharmacy profession was long and detailed (Pharmaceutical Journal Index to Volumes 236, 237, 238, 239). The Council of the Pharmaceutical Society discussed the Report at its meeting on April 8 1986 (Pharmaceutical Journal April 19 1986, page 472). Its initial reaction was to describe the Report as being especially valuable because it was produced by a committee on which pharmacists were in the minority. As such, the fact that the Report was so positive and constructive in its approach to pharmacy practice was to be particularly welcomed. The Council noted that it was apparent throughout the Report that representatives of other professions and members of consumer organisations on the Committee expressed the view that pharmacists played an indispensable role in health care. Although those views stressed the change in emphasis from supply of medicines to the provision of a wide range of pharmaceutical services, they also recognised that there existed a source of untapped potential which would enable pharmacists to contribute even more to the development of the health services, ultimately for the benefit of the patient. In further detail, the Council accepted without question and with enthusiasm the pivotal role which had been given to

the Society in relation to the implementation of the recommendations contained in the Report. In carrying out this function, the Society referred various recommendations to relevant standing committees, subcommittees and working parties of the Council for detailed consideration.

Despite this, there were certain recommendations which could be welcomed unequivocally because they reflected long held views of the Council itself. In relation to community pharmacy, these included the recommendations relating to the provision of advice on health promotion and the administration and control of medicines in residential homes. However there were other recommendations, such as that relating to the means of ensuring satisfactory basic standards of premises and equipment for all pharmacies, which were more controversial and which would need further discussion and consideration.

On the specific recommendations relating to community pharmacy, the Council was enthusiastic in its welcome for the proposals for collaboration with other professions and for widening the activities of community pharmacists, especially advisory services on medicines both within and outside the pharmacy.

"The principle underlying the recommendations and conclusions on community pharmacy is that greater emphasis should be given to professional responsibility and less to detailed legislative requirements. The philosophy is one which will be debated at some length but the overall thrust towards flexibility and proper use of the pharmacist's time and expertise is certainly in line with considerations within the Council." (Pharmaceutical Journal 19 April 1986, page 496)

These initial conclusions were supported in the pharmaceutical press. In an editorial (Pharmaceutical Journal 19 April 1986, page 471), the Pharmaceutical Journal endorsed the

views of the Society's Council and added one or two concerns concerning the intake numbers to the pharmacy profession and to aspects of the medicines legislation.

One week later, the first of what would turn out to be a long series of consultative meetings on the implications of the Nuffield recommendations was held in London (Pharmaceutical Journal April 26 1986, page 513). The meeting was addressed by Sir Kenneth Clucas who had chaired the Nuffield Enquiry. He began his address by stating that the Nuffield Report represented a resounding vote of confidence in the profession of pharmacy and what it was capable of becoming. The pharmacist had a valuable and unique role to play in the provision of health care because of his education and training.

On the specific aspects of the Report relating to community pharmacy, Sir Kenneth repeated that the pharmacist was required to undertake the dispensing function in the pharmacy. However that function should be viewed as having two aspects. First the pharmacist should ensure that the dispensing process was efficient, effective and safe. The second responsibility related to the pharmacist dealing personally with a small number of cases which required the academic knowledge of the graduate. This second duty would involve an extension of the dispensing function - backwards into the preprescribing stage and forwards towards the recipients of the medicine. The preprescribing stage, arising from experience gained in hospital pharmacy, would involve the pharmacist in assisting the doctor in the prescribing process and was generally to be welcomed by the medical profession.

The pharmacist would find time to extend his role into these areas by redefining the pharmacist's role within the pharmacy in relation to the dispensing process. The medicines and national health

services legislation meant that there were three expressions of the dispensing process. First, no pharmacy could operate unless under the personal control of a pharmacist. Second, sales of pharmacy only medicines could only be made under the supervision of a pharmacist. Third, the dispensing of national health service prescriptions must be under the direct supervision of the pharmacist.

Sir Kenneth believed that the Nuffield Inquiry had thought that only one expression of the law was required and that was the concept of personal control i.e. that each pharmacy must be under the personal control of the pharmacist. This concept of personal control meant that the pharmacist was personally answerable for everything that went on in the pharmacy but that this did not necessarily imply that he had to do everything himself.

"The pharmacists should define the procedures that his staff should follow, he should define the degree of authority he was prepared to delegate and he should define the competence required of the people who were going to perform the various functions under his direction." (Pharmaceutical Journal 26 April 1986:513)

Research had shown that only a minority of prescriptions required the personal supervision of the pharmacist. The advance identification of which prescriptions would require such supervision was possible with repeat prescriptions if proper use was made of computer technology. A similar system ought to be devised for all other prescriptions. The consequent release of time should make it possible for the pharmacist to do other more professional and worthwhile things including the giving of advice. The extension of the pharmacist's role to giving advice would not conflict with the responsibility of the general practitioner.

If the extensions to the pharmacist's role were to be introduced then changes would be required in three principal areas. A new attitude would have to be introduced to the manner of the reimbursement of pharmacists. The current payment system loaded too much onto the dispensing process which encouraged too much attention to dispensing and discouraged the pharmacist from carrying out his advisory role.

"If the pharmacist was to have a consulting and advisory role the sale of medicines must be subsidiary to that and the payment to the pharmacist must not be through profits from the sale of medicines but there must be direct reimbursement for giving advice. That was the pharmacist's primary role and that was what he should be paid for." (Pharmaceutical Journal 26 April 1986:513)

The second change related to the law. The manner in which the profession conducted itself must be determined less by the requirements of the law and more by what the profession itself decides. Sir Kenneth indicated that this recommendation was controversial. The pharmacy profession had indicated through its journal that it was relatively happy with the idea of working within the law. Sir Kenneth disagreed, preferring to recommend that the profession ought to look after its own standards and its own regulations. The Nuffield Inquiry had concluded that it was not enough for the commercial pharmacist (in his/her non-professional role) to ask what the law was and state that he/she intended to obey it. The non-commercial pharmacist had to obey the law anyway. Equally it was not enough for the professional pharmacist to operate within the law. The professional pharmacist had to apply professional standards which went beyond the law.

The third area where change was required was in the education of pharmacists. The present curriculum was essentially science based but the Nuffield Inquiry favoured the introduction of social science to the pharmacy degree so that pharmacists could learn that they were not dealing in abstractions but with people. Pharmacists, already experts in the nature of drugs, also needed

to know why individuals behaved in the way that they did and their social setting.

Six months later the debate on Nuffield within the pharmacy profession was still very lively. The British Pharmaceutical Conference devoted much of its time to a discussion of the issues arising from the Report (Pharmaceutical Journal 27 September 1986:356-372). A distillation of that debate and the continuing discussions which had taken place in the interim appeared in a Pharmaceutical Journal editorial (Pharmaceutical Journal 27 September 1986:341-342).

The comment began by stating that there had been so much debate and that so much had been written about the Report that there was a danger of it going out of focus. However one contributor to that year's British Pharmaceutical Conference by the Secretary and Registrar of the Pharmaceutical Conference had succeeded in bringing the debate back into perspective. He had sought to identify what the Nuffield Report had meant by the "unique and vital" role of the pharmacist in the provision of health care in the community. The Secretary's conclusion was that the unique and vital role was to apply professional assessment to safeguard the patient's interest in relation to the dispensing of prescriptions and the sale of pharmacy medicines. That role could only be exercised if the pharmacist saw every prescription, either original or repeat, at some stage in the dispensing process. It was also necessary that the pharmacist should intervene personally where professional advice was required in relation to the sale of pharmacy medicines or in response to symptoms.

The journal agreed that the prudent delegation of certain mechanical tasks in the pharmacy was possible but the pharmacist must never delegate the unique and vital tasks that only he/she was

trained to perform. Any delegation of those tasks would have to be to other pharmacists necessarily implying the possibility of an increase in the number of pharmacists per pharmacy. The editorial concluded that the bottom line for a full and successful implementation of the Nuffield Report and a genuine practical recognition of the value of the pharmacist to the community was how much money the Government was willing to make available.

The major reaction of the pharmacy profession to the Nuffield Report was published over a year after the Report had been published. The fact of that delay demonstrated the extent of the importance of the Report to the profession and the genuine ongoing nature of the debate and the importance which was placed on the Report's recommendations by the pharmacy profession as setting the pattern for the development of pharmacy in the United Kingdom into the 21st century.

The Council of the Royal Pharmaceutical Society had, in the interim, met on 10 occasions to consider the Nuffield Report and, in addition, a working party on practice procedures relating to supervision had met and reported to the Council three times. The Council produced its views on the Nuffield report in a twelve page consultation document which was sent to all members of the profession as a precursor to individual branch meetings which would comment on the Council's views. The Council would decide on what action to take on the Nuffield Report after these comments had been received (Pharmaceutical Journal 25 July 1987:N2-N14).

The Council's document began by describing, in general terms, those areas which it thought was likely to cause controversy. These were:

1. Delegation and the place of the pharmacist

The Council was of the unanimous view that the pharmacist should delegate as much work as possible to properly trained members of staff. The purpose of this would be to release the pharmacist to concentrate on the provision of the service which he/she was, by virtue of his/her training and education, uniquely qualified to provide. This service involved the giving of advice on all aspects of medicines, health education and the giving of advice on particular symptoms.

"The pharmacist's place is not in the dispensary counting, pouring or labelling, but in virtually constant contact with those - customer, patient or health care professional - who will benefit most from direct involvement with the pharmacist."
(Pharmaceutical Journal 25 July 1987:N3).

2. Final professional responsibility lies with the pharmacist

The Council was equally firmly of the view that the pharmacist must continue to take final professional responsibility for all aspects of the pharmaceutical service. Any proposed system must be for the greater benefit of the customer but must mean the essential involvement of the pharmacist, in all but the most exceptional circumstances, whenever prescriptions are dispensed or restricted medicines are sold.

3 Supervision of dispensing and sales of pharmacy medicines

The Council indicated that it believed that its proposals on practice procedures relating to the supervision of dispensing and sales of pharmacy medicines would achieve the necessary balance between supervision and delegation. In relation to dispensing, this would involve the pharmacist seeing each prescription at some stage - to be determined by the pharmacist - during the dispensing process. In relation to sales, the Council was of the view that no sales of pharmacy medicines should take place from a pharmacy in the absence of a pharmacist. General sale list medicines could be sold or supplied other than by, or under the supervision of, a pharmacist. The proposals relating to the sale of pharmacy medicines did not necessarily mean that the pharmacist had to be aware of every sale of a pharmacy medicine. The pharmacist could identify and list in writing those medicines which could only be sold following direct contact between the pharmacist and purchaser. The pharmacist would not need to be aware of all other sales, providing that such sales were made by specifically nominated, adequately trained, members of staff under a procedure laid down in writing and providing appropriate records were kept. This necessarily implied new requirements for the training of staff and the maintenance of records.

4 Legislation needed if changes to be made

The Council was of the view that implementation of its proposals on supervision could only be achieved following amendments to legislation or by a new decision in the courts.

The Council then went on to outline in detail its response to the various recommendations contained in the Nuffield Report. It began this analysis by emphasising its belief that the

development of pharmacy's distinctive and indispensable contribution to health care required not only the adoption by the Society of appropriate policies but also a firm commitment from individual pharmacists to the extension of pharmaceutical services. In so doing the Council endorsed the Nuffield Report's suggestion for a greater reliance on professional responsibility which would necessarily increase the professional responsibility of individual pharmacists. In relation to the Nuffield Report's specific recommendations relating to community pharmacy, the Council endorsed without further comment the recommendations relating to the introduction of new technology and the general recommendation that the pharmacist's future professional role should be seen in terms of greater collaboration with other health care professionals. However it had more detailed comments to make on other aspects of community pharmacy.

The Council proposed that local liaison groups be established, along the same lines as the drug and therapeutics committees in the hospital service, at practice level, between the medical practitioners and community pharmacists who have a similar cohort of patients. The purpose of these groups would be to discuss, at regular meetings, such matters as prescribing and dispensing procedures, the latest medicinal developments in therapeutic groupings and how community pharmacies could assist in the development and publicising of policies related to the prevention of ill health and promotion of better health. The Council also endorsed the recommendation relating to the value of community pharmacists reporting the pharmaceutical aspects of troublesome reactions to medicine.

In relation to the important question of pharmacist involvement in the giving of advice, the Council believed that it was essential that the community pharmacist's role in relation to

symptoms should be further developed. Specifically, the pharmacist could benefit from the introduction of a card, to be developed in collaboration with pharmaceutical manufacturers, reminding him/her of the basic questions which needed to be asked when advice was sought on symptoms. Further the Council believed that the pharmacist should use professional discretion to decide whether or not advice on certain symptoms should be given only by a pharmacist (in a "quiet spot" in the pharmacy). In certain circumstances such advice, and if necessary the sale of medicines, might be given by appropriately trained members of staff, provided such sales were made in accordance with a written procedure which gave details of the procedure for dealing with requests for advice and which emphasised that symptoms which were listed could only be dealt with if they had been recently experienced. Further, any sales made under these procedures would be subject to the Council's recommendations relating to the sale of pharmacy medicines (to be discussed below).

The Council had important recommendations to make in relation to the giving of advice on medications:

"The Council shares the view of the Nuffield inquiry that wherever medicines form an important part of NHS treatment, both the patient and the Service will benefit from a more active involvement of the pharmacist. The Society is closely involved in the development of better ways of providing information to patients, through verbal advice given by medical practitioners and pharmacists and by the provision of written information with dispensed medicines." (Pharmaceutical Journal 25 July 1987:N4).

As a development of this general recommendation, the Council accepted the inquiry's proposal that particular groups of patients, such as the elderly, should be encouraged to register with a

single pharmacy.

The Council also endorsed the recommendation of the Nuffield Report that pharmacists could assist in the treatment of certain patients at home and in the provision of pharmaceutical services to nursing homes and other residential establishments. Housebound patients would benefit from domiciliary visits by pharmacists including the giving of advice on the quantities and storage conditions of medicines kept in the home. The Council also wished to see the implementation of its previously published views on the provision of pharmaceutical services in nursing and residential homes. The Council also strongly endorsed the Nuffield Report's recommendation that pharmacists have a role in health education in co-operation with other health care professionals. The Council was of the view that the Society ought to positively promote the under-utilised advisory role of the pharmacist in this area.

The Council fully supported the recommendation that the Pharmaceutical Society should require a commitment by its members to the standards of professional identity and presentation which in the public interest it considers should define a pharmacy operation. The Council believed that this objective could be achieved through the use of existing professional requirements through the Code of Ethics and that no particular change would be necessary.

The Council accepted the recommendation that the present system for remunerating community pharmacists under the National Health Service contract acted counter to the exercise of their professional role and needed to be changed. In so doing, the Council regretted that the basic practice allowance, which recognised the wider professional role of community pharmacists within the National Health service by not being related numerically to the dispensing of

prescriptions, had been removed. The Council welcomed the proposals for the introduction of a good practice allowance and considered that the remuneration for the provision of National Health Service pharmaceutical services should reflect the full professional role of community pharmacists working within the National Health Service.

The Council agreed with the Nuffield Report's conclusion that the law should continue to require pharmacies to be under the personal control of a pharmacist. In the context of the pharmacist's extended role, the Council recognised that short periods of absence might be occasioned by the discharge of other professional duties. However the Council did not agree that the short absences permitted while personal control continues to operate should be restricted solely to absences to undertake other professional work. Such a distinction would be impossible to enforce and the Council could see no reason to depart from the current interpretation of personal control which required the presence of the pharmacist on the premises except for short periods during which only General Sale List medicines may be sold.

The Council accepted the conclusion of the Nuffield Report that many pharmacies did not come up to the standards laid down by the Pharmaceutical Society and that the Statutory Committee should do more to enforce them. It also considered that there was a need for regulations to be made under the medicines legislation to ensure that only satisfactory premises could be registered and for providing better means for controlling the environmental standards in registered premises. The Council indicated that it had introduced new procedures and had expanded the inspectorate as part of its continuing endeavours to ensure the maintenance of high professional standards in pharmacies. The Council also accepted the Nuffield Report's recommendation that the part of the premises which provided pharmacy services should be visually distinguishable

from parts devoted to other retail activities.

The Council agreed that it should be for the pharmacist to determine how he exercises his professional responsibilities subject to the guidance and jurisdiction of the Society and indicated that it would continue to provide guidance to pharmacists to assist them in this process. It also agreed that there was a need for the introduction of a computer based system for handling repeat prescriptions. This would remove the possibility of errors in the writing of repeat prescriptions.

The Council had detailed comments to make on the recommendations in the Nuffield Report relating to supervision. The Council agreed that there was a need to redefine the procedures for the supervision of dispensing. While supervision procedures would continue to be the responsibility of the pharmacist, he/she should not be required to be aware of every action related to the dispensing of a particular prescription. The pharmacist should be permitted to delegate specific tasks to appropriately trained and experienced members of staff. Normally, supervision of dispensing could be exercised by the pharmacist seeing each prescription at some stage - to be decided by the pharmacist when he/she will also decide what further action is needed and by whom - prior to the dispensed medicine being handed out. The pharmacist could authorise the handing out of a dispensed medicine in his absence provided he/she had seen the prescription at some stage during the dispensing process and provided the pharmacist who had authorised the issue of the dispensed medicine could be identified.

Certain exemptions from these normal requirements for the supervision of dispensing could exist as a means of assisting the development of professional services outside the pharmacy. These

exemptions could relate to prescriptions for appliances, dressing and General Sale List medicines. However those exemptions should be subject to a number of conditions: the dispensing must be undertaken by appropriately trained staff under a dispensing procedure laid down in writing by the pharmacist in charge; the dispensing procedure must ensure that the pharmacist taking responsibility for the issue of each medicine can be identified; within the procedure there is a requirement that prescriptions should be checked by another appropriate member of staff; that the prescription has been mechanically printed; that a pharmacist sees each prescription dispensed without supervision on his/her return to the pharmacy and is able to confirm the item that has been supplied against each prescription and that any period of absence from the pharmacy should be short and usually occasioned by other professional duties.

The Council also considered that within specified safeguards for the public and within the overall responsibility of the pharmacist in charge, certain prescriptions for repeat supplies of medicines previously prescribed for the same patient, other than medicines which are Controlled Drugs, should be permitted to be dispensed without involvement of a pharmacist. This relaxation of the normal procedures would be subject to a number of conditions: those conditions (outlined above) relating to the dressings, appliances and General Sale List medicines; that the prescription is for a patient for whom reference can be made to a medication record at the time of dispensing; that the prescription is for a medicine identical in dose, form and strength to a medicine already included on the record for that patient, and the pharmacist has not endorsed the record to the effect that no repeat should be provided in his/her absence; that the medicine is dispensed in an unopened original pack; that the prescription is presented not more than six months after the previously recorded entry related to the dispensing of the medicine concerned; that the person presenting the prescription does not raise a query that relates to the prescribed medicine that can only properly

be dealt with by a pharmacist; that the dispensing is recorded in a suitable manner and checked by the pharmacist at the earliest opportunity, the system being such that the pharmacist is able to confirm that the correct medicine has been supplied and that the prescription is computer generated. The implementation of these exceptions would require amendments to the terms of service of chemist contractors.

The Council took the view that no Pharmacy medicines should be sold from the pharmacy premises in the absence of a pharmacist. However it recognised that there could be an alternative optional arrangement whereby the pharmacist could list those Pharmacy medicines which, in his/her professional discretion, require a direct contact between a pharmacist and the purchaser on the occasion of each sale. It would then be possible for those medicines not so listed to be sold, under certain conditions, while the pharmacist is on the premises, but not necessarily aware of any particular sale at the time of the sale.

Those conditions were that the sale should only be undertaken by members of staff nominated by the pharmacist in charge; that nominated members of staff should have satisfactorily completed a course of training; that each sale should be recorded in one of the pharmacy record books and that such sales should take place in accordance with a written procedure, laid down by the pharmacist in charge and including the information to be given to the customer when such sales are made. The Council also took the view that Pharmacy medicines should not be accessible to the public, but should normally be displayed in the pharmacy.

Central to the Council's proposals for a redefinition of practice procedures relating to supervision was the requirement for adequately trained staff and for record keeping. This would mean that the

pharmacist would continue to be aware of every sale of a Pharmacy medicine although in some cases, this would be after the sale had taken place. However the pharmacist will have already decided which medicines could only be sold in advance with his prior involvement and his direct involvement in each sale. In turn records would permit regular monitoring of other sales and review of procedures and lists where considered appropriate.

The Council agreed that separate payments should be made for professional activities other than dispensing, within the National Health Service and considered that these should be additional payments. In a parallel way the Council deprecated the suggestion that payments in respect of prescriptions dispensed should be reduced.

Finally, the Council had specific recommendations in relation to the transfer of medicines from the Prescription Only Medicine category to Pharmacy category; the maintenance of the General Sale list; the ownership of pharmacies and the maintenance of National Health Service contracts with the pharmacy owner, the reduction in the number of pharmacies and the provision of pharmaceutical services in rural areas.

As indicated above, the purpose of the publication of the Council's provisional views was to elicit comments and stimulate debate. At the end of the consultation period, the Council had received comments from 12 national bodies, 67 branches and 33 members. These comments were considered at a further 6 Council meetings. The final conclusions of the Council were published at various times in the Pharmaceutical Journal and were finally consolidated in the Journal on 27 August 1988 (Pharmaceutical Journal 27 August 1988:N2-N9). The Council's final conclusions on the Nuffield Report were very similar to their initial views as outlined above. One significant

area where there was change related to the degree of supervision needed in dispensing of prescriptions.

In their initial view, the Council had been of the opinion that exceptions to the policy that satisfactory dispensing requires a pharmacist to see each prescription at some stage prior to the medicine being handed out should be permissible in relation to, inter alia, prescriptions for General Sale List Medicines, subject to a number of conditions. Their final view eliminates this opinion together with a number of conditions relating to the other exceptions. However the Council was also equally clear that the proposed relaxations in the policy did not mean that a relaxation in the overall control of the pharmacy:

"On the contrary, the Council's proposals, when implemented, will reflect the changes in the nature of community pharmacy practice - the phasing out of the manipulative role and its replacement by that of assessment and advice; expertise in action and uses of medicines rather than manual dexterity in dispensing elegant preparations." (Pharmaceutical Journal 27 August 1988:N7)

The issue of supervision and the publication of the Council's recommendations in relation to this issue caused considerable debate over the next year. The Council's proposals that certain medicines should be dispensed, even under fairly rigorous conditions, without the pharmacist having seen them were challenged by the profession itself through a special general meeting (Pharmaceutical Journal 14 October 1989:467). The net result of the rejection of the Council's policy was the election of one of the main challengers to the Council and a series of meetings to attempt to find a new common policy. This was finally issued as a Council Statement in October 1989 (Pharmaceutical Journal 14 October 1989:485).

By 1995 a number of the Nuffield recommendations had been implemented. These related primarily to the maintenance of patient medication records, the provision of advice to residential homes, the provision of a practice leaflet and the display of various health promotion leaflets, introduced by the National Health Service (Charges for Drugs and Appliances) Regulations 1989 and the National Health Service (Pharmaceutical Services) Amendment Regulations 1993. In addition the Council has published a set of standards for good professional practice which must be met by registered pharmacists. One of these standards relates to the provision of counselling information and advice. The Council has also issued a number of Statements (such as the one described above) which supplement the obligations set out in the Code of Ethics. One particularly important Council Statement relates to the provision of a written protocol in each pharmacy to be followed when a medicine is supplied or advice on treatment of a medical condition is sought and the requirement that each member of staff whose work in a pharmacy will regularly include the sale of medicines must have completed a course of training.

Primary Health Care - An Agenda for Discussion

In April 1986, for the first time since the National Health Service had been introduced in 1948, the Government commenced a review of the primary health care services. In the introduction to its discussion paper **Primary Health Care - An Agenda Discussion** (Great Britain 1986), the Secretaries of State for Social Services, Wales, Northern Ireland and Scotland, after outlining the extent of the provision of primary health care services and the reforms which had been introduced since 1989, made it clear that while the primary health care services in the United Kingdom were good, there was scope for improving the quality, effectiveness and value for money which patients get from them. The purpose of the discussion paper was to provide the

opportunity for a wide-ranging examination of the main elements of the primary health care services.

In so doing the Government had four main purposes in mind:

- to give patients the widest choice in obtaining high quality primary health care services;
- to encourage the providers of services to aim for the highest standards and to be responsive to the needs of the public;
- to provide the taxpayer with the best value for money from NHS expenditure on the family practitioner services;
- to enable clearer priorities to be set for the family practitioner services in relation to the rest of the NHS (Great Britain 1986:2).

One of the main elements of the primary health care services was obviously the provision of pharmaceutical services and the discussion paper devoted one chapter to an analysis of the this issue. This chapter gives an interesting insight into the perception of the role and function of the pharmacy profession by Government.

The discussion began with a recognition of the importance of pharmacy. That importance was reflected in the fact that there was a rising interest in medicines and in health. Patients not only

required a prompt and accurate dispensing of their medicines but also wished to understand more about their treatment and possible side-effects. They also wished to accept greater responsibility for their own health by making a significant contribution to avoiding ill-health. The pharmacist's traditional role was to act as an accessible and responsible source of advice about the treatment of minor ailments which could include suggestions for medicines available without prescription or a suggestion to consult a doctor. The pharmacist's advisory role was in addition to the fundamental task of accurately and promptly dispensing prescribed medicines and counselling patients on their use (Great Britain 1986:27).

However it was equally clear that the Government recognised how the pharmacist's role had altered. Community pharmacists would rarely be called upon to compound medicines which were now supplied in a form suitable for dispensing and for direct supply to the patient. In addition, medicines had become more numerous and powerful, able to provide treatment for a range of illnesses. The result was a change of role and function.

"While the pharmacist's knowledge about the composition and formulation of medicines is now a less important component of retail pharmacy, other components of the pharmacist's knowledge are increasingly important. The action of medicines in patients, the limitations of medicines, their contra-indications and side-effects, and the interactions between different medicines and foods are all important in modern treatment as are the varying ways different people respond to medicines."
(Great Britain 1986:27)

The Government believed that such developments created a need and provided an opportunity for pharmacy skills and expertise to be put to more and better use. The discussion paper endorsed the initiative undertaken by the Nuffield Foundation (summarised above) and recognised that the role and future development of pharmacy was already the subject of lively debate within the pharmacy

profession. It therefore welcomed the development of an extended role for pharmacists but recognised that the questions under discussion would have implications for other professions as well as for patients and the National Health Service. As such, the Government did not wish to see the proposed extension of the pharmacist's role resulting in confusion over responsibilities to the patient (Great Britain 1986:28).

In addition to these general comments on the role and function of pharmacists, the discussion paper also made recommendations on the specific issues of the National Health service contract for pharmacies, the supervising of dispensing, standards of service within the pharmacy, training for an extended role and restrictions on the sale of medicines.

The Reaction of the Pharmacy Profession to the Discussion Paper

The pharmacy profession reacted to the publication of the Green Paper with its usual vigour through a series of articles, reports, editorials, meetings and journal correspondence (Pharmaceutical Journal Index Volume 238). From that wealth of material, the effect of the Green Paper can be gauged through an analysis of one editorial in the Pharmaceutical Journal (Pharmaceutical Journal 26 April 1986, page 503).

The editorial began by stating that the potential value to the community of the pharmaceutical services had long been unrecognised. The inclusion of a long chapter on pharmaceutical services in the Green Paper was seen as evidence of progress towards an improving recognition of that value. Indeed the editorial thought it to be an achievement of some magnitude to have a categorical statement from the government that it believed that developments in medicine had

created a need and provided an opportunity for the skills of pharmacists to be put to more and better use.

The editorial noted that the publication of the Green Paper had been delayed to include a consideration of the conclusions of the Nuffield Enquiry into pharmacy. As the Green Paper's conclusions and recommendations drew heavily on the findings of Nuffield, the editorial believed that the hesitations which the pharmacy profession had about the Nuffield proposals applied equally to the Green Paper. Specifically, the Green Paper's acceptance of the Nuffield recommendation that the legal requirement that medicines should be dispensed by a pharmacist or under his direct supervision could be replaced by a more flexible requirement whereby pharmacists could delegate to assistants some of their responsibilities for dispensing individual prescriptions, while retaining personal responsibility for dispensing standards, caused concern.

The Green Paper noted that this flexible approach would release a substantial amount of professional time for other activities such as giving advice to patients. What concerned the editor was a particular phrase in the Green Paper relating to the possibility of a requirement for pharmacists to be redeployed. This could possibly carry the connotation that some pharmacists could cease to do what they were doing at present and move elsewhere to other jobs or the doomsday situation of no jobs at all. The danger lay in the fact that as long as pharmacists have a distinct role to play in terms of direct supervision of dispensing, a requirement supported by legislation, the work of the pharmacist is clearly required and must be paid for. Any marginalisation in this role and an inclusion of other activities in an expanded role, might result in a future plea of financial stringency as a reason for curtailing the expanded role.

"Let us be quite clear what has been argued in the past concerning the pharmacist's role. It is that the artisan type of work that the pharmacist used to perform in terms of pharmaceutical manipulation has, with the development of the manufacturing industry, largely disappeared. But the need for the pharmacist has not disappeared. The pharmacist has become what may be described as a technologist, who is concerned not with the mechanics of dispensing, but with ensuring that the patient receives not only the correct medicine (and not necessarily the medicine that was prescribed in the first instance) but also the advice needed to ensure that he or she obtains the maximum benefit from it."
(Pharmaceutical Journal 26 April 1986, page 504)

The pharmacist should not be prevented from carrying out this new role because of the need for direct supervising of dispensing. The pharmacist should bring to his reading of a prescription a totality of knowledge that no-one else in the pharmacy would possess.

Promoting Better Health

An invitation for comments was issued by the Government with publication of its Primary Health Care discussion paper. Six thousand copies of the discussion paper were distributed to two thousand seven hundred organisations and it was made available through HMSO bookshops. In addition one hundred and eighty thousand copies of a leaflet summarising the discussion paper were distributed through extensive advertising in the national press. Twelve public consultation meetings on different aspects of the review took evidence from three hundred and seventy witnesses representing seventy-three organisations. Two thousand two hundred written comments from two hundred and fifty bodies were also received. The discussion paper was also considered by the House of Commons Social Services Committee which, inter alia, endorsed the Government's plans for the extension of the role of community pharmacists (Great Britain 1987a).

The outcome of this extensive review was the publication of a Government White Paper - **Promoting Better Health** (Great Britain 1987). In its introduction, the Government outlined that a number of general themes emerged as an outcome of the consultation process and that it accepted that the best way of addressing those themes was to require practitioners to increase the range and quality of the services they provided. As such, the Government intended to enter into discussions with the professions with a view to introducing a number of specific changes. One of those changes was the extended use of pharmacists' skills. Details of the proposed change were outlined in Chapter 6 of the White Paper.

The discussion about the proposed reformation in the provision of pharmaceutical services began with a review of the increase in the average number of prescriptions dispensed annually by each pharmacy and the changes in the scope and nature of the dispensing function. It also commented on the introduction of a new contract for community services from 1 April 1987 and the findings of the Nuffield Report on the wider role for pharmacists within the National Health Service.

The Government stated that the two factors which led to the introduction of the new contract were the need to avoid the build-up of large under or overpayments to pharmacies and the requirement to have more influence over the distribution of pharmacies in order to avoid excessive expenditure on dispensing. As the contract was relatively new, the Government did not feel that it could comment upon it further. As such, it decided to build upon the recommendations of the Nuffield Report.

The White Paper commented on the specific recommendation of Nuffield that pharmacists should become more involved in the continuing education of other workers who contributed

towards community health, among whom were those who were responsible for residential homes for the elderly, handicapped and children. Believing that pharmaceutical supervision of the supply and safekeeping of medicines in such homes was of particular importance, the Government recommended the introduction of an allowance to pharmacy contractors who provided such a service (Great Britain 1988:36).

Secondly, the White Paper addressed the specific recommendation of Nuffield that pharmacists should keep records of medicines prescribed for or purchased by patients. This arrangement would assist doctors and patients by simplifying the detection of adverse reactions and interactions for individual patients and would be particularly beneficial for elderly patients who often took a number of different medicines but who regularly used the same pharmacy. On this basis, the Government intended to introduce a further allowance payable to those pharmacies who maintained a substantial number of records relating to the long-term medication of elderly or confused patients. The White Paper also endorsed the recommendation of the Nuffield Report that pharmacists could make an important contribution to health promotion and recommended that funds should be made available for the provision of such material for display in pharmacies (Great Britain 1988:37).

Other important recommendations contained in the White Paper relating to the provision of pharmaceutical services included the provision of funds to foster developments at a local level to allow pharmacists to assist in the development of policies on effective and economic prescribing as well as on the effects of medicines, their interactions with each other and ways of encouraging patients to gain the maximum benefit from medicines; the provision of funds for pharmacy practice research and the provision of funds for continuing education and in-service training for

pharmacists (Great Britain 1988:37).

The White Paper approached with caution the idea, recommended by Nuffield, that there should be a more relaxed approach to the supervision of dispensing by the delegation to appropriately trained assistants of some of the present responsibilities for the dispensing of prescriptions, while retaining personal responsibility for dispensing standards generally. However it did recommend that the profession examine the idea more closely.

Finally the White Paper made certain recommendations relating to the attraction of pharmacies to, and the improvement of standards in, inner cities and other deprived areas; the scope for making procedural changes in the statutory procedures for the classification of medicines and for ensuring that the prices which the National Health Service paid for medicines are reasonable while at the same time encouraging the maintenance and development of a strong and efficient pharmaceutical industry in the United Kingdom (Great Britain 1988:38).

The Reaction of the Pharmacy Profession to the White Paper

The reaction of the pharmacy profession to the White Paper was remarkably brief given its prior propensity for detailed comment on proposals for the potential for change in the pharmacist's role. (Pharmaceutical Journal Index Volume 240) After outlining the details of the changes and how they related to the practice of pharmacy, the Pharmaceutical Society gave the White Paper a positive but guarded response (Pharmaceutical Journal 28 November 1987, page 646).

The President of the Society (at that time Mr Bernard Silverman) indicated that he was delighted

that the Government had acknowledged the benefits to be gained from expanding the role of the pharmacist as a leader in the front line of primary health care and had committed funding for the new roles of providing specific services to residential homes and for the maintenance of medication records for patients who are confused or on long-term medication. However the President also had misgivings about the statements in the White Paper which made it clear that there would not be any commitment to additional funding for other improvements. In particular, the President indicated that the pharmacists had long recognised that the pharmacy was the ideal centre for health promotion activities and that government funding for promotional campaigns in pharmacies could save national health service expenditure in the medium and longer terms.

In a similar way the President was seriously disappointed with the limited promise to provide funding for a co-ordination centre to foster local liaison with doctors in achieving effective and economic use of medicines. The conclusion was that money invested in ensuring economical prescribing was bound to produce a net saving in overall health service expenditure and should be treated as a priority. In relation to the Government's expectation on a more flexible approach to the supervision of dispensing, the President indicated that the first priority must be to maintain for the public a pharmaceutical service of the highest quality - a challenge which he was confident the profession could meet. In conclusion the profession would be encouraged by the chapter in the White Paper relating to pharmaceutical services.

The Medical Profession Contributes to the Debate

The debate concerning the changing role and functions of pharmacists entered the pages of the professional medical literature in the late 1980s. Roberts (1988:563), a general practitioner, quotes from a speech made by the Chairman of the Nuffield Inquiry Report who is reported in a speech as having stated that the dispensing role of the community was in unstoppable decline. Roberts sought to discuss whether the proposed new roles for pharmacists were unique to pharmacists or whether they were being filled by other agencies. In addition he wished to examine the cost-effectiveness of high-street dispensing and to suggest an alternative method of supplying patients with medication. In so doing he has some strong remarks to make about the need for pharmacists in the first place.

Roberts states that the main role of the pharmacist is to supply medicines in accordance with prescriptions written by a doctor. He contends that it is the doctor who takes full responsibility for inappropriate prescribing being aware of the effects of the medicines which he/she does prescribe.

"In effect, the chemist acts rather like a chef in a kitchen, preparing the order as written on a piece of paper presented to him. Unlike the chef, however, he is not allowed to embellish it in any way. He is simply a supplier of goods, a storekeeper reaching for goods from a shelf. Industry has, furthermore, seen to it that those goods are prepacked in standard boxes or containers. This is original pack dispensing which will account for upwards of 80% of dispensing within the next 12 months ... The mixing role of the chemist has thus been eliminated" (Roberts 1988:563)

Roberts is seemingly not impressed by the argument that by double-checking prescriptions, the pharmacist has saved patients from the mistakes of doctors. In his view that role was being taken over by computer technology in doctors' surgeries and clinics which prevented patients from receiving drugs which were inappropriate to their current medication or their disease. As much of

this information remains confidential to the doctor-patient relationship, the back-up role of the pharmacist was rapidly disappearing. On the question of the supervision of dispensing, Roberts states that pharmacists employ well qualified dispensers who prepare the medicines which are then checked by the chemist.

"A degree in pharmacy seems to be an over-qualification for reading a label on a box and comparing it with details on a prescription form. The qualified dispensary assistant is more than capable of this simple task ... The chemists' dilemma is that only compulsory supervision differentiates them from dispensing doctors." (Roberts 1988:563)

Having decided that the pharmacist's existing roles and functions had all but disappeared, Roberts suggests that the new roles which have been proposed by Nuffield and others are equally inappropriate. The supervision of medication in residential homes was the responsibility of the prescribing doctor and home supervisor. Any interference by way of advice from the pharmacist could lead to confusion and a resultant adverse effect on the patient. In addition, health education and advice was adequately carried out by other health care professionals and the supply of literature on health education could easily be undertaken by non-dispensing pharmacists.

Roberts is strongly of the view that pharmacists do not have any training in the giving of advice about health and suggests that the advice which pharmacists give may be inappropriate and even dangerous (Roberts 1988:563). He goes on to suggest that the duality of role of the pharmacist as retailer as well as adviser may have a prejudicial effect on any advice which is given e.g. to purchase an appropriate over-the-counter medication. Visiting the elderly to supervise their medications is also not suitable. The elderly are likely to be visited by a number of health care professionals including the general practitioner. As such any proposed further visit from a

pharmacist would be censured by the medical profession as being excessive.

"Far from being the unique providers of some new aspect of health care, the chemist in his new role, with no training in medicine, would perform identical tasks to appropriately trained members of the primary health care team, and would expect payment for these sinecures without a reduction in fees for the now less arduous dispensing role." (1988:563)

Equally an analysis of the costs of dispensing and prescribing would show that the service provided by doctors is more cost effective than that provided by chemists. All of this would lead to the conclusion that dispensing by doctors would be a better alternative being safer, more convenient and cost-effective.

As might be imagined, this intervention generated a great deal of further comment. Correspondents to the Journal of Royal College of General Practitioners (May 1989) from the pharmacy profession tended to take a different view. Balon, Evans and Greene re-emphasised the Nuffield report's extended role in providing a service to general practitioners which would enable them to make better prescribing decisions and to assist patients in the handling of their medicines. They felt that the fact that patients spoke to the pharmacist as well as to the general practitioner could only be beneficial to the patient and did not necessarily interfere with the patient/doctor relationship. The pharmacist's current training equipped him/her very well for the proposed extension of his/her role.

The fightback by the pharmacy profession continued with the publication in the same journal of an article by Taylor and Harding (1989). In a direct reply to Roberts, the authors began by indicating that most pharmacists welcomed the recent changes in the nature of dispensing which

meant that the pharmacist now spent less time on this function than before. However this decrease in the amount of time spent on the dispensing function did not result in a parallel reduction in the importance of the overall role in the dispensing process. Pharmacists have the necessary knowledge base and skill to ensure that prescriptions are checked thoroughly and the appropriate medication is dispensed - a current legal requirement - and can make appropriate clinical, pharmaceutical or professional judgments for the ultimate benefit of the patient.

Taylor and Harding point out that the undergraduate and pre-registration training undertaken by pharmacists, involving gaining pharmacological, pharmaceutical and clinical knowledge of drug compounds and medicaments, equipped them to provide a service over and above the mere dispensing of medicines. That service included the reiteration of the prescriber's instructions and the giving of additional advice. This helped to enhance compliance with a drug regime. In addition pharmacists were also a ready source of drug information for other health care professionals.

Any future extended role for the pharmacist should centre around the recommendations contained in the Nuffield Report and White paper (as outlined above). The authors hoped that the proposed expansion of the pharmacist's role would be welcomed by the other health care professions and be seen by them to be a beneficial development for both the professions and the patient.

This article stimulated further correspondence to the same journal, most of which was again uncomplimentary to the pharmacy profession. Ford (*Journal of the Royal College of General Practitioners* August 1989:348) described as "recklessly undiplomatic", Taylor and Harding's suggestion that pharmacists were the only health professionals to whom there was quick and easy

access. Eastaugh, and Ford (Journal of the Royal College of General Practitioners August 1989:348) writing in the same journal at the same time, supported Roberts' view that dispensing by the doctor had more in common with the medical environment than high street pharmacies "the vast majority of whose trade is in flannels, cosmetics and similar consumer-oriented products".

Harding and Taylor returned to their theme on the safer ground of the Pharmaceutical Journal (1990:245). Having reviewed the characteristics which in their view allowed pharmacy to describe itself as a profession, the authors conclude that pharmacists had unique knowledge and skill relating to the preparation and clinical use of drugs. The recent trend towards the demystification of the pharmacist's traditional compounding and dispensing role did not undermine the pharmacist's claim to professional status. Now opportunities existed for the promotion of the development of pharmacy into areas with which it has not traditionally been associated. These developments:

" ... indicate that pharmacists are increasingly involved in the provision of health care advice and health education to the community, Such developments will produce a commensurate rise in the level of pharmacists' indeterminate knowledge and reinforce pharmacy's claim to full professional status." (1990:245)

The Report of the Joint Working Party on the Future Role of the Community Pharmaceutical Services

In November 1990 a Joint Working Party of the Health Department (Joint Working Party 1992) and the pharmaceutical profession was set up with the following terms of reference:

"To consider ways in which the National Health Service community pharmaceutical services might be developed to increase their contribution to health care; and to make recommendations"

The Joint Working Party had been set up against substantially the same background as that faced by the Nuffield Inquiry, namely, changes both in the practice of community pharmacy itself and the context within which it is practised. The Joint Working Party noted the developments which have been the subject of this thesis to date.

"There are more medicines, and more powerful, complex and effective medicines than ever before and their proper use is therefore all the more important. More medicines are now supplied in manufacturers' original packs. New medicine delivery systems such as those for patient controlled analgesia are being developed, often initially in hospital, but with scope for extension to the community. There have been extensive developments in information technology, such that there are few if any pharmacies which do not have computers performing a range of functions; and we can expect development to continue.

At the same time the public are taking a much more active and informed interest in their health and health care, seeking more information and a greater involvement in decisions affecting their lives. The Government is actively encouraging such an approach ... Professions generally, and the health care professions in particular, are reviewing the way they conduct their business and developing systems of review, audit and quality control.

Health needs in the community are also changing, as the population ages, as some of the diseases of the past are controlled, and as new diseases appear. Coupled with the increasing emphasis on enabling patients to remain in their own homes or to leave hospitals earlier - an emphasis which is in accordance with patients' own preferences - and to the growth of day surgery this has led to an increasing role for all the health care professionals in the primary sector. (Joint Working Party 1992:1)

The Joint Working Party consisted of representatives of the pharmaceutical profession and officials of the Department of Health with other health officials in attendance as observers. The Joint Working Party issued an open invitation to submit evidence and in response received a number of submissions. It also held a national conference on the Future Role of the Community

Pharmaceutical Society and undertook a number of visits to other countries.

The Joint Working Party began its Report by contending that community pharmacists constituted a valuable resource. Their evidence for this was the number of pharmacists in professional practice, the length and nature of their training, and the accessibility of pharmacies in the community. In addition, the increasing expenditure on the provision of pharmaceutical services justified the continued use of those who were experts in the use of medicines. The Joint Working Party also undertook a review of community pharmacy as it existed in 1992 under the headings of the legal framework, education and training, dispensing of medicines, treatment of ailments, health care advice and the typical pharmacy.

The Final Report of the Joint Working Party contained an extensive list of 30 recommendations. These recommendations are very practical in nature and concern such issues as the establishment of specific new services for community pharmacists, such as limited National Health Service prescribing, the investigation of the scope for new services, such as therapeutic drug monitoring, and the maintenance of certain services already on offer, such as the extension of the keeping of patient medication records (Joint Working Party 1992:24).

Of more obvious concern to this thesis is the final chapter of the Report which discusses, in general terms and without specific recommendations, the future of community pharmacy. This part of the Report recognises that the recommendations which have been made would have the effect of extending clinical pharmacy in the community. However the Working Party also recognises that their investigation also provided an opportunity for the development of a distinctive relationship between pharmacist and the patient in the community pharmacy:

"- a relationship based on continuity over a potentially long period, cognisance of the full pharmacological history and a knowledge of the social context within which the patient is being treated. This broader perspective has been encapsulated in the concept of 'pharmaceutical care'. The concept requires the pharmacist to accept the responsibility not simply for the provision or monitoring of medicines, but to partnership with others for the overall effects of the therapeutic process" (Joint Working Party 1992:20)

The Working Party was of the view that pharmaceutical care embraced a number of distinct elements. Firstly, at the heart of the pharmacist's role should remain the supply of medicines, both against prescriptions and to treat the symptoms of common ailments. However the Working Party was clear that this involved not only the filling of prescriptions, but also encompassed the reviewing and confirming the appropriateness of the prescription and advising the patient on the safe and effective use of the medicine dispensed:

"Looked at in this way dispensing is far from the mechanical task that is sometimes portrayed. It makes full use of the knowledge and expertise of the community pharmacist for the benefit of the patient. It follows from this that we are strongly of the view that the dispensing process should continue to be conducted by or under the direct supervision of the pharmacist. We can see no other way of ensuring that the patient gains the benefits of a full pharmaceutical service on every occasion." (Joint Working Party 1992:20)

The second distinct element of pharmaceutical care meant the recognition that the pharmacist could not work effectively in isolation. The pharmacist would have to see him or her self as part of a team working together for the benefit of a patient. The most fundamental relationship which the pharmacist would have would be with the general practitioners from whom prescriptions originated and who was responsible for the maintenance of medical care but the relationships with other members of the health care team were of increasing importance. Effective liaison was required at two levels - that of individual patients and the level of planning and providing services for the local population.

The third aspect of pharmaceutical care is the most important:

" ... the community pharmacist must aim to provide a "patient oriented" service. This involves seeing the patient not as a set of interacting biochemical systems, but as a whole person. The patient is not the object on which the pharmacist performs his functions, but as an active participant, with the pharmacist, in the therapeutic process. Teamworking must extend not just to other health care professionals but to the patient and his family or other non-professional carers." (Joint Working Party 1992:20)

While the Joint Working Party saw the dispensing function and the effective use of drug therapy to maximise the therapeutic benefit to the patient as being at the core of community pharmacy, it also regarded community pharmaceutical services as involving a wider component. Every health care professional had a responsibility in relation to the provision of health promotion and healthy living and pharmacists, with their extensive contact with the public, had ample opportunity to exercise this responsibility. In addition the pharmacist's expertise left him/her in an advantageous position to capitalise on the increasing interest among the public for health screening and testing.

The core of services which the Joint Working Party identified in its recommendations centred around dispensing, effective relationships with other health professions and advice on ailments, should be undertaken by all community pharmacies as part of the arrangements which they made with family health service authorities for the provision of pharmaceutical services. In addition the Working Party identified a further range of services which community pharmacies could effectively undertake.

Two major consequences arose from these specific recommendations. Firstly the terms of service of pharmacists would have to be relaxed to allow pharmacists to advertise the range of services

they provide. In this way both the public and fellow health care professionals could make informed decisions about where they wished to obtain their required pharmaceutical services. Secondly, the family health service authorities would need to ensure that patients had ready access to a full range of balanced and appropriate pharmaceutical services (Joint Working Party 1992:20-21).

The Reaction of the Pharmacy Profession to the Working Party Report

The pharmacy profession's reaction to the Working Party report was to welcome its recommendations. The Royal Pharmaceutical Society believed that the Report provided the right solution for pharmacy, the National Health Service and the health of the nation (Pharmaceutical Journal 7 March 1992). However it was also anxious to see that the Government introduced sufficient funds to extend the pharmacist's role:

"We believe that there is much to be gained from developing the pharmacist's considerable role in health promotion and disease prevention. Pharmacists have a unique body of knowledge that is of vital importance to the work of other health professions and we are actively seeking ways of working more closely with other members of the health team. As a profession, pharmacists are willing to meet the challenges that a broader role will bring them." (Pharmaceutical Journal 7 March 1992 at page 305)

Those sentiments were echoed in an editorial in the Pharmaceutical Journal (Pharmaceutical Journal 7 March 1992). In particular, it welcomed the continued recognition, from the Nuffield report through to the Joint Working Party Report, of the fact that the pharmacy profession had a distinctive and indispensable contribution to make to health care which was capable of further development. Seeing that the Joint Working Party Report was one of the most important

documents to emerge in relation to the development of the profession, the Journal was encouraged that there had been a recognition that the time was right for pharmacists to take on a more active role.

Later in the year, however, the Journal was concerned that progress was not being made (Pharmaceutical Journal 12 September 1992). In particular, the Journal was concerned at the lack of action on the part of the Government to introduce the report and believed that its successful implementation would nullify any criticisms of the pharmacy profession and the provision of pharmaceutical services.

Pharmacy in a New Age

In its continuing role as overseer of the pharmacy profession the Council of the Royal Pharmaceutical Society has recently introduced a new initiative **Pharmacy in a New Age** which is aimed at allowing the pharmaceutical profession to have a clear view of its future. The Council of the Royal Pharmaceutical Society repeated its view that pharmacists, with their expert scientific and practical knowledge of all aspects of medicines and their use, were at the heart of health care. As medicines were likely to remain at the core of health care, there would be an increasing demand for information about them from both the public and other health care professionals. The pharmacist's strengths of accessibility to the public, communication skills and long experience in the provision of customer service meant that the profession would enjoy a prosperous future. However that future should be based on agreed principles. The Council believed that future progress should be based on the following four principles:

"The core pharmaceutical skills combine a deep understanding of the proper use of medicines with an appreciation of the risks of inappropriate use. Pharmacists' full potential must be tapped if medicines are to be used safely, effectively and cost-efficiently.

It is of benefit to society that pharmacists should make use both of their skills and close contact with the public to advise on the treatment of common ailments and on maintaining a healthy lifestyle.

This pharmaceutical advice should continue to be available to the public and other health professions whenever required.

The pharmacist's role should be properly supported by education, training, research and audit at all levels." (Royal Pharmaceutical Society 1995: 5)

The Council of the Royal Pharmaceutical Society has sought debate within the profession and with the public about the future of pharmacy based on these principles. In order to assist and inform the debate the Council has commissioned and published a number of short, focused background papers ('The New Horizon', September 1996, 'Building the Future', September 1997, 'Over to You', September 1998) dealing with issues which it believes will influence the future development of pharmacy. In addition it has organised a series of talks and group meetings. These developments are ongoing.

The Council of the Royal Pharmaceutical Society has set out the following declaration of strategic intent as expressing the vision arising from the Pharmacy in a New Age:

'The pharmacy profession will work for a future in which it can make the greatest possible contribution to the health of the people of Britain in ways that are efficient, sustainable and that meet people's needs.' (Royal Pharmaceutical Society 1995: 4)

In addition, the Council has set out a number of strategic aims which show how the Council sees

the development of pharmacy's contribution to healthcare, across five main areas of activity – the management of prescribed medicines, the management of long term conditions, the management of common ailments, the promotion and support of healthy lifestyles and advice and support for other healthcare professionals.

In 1999, the Council of the Royal Pharmaceutical Society sought to analyse the impact of the Pharmacy in a New Age project by commissioning research designed to find out what problems pharmacists experienced in their everyday practice and to see how these affected the realisation of their aspirations identified in the Pharmacy in a New Age consultation. The published results ('Catalyst for pharmacy's future' The Pharmaceutical Journal Vol 265 N0 7125 pp814-815) showed that the majority of issues on which pharmacists expressed concern were professional matters that involve providing care to patients and supporting the work of colleagues. Secondly the professional future foreseen in the Pharmacy in a New Age initiative was well supported by most members of the profession.

The National Health Service plan

On July 27 2000, the Government announced details of the future plans for the National Health Service. The plan, subtitled 'A plan for investment, a plan for reform' ('Ten year modernisation plan for NHS' The Pharmaceutical Journal Vol 265 No 7108, pp 182-183) envisages 7000 extra beds in hospitals and intermediate care, over 100 new hospitals and 500 one stop primary care centres, 2000 more general medical practitioners, 20000 extra nurses and 6500 extra therapists and other health care professionals. Other proposals include improved pay for NHS staff, an increase in the budget for the National Institute for Clinical Excellence (NICE), and new care

trusts to integrate health and social services, each trust to have a patient advocate and liaison service and a new occupational health service.

The plan, when first announced, made specific reference to the future for pharmacy. It stated that pharmacists were to take on a new role, shifting from being paid mainly for the dispensing of individual prescriptions towards rewarding overall service. The plan envisaged that proposals would be invited for personal medical services-type schemes that pilot alternative contracts for community pharmacy services. These schemes would cover areas such as medicines management and repeat prescribing. The plan also visualised that by 2002 all NHS Direct sites would refer people, where appropriate, to help from their local pharmacy. In addition there would be better out of hours pharmacy services and a wider range of over the counter medicines available. By 2004 every primary care group or trust would have schemes in place so that patients could get more help from pharmacists in using their medicines. The plan also stated that new one stop primary care centres would be built where GPs would be working in teams from modern multipurpose premises alongside nurses, pharmacists, dentists, therapists, opticians, midwives and social care staff. Electronic prescribing of medicines was set to happen by 2004.

The NHS plan, when first published, was given a guarded but positive welcome by the pharmacy profession ('Promising plan' *The Pharmaceutical Journal* Vol 265 No 7108 p 181). It was seen to promise to be of immense significance for the practice of community pharmacy, making clear that the Government was prepared to pay for medicines management services in other words, to pay pharmacists to help patients in a structured way to get the best out of the medicines they take. The profession hoped that the proposed medicines management services would involve regular meetings taking place between pharmacist and patient to review treatment and identify problems,

to develop a care plan and to review the progress of treatment. For the profession, medicines management has the characteristics of pharmaceutical care. Further:

‘The NHS plan will mark a further step in the process of switching the provision of pharmaceutical services from a commodity supply operation to a knowledge-based system where the pharmacist has the information he or she needs to manage a patient’s therapy. The process started in 1996 with the Nuffield report, which urged a change in the way that pharmacists use their time in order to support them in their professional role, and continued with the Pharmacy in a New Age consultation process, which envisaged pharmacist taking the initiative in managing the medication of certain patients.’ (‘Promising plan’ The Pharmaceutical Journal Vol 265 No 7108 p 181)

The detail of how the NHS plan would impact on pharmacy was outlined by the Government in September 2000 (‘Plan sets out how pharmacy can build a future for itself, says Minister’ The Pharmaceutical Journal Vol 265 No 7114 pp 397-400). In a keynote speech to the 137th British Pharmaceutical Conference, Lord Hunt, Parliamentary Under-Secretary for Health, outlined three particular challenges which pharmacy had to face. The first of these was to meet patients’ needs. In turn this meant that people could get medicines or pharmaceutical advice easily and, as far as possible, in a way, at a time and in a place of their choosing; secondly providing more support in using medicines; and thirdly, giving patients the confidence that they were getting good advice when they consulted a pharmacist.

The second challenge was for pharmacists to respond positively to the competitive environment in which community pharmacists would find themselves. The third and final challenge was to ensure that public confidence in the profession was maintained and enhanced. In providing more detail on how these challenges might be met, Lord Hunt submitted that patients had to be

involved a lot more in decisions about their treatments and had to be provided with better services once they had been prescribed their medicines:

‘A good community pharmacy service is one where the patient comes first; where medicines are available conveniently when patients want them; where pharmacists make themselves available to respond to requests for advice and take the initiative in offering help where appropriate; where patients can discuss personal matters in privacy if they wish with the absolute confidence that the pharmacist is equipped with up-to-date experience and skills. This is the kind of community service which should be available everywhere...’ (‘Plan sets out how pharmacy can build a future for itself, says Minister’ The Pharmaceutical Journal Vol 265 No 7114 p 399)

Again, the response of the profession was one of enthusiasm. Speaking at the same conference as Lord Hunt, the President of the Royal Pharmaceutical Society described the announcement of the pharmacy strategy as a watershed:

‘There is now a real opportunity for our profession to realise its full potential. The Society has been focusing on this very objective ever since it embarked on the Pharmacy in a New Age strategy’ (‘“A watershed for the profession” says the President’ The Pharmaceutical Journal Vol 265 No 7114 p 400)

A New Role? Which Role? Pharmaceutical Care?

While the idea of a "patient-oriented" practice for pharmacy has been around for some time (Webb 1976), the debate has recently taken off in the United States of America. Penna (1990) states that as part of an overall expansion of the health care system, pharmacy is undergoing its own rapid and vigorous expansion and development. He points to the work of Brodie (1965 & 1967) who had advanced the suggestion that the control of drug-use was central to the purpose of the pharmacy profession. He is of the belief that Brodie's ideas were central to the development

of pharmacy from a purely **distributive** to a **clinical** profession. Brodie's ideas were further developed by Hepler (1985 & 1987) and Hepler and Strand (1990). Hepler had introduced the idea of pharmaceutical care, initially defining it as:

"... the covenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions ... governed by awareness of and commitment to the patient's interest."

and:

'The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a person's quality of life'

Penna is of the view that pharmaceutical care:

"requires that a professional with demonstrated expertise in drug therapy (a pharmacist) be responsible for the outcomes of drug therapy in patients and be responsible for ensuring that the desired therapeutic goals are achieved and that drug-induced illness does not occur. Pharmaceutical care improves patient outcomes by ensuring more effective and efficient use of drugs as therapeutic tools." (1990:544)

In short, as the title of his article suggests, Penna sees pharmaceutical care as pharmacy's mission for the 1990s. The pharmacist's share of the responsibility for the outcomes of drug therapy is seen as an imperative, such has been the development of clinical pharmacy skills.

The practice of pharmaceutical care obliges the pharmacist to share responsibility for the design, implementation and monitoring of a therapeutic plan which seeks to achieve a set of desired therapeutic objectives. As an essential element of health care, the practice of pharmaceutical care must be carried out in co-operation with patients and other professional members of the health

care team. It is clear, however, that pharmaceutical care is provided for the direct benefit of the patient and the pharmacist must accept direct responsibility for the quality of that care.

Pharmaceutical care moves the practice of pharmacy beyond the traditional model where the primary function of the community pharmacist is to dispense prescriptions, to a new model where the pharmacist is involved in rational drug therapy. Within this new model, pharmacists, in their professional capacity, continue to function as experts in the dispensing of drugs but also collect/find and interpret evidence relating to specific clinical questions and provide information that permits patients to assess risk, enhance their autonomy, and develop their own medication practice (Brushwood and Schulz (1991)).

When patients obtain their medicines they may choose not to take the drug at all or to take it in a certain way based on their own individual social and familial circumstances. The patient has a great deal of autonomy in deciding whether or not to take a drug, is largely unsupervised in making that decision and has no-one with the appropriate knowledge of their individual circumstances to assist them in making rational and careful decisions about self-administration and re-administration.

The community pharmacist is well placed to fill this void and assume a client-specific role with respect to decisions about drug taking. Pharmacists are highly trained in the science of drug therapy (Hepler and Grainger-Rousseau, 1995), are readily available in the community in which they live and are highly regarded and trusted by members of that community. As a result of this, pharmacists often have a greater access to information about the prescription process relating to a particular patient (Brushwood and Schulz, 1991, Walker and Hoag 1996).

The pharmacist in this new role is still concerned with the initial choice of prescription and more concerned with patient outcomes, using patient-specific evidence to monitor and manage the patient's care. This role equates with the current expectations of the profession, applying existing knowledge of drug therapy in original and creative ways to improve patient outcomes.

The new role naturally requires co-operation with patients and other members of the primary health care team. However the pharmacist's intervention is provided for the direct benefit of the patient and the pharmacist must accept direct professional responsibility for the quality of that intervention.

The pharmacist in the pharmaceutical care system is less concerned with initial choice of prescription and more concerned with monitoring, management and patient outcomes. The pharmacist in such a system will use patient-specific evidence to monitor and manage the patient's care. Pharmaceutical care changes episodic drug therapy to coherent, continual care (Hepler 1995). Responsibility for patient outcomes is spread from the individual (doctor) to the team (all healthcare providers).

Further research (Brushwood and Schulz 1991) on the role of the pharmacist in patient care is confirming that pharmacy should expand into new areas beyond those traditionally expected of the profession. The authors principal suggestion is that pharmacy practice should move a step beyond the traditional technical model where the primary function of the pharmacist is to process prescriptions, to a new **clinical** model where the pharmacist is involved in rational drug therapy. Within this new model, pharmacists, in their professional capacity, would continue to function

as experts in the dispensing of drugs but would also be seen as **patient advocates**, providing information, as noted above, that permits patients to assess risk, enhance their autonomy and develop their own medication practice.

Brushwood and Schulz offer a number of justifications for this proposed expansion including the requirement for someone to perform a patient advocacy function with respect to drug-taking decisions. As a result of a trend towards centralised decision-making concerning the safety and use of particular drugs, there is a presumption that once a prescription is written, then questions about safety and use are already settled. Doctors may not be fully involving their patients in decisions regarding drug use, the prescription of a particular drug may be automatic and without regard to the individual circumstances of a patient.

The authors are also of the view that it may be the case that it is not acknowledged that risk evaluation may occur when patients get the drugs into their hands. They may choose not to take the drug at all or to take it in a certain way based on their own individual circumstances. They may seek advice from relatives and friends. The patient has a great deal of independence in deciding whether or not to take a drug, is largely unsupervised in making that decision and has no-one with the appropriate knowledge of their individual circumstances to assist them in making rational and careful decisions about self-administration. As a result the entire system of drug administration can be easily undermined. Those who could benefit from the development of an advocacy role for pharmacists would be the impoverished and uninformed who suffer more than most from a lack of understanding of the nature and function of drugs and who often feel reluctant to expose their ignorance to the prescribing doctor.

Brushwood returns to and develops this theme in his book written with Richard Abood (Brushwood and Abood, 1994). They are of the view that although patient counselling and patient-oriented facets of pharmacy practice have been around for several decades, many pharmacists still operated within the technical model of pharmacy, limiting their responsibility to the patient to the provision of restricted information. Clinical pharmacy developed the role of the pharmacy further but historically, an important aspect of clinical pharmacy involved the pharmacist in assuring the patient that what has been proposed for him/her by the physician is correct and deviance from the physician's instructions should not be permitted. The authors agreed with Penna that this approach to clinical pharmacy was acceding to one of pharmaceutical care:

"The pharmaceutical care model, a new approach to pharmacy practice, empowers a pharmacist to encourage patients to assume responsibility for drug therapy within the framework of their own lifestyle, values and environmental factors. Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life. A pharmacist who practices pharmaceutical care is not as concerned with the objective correctness of therapy from a medical view as with the subjective appropriateness of therapy from a patient view. Pharmaceutical care is patient-oriented rather than physician-oriented." (1994:211)

Does the description above reflect the expansion in role which is being proposed for the pharmacy profession? Some examples from the recent debate show that this would appear to be the case. In a review of pharmacy developments in the pharmacy profession's own journal, the Pharmaceutical Journal, a report of the National Association of Health Authorities and Trusts was welcomed which advocated a greater use of pharmacists in the giving of advice to patients and in having a greater involvement in the repeat prescription process (Pharmaceutical Journal 29 January 1994).

"This is a traditional role of community pharmacists and, subject to the appropriate safeguards, should be encouraged on the grounds of convenience to patients, the avoidance of unnecessary NHS drugs expenditure. It is essential that this is seen as complementary to the role of the family doctor service and is in no way regarded as a second rate service" (Pharmaceutical Journal 29 January 1994 at page 148)

This confirms earlier statements about the extent and form of the role which should be taken, and is reinforced by the quotations above from the Pharmacy in a New Age debate and response.

To quote again from Taylor and Harding (1989:209-210) enthusiasts for the development of an extended role:

"Pharmacists' undergraduate and pre-registration training involves gaining pharmacological, pharmaceutical and clinical knowledge of drug compounds and medicaments, and the acquisition of pharmaceutical skills unique among health professionals. These attributes equip pharmacists to provide a service over and above that of dispensing medicines ...

At the point of handing over a dispensed medicine, pharmacists' reiterate prescriber's instructions and give additional information where appropriate. By reinforcing the prescriber's instructions, the pharmacists enhances the compliance of patients with their drug regimen. in addition, because of the ready accessibility of pharmacies in most communities, pharmacists are frequently sought for ... advice ...

Community pharmacies are well placed to provide such advice since they are visited daily by an estimated six million people ...

The expansion of the community pharmacist's role ... is raising the profile of community pharmacists as providers of health care."

Again, one of the recommendations of the joint pharmacy profession/Department of Health

Working Party investigating the future of community pharmacy was that pharmaceutical consultations in which patients are advised on their treatment and their compliance is evaluated could be introduced ('Pharmaceutical Care: The Future for Community Pharmacy' Royal Pharmaceutical Society March 1992). The Working Party concluded by indicating that the model for community pharmacy which provides the best basis for the future was that of a "patient-orientated" practice.

The change in role and function for community pharmacists is well summarised by Walker and Hoag (1996:i):

'The roles and responsibilities of pharmacists have greatly expanded over the past thirty years. From a professional practice model that focused almost exclusively on fast and accurate dispensing of prescription medications, we can now observe practitioners involved in planning specific drug therapy for individual patients and in sharing responsibility for drug therapy outcomes.'

Conclusion

Two determinants - the advent of the National Health Service and the spectacular growth of the international research-based pharmaceutical industry - have forced community pharmacy, and others, into analysing its roles and functions as a provider of health care. That analysis has resulted in agreement that pharmacists need to adopt some sort of new or "extended" role. That role should be one which builds upon the existing expertise of the pharmacist in relation to drugs and drug therapy (the basis of their technical training) but which would see the pharmacist becoming more actively and directly involved in patient care. Current research on the role of the pharmacist in patient care in the United States of America is confirming that pharmacy should

expand into new areas beyond those traditionally expected of the profession and that the term 'pharmaceutical care' is appropriate to define pharmacy's new mission.

The adoption of new roles and functions have a number of implications. Walker and Hoag (1996:iii) outline the implications from a legal perspective:

'Necessarily the role of pharmacists in America's evolving health care system will be shaped by law. The extent to which pharmacy becomes under law the mission of pharmaceutical care depends significantly upon the extent to which such an expanded role is recognised by judges, legislators and regulators. What duties pharmacists owe, to whom such duties are owed, what is the relevant standard of care, and what constitutes breach all define the role of pharmacists and the conduct expected of them.'

The purpose of the next chapter will be to examine the developments predicted by Walker and Hoag and explore the extent to which judges and legislators, in particular, have recognised the pharmacist's extended role.

Judicial Attitudes to Pharmacist Responsibility in the United States of America

Purpose

In the previous chapter, it was concluded that the practice of pharmacy is moving beyond the traditional model where the primary function of the community pharmacist is to dispense prescriptions, to a new model where the pharmacist is involved in rational drug therapy. Within this new model, pharmacists, in their professional capacity, continue to function as experts in the dispensing of drugs but also collect/find and interpret evidence relating to specific clinical questions and provide information that permits patients to assess risk, enhance their autonomy, and develop their own medication practice.

It was also concluded that Walker and Hoag (1996:i) were correct that the role of pharmacists in the health care system is necessarily shaped by law and that the extent to which pharmaceutical care becomes the mission of pharmacy depended upon a recognition of that expanded role by judges and legislators. The purpose of this chapter is to begin the process of analysing how the expanded role of pharmacists has been recognised by the **courts** in the United States of America. The next chapter will undertake a similar analysis in relation to the **legislature** within that jurisdiction.

An analysis of judicial attitudes towards pharmacist responsibility shows distinct patterns or trends. Walker and Hoag (1996:iii), and Brushwood (1996:44 and 1988:4), are of the view that, in the current period, dating from 1985 to the present, judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. All three authors also agree that the movement towards a recognition of expanded

responsibility must be viewed against a recent background of traditional legal analysis which had limited pharmacist responsibility to the accurate processing of prescriptions and which had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor. Finally, Brushwood (1996:3), concludes that the recent judicial creativity in expanding pharmacist responsibility has its basis in a series of very early cases, from as far back as the early nineteenth century.

As such, the analysis in this chapter will look at three periods of judicial activity. The first, from **1852-1932**, will analyse the early perspective on pharmacist responsibility, and will conclude that the early cases set the standards for pharmacists at a high professional level. The second, from **1932-1985**, will evaluate a period of traditional legal analysis which resiled from the earlier expansion of pharmacist responsibility and restricted liability to technical inaccuracy in prescription processing. The third, and most recent period, from **1985 to present**, will show that the judiciary may be returning to first principles and are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions.

An Initial View of Pharmacist Duty - 1852-1932

One of the first cases in the United States of America to examine the issue of pharmacist liability and duty was *Fleet and Semple v Hollenkemp* (13 B.Monr. 219(Ky.1852). In this case, John Hollenkemp, had been sick for some time, but was improving and was convalescing. His doctor had recommended a tonic preparation and had made out a written prescription. The prescription was taken by the Hollenkemp to the drugstore, owned and operated by William Fleet and Samuel Semple in partnership. During the dispensing process in

the drugstore, the compounded medicine became contaminated with a foreign product. The evidence all pointed to contamination of the proposed innocuous mixture by remnants of a product called cantharides which had remained in an uncleaned grinding mill from a previous task. Hollenkemp made a tea out of the dispensed medication, consumed it and shortly afterward became seriously (and arguably, permanently) ill.

Hollenkemp brought an action against Fleet and Semple and was awarded \$1,141.75 in damages. Fleet and Semple appealed, alleging, *inter alia*, that the trial judge had improperly instructed the jury upon the law. On the question of the appropriate law, Judge Hise in the Kentucky Supreme Court began by indicating that it was a well established rule (*Van Bracklin v Fonda* 12 Johns R. 468) and principle of law that a vendor of provisions for domestic use was bound to know, at his/her peril, that the provisions were sound and wholesome. In contracts for the sale of provisions, there was an implied term on the part of vendor that they were sound and wholesome (3 Black. Com. 165).

Judge Hise asked whether such a rule could apply with equal (or indeed greater) force to vendors of drugs from a drug store:

“The purchasers of wines and provisions, by sight, smell and taste, may be able, without incurring any material injury, to detect their bad and unwholesome qualities; but many are wholly unable, by the taste and appearance of many drugs, to distinguish those which are poisonous from others which are innoxious (sic), so close is their resemblance to each other; purchasers have, therefore, to trust the druggist. It is upon his skill and prudence they must rely. It is, therefore, incumbent upon him that he understands his business. It is his duty to know the properties of his drugs, and to be able to distinguish them from each other. It is his duty so to qualify himself, or employ those who are so qualified, to attend to the business of compounding and vending medicines and drugs, as that one drug

may not be sold for another; and so that, when a prescription is presented to be made up, the proper medicines, and none other, be used in mixing and compounding it. As applicable to the owners of drug stores, or persons engaged in vending drugs and medicines by retail, the legal maxim should be reversed. Instead of *caveat emptor*, it should be *caveat vendor* ... If he does these things, he can not escape civil responsibility, upon the alleged pretexts that it was an *accidental* or an innocent mistake; that he had been very careful and particular, and had used *extraordinary care and diligence* in preparing or compounding the medicines as required etc. Such excuses will not avail him, and he will be liable, at the suit of the party injured, for damages ..." (13 B.Monr. 219 at 228 (KY 1852))

The decision in *Fleet & Semple v Hollenkemp* has been described by King (1958:697) as representing a finding that pharmacists should be regarded as **insurers** of their products and by Brushwood (1986:180) as the first example of the application of the **strict liability** retailer theory to the sale of medicinal products. Brushwood (1996:8) has added, however, that the judgment also provides the first illustration of a recognition by the judiciary that pharmacy has a special character, distinct from that of other providers of products to the public and that the case provides the first demonstration of the imposition of a responsibility on pharmacists to protect patients who cannot protect themselves. In Brushwood's view, this goes beyond retailer liability and is a public trust derivative from the knowledge possessed by pharmacists.

In the same year as *Fleet and Semple v Hollenkemp* was being decided, the New York Court of Appeals was also asked to examine the nature of the duty which was owed by a pharmacist to a patient. In *Thomas v Winchester* (6 N.Y. 397 (1852)), Mrs Mary Ann Thomas was unwell and had been prescribed a dose of dandelion by her doctor. Her husband purchased what was believed to be the medicine prescribed, at the store of a physician and druggist in the town where the plaintiffs lived. A small quantity of the medicine was administered to Mrs Thomas who suffered "alarming effects". The medicine which was administered was belladonna rather

than extract of dandelion. The jar from which it was taken had been purchased by Dr Foord as extract of dandelion from a third party, Aspinwall, who in turn had innocently purchased it from Winchester. The defendant was in the business of manufacturing, purchasing and selling vegetable extracts for medicinal purposes and it was one of his employees who had labelled the jar as extract of dandelion. It was shown as a fact that extract of dandelion and belladonna resemble each other in colour, consistency, smell and taste, although they could be distinguished, on careful examination, by those who were well acquainted with the materials. Judgement was entered initially for Mr and Mrs Thomas and Winchester appealed.

One of the grounds of appeal on behalf of Winchester was that the only duty which he owed was to Aspinwall, the person to whom he had initially and immediately sold the product, and that the ultimate consumer of the product, Mrs Thomas was too remote and had no connection or privity with him. In analysing the concept of duty, Chief Justice Ruggles distinguished the ruling in *Winterbottom v Wright* (10 Mees & Welsb. 109). Chief Justice Ruggles was of the view that the present case before him stood on different grounds. In his view, the fact that the defendant, Winchester, was a dealer in poisonous drugs, that his employee prepared them for market and that the death or great bodily harm of some person was the natural and almost inevitable consequence of the sale of belladonna by means of the false label put the case in a different category to that contemplated in *Winterbottom v Wright*.

The judge confirmed the unique significance of those facts by reviewing the criminal liability of an individual in such circumstances. In *Tessymond's case* (1 Lewin's Crown Cases, 169), an English case of 1828, the defendant chemist had been indicted for manslaughter, in causing

the death of an infant child by negligently delivering laudanum for paregoric. The judge in the case directed the jury that if a party was guilty of negligence, and death resulted, the party guilty of that negligence was also guilty of manslaughter. He indicated that if the jury thought that there was negligence on the part of the defendant pharmacist, then they must find him guilty. The jury did find the defendant guilty of manslaughter and he was fined £5.

In applying this decision in *Thomas v Winchester*, Chief Justice Ruggles thought that although the defendant Winchester might not be answerable criminally for the negligence of his agent, there could be no doubt of his liability in a civil action, in which the act of the agent was to be regarded as the act of the principal. In further seeking to analyse the duty which the pharmacist owed to the patient, the judge indicated that the liability of a dealer in poisonous articles was greater than that of retailers of other products. When one considered that the initial sale was made to another dealer in drugs rather than a consumer, this made it more likely that an injury, caused by the original negligence, would fall on a remote purchaser, as had actually happened in the case.

“The defendant’s negligence put human life in imminent danger. Can it be said that there was no duty on the part of the defendant to avoid the creation of that danger by the exercise of greater caution? Or that the exercise of that caution was a duty only to his immediate vendee, whose life was not endangered? The defendant’s duty arose out of the nature of his business and the danger to others incident to its mismanagement. Nothing but mischief like that which actually happened could have been expected from sending the poison falsely labeled into the market; and this defendant is justly responsible for the probable consequences of the act.” (6 N.Y. 397 at 410)

The judge went on to consider the argument which had been put forward by the defendant that the pharmacist was guilty of negligence in selling the article in question for what it was

represented to be in the label and that the action, if it could be sustained at all, should have been brought against the pharmacist. In agreeing that the defendant pharmacist should be liable in this case, Judge Gardiner based his decision on the ground that selling the belladonna without a label indicating it was a poison was a statutory misdemeanour by statute but expressed no view as to whether the defendant would have been liable to the plaintiff, independent of the statute.

Brushwood (1996:7) is of the view that the decision in *Thomas v Winchester* recognises that the duty of a pharmacist arises out of the nature of the relationship between a pharmacist and a patient and out of the expectations that society has of a pharmacist as a public figure who can be trusted to meet the responsibilities which society imposes on him/her.

“The pharmacist’s duty does not derive from an agreement (contract) between a specific patient and a specific pharmacist. Thus the pharmacist’s duty does not vary from one patient to the next depending on the specifics of an agreement; it remains constant for all patients due to a socially recognised standard.”

The two cases of *Fleet and Semple v Hollenkemp* and *Thomas v Winchester* are unusual (and yet welcome) in that the judges in the two cases, at an early stage in the development of pharmacist responsibility/liability, are prepared to recognise that the pharmacist’s role goes beyond that of the technician and that pharmacists have a clear duty and responsibility to protect patients.

That trend continued in *McClardy’s Admr. v Chandler* ((1858) 30 **Ohio** Dec Rep 1 2 WL Gaz

1)(1). Here the court was considering for the first time the liability of a pharmacist for the incorrect addition or substitution of a substance in the prescribed compound, which, it was argued, caused the death of the plaintiff. The defendant pharmacist had contended that he was not liable since the death resulted from cancer of the stomach from which the deceased was suffering at the time he ingested the prescribed substances.

The court held that even though the deceased was suffering from a mortal illness, the pharmacist would still be liable if the incorrectly prescribed drug had shortened his life. In arriving at this conclusion the court also had some comments to make on the nature of pharmacist liability:

1 The case of *Thomas v Winchester* was also approved in *Davidson v Nichols and another* (11 Allen.514 (1866)). This case is not a pharmacist liability case but rather involved the analysis of the duty owed by a manufacturer and retailer of a carelessly described product which has passed through the hands of a third party retailer to the ultimate consumer of the product who is injured by combining that product, in the belief that it was as described, with one of his own. In deciding that no duty was owed by the manufacturer/ retailer, the court nonetheless confirmed the reasoning of the court in *Thomas v Winchester* in relation to the duty owed by a pharmacist to the patient in the circumstances described in that case:

“In such cases, although the contract ... may not be made with the person injured, nevertheless the patient suffers directly and immediately from the acts of the party who treats him carelessly or unskilfully.” (11 Allen. 514 at 520)

‘To show carelessness on him in a case of this description, it should be shown that he was acquainted with the dangerous properties of the medicine. Before finding negligence on the part of the defendant, [the jury] should inquire whether the prescription itself was legibly written, so that a man with ordinary care, suitable to the situation this defendant occupied, would have known what it was? If it was so written that it could not be readily mistaken, it was the obligation of the druggist to put it up accurately; and if he did not, he would be responsible for the evil consequences.’(1858) 30 Ohio Dec Rep 1 2 WL Gaz 1 at page 2

The cases of *Norton v Sewall* (106 Mass. 143 (1870)), *McDonald v Snelling*, *Hansford’s Adrmx v Payne & Co* ((1875) 74 Ky 380), and *McCubbin v Hastings* ((1875) 27 La Ann 713), all further incorrect dispensing cases, demonstrate the continuing practice of the courts to recognise the reality of expansion of responsibility for pharmacists. As in *McClardy*, the facts were that the incorrect dispensing, and careless substitution of a dangerous drug product, had led to the death of the plaintiffs concerned.

The court in *Norton* approved the decision in *Thomas v Winchester*(2) and reinforced the view that the apothecary or pharmacist owed a duty to the deceased plaintiff’s wife, in respect of the making up and selling of medicinal products, irrespective of the question of privity of contract between them. The defendant pharmacist was responsible for the violation of that duty and the

(2) The enthusiasm demonstrated by the courts, in these early cases, for the precedent of *Thomas v Winchester*, and the consequent expansion of responsibility, was not shared by all of those judges seeking, at the time, to define the pharmacist’s role. It should be emphasised that a parallel jurisprudence was developing in which the pharmacist’s role was equated to that of technician, responsible only for the accurate processing of the prescription. See, for example, the fascinating case, on its facts, of *Ray v Burbank & Jones* (61 Ga. 506 (1878)).

injury resulting to the plaintiff's husband.

'This finding includes a violation of duty on the part of the defendant, and an injury resulting therefrom to the intestate, for which the defendant was responsible, without regard to the question of privity of contract between them.'
106 Mass. 143 (1870) at 144 (3)

In *Hansford*, Judge Lindsay relied heavily on *Fleet & Semple v Hollenkemp* for the proposition that where an apothecary's clerk, in filling a physician's prescription, delivers a poison instead of a harmless drug, through gross negligence, whereby the person taking it is caused great suffering and serious injury, then that person has a right of action at common law for damages against the apothecary. This finding re-emphasises that a pharmacist owes a duty to his/her patient and confirms again the extent of the duty owed.

In *McCubbin*, the court made some significant remarks about the liability of a pharmacist for both individual and employee mistakes in the preparation and compounding of prescriptions:

'And can it be said that if a physician should prescribe for his slightly ailing patient a small quantity of calomel and soda, and the druggist were to substitute arsenic for soda, that he could shield himself from the consequences which might result, by saying, if the prescription was compounded by himself, that it was a mistake, and if the act of his servant that he could not have prevented it? The law does not place a community in the position of being poisoned by mistakes, with no

3 This case was cited with approval in the subsequent pivotal case of *Tremblay v Kimball*, to be discussed below. In addition, Brushwood (1996: 7) is of the view that the result in this case, and in *McDonald v Snelling*, are both consistent with the views expressed in the further critical case of *Brown v Marshall*.

one to be held responsible therefor. If it was the master who did the wrong, the master is responsible. If it was his servant who did it, he is still responsible, for the master is responsible for the acts of his servant when done in the course of his usual employment.' (1875) 27 La Ann 713 at page 717

Brown v Marshall (47 Mich. 576 (1882), is the first major case involving the incorrect dispensing (rather than substitution) of a drug, and, as will be noted below, is critical in the early development of the jurisprudence on pharmacist liability. The case continues the pattern of the expansion, rather than limitation, of pharmacist liability.

The Supreme Court of Michigan reversed an earlier verdict in favour of the plaintiff on the ground that the trial court had erred in law in not providing to the jury an instruction which included negligence as an element of liability. However the court also discussed the extent of the duty owed by the druggist or pharmacist to the patient:

"The case, it must be conceded, is one in which a very high degree of care may be required. People trust not merely their health but their lives to the knowledge, care and prudence of druggists, and in many cases a slight want of care is liable to prove fatal to some one. It is therefore proper and reasonable that the care required shall be proportionate to the danger involved." (47 Mich. 576 at 583)

The court reinforced this view of the role of the pharmacist by approving the earlier decisions in *Thomas v Winchester*, *Fleet v Hollenkemp* and *George v Skivington*.

The decision in *Brown* is important for two reasons. First, it is the first case which seeks to introduce actual negligence as a necessary element in the liability of pharmacists when a mistake has occurred. To this extent the case is a development of the pharmacist-as-retailer/insurer cases discussed above. Second, the case reinforces the view that the

pharmacist's duty is to be knowledgeable and to protect patients (Brushwood 1996:7, King 1958:697-698). Brushwood is also of the view, as noted above, that the results of the decisions in *Norton v Sewall* and *McDonald v Snelling*, are also consistent with the view expressed in *Brown* (4).

The pattern of approval of the earlier authorities continued in a series of late nineteenth century cases. In *Walton v Booth* (34 La. Ann 913 (1882)), and *Minner v Scherpich* ((1886) City Ct Brooklyn) 5 NYSR 851) two other incorrect dispensing cases, resulting in the death of the plaintiffs, the courts made significant comments on the nature of the duty owed by pharmacist to their patients. In *Walton*, the court stated:

'That the defendant was greatly negligent is apparent. In the discharge of their functions, druggists and apothecaries, persons dealing in drugs and medicines, should be required not only to be skilful, but also exceedingly cautious and prudent, in view of the terrific consequences which may attend, as they have not infrequently in the past, the least inattention on their part.

All persons who deal with deadly poisons are held to a strict accountability for their use. The highest degree of care known among practical men must be used to prevent injury from the use of such poisons. A druggist is undoubtedly held to a special responsibility, for the erroneous use of poisons, corresponding with his superior knowledge of the business.' 34 La. Ann 913 (1882) at page 915

In arriving at this latter conclusion the court, again, expressly approved the decisions in

4 *Brown v Marshall* was to join *Fleet & Semple v Hollenkemp* and *Thomas v Winchester*, in being cited as a significant precedent in a further series of cases, seeking to reinforce the trend in the expansion of pharmacist responsibility.

Thomas v Winchester, *Fleet v Hollenkemp* and *McCubbin v Hastings*.

In *Smith v Hays* (Appellate Courts of Illinois December 244 (1886)), in *Davis v Guarnieri* (45 Ohio St. 470, N.E. 350 (1887)), and in *Beckwith v Oatman* (43 Hun. 265, 5 N.Y. St. Rep. 445 (1887)), on the general issue of the duty owed by a pharmacist to the patient, the courts generally favoured the judgments in *Brown v Marshall* and *Fleet v Semple & Hollenkemp*, discussed above (5). In *Davis* the court favoured the decision in *Thomas v Winchester*(6) and *Norton v Sewall*, discussed above, to confirm their finding of liability:

‘It is not a sound proposition to say that a dealer in drugs, having in his stock and for sale deadly poisons, owes no duty to persons who do not deal directly with him in relation to them. The public safety and security against the fatal consequences of negligence in keeping, handling, and disposing of such dangerous drugs, is a consideration to which no dealer can safely close his eyes. An imperative social duty required of him that he use such precautions as are likely to prevent death or serious injury to those who may, in the ordinary course of events, be exposed to dangers incident to the traffic in poisonous drugs.’ 45 Ohio St. 470, N.E. 350 (1887) at page 361

On the question of the carelessness of a pharmacy employee, in carelessly preparing medications, the court in *Smith* also favoured the approach in the earlier cases:

If it be admitted that it is entirely lawful for druggists who are registered pharmacists to employ servants to sell paints, oils notions and all goods other than drugs, medicines or poisons and authorize and permit such servants, under their supervision, to vend drugs, yet there can be no doubt that if in so vending drugs a deadly poison is negligently sold and delivered, by mistake, in place of a harmless

5 See also the decision of the New York Court of Appeals in *Wohlfart v Beckert* 92 N.Y. 490 (Ct. App 1883)

6 See also the decisions in *Blood Balm v Cooper* (1889) 83 Ga. 457, *Fisher v Golladay* (1889) 38 Missouri Appeal Reports 531 and *Hargreave v Vaughan* (1891) 82 Tex 347, 18 SW 695

medicine called for, and an injury to the purchaser thereby occasioned, the druggists will be liable for the injury, and that it is wholly immaterial whether the negligence and mistake is that of the servant, or of the druggist, or of both combined.’ Appellate Courts of Illinois December 244 (1886) at page 247

In *Beckwith*, Judge Childs made some significant remarks about the duty which was owed by a pharmacist to the patient:

‘The right of plaintiff to recover in this action rested upon, and had its foundation in, the rule of liability established in the case of the entire class of professional persons whose work or employment requires special knowledge or skill. Under that rule the defendant undertook, when he assumed to fill the prescription for plaintiff, that he possessed the ordinary skill of a druggist or apothecary, and that he would exercise due and proper care and skill in putting up the medicine required ...

The degree of care required being proportionate to the gravity of the injury that would naturally result from a want of care, and the failure to exercise such due and proper care, is the ground of an action in negligence, and the only ground upon which plaintiff sought to or could recover in this action.’ 43 Hun. 265, 5 N.Y. St. Rep. 445 (1887) at page 267

In *Allan v State S. S. Co., Limited* ((1892) 30 N.E. Rep. 482) Justice Brown approved of the comments in the cases of *Brown v Marshall* and *Beckwith v Oatman*, on the liability of pharmacists in those cases and concluded that they were authoritative statements of the law:

“The rule of liability applicable to a druggist in cases of this character is the same as that which governs the liability of professional persons whose work requires special knowledge or skill, and a person is not legally responsible for any unintentional consequential injury resulting from a lawful act when the failure to exercise due and proper care cannot be imputed to him, and the burden of proving such a lack of care, when the act is lawful is upon the plaintiff.” (1892) 30 N.E. Rep. 482 at page 483

In *Howes et al v Rose* ((1895) Ind. 42 Northeastern Reporter 303) the Appellate Court of Indiana began by analysing the general duty which owed by pharmacists to their patients:

“In view of the dire consequences that may result from the least inattention or want of care or skill, druggists, apothecaries and all persons engaged in manufacturing, compounding, or vending drugs and medicines should not only be required to be skilful, but should also be exceedingly cautious and prudent. All persons who deal with deadly poisons, noxious and dangerous substances, are held to a strict accountability. The highest degree of care known to practical men must be used to prevent injury from the use of drugs and poisons. It is for these reasons that a druggist is held to a special degree of responsibility. The care required must be commensurate with the danger involved. The skill employed must correspond with that superior knowledge of the business which the law requires.”(1895) Ind. 42 Northeastern Reporter 303 at page 304

In arriving at this conclusion, the court applied the decisions in *Walton v Booth* and *Thomas v Winchester*. The court also ruled that the case of *Brown v Marshall* was not authority for any proposition that there could be no liability for an injury caused by an inevitable accident. However the court was clear that that case and the case of *Fleet v Hollenkemp* were authority for the proposition that proof of negligence was required and that the mere sale of a wrong drug did not establish a prima facie case. On that basis the court would have to order a new trial.

This case is important in confirming the trends in expansion rather than limitation of pharmacist liability and in demonstrating the degree of care required of the professional pharmacist (7). Those trends towards expansion continued in the early twentieth century.

⁷ The case of *Wise v Morgan* ((1898) 101 Tenn. 278 971) is another case on proximate cause but also contains some important findings on the question of the negligence of a pharmacist

In *Smith's Adm'x v Middleton* ((1902) 122 Ky. 588 66 SW 388) and *Peters v Johnson et al* ((1902) 41 SE 190) the courts were concerned with the degree of care expected of a professional pharmacist, as were the questions of the existence of a duty to a third party and privity of contract. In *Smith's*, the Court of Appeals of Kentucky outlined that the degree of care expected of the professional pharmacist is high:

“In a business so hazardous, having to do so directly with the health and lives of so great a number of people, the highest degree of care and prudence for the safety of those dealing with such dealer is required. And that degree of care exacted of such dealer will be required, also, of each servant intrusted by him with the conduct of his calling.”(1902) 122 Ky. 588 66 SW 388 at page 389

In *Peters*, the court analysed the issue of the existence of a duty to a third party and the submission by the defendant that the plaintiff's claim should fail under the doctrine of privity of contract or lack of duty:

“But the law will not sustain this line of reasoning. Can a druggist, from incompetency or negligence, sell to one person the wrong, poisonous article as medicine, which, being taken by such person lying sick in the purchaser's house, inflicts injury upon such third person, without any liability to that third person? The law says that he is liable to the third person. We know that drugs and medicines are kept in homes, and may, and probably will, be used by other persons than the one buying. Such is the probable, usual case. Is it possible that there is no reparation to this third person for irreparable harm to him from such incompetency or negligence? Considering the frightful dangers lurking in drugs, poisons and medicines, this would be a disastrous rule. Is there no duty upon a seller of medicine, as to persons who may use them, beyond the immediate purchaser, simply because there is no contract between the seller and the third person?” (1902) 41 SE 190 at page 191

for failure properly to label a medicine.

The court felt that there was such a duty and then sought to analyse the source of it:

“If he simply has broken his contract, none can sue him but a party to it; but, if he violated a duty to others, he is liable to them. The single question in a given case is, was there a duty on the part of the defendant to the person suing him? Whence does duty come?”(1902) 41 SE 190 at page 191

An analysis of a series of cases, including *Howes v Rose*, *Walton v Booth*, *Fleet v Hollenkemp* and *Thomas v Winchester*, showed that a duty would be owed in a case such as this. On the appropriate level of duty, the court felt that the greatest care was required of those who sold dangerous drugs (8).

It will be seen below that the court’s findings in relation to the duty owed to an unknown third party are contradicted by some more recent US cases.

In *Faulkner v Birch* ((1905) 120 Ill. App 281) although the plaintiff lost the action on evidentiary points, the court held that she had established a prima facie case against the defendant for consideration by the jury:

“In compounding medicines the health and lives of the public may with impunity be taken or injured by druggists who compound prescriptions with the degree of care managed by such proof.”(1905) 120 Ill. App 281 at page 284

Brushwood (1996:5) confirms that this case, amongst others, recognises the principle that

⁸ We shall see below that the courts finding in relation to the duty owed to an unknown third party are contradicted by some more recent U.S. cases.

pharmacists must accept responsibility for their actions or for their failure to act. Further, a pharmacist cannot point to another party as being solely responsible for causing drug related harm, if the pharmacist had the opportunity to prevent the harm.

The issue in *Sutton's Adm'r v Wood* ((1905) 120 Ky. 23, 85 SW 201) was the extent of the duty owed under both common law and statute. The Court of Appeals of Kentucky began by considering the effect of certain legislative provisions within that State. A statute (Ky. St. 1903) regulating the sale of poisons by druggists stated that no person should sell any poison without labeling the material as such and entering the sale of the poison in an appropriate book. In addition the same statute prohibited all person who were not registered pharmacists from selling drugs or medicines. Breach of these provisions amounted to a criminal offence. The Court of Appeals was clear that violation of the legislative provisions also established a prima facie case of actionable negligence:

“Before the statute above quoted, an action would lie against a druggist who negligently furnished a customer poisonous drug, instead of some other and different one which had been bought of him, not calling the customer’s attention to the substitution, where damage resulted from the act. By the statutes regulating the practice of pharmacy, a comprehensive system has been devised, to guard the public against incompetent, inexpert handlers of subtle, dangerous drugs, designed and sold to be administered to people. Great care has been observed in prescribing rules which, in their application, are believed to minimize the dangers incident to this business. As the legislation was to enhance the public’s protection, the duties imposed on the druggists were intended as statutory tests of care, in so far as the statutes went. Their nonobservance is per se neglect of duty, as well as neglect of care. Where special damage flows from it, there exists prima facie a case of actionable negligence.”(1905) 120 Ky. 23, 85 SW 201 at page 202

The defendants in the case attempted to assert that the plaintiff herself had been negligent. The court held that it could be possible that a plaintiff in this situation could be guilty of

contributory negligence as could a nurse or servant. That contributory negligence could not however excuse the negligence of the druggist. Equally it was not true, as had suggested the defendants, that the druggists and the customer were under the same degree of care in furnishing and taking the drug. The druggist was required to exercise the highest degree of care for the safety of the public dealing with him. The customer was only bound to exercise ordinary care for his own safety.

Bruckel v Milhau's Son ((1907) 116 App. Div. 832) (9) was a case concerned with the vending by a druggist of an appliance manufactured by a third party. The court was quick to distinguish the present case from others, such as *Thomas v Winchester*, where liability was imposed on druggists in relation to dangerous drugs. The court could not find that the sale of the apparatus in this case was the sale of an instrument "essentially dangerous" like the belladonna in *Thomas*. The court also found that the vendor of such an article was not under an obligation to test each article before selling it, if it was not inherently dangerous. The defendant was, therefore, not liable in damages to the plaintiff.

This case is important, in amounting to an early attempt to define the joint responsibilities of manufacturer and pharmacist. It shall be seen below that the reasoning employed in this case forms the basis of the current judicial thinking on this important issue.

The tendency to continue to expand pharmacist responsibility continued in the early 1900s. In *Horst v Walter* ((1907) 53 Misc. Rep. 591) 103 N.Y. Supp. 750), the plaintiff had suffered

⁹ See also *Lauturen v Bolton Drug Co* (1905) 93 NYS 1035

serious injury after being supplied with a dangerous product by an employee of the defendant pharmacist. The Supreme Court of New York thought that there were two questions to answer - was the act of selling the preparation one which constituted negligence and was the defendant liable for the wrongful act of his employee? In relation to the first question, the court applied the case of *Wohlfahrt v Beckert* to find that a druggist was liable in negligence for damage caused by the sale of poisonous medicine without label or instructions. That finding was reinforced by the provisions of the New York Sanitary Code which stated that no druggist had the right to sell certain dangerous products unless accompanied by the prescription of a doctor. The court was at pains to stress that, aside from that statutory prohibition, there was no doubt that it was an act of negligence for a druggist, when asked for an innocent product, to sell a preparation of such a dangerous character.

The court was equally of no doubt that the defendant was liable for the clerk's wrongful act. The court pointed to several general vicarious liability cases which had been applied specifically to cases involving the preparation and sale of drugs (*Thomas v Winchester* and *Norton v Sewall*, for example). Finally the court could not find that the plaintiff was guilty of contributory negligence. He had a right to assume that the defendant and his employees would perform their duty with care and, when asked for an innocent solution, would supply something both efficient and harmless. The defendant was equally justified in applying the solution without further enquiry.

Knoefel v Atkins ((1907) Ind. 81 NE 600) was a case which was eventually disposed of by an analysis of the law relating to damages. However the court also had much to say about the

liability of druggists for careless acts. The Appellate Court of Indiana was clear on the issue of negligence:

“What duty does the druggist owe to the customer? All the authorities agree, and the very necessities of the case require, that the highest degree of care known to practical men must be used to prevent injuries from the use of drugs and poisons. It is for these reasons that a druggist is held to a special degree of responsibility. The care required must be commensurate with the danger involved. The skill employed must correspond with that superior knowledge of the business which the law requires. (1907) Ind. 81 NE 600 at page 603

The authorities cited by the court in support of this finding were *Davis v Guarnieri*, *Fisher v Gollady*, *Thomas v Winchester* and *Howes v Rose* (all discussed above) (10).

In *Goldberg v Hegeman & Co.* ((1908) 60 Misc. Rep. 107, 111 NY Supp 679) the issue concerned the fitness for purpose of a drug product sold by a druggist over the counter. No prescription was involved. The New York Supreme Court was clear on liability:

“Here the plaintiff asked for a drug for a particular, specified purpose, and when the defendant sold him a drug for this purpose it thereby impliedly represented the drug which it sold suitable for the purpose for which it was sold. The plaintiff used it for the purpose for which the defendant had sold it to him, and thereby sustained injury.”(1908) 60 Misc. Rep. 107, 111 NY Supp 679 at page 680

The court applied the case of *Thomas v Winchester*, and drew an analogy between the present case and a case where a druggist sells a harmful drug as a harmless drug. Despite the fact that the druggist put no label on the drug in the present case, he had declared the drug to be fit for the purpose for which he sold it, just as clearly as if he had labeled it as fit for the purpose.

¹⁰ See also the decision in *McKibbin v FE Bax & Co* (1907) 79 NEB. 577, 113 NW 158)

Again, it shall be seen below that the reasoning employed by the court in this early case on liability for 'fitness' or 'suitability' of drug products sold by a pharmacist, without the need for a prescription, forms the basis for much of the modern judicial thinking on this subject.

The courts in this early period were, however, prepared to absolve a pharmacist from liability where there were other intervening factors. In *Scherer v Schlager* ((1909) 122 NW 1000), the defendant pharmacist was held to be not liable in negligence due to the contributory negligence of the plaintiff. The majority of the Supreme Court of North Dakota agreed that the defendants had been grossly negligent in failing to compound a prescription according to the prescribing doctor's instructions. However, the court was also of the view that there would have been no ill effects of that gross negligence were it not for further negligence of the plaintiff, the father of the child patient who died as a result of in permitting a first and second doses of the medicine. That negligence was the proximate cause of the injuries to the child for which the plaintiff could not recover. There was one strong dissenting opinion from Judge Ellsworth. He was clearly of the view that to measure the conduct of the plaintiff in the circumstances against the legal principles and rules of contributory negligence was grossly unjust given that the plaintiff's primary motivation, at all times, was for the welfare of his child.

A case which was to become a leading authority in relation to liability for errors in filling prescriptions was *Tremblay v Kimball* ((1910) 107 ME 53, 77 A 405). In this case the Supreme Judicial Court of Maine made some significant comments on the nature of the duty owed by

druggists to their patients. Because of the significance of this judgment in future cases, these comments are worth citing in full:

“A registered apothecary or any person who undertakes to act in the capacity of a qualified druggist in preparing medicines and filling physicians’ prescriptions is required by law, in the first place, to possess a reasonable and ordinary degree of knowledge and skill with respect to pharmaceutical duties which he professes to be competent to perform. He is not required to possess the highest degree of knowledge and skill to which the art and science may have attained. He is not required to have skill and experience equal to the most eminent in his profession. He is only required to have that reasonable degree of learning and skill which is ordinarily possessed by other druggists in good standing as to qualifications in similar communities.

In the second place, the law imposes upon the druggist the obligation to exercise all reasonable and ordinary care and prudence in applying his knowledge and skill in compounding medicines, filling prescriptions, and performing all of the other duties of an apothecary. He is not bound to use extraordinary care and prudence, or a greater degree of care than is ordinarily exercised by other qualified druggists. Ordinary skill is the test of qualifications, and ordinary care is the test of the application of it.

Finally, in applying his knowledge and exercising care and diligence, the druggist is bound to give his patrons the benefit of best judgment; for even in pharmacy there is a class of cases in which judgment and discretion must or may be exercised. The druggist is not necessarily responsible for the results of an error of judgment which is reconcilable and consistent with the exercise of ordinary skill and care. He does not absolutely guarantee that no error shall ever be committed in the discharge of his duties. It is conceivable that there might be an error on the part of a qualified druggist which would not be held actionable negligence.

But while , as has been seen, the legal measure of the duty of druggists towards their patrons, as in all other relations of life, is properly expressed by the phrase “ordinary care” yet it must not be forgotten that it is “ordinary care” with reference to that special and peculiar business. In determining what degree of prudence, vigilance, and thoughtfulness will fill the requirement of “ordinary care” in compounding medicines and filling prescriptions, it is necessary to consider the poisonous character of so many of the drugs with which the apothecary deals, and the grave and fatal consequence which may follow the want of due care. In such a case “ordinary care” calls for a degree of vigilance and prudence commensurate with the dangers involved. The general customer has no definite knowledge concerning the numerous medicines and poisons specified in the “U.S. Dispensatory and Pharmacopoeia” which registered apothecaries are by our

statutes expressly allowed to keep, but must rely implicitly upon the druggist who holds himself out as one having the peculiar learning and skill and conceptions of legal duty necessary to a safe and proper discharge of that duty. "Ordinary care" with respect to the business of a druggist must therefore be held to signify the highest practical degree of prudence, thoughtfulness and vigilance and the most exact and reliable safeguards consistent with the reasonable conduct of the business in order that human life may not constantly be exposed to the danger flowing from the substitution of deadly poisons for harmless medicine." (1910) 107 ME 53, 77 A 405 at pages 407-408

In stating these principles, Judge Whitehouse relied, as authorities, on *Thomas v Winchester*, *Norton v Sewall*, *McDonald v Snelling*, and *Brown v Marshall*.

Brushwood (1996:5-6) believes that the language used by the court is noteworthy for a number of reasons. To begin with, pharmacy was recognised as a profession, akin to medicine. That recognition also included an analysis of the varying levels of skill among pharmacists and reaffirms that the level owed is that of the ordinary, skilful pharmacist. Secondly, the court distinguishes skill and care. It is possible to be skilful and careless or unskilled and careful. It would be possible to violate a duty to the patient in both situations, the pharmacist having a professional responsibility to be both skilful and careful. Finally, according to Brushwood, the court recognises that judgment is a part of what pharmacists do. The pharmacist will not necessarily be responsible for an error of judgment simply because there has been an error in judgment:

"Pharmacists can guarantee only that they will be skilful and careful; not that the results of their skill and care will be good. For there to be negligence by a pharmacist, it must be shown that there was a lack of skill and/or care, not just that a mistake occurred." (1996:5-6)

Brushwood also believes that the *Tremblay* opinion has further reasons to be thought of as

pivotal in the development of pharmacist malpractice. He argues that the type of analysis of pharmacist responsibilities which took place in this case has recently begun to reappear in pharmacist litigation following a distinct period of legal analysis (to be discussed in the next section) where the role of judgment in pharmacy was denied by the courts. Rather the courts were essentially presuming negligence every time an error took place. The modern trend in pharmacist litigation which recognises that pharmacists have a judgmental role in pharmacotherapy has its roots in the *Tremblay* case when pharmacists were recognised as having knowledge and skill separate from their technical ability.

The *Tremblay* case also provides, according to Brushwood, the fundamental requirements applicable to any pharmacist malpractice case:

“Pharmacists are required to be knowledgeable (the prudence requirement), alert to potential problems (the thoughtfulness requirement) and attentive to the patient’s interests (the vigilance requirement). These requirements are not absolute but instead are balanced against the need to be efficient in the conduct of business. Pharmacists must exercise a high level of care when the dangers to the patient are great. It would be fully consistent with this analysis to expand pharmacists’ responsibilities as pharmacotherapy becomes more complex, because the dangers to the patient increase. While the fundamental rule of responsibility would stay the same, the actions expected of pharmacists would increase due to the circumstances.” (1996:5-6)

It shall be seen below that the judgment in the *Tremblay* case is focal to a number of other significant pharmacist liability cases and that explore further Brushwood’s submissions on the reversion in modern pharmacist litigation to earlier concepts and principles.

The opinion in *Tremblay* found immediate approval in *Tombari v Connors* ((1912) 85 Conn

231, 82 A 640). In deciding that the defendant pharmacist was liable for the negligent act of the clerk, in dispensing an incorrect product, Judge Roraback quoted with approval the passages from *Tremblay* cited above. In addition, the judge also rejected the defendant's argument that he was not liable as the prescription was written in Latin, was illegible and doubtful as to what drug was really intended. The court was clear that if there had been any doubt as to the identity of the medicine prescribed, he should have taken all reasonable precautions to be certain that he did not sell one thing when another thing had been called for. The court also repeated the warnings from *Tremblay* that, the fact that an individual compounding a prescription was competent and experienced "had no tendency to prove due care on a particular occasion." ((1912) 85 Conn 231, 82 A 640), at page 234)

It will be seen below that the decision in *Tombari* would also prove to be pivotal as precedent in future cases which sought to develop the scope of pharmacist liability in negligence.

The case of *Willson v Faxon, Williams and Faxon* ((1913) 101 N.E.799) explored the relationship between manufacturer, retailer pharmacist and patient. The plaintiff had purchased a box of tablets from the defendant pharmacist had taken them as directed and had been injured as a result. The defendants alleged that they had purchased the tablets in question from the manufacturers and that the product had been made up by them with a special label containing the defendants' name attached.

The lower court had decided that the defendants were not liable in negligence because they did not know that the tablets sold to the plaintiff were dangerous and having purchased them from

a long established manufacturer of excellent reputation, was justified in placing reliance on the vendor. The lower court was also of the view that the defendants were protected by the provisions of the Public Health Law (Consol. Laws 1909, c.45, section 45, sub-section 2) which read as follows:

“Every proprietor of a wholesale or retail drug store, pharmacy, or other place where drugs, medicines or chemicals are sold, shall be held responsible for the quality and strength of all drugs, medicines or chemicals or medicines sold or dispensed by him except those sold in original packages of the manufacturer, and those articles or preparations known as patent or proprietary medicines.”

The Court of Appeals of New York agreed that where the contents of the medicine were concealed from the public generally, and the manufacturer of the drug knows the contents and sells it recommending its use and prescribing the method by which it should be taken, then the manufacturer should be liable to any purchaser who takes the product and is injured by it. The Court of Appeals cited with approval a passage from *Blood Balm Co. v Cooper* where it was agreed that the purchaser had the right to rely upon the statement and recommendation of the proprietor “printed and published to the world”, and, if in so relying, he takes the drug and is injured as a result of some concealed element of which he is unaware, the proprietor is liable for any injury caused. Liability in these circumstances, according to the Court in the present case, arose from misleading concealment of a material fact.

The relationship between manufacturer, pharmacist and patient (and indeed doctor) is pivotal in the analysis undertaken in this work. This case provides an early analysis of the components of that relationship which forms the basis of much of the current thinking on this subject.

In a further series of cases, up to the mid 1920s, the courts in various states of the United States continued to approve of the early decisions in cases such as *Thomas v Winchester*, *Horst v Walter*, *Norton v Sewall*, *Davis v Guarnieri*, and *Goldberg v Hegeman Co.* In *Godwin v Rowe et al* ((1913) 135 Pacific Reporter 171), the Supreme Court of Oregon found that it constituted negligence to sell a harmful drug when a harmless drug has been prescribed. In this regard the negligence of the clerk was the negligence of the proprietor.

The Supreme Court also considered the application of an Oregon statute (Section 4750, L. O. L.). Under this provision, it was obligatory for every pharmacy selling, dispensing or compounding medicines to be under the charge of a registered pharmacist. The Supreme Court was of the view that since the adoption of this statutory rule, any violation of it resulting in an injury, was conclusive evidence of negligence. The defendants were therefore as liable under the statute as under the common law and the plaintiff could recover under either.

In *Rosenbusch v Ambrosia Milk Corporation* ((1917) 181 App. Div. 97, 168 NY Supp. 505), the Supreme Court of New York, relying on *Thomas v Winchester*, *Willson v Faxon* and *Blood Balm Co. v Cooper*, the Supreme Court agreed that one who prepares poisons or medications and places them on the market under a false label, or without disclosing the composition of the medicine, and recommends its use for indicated ailments, is presumptively liable to anyone injured as a result. The Supreme Court also agreed that the mere vendor of patent medicines or other preparations manufactured or prepared by others is not liable to third parties for resultant injuries without proof of further negligence on the part of the vendor. Justice

Laughlin was prepared to extend these principles to the facts of the present case:

“I am of the opinion that it will not be an unreasonable extension of principles of liability already established to hold that the manufacturer in such case is chargeable with negligence, where it knows or should know that the product is liable to deteriorate either by time, climate, or temperature, or the manner in which it is kept, if it fails to affix to the package the date of manufacture and the time during which the ingredients may safely be used, or the manner in which they should be handled and preserved to avoid deterioration.” ((1917) 181 App. Div. 97, 168 NY Supp. 505 at page 508)

There was no suggestion on the labels of the product that it was liable to deterioration and the date of the manufacture was not given. Similarly, there was no such suggestion in the circulars advertising the product. The Supreme Court was of no doubt that the defendant knew, and chemists would know, whether the product was subject to deterioration. Those using the product could not be presumed to possess such knowledge without first taking it to a chemist for analysis. If the product was subject to deterioration, then this danger should have been reported in the labels and circulars accompanying the product together with details of safe time limits for use and procedures for safe handling of it. For its failure to do so, the defendant would be liable in negligence. It was the duty of a manufacturer to issue with a food product proper instructions with respect to its preservation and use to insure the safety of its use if they are observed.

In *Spry v Kiser* ((1920) 179 NC 417, 102 SE 708) the Supreme Court of North Carolina reviewed a number of general principles of the law in relation to the liability of apothecaries, druggists and pharmacists in the conduct of their business. In particular the Supreme Court reviewed the nature of the duty owed and the measure of the care required. Although

described in different ways, those principles were sufficient to establish that apothecaries, druggists and pharmacists owed a duty to their patients. On the facts of the case, there was sufficient evidence to defeat an earlier nonsuit in that the defendant had delivered a harmful medicine in place of the harmless medicine which had been called for.

In *Tucker et al v Graves* ((1920) 17 Al. App. 602, 88 SE 40), Judge Samford, in the Court of Appeals of Alabama, in applying *Brown v Marshall* (noted above), confirmed that:

“It is the duty of druggists to know the purposes of drugs which they sell, and to employ such persons who are capable of discriminating between them ... It was the duty of the defendant to have sold the plaintiff paregoric, the harmless drug; instead defendant delivered to plaintiff a poisonous drug. This was a breach of duty ... There is reputable authority to the effect that the mistake by a druggist, in giving a poisonous, in place of a harmless drug, is *res ipsa loquitur*, and in itself sufficient to impute negligence. (1920) 17 Al. App. 602, 88 SE 40 at page 43

In *Martin v Manning* ((1922) 207 Ala 360, 92 So 659), the Supreme Court of Alabama began by outlining the extent of the statutory duty which was owed by pharmacists and apothecaries.

Citing Section 1624 of the Code of 1907, the Supreme Court agreed that:

“Every registered pharmacist, apothecary, or owner of a drug store, shall be held responsible for the quality of all drugs, chemicals, or medicines he may sell or dispense, with the exception of those sold in original packages of the manufacturer, and also those known as proprietary.” (1922) 207 Ala 360, 92 So 659 at page 659

That statutory duty was reinforced by the common law duty of pharmacists to conduct their business so as to avoid acts in their nature dangerous to the lives of others, and a pharmacist

who was negligent in the performance of such a duty would be liable to anyone injured as a result. The Supreme Court also noted that a pharmacist would also be liable for the equivalent breach of duty by an employed clerk. On the facts, the Court found that the druggists in question owed to the plaintiff the duty to fill the prescription, after they undertook to do so, with care and with the degree of vigilance and prudence commensurate with the danger involved.

The decision in *Martin v Manning* was cited as precedent in the important case of *Jones v Walgreen*, to be discussed below. Brushwood (1996:5) repeats his view that this case (and others) demonstrates that pharmacists must accept responsibility for their actions and omissions. Further, if they have had the opportunity to prevent drug related harm, they must take that opportunity and cannot be excused by blaming another party who had the same opportunity.

In *Hendry v Judge & Dolph Drug Co* (1922 211 Mo. App. 166, 245 SW 358), St Louis Court of Appeals concluded that the issue to be determined was the negligent selling and delivering to the plaintiff of a poison instead of the harmless product which had been requested.

'The defendant, in selling the drug in question, impliedly warranted that it was the article called for and purchased by the plaintiff. The evidence is conclusive that the plaintiff was not aware of the poisonous character of the article delivered to her, when she partook of it, but relied on the defendant's warranty to furnish the article called for. The substitution of the poisonous for the harmless article rendered the defendant liable to the plaintiff for injury proximately resulting from its negligence or breach of duty.' 1922 211 Mo. App. 166, 245 SW 358 at 360

The findings that the defendant druggist was liable was reinforced by looking at the statute law of

Missouri. Section 3625 of R.S. 1919 imposed on the defendant the duty not to sell any substance, usually denominated a poison, without having the word 'Poison' plainly written or printed on a label attached to the container containing the product. Breach of that duty would be punishable as a crime.

'It is conceded that the defendant failed to place a label on the box in question containing the word 'Poison'. If the contents of the box was a substance usually denominated a poison, then the failure to label the box, as required by the statute, constituted negligence per se, and rendered the defendant liable to plaintiff for injuries resulting from such breach. This statute was designed to protect the public against injury of the character suffered by the plaintiff. It prescribes a legal way in which the seller shall advise the purchaser of the poisonous character of the substance sold, to wit, to plainly mark said substance 'Poison'; and any other marking will not protect the seller.'1922 211 Mo. App. 166, 245 SW 358 at 360

Finally the St Louis Court of Appeals had to consider whether the plaintiff had contributed to her own downfall by failing to examine and read the existing label on the can containing the product, which clearly marked the product as 'Roachsault' (though not as a poison). Applying the decisions in *Fisher v Gollady* and *Knoefel v Atkins* (both noted above), the court was of the view that her actions did not constitute negligence as a matter of law.

In *Edelstein v Cook* (1923 140 NE 765), the Supreme Court of Ohio reviewed a series of cases on the liability of pharmacists for selling poisonous drug products when harmless products had been asked for. These cases included *Brown v Marshall*, *Howes v Rose*, *Knoefel v Atkins* and *Davis v Guarnieri*. Judge Jones was of the view that the following principle had emerged:

'It is clear that the principle res ipsa loquitur should be applied in cases of this character. The druggist has the sole control of the drugs which he offers for sale, both harmful and harmless. His relation to the community is such that there is an obligation cast upon him to see that no harmful or poisonous drug shall be delivered

to a customer when a harmless one is asked for; proof of a mistake or inadvertence upon the part of the druggist furnishes an inference sufficient to establish a prima facie case. It raises a presumption of negligence which entitles the customer to recover unless that presumption is rebutted.' 1923 140 NE 765 at 766

The Supreme Court was particularly impressed by the reasoning adopted in *Davis v Guanieri*, and the repeated the comments of the judge in that case concerning the duty owed by pharmacists in this area, based on principles of public safety and security. King (1958:700) emphasises the Supreme Court's findings that there was no distinction in principle between a case in which a deadly poison was substituted for a harmless drug and one in which a harmful and injurious medicine, but not deadly was substituted.

The case of *Ohio County Drug Co v Howard* ((1923) 201 Ky 346, 256 SW 705, 31 ALR 1355) stopped the momentum of judicial expansion of pharmacist responsibility/liability and, perhaps, gave an indication of the approach which would be taken during the subsequent period. The Court of Appeals of Kentucky reviewed a series of cases of pharmacist liability, including *Fleet & Semple v Hollenkemp*, *Smith's Adm'x v Middleton* and *Sutton's Adm'r v Wood*. Judge Clarke held that the *ratio* of *Fleet & Semple*, where it was held that the liability of a pharmacist, in dispensing dangerous drugs, was for all practical purposes that of insurer did not correctly state the law. Rather, Judge Clarke was of the view that a druggist is liable only for the failure to exercise such care as ordinary skilful and prudent men [sic] usually exercise in like businesses and under similar circumstances. While not underestimating the degree and standard of care which the court thought appropriate for pharmacists in this case, it is submitted that the reasoning amounts to a dilution of the degree and requirements noted in the earlier cases. It will be seen below that this equation of the role of the pharmacist as that of technician, with appropriate degree of care, is indicative of the attitude adopted by the courts in cases determined in the

subsequent period.

The issue in *Model Drug Co v Patton* ((1925) 208 Ky 112, 270 SW 998), was the improper labelling of an otherwise acceptable drug product. Judge Sampson, in the Court of Appeals of Kentucky, was clear that the defendant should be liable in these circumstances. The plaintiff's evidence proved beyond question that she was poisoned as a result of the carelessness of the agents and servants of the drugstore in putting the wrong label upon the bottle from which she was administered the poisonous medicine.

In *Highland Pharmacy v White* ((1926) 144 Va. 106, 131 SE 198, 44 ALR 1478), the Supreme Court of Appeals of Virginia reviewed a series of cases dealing with this issue, including *Tucker v Graves*, *Edelstein v Cook*, *Peters v Johnson* and *Walton v Booth*. The analysis of those cases elicited the following principles:

'Druggists deal in many poisonous drugs and medicines which, if improperly used, may endanger human health and life. They are required to exercise a degree of care fully commensurate with the dangers to which their patrons are exposed.

Where the retailer fills a prescription, or buys in bulk and bottles the drug and places his own label on it, he impliedly warrants it to be what he represents it to be, and upon proof of the slightest negligence is liable for any injury resulting from the use of such drug.

When a druggist delivers to a customer calling for it a patent or proprietary medicine, in the original package, and sealed and labelled by the manufacturer or patentee, in the absence of any knowledge of its ingredients, he cannot be held liable for any injury resulting from its use. He is not required to analyze the contents of each bottle or package he buys and sells in order to relieve himself from liability for such injury.

When a patron orders a harmless drug, the druggist is under a legal duty to deliver it to him. If instead, he delivers to him a harmful drug, from which the injury results, he violates his duty and is prima facie guilty of negligence. The burden is

then upon him to rebut the presumption of negligence. Failing to do so, he is liable for the damages resulting from such injury.' (1926) 144 Va. 106, 131 SE 198 at page 199

On the facts of the particular case, the defendants had failed to rebut the presumption of negligence, and there was sufficient evidence to support the verdict of the trial court jury in favour of the plaintiff.

In the case of *Dunlap v Oak Cliff Pharmacy* ((1926) 288 SW 236), the Court of Civil Appeals of Texas, reaffirmed that the care required of pharmacists in the sale of medicines to the public was well stated in *Tremblay v Kimball*. Applying the *ratio* of *Tremblay v Kimball*, Judge Baugh was clear as to the legal principles involved:

'In the absence of mitigating circumstances, the sale by a druggist to a customer, who calls for a harmless, soothing, alkaline, non-poisonous, antiseptic tablet, of a highly poisonous, mercurial, antiseptic tablet, with the representation to the purchaser that they were the same or practically the same, when such druggist knew the constituent elements of both tablets, raises a question of negligence, if indeed it does not make a prima facie case of negligence as a matter of law.' (1926) 288 SW 236 at 238

The evidence which had been presented was sufficient to allow the case to go to a jury. The Court of Civil Appeals was also of the view that the issue of contributory negligence, in that the defendant alleged that the plaintiff should not have ignored the obvious signs that the product was poisonous, was also one for the jury and could not be determined as a matter of law.

The case of *McGahey v Albritton* ((1926) 107 So. 751) is pivotal in that it would eventually be cited as a precedent in the important case of *Jones v Walgreen*, to be discussed below.

Judge Miller, in the Supreme Court of Alabama, applied the ruling in *Martin v Manning*, to find that it was the duty of the pharmacist to fill the prescription, after it undertook to do so, with care and with that degree of diligence and prudence which is commensurate with the danger involved. Brushwood (1996:5) repeats his view that this case, with significant others already mentioned above, demonstrates that pharmacists must accept responsibility for their acts and omissions. Further, pharmacists cannot ascribe blame to others for a failure to prevent drug-related harm if the pharmacists, themselves, had the opportunity to prevent that harm.

The case of *Andreotalla v Gaeta* ((1927) 260 Mass. 105, 156 NE 731), provides an early insight into the judiciary's reaction to a pharmacist's failure to fill a prescription. Judge Braley in the Supreme Judicial Court of Massachusetts was strongly of the view that the facts, as proved, raised a question of negligence for the jury. This finding reinforces the trend of expansion of pharmacist responsibility/ liability, as evidenced in the cases already outlined above. The court is insisting that pharmacist responsibility goes beyond technical accuracy in dispensing prescriptions to making judgments of their appropriateness for a given patient in particular circumstances.

The case of *Peavy v Hardin* ((1926) 288 SW 588), is another early example of liability being established for the unconscious supply of the wrong drug. The Court of Civil Appeals of Texas was asked to review the directions concerning negligence and pharmacists which had been given by the trial judge to the jury in the lower court. The lower court had charged the jury that:

'All persons, engaged in handling and dispensing drugs to be used as medicine by those to whom sold and delivered are bound to exercise, in connection with said business, that high degree of care which a very prudent and cautious person would

exercise under the same or similar circumstances in that business, and a failure to do so is negligence.' (1926) 288 SW 588 at 589

The defendants had claimed that this charge fixed too high a duty for persons dispensing medicines. Judge Walthall, in the Court of Civil Appeals, thought that it did not. The judge was also of the view that to create liability, the alleged negligence, in this type of situation, must also be the proximate cause of the patient's death (11).

In *Tiedje v Haney* ((1931) 184 **Minn.** 569, 239 NW 611, the Supreme Court of Minnesota reviewed a series of cases of pharmacist liability. Applying the *ratio* in *Highland Pharmacy v White* (noted above), the Supreme Court found that, at common law, a pharmacist is bound to exercise towards his patients that degree of care which is commensurate with the hazards and

11 It is important to note, that during this period of establishment of pharmacist liability, followed by expansion of pharmacist responsibility, the courts were quick to absolve pharmacists of liability in negligence where that could not be supported. See, for example, the cases of *Watkins v Potts* ((1929) 219 **Ala** 427, 122 So 416, 65 ALR 1097) and *Jones v Damtoft* ((1929) 109 **Conn** 350, 146 A 490), absolving the pharmacist of liability on the facts found.

dangers to which those patients are exposed. The Supreme Court was also of the view that, applying *Tremblay v Kimball* (noted above), the ordinary care which a pharmacist is bound to exercise in filling prescriptions is:

‘the highest possible degree of prudence, thoughtfulness, and diligence, and the employment of the most exact and reliable safeguards consistent with the reasonable conduct of the business, in order that human life may not be exposed to the danger following the substitution of deadly poison for harmless medicine.’ (1931) 184 Minn. 569, 239 NW 611 at 613

The Supreme Court was also of the view that where a pharmacist obtains tablets or medicine from a manufacturer which he does not sell under the name of the manufacturer, but under his own name, accompanied by a statement that it was manufactured or prepared by him, then the pharmacist must assume a responsibility equivalent to that of the manufacturer of the drugs. That rule was to be found in the case of *Willson v Faxon, Williams & Faxon* (noted above).

The most significant case, decided in the early period, on the appropriate legal standards defining the role of pharmacists in drug distribution, is *Anna Jones v Walgreen* ((1932) 165 Ill.App. 308). Brushwood (1996:4), states that the Appellate Court of Illinois’ lengthy opinion in this case ‘serves as a significant bridge between early pharmacy precedents and contemporary pharmacist malpractice judicial opinions’. The decision in this case does a number of things:

- it reviews the series of cases on pharmacist liability to date and reaffirms that the standards expected of pharmacists are high, obliging them to practice at a level of care that is commensurate with the danger to which their patients are exposed (Brushwood 1996:4);

- it represents the culmination of a series of cases establishing those standards at particular levels;
- it begins a significant period of judicial activity which dilutes the strength of the opinions expressed, in the cases up to *Jones* on the standards of care expected of pharmacists; and
- finally, it is now being relied upon by those courts seeking to re-establish significant standards for pharmacists commensurate with the current expectations of the profession to deliver pharmaceutical care.

The facts were that, on 13 July 1929, the plaintiff was suffering from a dull pain in her arm. Her family doctor diagnosed her ailment as muscular rheumatism. Her doctor gave her a prescription which read “Strontium Salicylate four ounces (Wyatt), teaspoonful in water four times per day”. The plaintiff’s son-in-law left the prescription with a clerk in the defendant’s pharmacy. The clerk, who had graduated in pharmacy the previous month, and who was then about twenty-two years of age, filled the prescription with pure strontium salicylate prepared by Parke-Davis & Company. This product was ten to twelve times stronger than the effervescent strontium salicylate which had been prescribed for her. As a result of using the dispensed medication, the plaintiff suffered severe harm.

The evidence further disclosed that John Wyeth & Brother was a drug manufacturer which prepared an effervescent strontium salicylate compound and that doctors sometimes indicated on

their prescriptions 'Wyeth' for "John Wyeth & Brother". The clerk indicated that he knew that the Wyeth Company did not make pure strontium salicylate and that he had filled the prescription with the pure compound made by Parke-Davis. He also stated that before he filled the prescription, he had seen the word 'Wyatt' printed on it, that it did not mean anything to him and seemed to indicate that the doctor had in mind a brand of strontium salicylate.

The defendant pharmacy contended that:

'The legal duty of a druggist to a purchaser can go no further than to dispense the identical substance which his prescription calls for.'(1932) 165 Ill.App. 308 at page 320

Brushwood (1996:4) indicates that, in effect, the pharmacy was arguing that any mistake in a prescription is the doctor's responsibility exclusively, and that pharmacists have no responsibility to detect and rectify prescribing errors. Brushwood is of the view that this **argument** is used by contemporary pharmacists.

The Appellate Court of Illinois was quick to reject this contention:

'No authority is cited by the defendant in support of this contention ... The instant contention is primarily based upon the assumption that a pharmacist is obliged to fill any and all prescriptions. Such is not the law. As a chemist he may know that the physician has erred in his prescription and that to fill it might cause death or serious injury to the patient.'(1932) 165 Ill.App. 308 at page 320

Mr Justice Scanlan also rejected the defendant's contention that, based on the clerk's evidence regarding the confusion in the names of the manufacturers and, in the absence of a named manufacturer of 'Wyatt', he was entitled to ignore that word and to fill the prescription with pure

strontium salicylate. The judge preferred, and relied, in part, on the evidence of a doctor who stated that when a doctor had prescribed an overdose of a particular drug, it was the duty of the pharmacist to refuse to fill the prescription.

The words used by Mr Justice Scanlan in rejection are significant:

‘The name Wyeth, however, would put any careful pharmacist upon his guard, and under such a situation, his duty is plain. If a prescription is doubtful as to what drug is really intended it is the duty of the pharmacist to be alert to avoid a mistake, and if there is any reasonable doubt as to the identical thing ordered, it is his duty to take all reasonable precaution to be certain that he does not sell one thing when another is called for ... A contrary rule would tend to make a pharmacy a menace, instead of an aid, to suffering humanity. (1932) 165 Ill.App. 308 at page 321

The judge relied on the case of *Tombari v Connors* (noted above) for his specific finding on this point. In general, the judge found a variety of cases to be significant precedents, reinforcing the importance of *Jones* in reassessing judicial activity in this area, to date. Foremost among the cited precedents was *Tremblay v Kimball* and the four other cases which, in turn, had been cited as authority in that case, *Thomas v Winchester*, *Norton v Sewall*, *McDonald v Snelling* and *Brown v Marshall*. Mr Justice Scanlan also relied on *McGahey v Albritton*, *Martin v Manning* and *Faulkner v Birch*.

Brushwood (1996:5) summarises the importance of *Jones v Walgreen*:

‘This case firmly established the pharmacist’s responsibility to screen prescriptions for potential problems and to contact the prescriber when a potential problem was evident. It recognized the pharmacist’s important gatekeeper role; to prevent harm to the patient from prescribed medications.’

While the case did not recognise a role for pharmacists in promoting benefit for patients, it provided the judicial foundations for that legal recognition in the future. Brushwood (1996:5) is also of the view that the judicial reasoning employed by Mr Justice Scanlan, relying on the pivotal precedents, already noted above, determines that the duty of a pharmacist goes beyond technical accuracy in prescription processing, to include monitoring for potential harm to the patient. That demonstrates a high level of expectation of pharmacists, to practice at a level of care appropriate to the danger to which their patients are exposed (1996:4).

As noted above, *Jones v Walgreen*, represents the high point in establishing and expanding responsibility for pharmacists. It ends a period of relative creativity in judicial reasoning. The cases in this period not only set the standards but set them at a significant level. Pharmacists were not only expected to be professional in the technical aspects of their work but were required to detect and rectify potential problems with drug therapy (Brushwood 1996:3). The trend towards expansion was not continued, however, in the next period from 1932-1985. The standards which were applied in this period were still high, but were restricted to technical accuracy in prescription processing.

Traditional Legal Analysis of Pharmacist Responsibility 1932-1985

The pattern of judicial reasoning on pharmacist responsibility is well summarised by Walker and Hoag (1996:iii):

‘Under the traditional view, pharmacists are responsible for accurately processing prescriptions; and the doctor is responsible for evaluating the patient’s condition, selecting the appropriate drug therapy, assessing the risks involved in such therapy,

and determining whether and what to advise the patient. It was thought that any such role for pharmacists could properly and harmfully intrude upon the physician-patient relationship. Pharmacists were thus held to have no duty to warn patients whose prescriptions they were filling, nor was the pharmacist viewed as an integral member of a “team” - providing health care to patients in co-ordination with the physician. No duty to notify or warn the patient’s physician was recognized. Moreover, although liability for bad outcomes could be imposed on the retail pharmacy as a seller, much like other situations in which a seller distributes goods that cause harm to a customer, the notion of a physician as a “learned intermediary” has fixed responsibility on the physician and insulated the pharmacist from responsibility to the patient.’

A very early example of what Walker and Hoag were talking about is provided in the case of *People’s Service Drug Stores v Somerville* ((1932) 161 Md 662, 158 A 12, 80 ALR 449). The facts were that the plaintiff had been given a prescription which he had taken to be filled at the defendant’s pharmacy. The plaintiff alleged that he suffered injury as a result of taking the dispensed medication, which contained strychnine.

The plaintiff did not claim that the prescription had been dispensed incorrectly. Rather, the plaintiff alleged that the dose prescribed had been too large and that the defendant pharmacist should have made enquiries concerning the prescription from either the prescribing doctor or from himself as the patient. The claim therefore sought to establish extended liability beyond technical accuracy in prescription processing. This is a remarkable legal argument for its time, and was perhaps based on an analysis of the extension of pharmacist liability which had taken place in the years before this case, culminating in *Jones v Walgreen*.

Mr Justice Adkins, in the Court of Appeals of Maryland, began by analysing the extent of the statutory duties imposed on pharmacists within the state. That analysis showed that pharmacists had specific responsibilities in relation to the labelling of poisons and the keeping of records

relating to their sale. On the facts before him, Mr Justice Adkins found that the box containing the medication, given to the plaintiff, had not been labelled 'poison' or strychnine'. To that extent the statute had been violated. However, violation of a statute would not support an action for damages on account of an injury sustained unless such violation is the proximate cause of the injury. The judge could not find that the failure to label the container, in the case before him, was the proximate cause of the plaintiff's injury. As such, the plaintiff's case must be dismissed.

The judge went on to analyse the extent of the pharmacist's extended duty beyond accuracy in prescription processing. Mr Justice Adkins began this analysis by commenting on the plaintiff's claim that a pharmacist could not escape liability in compounding and dispensing poisons in unusual doses even though the doctor's prescription had called for such doses. The plaintiff's lawyers had claimed that this rule was supported by the decision in *Tombari v Connors*. The judge was of the view that this case, and others cited by the plaintiff, was not on the point, and related to a failure of a pharmacist to fill the prescription correctly.

The judge then asked the question, under what circumstances should a pharmacist compare and impose his (sic) own judgment against that of the prescribing doctor. His answer summarises the judicial attitude, in this second period, to extended pharmacist liability:

'No witness has undertaken to say that ordinary care would have required any pharmacist to decline to fill the prescription in this case; and ordinary care, in view of the nature of the business, is the test. Of course, if a druggist is negligent in filling a prescription, he cannot escape liability because the doctor who wrote the prescription is also liable.'

But it does not follow because a physician in a given case is liable, that the druggist who filled the prescription is also liable. It would be a dangerous principle to establish that a druggist cannot safely fill a prescription merely because it is out of

the ordinary. If that were done, many patients might die from being denied unusual remedies in extreme cases. '(1932) 161 Md 662, 158 A 12 at 13

The case of *Fuhs v Barber* ((1934) 140 Kan 373, 36 P.2d 962), appears, at first reading, to be a case in which the court was reverting to a policy of expanding pharmacist liability. Indeed, Brushwood (1983:367-368), indicates that this case is often used by those who argue that pharmacists have a legal duty to warn patients of dangers associated with the drugs pharmacists dispense.

The Supreme Court of Kansas confirmed a jury verdict in favour of the plaintiff. Chief Justice Johnston reviewed a series of cases on the duty of care owed by pharmacists including *Davidson v Nichols*, *Howes v Rose*, *Walton v Booth*, *Allan v State SS Co.*, *Smith v Hays*, *Fleet & Semple v Hollenkemp*, *Brown v Marshall* and *Beckwith v Oatman*. The language used in the judgment is bullish:

'... where a drug, harmless in itself, is to be mixed or used in connection with another, which would then have an injurious effect, he should exercise a high degree of care in advising the purchaser of this injurious effect and of the combination. A failure to exercise such care will make him liable for the consequence.' (1934) 140 Kan 373, 36 P.2d 962 at 962

However Brushwood (1983:368-369) believes that the judgment is more narrow than this and should not be relied upon as a precedent for a comprehensive duty to warn. He offers a number of reasons for this. Firstly the court was dealing with two distinct duties - the duty to warn prior to the occurrence of an inevitable injury and the duty to warn of further effects after the injury already has occurred. The reasoning of the court relates to both duties which necessarily limits its strength as a precedent. The second reason relates to the fact that the medication involved was

purchased without a doctor's prescription as an over-the-counter product. The reasoning must be restricted to those particular facts and could not be applied to prescription drugs.

Finally, according to Brushwood, the court could simply not have intended that its decision be interpreted as precedent for a pharmacist's duty to warn patients routinely of the risks inherent versus the benefits of drug therapy. The fact was that the judgment was handed down over fifty years ago, before the revolution in pharmacotherapeutics, leads to a conclusion that the case must be judged on its individual facts. As such, the judgment must be seen to be a narrow one and should not be relied on as precedent for a general duty to warn.

In *Taughner v Ling* ((1933) 127 Ohio St. 142, 187 N.E. 19) Chief Justice Weygandt, in the Supreme Court of Ohio, reviewed a series of cases on pharmacist liability including *Davis v Guarnieri* and *Edelstein v Cook*, and came to the following conclusion:

'In fact, the practical result of the cases is that a druggist who, by mistake or inadvertence, sells a harmful drug in place of the harmless one called for, is liable for the injurious consequences thereof ... negligence here, as in other cases, is the failure to exercise ordinary care; what is ordinary care, however, depends on the circumstances of the particular transaction. In the case of a druggist selling drugs, it is care to give the medicine asked for, and not some other medicine likely to cause injury. On the other hand, the druggist is bound only to exercise the skill generally possessed by well-educated druggists, not the highest skill and learning which can be attained by a few men of rare genius, endowments or opportunities, for this would be impracticable - but that usually possessed by those esteemed competent in their business. A druggist, in the conduct of a drug store and in dispensing its commodities, is bound to use that degree of care in the dispensing of the drugs that persons of ordinary prudence engaged in that business are accustomed to use under the same or similar circumstances.' (1933) 127 Ohio St. 142, 187 N.E. 19 at page 21

On the basis of that analysis of pharmacist responsibility, the Chief Justice had no difficulty in holding that the defendants were liable. What is significant about the legal reasoning is that it restricts pharmacist liability to ordinary care in respect of technical decision making. The days of expanded pharmacist responsibility appear long gone.

In *Trumbaturi v Katz & Besthoff* ((1934) 180 La. 915, 158 So. 16), Justice Odom, in the Supreme Court of Louisiana, reviewed a series of cases on pharmacist responsibility, including *Wlton v Booth*, *Thomas v Winchester* and *Fleet v Hollenkemp*. The judge was of the view that the clerk in the defendant pharmacy had a duty to make enquiries about the purpose for which the requested poison was required. That duty arose from statute (Food and Drug laws) which not only imposed the requirement of enquiry but also of record of the sale. Had appropriate enquiries been made by the clerk, he would have discovered the plaintiff's mental disability and would have known not to supply the poison to her.

Again, it is important to note that the extent of the duty owed by the pharmacist is one of technical accuracy. The relevant statute imposed the technical requirement to enquire and record. The defendant's clerk had failed to adhere to these technical requirements and was found to be liable in damages as a result.

In *Johnson v Smolinsky* ((1935) 229 Mo App 652, 81 S.W. 2d 434), the plaintiff was injured as a result of the careless preparation of a prescription. The Kansas City Court of Appeals rejected the defendant's contentions that the plaintiff, through the actions for her mother and husband, in forcing her to take the medication as dispensed, was guilty of contributory negligence. The court pointed out that the mother had the right to assume that the dispensed prescription was the same

one which the doctor had prescribed. Accordingly, the defendant druggist would be liable in damages to the injured plaintiff. This case reaffirms the trend in pharmacist liability cases in this period, that technical accuracy is the extent of the liability owed by the pharmacist to the patient. Had the prescription been filled correctly in this case, no liability would have attracted to the defendant.

The conclusion that pharmacists are liable for technical inaccuracy associated with duties imposed by statute, noted above in *Trambutari v Katz & Besthoff Ltd*, was reaffirmed in *Eckerd's Inc. v McGhee* ((1935) 19 **Tenn. App** 277, 86 S.W. 3d 570). The Court of Appeals of Tennessee noted that a statute of Tennessee, Chapter 162 of the Public Acts of 1919, made it unlawful to sell poison to any person under the age of 16, as had happened in the case. In the view of Presiding Judge Faw, the violation of the statute was negligence *per se*, and if it was the proximate cause of the injuries suffered by the plaintiffs, the defendant would be liable. After reviewing a series of cases on proximate cause, including *Wise & Co v Morgan*, and *Meyer v King*, the judge was of the view that the proximate cause of the plaintiff's injury was her own voluntary act in taking the poisons, after forming a clear intent to do so.

Failure to discharge a statutory duty was, *inter alia*, also at issue in *Marigny v Dejoie* ((1937) **La App** 176, So 808). The plaintiff was injured by a failure on the part of the defendant pharmacy to dispense a prescription appropriately. The Court of Appeal of Louisiana reviewed a series of cases on pharmacist responsibility for dispensing poisons including, *Trumbaturi v Katz & Besthoff*, *Thomas v Winchester*, *Fleet v Hollenkemp*, *Walton v Booth* and *McCubbin v Hastings*. Judge Janvier quoted directly from the judgments in *Trumbaturi* in confirming the duty of pharmacists to use extreme care in dealing with dangerous drugs.

The defendant also contended that the plaintiff was contributorily negligent in taking the tablets in that the box in which they were contained bore the inscription 'for external use only' and the pills had the word 'poison' on them as well as the picture of a skull and crossbones. Judge Janvier rejected this contention, holding that the plaintiff was justified in following the doctor's instructions, which were repeated on the box.

The court also considered that it was 'extreme negligence' on the part of the pharmacist to supply the plaintiff with a deadly poison in a container which did not on its face show the dangerous character of contents, in violation of a statute (Section 7 of Act No 66 of 1888), requiring a container of poisonous medicines to have printed thereon a skull and crossbones with the word 'poison' in large, heavy lettering. The printing of the word 'poison' and the skull and crossbones might in many instances serve a useful purpose, but the pharmacist was negligent in failing to plainly mark the container with such warnings as might have been readily noticed.

The establishment of liability might seem obvious from the facts of cases such as *Marigny*. However the point to be made is that liability only attaches to technical inaccuracy. Had the pharmacist dispensed the correct drug and/or provided the relevant statutory warning then no duty would lie and liability would not have been established.

In *Hoar v Rasmussen* ((1938) 229 Wis 509, 282 NW 652), Justice Fairchild, in the Supreme Court of Wisconsin, was of the view that pharmacists were ordinarily expected to fill prescriptions according to the National Formulary or the United States Pharmacopoeia unless the

contrary was indicated. The pharmacist had misrepresented a fact when he delivered to the plaintiff's wife a proprietary compound containing mercury instead of the prescribed medicinal compound (without mercury) as described in the National Formulary.

The pharmacist may have had reason to suppose that the medicine which he had supplied was just as good as that prescribed by the doctor. However Justice Fairchild was firmly of the view that the risk of harm from the act of making the substitution without informing the plaintiff outweighed any possible utility which the act might have had. It was even more apparent that an unreasonable act was involved in misinforming the doctor. In the judge's view it was settled law that:

'Where an act is one which a reasonable man would recognise as involving a risk of harm to another, the risk is unreasonable and the act is negligent is the risk is of such a magnitude as to outweigh what the law regards as the utility of the act.'(1938) 229 Wis 509, 282 NW 652 at page 654

The judge was of the view that the circumstances of the pharmacy profession demanded the exercise of a high degree of care and skill consistent with the reasonable conduct of a business. The nature of the profession was such that the effect of a mistake could be swift and dangerous. Referring to a series of cases which had established pharmacist liability for negligent acts, including, *Tremblay v Kimball*, *Brown v Marshall* and *Edelstein v Cook*, the judge thought that liability in the present case was more apparent because the substitution of the required drug product was deliberately made under the mistaken impression that the prescription could be changed in accordance with the pharmacist's judgment.

It is important to note the reasoning of the court in this case and to place it in context. Had the

pharmacist dispensed the prescription in conformity with the requirements of the National Formulary or United States Pharmacopeia, there would have been no liability. The court does not discuss any requirement for the pharmacist to enquire, or to inform or to warn. We shall see below that such requirements are appropriate to an extended duty rather than to a simple duty to be technically accurate.

The technically incorrect dispensing of the wrong drug product was the issue in *Boeck v Katz Drug Co* ((1942) 155 Kan 656, 127 P 2d 506). Judge Smith, in the Supreme Court of Kansas, was of the view that the defendants should be held liable for their negligence in aggravating the plaintiff's disease by the careless substitution of a drug product:

'If the latent susceptibility to the disease was there when the atropine was used the defendants would be liable if their negligence damaged the eyesight of the plaintiff even though the damage was rendered worse or aggravated by the latent existence of the disease.' (1942) 155 Kan 656, 127 P 2d 506 at page 660

The court was equally clear in rejecting the contention of the defendant that the plaintiff had been contributorily negligent in continuing to use the medicine after it had started to make him ill. Judge Smith was of the view that if the plaintiff had confidence enough to go to the doctor and to ask him to prescribe a medication, the court could not say that it was contributory negligence for him to follow the directions on the medicine bottle even though it nauseated him.

It is clear that the reasoning employed by the Supreme Court of Kansas demonstrates that a pharmacist will be liable for all of the consequences of a negligent act. The fact that the plaintiff may have been pre-disposed to the type of injury which he eventually suffered made no difference where there was ample evidence to show that the pharmacist's error in substitution

accelerated the injurious process. The error was one of substitution, a technical error. Absent the technical error no duty would lie and no liability would adhere.

In *Cody v Toller Drug Co* ((1942) 232 **Iowa** 475, 5 N.W. 2d 824), the plaintiff claimed that the defendant negligently included a foreign substance in a compounded product when that element was not called for by the prescription, and that this error had caused him injury.

Holding that there was sufficient evidence that the compounded product did contain the foreign substance, the court stated that it was not necessary for the plaintiff to prove conclusively that the medicine contained the foreign substance or to exclude to a certainty every other suggested poison. It was sufficient that the evidence was such as to make the plaintiff's theory of poisoning by the foreign substance more probable than any other theory based on the evidence. The court also rejected the defendant's contention that the evidence showed that one of the other ingredients in the medicine prescribed could have caused some of the plaintiff's symptoms. Justice Garfield noted that this evidence was vigorously denied by the plaintiff's expert witnesses. That would become a disputed question of fact for the jury.

Again, the issues in this case might appear obvious from the facts. However it is important to remember that the errors causing the negligence were once again technical in nature. The pharmacist in this case was prepared to challenge the factual nature of the technical error before the trial jury and appellate court. Once the fact of the technical error was established to the satisfaction of the trial jury and the appellate court, the negligence was proved. The extent of the duty of care, as discussed by the appellate court, related to technical accuracy, and not beyond.

In *Wadsworth v McRae Drug Co* ((1943) 203 S.C. 543, 28 S.E. 2d 417), the Supreme Court of South Carolina restated the extent of the duty which was owed by a pharmacist to the patient. The case was mainly concerned with the issue of whether the defendant's employee was engaged in the practice of medicine, contrary to a statute of South Carolina, the credibility of the witnesses in the case, and the causal connection between the defendant's alleged negligent act and the plaintiff's injuries. However the Supreme Court judgment also contains some significant comments on the extent of duty owed by the pharmacist to the patient:

'The principles of law relating to the liability of druggists are really elementary and may be summed up in the phrase 'due care' or 'ordinary care' which is to be measured by the existing circumstances ... The legal measure of the duty of druggists towards their patrons, as in all other relations of life, is properly expressed by the phrase 'ordinary care', yet it must not be forgotten that it is 'ordinary care' with reference to that special and peculiar business; in determining what degree of prudence, vigilance, and thoughtfulness will fill the requirements of 'ordinary care', it is necessary to consider the poisonous character of many of the drugs with which the apothecary deals, and the grave and fatal consequence which may follow the want of due care.'(1943) 203 S.C. 543, 28 S.E. 2d 417 at page 421

The Supreme Court also was of the view that where a pharmacist's employee, in the course of employment, negligently supplied a harmful drug in place of a harmless one called for (by prescription or by the patient) and injury results from taking it, the pharmacist should be liable in damages.

The case of *Scott v Greenville Pharmacy* ((1948) 212 S.C. 485, 48 S.E. 2d 324) is one where, on the facts, the court could have explored the issue of expanded pharmacist responsibility. The plaintiff's husband had been sold a number of boxes of barbiturate tablets over the period of one year, which, it was alleged, led to him being addicted to the drug and resulted in his suicide by hanging. That expectation did not become reality as the court felt that it was able to dispose of

the issue on the grounds that the sale of the barbiturates, unlawful though it was, was not the precipitative factor in the suicidal intent of the husband; that the actual suicide was not the natural and probable consequence of the sale and that this result could not have reasonably been foreseen by the defendant.

Implicit in the court's reasoning is a finding that the defendant pharmacy had no duty to warn the plaintiff's husband of the potential for addiction to the drug. The court found as a fact that there was nothing to suggest that the defendant knew that the plaintiff's husband was incapable or lacked volition in making the purchases, or was under the influence of any drug when he bought the barbiturates. Nor were there any allegations that the plaintiff's husband was incapable of consenting to any one or more of the sales of the capsules. The court went further and found that the plaintiff's husband knew the nature of the drug which he was purchasing. Long before he had become a drug addict he must have realized the effect which the drug was having on him.

The inference to be drawn from this reasoning is that a pharmacist has no duty to warn, at least where it appears that the patient is competent, or is not apparently lacking in volition, of the hazardous nature of drugs. No duty arises, according to the Supreme Court of South Carolina, even where the sale is otherwise an unlawful one. A duty to warn is an example of how pharmacist responsibility might be extended. The reasoning in *Scott* amounts to judicial restriction of pharmacist liability, and summarises a period where the courts reaffirm that technical accuracy is all that is expected of pharmacists.

The case of *Bean v Dempsey* ((1950) 313 Ky 717, 233 SW 2d 417) provides a good example of

the judicial tendency, in this period, to restrict the extent of the duty owed by a pharmacist to technical accuracy in the dispensing of prescriptions. In the Court of Appeals of Kentucky, Justice Latimer was quick to uphold the initial trial judgment in favour of the druggist. He was strongly of the view that the evidence of the defendant was 'of substance, and amply sufficient to support the verdict.' ((1950) 313 Ky 717, 233 SW 2d 417 at page 418). As noted above, this confirms the judicial attitude that technical accuracy in the dispensing of prescriptions equates to an absence of liability. The defendant's evidence that the prescription had been properly filled when it left the drugstore was sufficient to negate liability. However it should be noted that the initial trial judgment in favour of the defendant was reversed by Justice Latimer on the basis of an erroneous trial court instruction on contributory negligence.

In *Boudot v Schwallie* ((1961) 176 N.E. 2d 599), the primary issue on appeal to the Court of Appeals of Ohio was concerned with the application of statutory limitation periods. The Presiding Judge made a number of comments, however, on the general duty owed by the pharmacist to the patient, and, more importantly, on the relationship between pharmacist and physician:

'...we find that [the plaintiff] comes to the pharmacist, clothed in the doctor-patient relationship, with a prescription, she asks the defendant, as a pharmacist of specialist in his field, to fill the prescription, the very basis of her cause of action is failure on the part of the pharmacist to exercise the degree of reasonable care employed by those called upon by doctors to fill prescriptions for the physical impediments of their patients...

It is clear to this Court that the plaintiff by her allegations, places the defendant in the category of a professional acting unskilfully within the framework or branch of the practice of medicine. The doctor relies upon the pharmacist for the specific medication prescribed for his patients. The practice of the profession of pharmacy is a part and parcel of the system of practice of modern medicine.' ((1961) 176 N.E. 2d 599)

Pharmacists have much to gain from the comments of Judge Long. His statements recognise the important role which pharmacists have to play in the practice of medicine and the significant contribution which they make to the care of patients. As has already been stated, the role of pharmacists in the health care system is necessarily shaped by law and that the extent to which individual roles become the purpose of pharmacy depended upon a recognition of that expanded role by judges and legislators. To that extent these comments have to be welcomed.

However, it is equally important to place the comments into context. The judge is indicating that pharmacists have a professional contribution to make to a system of medicine and health care where the physician's role is primary. Judge Long's finding that the patient arrives in the pharmacy 'clothed in the doctor-patient relationship' and that the pharmacist is 'called upon' or 'relied upon' to fill prescriptions for doctors emphasises doctor primacy. Pharmacists, as professionals, are expected to carry out their roles carefully and responsibly, but the extent of the function is to carry out the legitimate expectations of the doctors. The pharmacist's professional role is a secondary one.

In *Burke v Bean* ((1962) 363 S.W. 2d 366), in the Court of Civil Appeals of Texas, Justice McNeill reaffirmed the nature of the duty owed by pharmacists. Applying *Peavy v Hardin*, the judge stated that in filling prescriptions a pharmacist was required to use the high degree of care which a very prudent and cautious person would exercise under the same or similar circumstances in that business:

‘The general customer ordinarily has no definite knowledge concerning many medicines, and must implicitly rely upon the druggist, who holds himself out as one having the peculiar learning and skill, and license from the state, to fill prescriptions. He owes to his customer purchasing a prescription that highest degree of prudence, thoughtfulness, and vigilance consistent with the reasonable conduct of business, in order that human life may not constantly be exposed to the danger flowing from the substitution of a harmful drug or a beneficial drug ordered by the customer’s physician.’ ((1962) 363 S.W. 2d 366)

The judge indicated that this high degree of prudence was extended when a mistake in the dispensing of a prescription was discovered. The duty was to ensure that the mistake was rectified. On the facts of the appeal before him, the plaintiff had failed in the initial duty to dispense correctly and in the further duty to correct the error in dispensing, once discovered. Not only had the plaintiff failed in the latter duty but had compounded that failure by an attempt to conceal the inaccuracy.

It is important to note that the Court of Civil Appeals of Texas is defining the pharmacist’s duty in terms of technical accuracy in the dispensing of prescriptions. No doubt the duty owed in carrying out this function is high, as evidenced by the comments of Justice McNeill. In addition, the duty is supplemented by a further obligation to rectify discovered mistakes. However that is the extent of the duty. Technical accuracy, or a failure to make mistakes, is the extent of the duty. There is no duty, for example, to identify potential errors, or other failures in drug therapy. As will be seen below, such an obligation lies at the heart of a duty to warn which, in turn, forms a significant aspect of the pharmacist’s extended role.

On first view, the case of *Johnson v Primm* ((1964) 396 P.R. 2d 126) looks like a ‘duty to warn’

case. The plaintiff had a number of refills of a prescription at the defendant's pharmacy on an increasingly regular basis so than eighteen months after the dispensing of the initial prescription she was taken three times as many tablets per day than had been prescribed. The plaintiff claimed damages for the brain and liver damage allegedly caused by the addiction to the drug product and for withdrawal treatment for addiction.

The Supreme Court of New Mexico was asked to decide whether the proximate cause of the injuries suffered by the plaintiff was the increasing of the dosage by the plaintiff over that prescribed, or the sale of equanil in greater lots than those prescribed. In addition, the Supreme Court was asked to determine whether the plaintiff's violation of the doctor's instructions amounted to contributory negligence that proximately caused the injury, thereby barring any recovery against the defendant.

Justice Moise thought that absent any question of the absence of will power induced by the pills, the court would have no difficulty in concluding that the lower court's ruling was correct: Applying the rationale in *Scott v Greenville Pharmacy Inc*, amongst other cases, the judge thought that the plaintiff's conscious violation of the instructions of her doctor, regardless of the number of tablets available to her, and her acts of daily taking more of the drug than directed would certainly deny her a recovery of damages. The judge went further and thought that, even if she did become addicted at some point in time and was thereby deprived of will power to discontinue the use of the drug, the plaintiff would again be prevented from recovering in the absence of showing that the defendant was or should have been aware of the fact of addiction.

However, the court was persuaded by the arguments, submitted on behalf of the plaintiff, that if the plaintiff was deprived of her will power and was so addicted to the use of the medication that she could not control her conduct, there would be a real question of whether her acts could be classed as contributory negligence. In light of the evidence before the court concerning the possible effect of the drug when taken as prescribed, together with the question concerning the defendant's knowledge of that fact, and the additional claim that the plaintiff's will was overcome, it was for the trial court (and the jury) to determine whether the defendant was negligent and, if so, whether the plaintiff was chargeable with contributory negligence proximately causing her own injury. The judge thought that these were substantial fact issues precluding summary judgement.

It is regrettable that this appeal was framed in terms of the procedural issue of the negation of the award of summary judgment, and that any substantive argument was structured around the question of contributory negligence. As noted above, the facts of this case are redolent of the significant issue of the 'duty to warn'. The defendant pharmacist could have argued that the extent of the duty owed to the plaintiff patient, under the existing jurisprudence, was to be technically accurate in the dispensing of the prescriptions and that this duty had been filled with each dispensed prescription. However, the plaintiff might also have argued that the increase in requests for the refilling of the prescriptions together with the obvious expansion in use of the medication ought to have put the defendant on guard, and give rise to a further or expanded duty. As will be seen below, it is precisely this sort of case which is beginning to lead the courts to re-evaluate the extent of the duty owed by pharmacists to patients, in line with the pharmacy profession's own expectations of an expansion in role and function.

In *McLeod v W.S. Merrell & Co and others* ((1965) S.R. 2d 736), in the Supreme Court of Florida, Justice Thornal was quick to dismiss any potential for action against the pharmacy, on the facts of the case. In so doing, he reiterated the limits of the duty owed by the pharmacist to the patient:

‘... a druggist who sells a prescription warrants that (1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug had not been infected with some adulterating foreign substance.’ (1965) S.R. 2d 736 at page 739)

In arriving at this statement, the judge applied the reasoning from the cases of *Watkins v Jacobs*, and *Gottsdanker v Cutter Laboratories*.

The decision in *Merrell v McLeod* is a classic of its type. It reaffirms that the extent of the duty owed by the pharmacy to the patient is that of technical accuracy. It also confirms that the pharmacist, in compounding and dispensing prescriptions according to the doctor’s instruction, and in distributing pre-prepared medicinal products, has no duty to warn the patient about potential failures in the drug therapy, whether known or unknown. The case also begins the process of defining the roles and functions of the main participants in the drug distribution process – the manufacturer, doctor and the pharmacist.

Brushwood (1983:362) postulates that the decision in *Merrell v McLeod* is the first in a series of cases in which the courts have been reluctant to extend products liability theory to retail

pharmacists selling prescription medicines. This is despite the fact that the general products liability law provides that the retailers of new goods are liable in warranty and strict liability for damages caused by a product. The effect of the reasoning in *Merrell*, and in a series of other cases, according to Brushwood, is to establish a precedent that pharmacists should not be held liable for failure to warn under the products liability theory of recovery:

‘These cases uniformly hold that, as long as a pharmacist fills a prescription accurately according to a prescriber’s orders, there can be no liability for failure to warn the patient of possible side effects or contraindications ... The *Mcleod* decision indicates that pharmacist liability under a products liability implied warranty theory is limited ...’ Brushwood (1983:362)

In *Troppe v Scarf* ((1971 N.W. 2d 511)) the main issue for the Court of Appeals in Michigan was to assess the extent to which the defendant would be civilly liable for the consequences of his negligence. Presiding Judge Levin began his analysis of that issue by reaffirming that a pharmacist is held to a very high standard of care in filling prescriptions. A pharmacist who negligently supplied a drug other than the drug requested would be liable for resulting harm to the purchaser. The judge thought that these principles had applied in Michigan from as far back as the 1882 case of *Brown v Marshall*. Secondly, in analysing the issue of whether public policy played a part in denying the potential for recovery in such a case, the judge considered the purpose of pharmacist civil liability:

‘... the imposition of civil liability encourages potential tortfeasors to exercise more care in the performance of their duties, and, hence, to avoid liability producing acts. Applying this theory to the case before us, public policy favours a tort scheme which encourages pharmacists to exercise great care in filling prescriptions. To absolve [the] defendant of all liability here would be to remove one deterrent against the negligent dispensing of drugs’. ((1971 N.W. 2d 511 at 517))

The judge thought that there could be no public policy grounds on which to absolve the defendant of liability in these circumstances. The judge was equally clear that the arguments of overriding benefit to the mother, mitigating loss, and the uncertainty of assessment of damages should also not play a part in absolving the defendant of liability.

Brushwood (1991:40), is of the view that the decision in *Troppe* confirms that the rationale underlying civil litigation involving pharmacists reflects the fact that as a matter of public policy, malpractice law serves not only to compensate victims of another person's negligence, but also to deter negligent conduct, so far as that is possible. Despite this:

'... civil courts have been reluctant to recognise that the pharmacist is a professional whose judgment must be utilised for the patient's benefit. The effect of deterring negligent conduct, which the recognition of the expanded pharmacist liability might cause, will not be fully achievable in a system that allows for judgment only by physicians.' (1991:40)

In *Batiste v American Home Products Corporation* ((1977) 231 S.E. 2d 269), the plaintiff made a number of claims for damages including one against the drug store where a prescription for her was dispensed, alleging that the drug store failed to warn the plaintiff of the risks, contraindications, harmful side effects and dangerous adverse reactions associated with the drug, which included a stroke from which she eventually suffered. In support of this claim, the plaintiff's representatives cited two cases – *Spry v Kiser* and *Davis v Radford* – arguing that the principle that a pharmacist owed a patient a duty of care in compounding and selling drugs could be extended to include a duty to warn. The court quickly disagreed:

'Certainly defendant is not qualified or licensed to advise plaintiff with respect to the best oral contraceptive for her to use to prevent pregnancy. Defendant is not a

physician. Perhaps had a druggist employed by defendant undertaken to prescribe the oral contraceptive she took or to advise her concerning it, the result might be different. That question is not before us.' ((1977) 231 S.E. 2d 269 at page 274)

The Court of Appeals of North Carolina also rejected any liability based on the theory of strict liability in tort. Applying the principle in *Mcleod v W.S. Merrell Co*, the court did not think that new advances in science and technology require the court to:

'... hold a druggist liable without fault because of injuries and damage resulting from the use of a drug compounded or sold in strict compliance with the physician's order, in the absence of any knowledge which would constitute negligence.' ((1977) 231 S.E. 2d 269 at page 275)

The decision in *Batiste* confirms that the extent of the pharmacist's duty is accuracy in prescription filling.

In *French Drug Co. Inc. v Jones* ((1978) Miss., 367 So. 2d 431), the Supreme Court of Mississippi confirmed that the standard of care expected of a pharmacist in the dispensing of a prescription is high, and that a pharmacist is liable for the resultant harm to a patient where the pharmacist negligently supplies a drug other than the drug requested. In so doing, the Supreme Court approved the decisions in *Edelstein v Cooke*, *Knoefel v Atkins*, *Tombari v Connors*, *Troppi v Scarf*, *Hoar v Rasmusen* and *Fuhs v Barber*.

The appeal of the plaintiff in *Ullman v Grant* ((1982) Sup., 450 N.Y.S 2d 955) was quickly dismissed by the Supreme Court of New York. The plaintiff's original claim had been against the defendant pharmacy alleging that the pharmacist had filled a prescription with a substitute drug without warning the plaintiff of any potential side effects. Under the legislative provisions which

were in force in New York at that time, a pharmacist was permitted to substitute a less expensive drug containing the same ingredients, dosage and strength, as the drug prescribed by the doctor provided that the doctor signed 'substitute permitted' on the prescription. The appropriate words had been included on the prescription at issue in the case, and substitution was made by the defendant pharmacist. The plaintiff had suffered a severe adverse reaction to the ingestion of the substituted drug.

In dismissing the appeal, the Supreme Court of New York made several short but extremely significant statements about the nature of pharmacist liability. They included the following:

'A pharmacist is not negligent unless he knowingly dispenses a drug that is inferior or defective.' and

'It is not the duty of the defendant [pharmacy] to warn the plaintiff of possible side effects in the use of a drug.' (1982) Sup., 450 N.Y.S 2d 955 at page 956)

In making the first statement, the Supreme Court relied on the case of *Bichler v Willing*, and *Parker v State of New York* (201 Misc. 416, 105 N.Y.S. 2d 735). Brushwood (1983:364), is of the view that the two statements noted above are illustrative of the problem that certain cases are the source of curious and confusing judicial language:

'The *Ullman* court correctly followed established precedent in granting summary judgment for the pharmacist. But, the statements quoted above go beyond what is necessary for a proper disposition of the case. These statements would seem to indicate that under no circumstances will a pharmacist be held liable for damages suffered by a patient so long as the pharmacist has dispensed the drug strictly in accordance with the prescriber's instructions. However, according to a continually evolving body of common law, the pharmacist's duty to the patient may go far beyond simply dispensing a prescription correctly.'

The precise detail of that evolving body of common law will be explored in detail below.

As was noted in the introduction to this chapter, an analysis of judicial attitudes towards pharmacist responsibility shows distinct patterns or trends. Walker and Hoag (1996:iii), Brushwood (1996:44 and 1988:4), are of the view that from 1985 to the present, judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. All three authors also agree that the movement towards a recognition of expanded responsibility must be viewed against the recent background of traditional legal analysis, reviewed in detail above, which had limited pharmacist responsibility to the accurate processing of prescriptions and which had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor.

Brushwood (1991:22), is also of the opinion that a number of well-reasoned opinions from the 1980s provide an insight on contemporary judicial expectations of pharmacists and give a useful overview of judicial reasoning in varying factual situations in which pharmacists have allegedly caused harm by failing to warn of a drug's potential adverse side effects. The first case in this series is that of *Hand v Karowski* ((1982) 89 A.D. 2d 650, 453 N.Y.S. 2d 121).

Brushwood (1991:33) notes that a number of widely publicised trial level verdicts and settlements (*Mahaffey v Sandoz* (Sedgwick County, Colo. Dist. Ct. May 1974), *Tonneson v Paul B. Elder Co.* (Santa Clara County, Cal., Superior Ct. March 1974 and *Kaiser v Fred Meyer Inc.* (King County Wash., Dist Ct. Jan 1982), led directly to the belief that the duty to warn was becoming a recognised legal standard for pharmacists (Salisbury 1977 and Fink 1977), and were

ultimately responsible for the findings in *Hand*.

The plaintiff in *Hand* was the executrix of the estate of a deceased female patient. Over a period of a number of years the defendant pharmacy had dispensed certain psychotropic drugs to the patient, pursuant to signed prescriptions from her doctor. It was undisputed that the defendant pharmacists knew that the patient was an alcoholic, her medical records being marked as such. The patient eventually died, and the autopsy report identified the cause of death as pancreatitis associated with a severe degree of cirrhosis.

The plaintiff alleged that the defendant pharmacists had breached the duty of care owed to a patient by issuing to an alcoholic patient psychotropic drugs knowing that these drugs were contraindicated with the use of alcohol, and therefore extremely dangerous to the well-being of the of the patient. The trial court gave a summary judgment in favour of the defendant pharmacist dismissing the plaintiff's complaint and she appealed.

On appeal, the defendant pharmacists attempted to rely on the decision in *Bichler v Willing* ((1977) 397 N.Y.S. 2d 57), arguing that the principle emerging from that case was that a pharmacist was not negligent when he/she filled a prescription precisely as ordered by the prescribing doctor, and had no further duty to test or inspect the drug or to warn the patient that the drug might be harmful.

The Supreme Court of New York reversed the summary judgment of the trial court. In so doing the court distinguished the decision in *Bichler v Willing*. The key issue was the knowledge of the

defendant pharmacists:

'Here, the decedent's pharmaceutical records identified her as an "alcoholic". Yet, [the defendants] during the ten month period preceding decedent's death, issued to her 728 units of psychotropic drugs knowing that such opiates are contraindicated with the use of alcohol ... Such conduct, in our view, could be found to constitute a breach of a druggist's duty of ordinary care in that it knowingly ignores the dangers and consequences of ingestion by an alcoholic of prescription drugs commonly recognised to be contraindicated.

... Here, [the defendants] knew that the decedent was alcoholic and knew, or should have known, that the prescribed drugs were contraindicated and, therefore, extremely dangerous to the well-being of its customer. Clearly under these circumstances, the dispensing druggist may have had a duty to warn decedent of the grave danger involved and to inquire of the prescribing doctors if such drugs should not be discontinued.' ((1982) 89 A.D. 2d 650, 453 N.Y.S. 2d 121 at page 122)

The case was remitted to the trial court for a further exploration of the facts in order that the failure to warn claim might be fully assessed.

In an initial reaction to the judgment in *Hand*, Brushwood (1983: 370-371), wonders whether it is the long-awaited judicial recognition of the pharmacist's duty to warn of the risks associated with prescription drugs:

'The most significant aspect of the *Hand* decision is its emphasis on the duty to warn as well as its tacit recognition of the continued development of patient-oriented clinical pharmacy practice. Only time will tell whether *Hand* is the first in a line of cases to firmly establish the pharmacist's duty to warn.'

By 1991, Brushwood (1991:34-35) had re-evaluated this initial optimistic analysis. While maintaining that the case was the first in a line to provide an insight on contemporary judicial

expectations of pharmacists, its narrow factual scenario had caused other courts to distinguish the rationale which the *Hand* court had developed. The decisions of these other courts will be explored in more detail below. In summary, *Hand* was not as significant as it might have been in defining the pharmacist's legal duty to warn.

According to Brushwood, the narrow factual scenario in *Hand* is evidenced both by the court's reliance on the fact of the defendant pharmacy's actual knowledge of the patient's condition, and by the fact that the court may have misunderstood the difference between 'contraindications' and 'warnings'. Contraindications are descriptions under which drugs absolutely should not be used while warnings refer to potential safety hazards and to steps that should be taken if certain adverse effects appear while the patient is taking the drug. The package inserts for the drugs at issue in *Hand* listed the potential for the drug to interact with alcohol as a warning rather than a contraindication. The emphasis of the court in *Hand* on contraindications, to the extent of citing authority for the meaning of contraindication, is therefore misplaced. Despite this, Brushwood does not dismiss the significance of *Hand*:

'The *Hand* opinion is significant because it recognises that there are circumstances under which a pharmacist may be required to provide a warning to a patient, and other circumstances under which no warning is required. The information at issue here (the potential interaction between drugs and alcohol) is generally considered to be risk management information. Therefore, the warning would be a responsibility of the pharmacist, because the patient may avoid the adverse effect by modifying her lifestyle, that is, by not using alcohol while continuing to use the drug.'

Bailey (1991:491) also agrees that the decision in *Hand* should be reserved to its own particular facts. The only reliable aspect of the decision is the proposition that the determination of the

parameters of the duty of care of the pharmacist presented a factual question for determination by the jury. Again, and as the cases below will show, Bailey believes that where the plaintiff cannot show actual knowledge on the part of the pharmacist, the case will raise more difficult questions.

Green (1991:1466) argues that the decision in *Hand* confirms that while a pharmacist may be found to be liable for a failure to warn a patient about specific physical properties of a medication, and is usually required to convey information necessary to assure that the patient uses the drug safely and effectively, the courts have limited this requirement to conveying utilisation or risk management information which all patients should know.

The decision in *Hand* was considered by the Court of Appeal of Louisiana in *Kinney v Hutchinson* ((1984) 449 S.R. 2d 696). The plaintiff suffered severe gunshot injuries after being shot by an individual who had consumed a combination of alcohol and the drug Preludin. The plaintiff sued the pharmacy from where the drug had been dispensed alleging that the pharmacy had failed to warn the patient of the proper use of the drug, and of any adverse effects and dangers of using the drug in combination with other substances. The pharmacy contended that a pharmacist is under no duty to warn patients of the effects of drugs.

The Court of Appeal of Louisiana agreed that the pharmacy was under no duty to the patient but approached its analysis of the absence of duty in a novel manner. It applied the decision in *Cobb v Syntax Laboratories Inc.* ((1983) 444 So. 2d 203), finding that the court in that case had held that there was no duty on either the manufacturer or the pharmacy to warn consumers directly of the adverse effects of a particular drug:

‘... the burden to warn of a prescription drug’s adverse effects is placed upon the prescribing physician. Where the manufacturer has informed the prescribing physician of the effects and benefits, the manufacturer is relieved of its duty to warn since the physician is the informed intermediary between the manufacturer and patient ... The holding in *Cobb, supra*, included and extended this analysis of liability to the pharmacist as well as to the manufacturer.’ ((1984) 449 S.R. 2d 696 at page 698)

As noted above, the court took note of the decision in *Hand* but indicated that this was purely as a matter of interest due to the paucity of jurisprudence on the issue of pharmacist responsibility. The decision in *Hand* was significantly distinguishable on the facts, probably due to the knowledge issue discussed above.

The novelty of the approach taken in *Kinney* lies in the fact that the court chose to adopt and adapt the informed or learned intermediary doctrine. Although the doctrine is well established in both United States (Brushwood 1983) and the United Kingdom (Mullan 2000) law, it is essential to distinguish between professional responsibility and product liability laws. Abood & Brushwood (1997:242) puts the matter quite well:

‘If a physician, a pharmacist, or a hospital is sued after harm occurs from drug use, the argument is usually that a safe and effective drug was improperly prescribed, improperly dispensed, or improperly administered, resulting in harm to the patient. Whereas professional malpractice litigation focuses on a problem with the way in which the product was used, drug product liability litigation focuses on the products itself. Drug product liability law deals with claims that a drug was so inherently dangerous that harm to someone was inevitable, no matter how carefully the drug was used, and that the risk of harm was unreasonable. Professional malpractice law deals with claims that a drug could have been used safely, but was not, because the professional who was responsible for the outcomes of drug therapy did not meet the requisite standard of care.’

The learned intermediary doctrine was developed in relation to drug product liability law rather than professional malpractice (or responsibility) law. Its place, then, in a discussion of the elements of professional malpractice law is misplaced. However, *Kinney* does confirm the emerging trend to distinguish *Hand* on its facts.

Although matters were shortly to change, the courts in the mid 1980s, while confirming that pharmacists owed a duty of care to warn their patients, were continuing to emphasise that the limit of the duty was technical accuracy in the dispensing of prescriptions. In *Cazes v Raisingier* ((1983) 430 So. 2d 104), Judge Boutall in the Court of Appeal of Louisiana confirmed that the degree of care, legally expected of pharmacists is high. In so doing, he approved of the judgments in *Trumbaturi v Katz*, *Walton v Booth*, *Marigny v Dejoie* and *Davis v Katz & Besthoff Inc.* The judge agreed that this level of care had not been reached by the defendant in the case before him, but was prepared to limit the award of damages to an award for pain and suffering attributable to the Lanoxin overdose but not the general worsening of her pre-existing heart condition.

Brushwood (1991:35) notes that:

‘To the extent that the decision in *Hand v Krakowski* appeared to open the door to pharmacist liability for failure to warn, that door was swiftly shut in *Psyz v Henry’s Drug Store*’.

In *Psyz* ((1984) 457 So. 2d 561), the District Court of Appeal of Florida was asked to answer two questions:

- 1 Whether a licensed pharmacist has a duty not only to properly fill a prescription

but also to warn the customer of the dangerous propensities of the prescription drug; and

- 2 Whether a licensed pharmacist who has actual or constructive knowledge of a customer's dependency and addiction to a prescription drug has a duty to warn the customer's treating physician of this fact.

The appellant had alleged that the pharmacist's failure to warn him of the addictive propensities of a particular drug constituted negligence, and further, that the filling of prescriptions for the drug for more than nine years also constituted negligence because the pharmacist knew or ought to have known that the use of the drug over an extended period of time would subject the appellant to physical and psychological dependence and addiction.

The District Court of Appeal of Florida was swift to respond that it was required to answer each of the questions outlined above in the negative. In so doing, it confirmed and approved the decision in *Mcleod v W.S. Merrell Co.*. In that case, the same District Court of Appeal had limited the duty owed by the pharmacist to the patient as follows:

'The rights of the consumer can be preserved, and the responsibilities of the retail prescription druggist can be imposed, under the concept that a druggist who sells a prescription warrants that (1) he will compound the drug prescribed; (2) he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; (4) the drug has not been infected with some adulterating process' ((1965) 174 So. 2d 736 at page 739)

The appellant had sought to distinguish the decision in *McLeod* on the basis that his was an action in negligence rather than warranty. His lawyers had cited a number of cases in support of this submission, including *Burke v Bean*, *Tombari v Connors*, *Kreuger v Knutson*, *Meyer v King* and *Tidd v Skinner*. The District Court of Appeal was able to distinguish these cases on the basis that they each related to a technical error of some kind – failure to give the correct drug (*Burke*, *Tombari*), or failure to give a statutory warning concerning poisons or chemicals (*Kreuger*, *Meyer*, and *Tidd*). None of the cases cited concerned a pharmacist who had properly filled a lawful prescription.

The District Court of Appeal was clear that it could not extend pharmacist responsibility in the manner contended by the appellant:

‘[The] appellant suggests that the pharmaceutical business has changed drastically in the past twenty years and that therefore this court should take a new look at the duty of a druggist to either warn the customer of the dangerous propensities of a drug prescribed by a licensed physician or in the alternative, to notify the physician of the dangerous propensities of the drug and/or the effect that it is having on the patient. Appellant argues that a pharmacist has greater knowledge of the propensity of drugs than that of the physician. Although this may be factually true in some instances, it is the physician who has the duty to know the drug that he is prescribing and to properly monitor the patient.’ ((1984) 457 So. 2d 561 at page 562)

Brushwood (1991: 36) is of the view that the court in *Psyzyz*, in deferring to the prescribing doctor as the person who was responsible for providing drug warnings, effectively excluded the pharmacist from that responsibility. Green (1991:1461), Raffath (1992:66) and Day & Marks (1991:108) agree. Bailey(1991:488), while noting that the District Court of Appeal did state that it was limiting its decision to the particular facts of the case, did not suggest what factual situation would result in culpable negligence on the part of the pharmacist for failure to warn.

Brushwood (1991:37) also warns that expansions of the *Pysz* rationale, under different factual situations, would be contrary to the warnings of that court, and should be resisted.

As noted in the introduction to this chapter, an analysis of judicial attitude towards pharmacist responsibility in the period from **1932-1985**, demonstrates a traditional legal analysis which resiled from the earlier expansion of pharmacist responsibility and which restricted liability to technical inaccuracy in prescription processing. The decision in *Pysz* sums up this era. Deference to the prescribing doctor as the individual responsible for drug warnings is paralleled by a restriction and limitation of the pharmacist's role and resultant responsibility.

A further analysis of judicial attitudes in the period from **1985 to present**, will show that the judiciary may be returning to first principles and are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions.

New roles – new responsibilities?

Brushwood (1996:9) notes that the pharmacist's shield against expanded liability began to crack in the early 1980s. However, the changes were not immediate and direct but emerged gradually in a series of distinct patterns, or waves. The first wave began with a series of cases taking place in 1985. The first case in this year to discuss the issue of expanded pharmacist responsibility was *Jones v Irvin* ((1985) 602 F. Supp 399).

As in *Pysz*, the allegation in *Jones* was that a pharmacist should be liable in damages for personal

injuries sustained as a result of a patient's consumption of excessive amounts of a prescription drug over a period of time and its reaction with other drugs. The United States District Court for the Southern District began its analysis by confirming that the precise issue before it was a narrow one. The plaintiff was not alleging that the pharmacist negligently substituted another drug for the prescribed drug or negligently gave the wrong instructions on the use of the drug. In each of these situations the plaintiff would have a valid claim. The issue was whether a pharmacist, who correctly fills a prescription, is negligent for failing to warn the patient or to notify the doctor that the drug is being prescribed in dangerous amounts, that the patient is being over-medicated or that the various drugs in their prescribed quantities could cause adverse reactions to the patient.

It was argued on the part of the plaintiff that the case of *Jones v Walgreen*, was authority for the proposition that the pharmacist's legal duty goes further than merely dispensing the identical substance which the prescription calls for. Chief Judge Foreman thought that although the language used in *Jones v Walgreen* seemed compelling, the case could be distinguished on its facts. In *Jones v Walgreen*, the pharmacist had filled the prescription with a different and stronger brand of the drug than that prescribed by the doctor, apparently because he could not make out the name of the brand on the prescription. What *Jones v Walgreen* had held was that if a prescription is doubtful on its face, the pharmacist's duty is to take all reasonable precautions to be certain that one thing is not sold when another is called for. There was no doubt in *Jones v Irvin* what the prescription was calling for.

On the basis that there was no other immediate Illinois authority on the subject, the court began a review of other state authority to help in its determination of the appeal. The court began by referring to the cases of *People's Service Drug Stores Inc., v Somerville*, *Fuhs v Barber*, and *Krueger v Knutson* but again distinguished all three cases on the basis that in each situation the pharmacist was selling a non-prescription drug, knowing either that the patient would be taking it in conjunction with a prescribed drug or other non-prescribed drugs. In the case before it, all the drugs which the plaintiff was taking were prescribed.

Chief Judge Foreman was also of the view that the overwhelming majority of recent state cases were against any proposition that the pharmacist should have a duty to warn. Different courts had taken different attitudes to the issue. In *Bichler v Willing*, the court had held generally that a pharmacist could not be held liable for correctly filling a prescription. By implication this was the extent of the duty and it did not include any further responsibility to warn. More particularly cases such as *Batiste v American Home Products Corp.*, *Ullman v Grant*, *Kinney and Hutchinson*, and *Pysz v Henry's Drug Store*, had specifically held that the pharmacist had no duty to warn. The decision in *Hand v Krawowski* could be distinguished on its facts.

This analysis of all of the available authority on the subject allowed the court to conclude that:

'...a pharmacist has no duty to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over-medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer. It is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give to his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug.

Further it is the duty of the patient to notify the physician of the other drugs the patient is taking. Finally it is the duty of the drug manufacturer to notify the physician of any adverse effects or other precautions that must be taken in administering the drug ... Placing these duties on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability' ((1985) 602 F. Supp 399 at page 402)

This language is very reminiscent of that used in *Psyz* and one would wonder, at first glance, where any significant movement towards a judicial recognition of expanded pharmacist responsibility is to be found. The key lies in the concluding remarks of Chief Judge Foreman where he emphasises that the court's holding is a narrow one and stresses that the pharmacist owes the patient the highest degree of prudence, thoughtfulness and diligence. He also stated that the court was expressing no view on whether a pharmacist owes a duty to warn the patient of side reactions, over dependence, misuse or restrictions on use associated with non-prescribed medicines which he or she dispenses.

Brushwood (1996:9) cites *Jones v Irvin* as first evidence, despite the finding of no liability, of a cracking of the shield. Bailey (1991:488) is of the view that the court's decision in *Jones v Irvin* not to impose a duty is perhaps attributable to the fact that the federal district court was not as free as a state appellate court to interpret state law. Laizure (1992:531) focuses on the 'burden to pharmacists' rationale of the decision, finding that it is consistent with the approach taken by other courts in promoting doctor primacy in decisions regarding drug therapy. Day & Marks (1991: 108-109) also recognise this aspect of the judgment, noting that it follows the existing trend of authority, and adding that the court's intention was to avoid pharmacists having to second guess a doctor in order to avoid liability.

In *Ingram v Hook's Drugs Inc*, ((1985) 476 N.E. 2d 881), the Court of Appeals of Indiana began by considering whether a state regulation vesting the Indiana Board of Pharmacy with the authority to regulate and control the practice of pharmacy included a statutory duty to warn customers of all of the hazards associated with a prescription drug. While the court could not accept that the regulation prohibited pharmacists from including their own warnings, as had been contended by the pharmacy's representatives, it concluded that a pharmacist did not have a statutory duty to warn.

The court then went on to consider whether a duty to warn existed at common law by examining the case law on the subject in Indiana and other jurisdictions. While the court could not discover direct Indiana authority on the point, it was of the view that the decision in *Ortho Pharmaceutical Corp. v Chapman* ((1974) 388 N.E. 2d 541) was authority for the proposition that the decision to warn of the potential side effects requires knowledge of the nature of the drug, and of the medical history and other facts about the patient. Such knowledge was usually in the possession of the prescribing doctor rather than the dispensing pharmacist.

Looking at the jurisprudence from other jurisdictions, the court was of the view that the decisions in *Mcleod v W.S. Merrell Co.*, *Batiste v American Home Products*, *Kinney v Hutchinson* and *Bichler v Willing*, were authority for the proposition that the duty to warn of hazards associated with prescription drugs is part and parcel of the doctor-patient relationship because it was best appreciated in such a context. Such a proposition was in keeping with the rationale of *Ortho Pharmaceutical*. The court concluded:

'The decision of weighing the benefits of a medication against potential dangers that are associated with it requires an individualised medical judgment. This individualised treatment is available in the context of a physician-patient relationship which has the benefits of medical history and extensive medical examinations. It is not present, however, in the context of a pharmacist filling a prescription for a retail customer. The injection of a third party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of the ongoing medical treatment. We perceive the better rule to be one which places the duty to warn of the hazards of the drug on the prescribing physician and requires of the pharmacist only that he includes those warnings found in the prescription.' ((1985) 476 N.E. 2d 881 at page 887)

The court did discuss the decision in *Hand v Krawoski*, although in a footnote to the main judgment. The court was quickly able to distinguish *Hand* on the facts, in keeping with the trend in judicial attitudes to this case. Incidentally, the court reinforced its findings on the particular and significant point of the pharmacist duty to warn by pointing to the official instructions and warnings relating to the taking of Valium, extracted from the *U.S. Pharmacopeia*, which had been included as part of the plaintiff's brief. Noting that there were twenty to twenty-five such instructions and warnings, the court stated that a pharmacist filling a prescription for Valium would be required to recite the entire list to the patient. This would only serve to confuse the normal customer and would be of dubious value, strengthening the view that the matter would be best left in the hands of the doctor.

Ingram could best be described as a hangover from the period of judicial attitude of confirming no duty on the part of the pharmacist to warn (Day & Marks 1991, Bailey 1991 and Green 1991), and a prelude to a series of cases where such perspectives were beginning to change. Hints of that change were apparent in the case of *Eldridge v Eli Lilly & Co.* ((1985) 485 N.E. 2d 551). The key to placing this judgment in the category of cases advocating or suggesting a change in

judicial attitude lies in the opening remarks of Justice McCullough:

‘A pharmacist owes a duty of ordinary care in practising his profession but such care requires the highest degree of prudence, thoughtfulness and diligence, and it is proportioned to the danger involved.’ ((1985) 485 N.E. 2d 551 at page 552)

In arriving at this conclusion, the judge relied on the seminal case of *Jones v Walgreen*. Brushwood (1996:9) is of the view that it is not surprising that, in seeking to expand or considering the possibility of expansion of pharmacist liability or responsibility should turn to *Jones* as authority for an evaluation of allegations that a pharmacist has a duty to warn the patient or notify the prescribing doctor that a drug is being prescribed in dangerous amounts.

Justice McCullough went on to consider the application of the decisions in *Psyz*, *Batiste* and *People’s Service Drug Store’s* and thought that these cases, and *Irvin*, were authority for the proposition that the duty to warn lay initially with manufacturer, and passed, through the learned intermediary doctrine, to the doctor. The pharmacist could have no part to play in either the manufacturer-doctor or doctor-patient relationships:

‘The plaintiff maintains many pharmacists may have greater knowledge of the propensities of drugs than physicians. He contends a pharmacist should, therefore, be under a duty to act as a safety supervisor and determine whether the physician has properly prescribed the drugs. The propriety of a prescription depends not only on the propensities of the drug but also on the patient’s condition. A prescription which is excessive for one patient may be entirely reasonable for another. To fulfil the duty which the plaintiff urges us to impose would require the pharmacist to learn the customer’s condition and monitor his drug usage. To accomplish this, the pharmacist would have to interject himself into the doctor-patient relationship and practice medicine without a license.’ ((1985) 485 N.E. 2d 551 at page 553)

The court could not find that the statutes controlling the practice of pharmacy in the state of Illinois also imposed a duty to refuse to fill a prescription simply because it was for a quantity beyond that normally prescribed or to warn the patient's doctor of that fact.

Again, it is interesting to note that the court was prepared to consider arguments on the potential liability of pharmacists for failure to warn, an issue which, as has been noted above, was not even considered in the period from 1932-1985. On the substantive reasoning, Brushwood (1996:9) is of the view that the possibility that the particular doctor-patient relationship arising in the appeal was harmful to the patient, and potentially warranted interference, should have been considered by the court. Bailey (1991:489) is of the view that the case is one of a series in which the courts, even when presented with facts suggesting that the pharmacist has in some way fallen short of the duty owed to the patient and contributed to the patient's injury, are reluctant to recognise a cause of action unsupported by any expert testimony of the extent of the pharmacist's actual standard of care. Laizure (1992:530-531) indicates that the case is an example of the many different approaches, in terms of rationale and policy argument, which the courts have taken in declining to impose a duty to warn.

The movement towards the expansion of pharmacist responsibility increased with the judgment in *Riff v Morgan Pharmacy* ((1986) 508 A 2d 1247). The plaintiff had suffered permanent injuries after taking excessive doses of a prescription drug refilled without authorisation by a pharmacist over a period of eight months. Judge Kelly began by confirming the nature of the duty which is owed by a pharmacist:

‘A pharmacist is a professional. In the performance of his professional duties he will be held to the standard of care, skill, intelligence which ordinarily characterises the profession. Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it.’ ((1986) 508 A 2d 1247 at page 1251)

Applying those principles to the facts before him, the judge found that there was sufficient credible evidence presented to establish that the defendant pharmacy breached its duty to exercise due care and diligence in the performance of its professional duties. It had done so by failing to warn the patient or notify the prescribing doctor of the **obvious** inadequacies appearing on the face of the prescription which created a **substantial risk of serious harm** to the plaintiff. But for this negligence the error and subsequent injuries would not have occurred.

Judge Kelly then went on to explore the relationship between the prescribing doctor and dispensing pharmacist – an issue which was to the fore in many of the cases already referred to above:

‘Fallibility is a condition of the human existence. Doctors, like other mortals, will from time to time err through ignorance or inadvertence. An error in the practice of medicine can be fatal; and so it is reasonable that the medical community including physicians, pharmacists, anaesthesiologists, nurses and support staff have established professional standards which require vigilance not only with respect to primary functions, but also regarding the acts and omissions of the other professionals and support personnel in the health care team. Each has an affirmative duty to be, to a limited extent, his brother’s keeper ... If the consensus of the medical community is that a safety net of overlapping responsibility is necessary to serve the best interests of patients, it is not for the judiciary to dismantle the safety net and leave patients at the peril of one man’s human frailty.’ ((1986) 508 A 2d 1247 at pages 1253-1254)

Brushwood (1991:37-38) is of the view that the duty, as framed in *Riff* is a narrow one. The duty is framed in terms of warning patient and/or doctor of an **obvious** inadequacy on the face of the prescription creating a risk of substantial harm to the patient. Brushwood is of the view that such situations are rare and that the decision in *Riff* is not authority for the proposition that there is a duty to countermand a doctor's order to assume control of a patient's drug therapy. Despite this, Brushwood is able to conclude that the decision in *Riff*:

'was a watershed in American malpractice litigation. It established a standard that required something more than correct prescription filling. *Riff* fits nicely into the risk assessment/risk management analysis. The plaintiff was not asserting that if she was given information, she would have decided not to use the drug at all. Rather, her contention was that she should have been warned of the harm that excessive drug use might cause, so that she could use the drug safely. This is the type of information that a pharmacist can provide to a patient without interfering with the physician-patient relationship ... *Riff* requires that a pharmacist apply knowledge about drugs to the facts of a situation and act for the patient's benefit by providing a warning, when a drug has been prescribed in a way that presents a substantial risk of serious harm.' (1991:38-39)

Lewis (1992:75) notes that what distinguishes the decision in *Riff* from other cases in which the courts have refused to impose a duty to warn is that competent expert testimony on the standard of care expected of the pharmacist was available. In cases like *Ingram*, according to Lewis, the plaintiffs had been arguing for a global duty to warn without giving the court the benefit of expert pharmacist testimony on the issue. The key to the success of *Riff* is that it nullified the argument that avoiding pharmacist interference in the doctor-patient relationship is a valid reason for not imposing a duty to warn.

Green (1991:1467) notes the court's recognition that public policy dictates that pharmacists who dispense medications must be held accountable for any failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it. Bailey (1991:493), again pointing to the public policy aspects of the decision, is of the view that it supports the conclusion that holding a pharmacist liable for negligent behaviour is both appropriate and manageable. Laizure (1991:534-535) is of the view that the decision in *Riff* is notable because of the court's bold statement that the pharmacist has an affirmative duty and notes that the decision might signal a trend toward expanded liability for the practising pharmacist.

In *Stebbins v Concord Wrigley Drugs Inc.* ((1987) 416 N.W. 2d 381), the plaintiff was seriously injured when she was involved in a road traffic accident. The driver of the other vehicle concerned in the accident had been treated regularly by his doctor for some psychiatric problems and had been prescribed an anti-depressant. The prescription was filled at the defendant's pharmacy. The plaintiff sued both the doctor and the pharmacy alleging that both failed to warn the other driver of the side effects of the anti-depressant and failed to warn him not to drive after taking it. The trial court granted summary dismissal for the pharmacy on the grounds that a pharmacist has no duty to warn customers of a drug's side effects, that duty remaining with the doctor. The plaintiff appealed to the Court of Appeals of Michigan.

Citing *Troppe v Scarf*, Presiding Judge Shepherd confirmed that the general rule in the State of Michigan was that a pharmacist was held to a very high standard of care in filling prescriptions and might be held liable for negligently dispensing a drug other than that prescribed. The

Michigan Supreme Court had also held, in *In re certified Questions* ((1984) 419 Mich. 686), that there was no rule in the state concerning the duty of a pharmaceutical manufacturer to disclose the risks and potential side effects of drugs directly to the patient. The Supreme Court had noted that the manufacturer's duty to warn patients directly could be determined only in the broader context of deciding whether and to what extent patients should be warned, and whether doctors or pharmacists should provide such warnings.

Against that background, Presiding Judge Shepherd noted that there were no Michigan cases squarely addressing a pharmacist's duty to warn patients directly. The judge did consider the decisions in *Psyz*, *Jones v Irvin*, *Eldridge* and *Kinney v Hutchinson* and concluded that Michigan should adopt the rule followed in *Psyz* and *Irvin*:

'We hold that a pharmacist has no duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face and neither the physician nor the manufacturer has required that any warning be given to the patient by the pharmacist.' . ((1987) 416 N.W. 2d 381 at pages 387-388)

The plaintiff's lawyers had cited the cases of *Hand v Krawoski*, *Kreuger v Knutson*, *Fuhs v Barber* and *Riff v Morgan Pharmacy* as authority for the proposition that a duty to warn was appropriate and should be imposed. The Court of Appeals was quickly able to distinguish all of these cases. *Hand*, as usual, was distinguished on the basis of the pharmacist's actual knowledge of the plaintiff's alcoholism, while continuing to dispense a medication strictly contraindicated for such a condition and failure to warn the plaintiff of the dangers. The Court of Appeals also found that there was other New York authority for a finding of no duty on the part of a pharmacist to warn patients of the potential side effects of prescribed medications, namely

Ullman v Grant ((1982) 450 N.Y. 2d 955).

Krueger was distinguishable on the basis that the case did not involve the filling of prescriptions while *Fuhs* could also be distinguished on the basis that, on the facts, a warning was clearly required. Finally *Riff* was distinguishable on the basis that the duty recognised there was the narrow one of a failure to exercise the duty to warn the patient and prescribing doctor of the obvious inadequacies on the face of the prescription. Equally the prescription in *Riff* substantially exceeded the accepted maximum dose and the pharmacy may have refilled the prescription without authorisation. No such allegation had been made in the appeal before the court.

Brushwood (1991:39) argues that the court in *Stebbins* may be missing the point that it was an omission on the prescription, and the pharmacist's failure cognitively to react to the omission, that created the duty in *Riff*. Brushwood is firmly of the view that refusing to follow *Riff* because no inaccuracy appears on the face of a prescription is too narrow a view of the case.

In *Leesley v West* ((1988) 518 N.E. 2d 758), the plaintiff commenced an action against her doctor, the pharmacy, and the drug company based on their failure to warn her of the side effects of the prescription drug which she was taking. The Appellate Court of Illinois began its determination of this question by considering the effect of the decision in *Kirk v Michael Reese Hospital & Medical Center* ((1987) 513 N.E. 2d 387) on the application of the 'learned intermediary doctrine'. The Appellate Court thought that *Kirk* was confirming that the Supreme Court of Illinois had adopted the learned intermediary doctrine with the effect that the manufacturer of a drug product had no duty directly to warn a consumer of the potential side

effects of a prescription drug. The manufacturer's duty is to warn prescribing doctors of the drug's known dangerous propensities and the doctors, in turn, using their medical judgement, have a duty to convey the warnings to their patients.

Turning to the issue of whether the pharmacy had an independent duty to warn the plaintiff of the drug's dangerous side effects, the Appellate Court stated that the question was one of law to be determined with three primary factors in mind – the foreseeability of injury to the plaintiff as a result of the defendant's actions or inactions, the magnitude of the burden to the defendant of guarding against the injury and the consequences of placing that burden on the defendant and the currently prevailing public policies and social attitudes of the community.

The Appellate Court noted that no Illinois court had until then decided whether a pharmacist has an independent duty to warn its customers of known potential hazards of a prescription drug. The Appellate Court reviewed the case of *Jones v Irvin*, finding that it was authority for the proposition that placing the duty to warn on a pharmacist would compel the pharmacist to second guess every prescription which the doctor orders in order to escape liability. Further the case of *Eldridge v Eli Lilly & Co.*, supported the principle that a pharmacist has no duty to warn a doctor who prescribed drugs for a patient in excessive quantities.

As noted above, the Appellate Court thought that the principles of foreseeability, burden and public policy should be applied in order to determine the issue of a pharmacist's independent duty to warn, as a matter of law. On the question of foreseeability, the Appellate Court thought that the foreseeability of injury to an individual consumer in the absence of any particular warning

varies greatly depending on the medical history and condition of the individual patient. These were facts which the pharmacist could not reasonably be expected to know. Further the fact that drug manufacturers cannot adequately evaluate the effect of the drug on any particular patient is one of the predominant reasons why the courts have adopted the learned intermediary doctrine exempting drug manufacturers from the duty directly to warn consumers.

Turning to the issue of burden, the Appellate Court was strongly of the view that requiring a pharmacist to convey the warnings which it receives to its customers would be very onerous, even if the pharmacist did receive the relevant cautionary information from the manufacturer. Pharmacists would have to bear the additional costs of reproducing any material which they receive, and even if they could receive additional unlimited copies of the warnings from the manufacturers, they would also face the 'oppressive' burden of retaining and cataloguing every document received to be certain each is distributed with the appropriate drug. Further, every method which the Appellate Court could think of to reduce that burden seemed necessarily to involve a complementary increase in the manufacturer's burden, either in altering the way prescription drugs are packaged for shipment to pharmacies or in adding simplified or condensed versions of the information the manufacturers currently supplied to pharmacies. Acquiescence by the drug manufacturers in the supply of the same information to patients as is supplied to doctors and pharmacies would effectively abrogate the exemption afforded to manufacturers by the learned intermediary doctrine and the policies behind the doctrine.

Finally, the Appellate Court concluded that its finding on declining to subject pharmacists to liability for failure to give warnings which the doctor had not requested was consistent with the

State's legislative policy against expanding the liability risks of health professionals. However, the Appellate Court, in agreeing that this public policy test was not satisfied, was at pains to state that it was not concluding that warnings beyond those given by the prescribing doctor should not be given, or are harmful, or should be discouraged.

The decision in *Leesley* has been examined in some detail by Milot (1989). He begins his critique by concluding that the Appellate Court was correct, on the narrow facts of the case, to refuse to impose a duty on the drug manufacturer directly to warn the plaintiff of the potential hazards of the drug in question under the 'learned intermediary' doctrine. He has, however, two reservations about this finding by the Appellate Court. The first relates to the court's failure to consider whether the drug at issue in the case, Feldene, was an 'unavoidably unsafe' product as the learned intermediary doctrine required (1989:1014-1016). The second related to the fact that for the learned intermediary doctrine to work, the intermediary must have sufficient contact with the patient in order to make an accurate assessment of the patient's medicinal needs. Where the doctor is absent, where there is limited contact, where the patient's use of the prescription drug becomes voluntary rather than necessary or where the manufacturer aggressively promotes its drug, the adequacy of the patient-doctor relationship has to be examined more closely. According to Milot, consideration of these critical components of the learned intermediary doctrine is absent in the *Leesley* opinion. The court should ask whether the doctor had sufficient opportunity to communicate to the plaintiff the material risks associated with taking the drug. Further evidence, concerning the nature and frequency of the visits to the doctor, and of any actual or constructive promotion of the drug, would be necessary (1989:1016-1017).

On the more substantive issue of the Appellate Court's finding that pharmacists have no independent duty to warn patients of the risks and side effects of the drugs which they dispense, Milot concludes that the decision effectively grants pharmacists complete immunity in failure to warn cases. However, he submits that the Appellate Court should not have automatically presumed that pharmacists have no duty to warn their patients without considering the surrounding circumstances.

Milot is of the view that the *Leesley* court should not have measured the foreseeability of injury solely by the absence of the patient's medical history and condition. According to Milot there are clear situations where knowledge of a patient's medical history or condition is not an important factor in foreseeing injury. He gives, as an example, the situation where a pharmacist receives a prescription for a drug which would harm any patient regardless of the patient's medical history and condition. He cites the cases of *Jones v Walgreen* and *Riff v Morgan* as examples of where this has occurred. Further, the pharmacist should have a duty to warn in situations where he or she has special knowledge of the patient's condition which is not likely to be known to the doctor:

'In short, there are situations where pharmacists possess a degree of foreseeability regarding injury to customers in the absence of a particular warning, which is equal or superior to what a physician might foresee from a different vantage point. ... Whether the pharmacist in *Leesley* had equivalent or superior knowledge in relation to the prescribing physician regarding the plaintiff's likely reaction to the drug Feldene is evidence that should have been allowed to rebut any presumption under the "learned intermediary" doctrine that physicians are in the best position to convey warnings.' (1989:1020)

On the question of burden, Milot is of the view that pharmacies may not necessarily experience a substantial increase in their warning activities. While conceding that pharmacies should be required only to convey what they know when dispensing the drug, the 'material risk' of it, any cost incurred by the pharmacist, or indeed the manufacturer, in employing preventative measures, would be offset by a reduction in prescription drug related injuries and consequent litigation. Further, research showed that consumers would be willing to pay extra in order to obtain prescription drug information. Further, Milot is of the view that the *Leesley* court misconstrued the purpose of the learned intermediary doctrine when it concluded that the doctrine would be abrogated by the imposition on drug manufacturers of the duty to supply drug product information to others than doctors:

'The purpose of the doctrine, then is not to save manufacturers the trouble of providing non-physicians with information and warnings pertaining to their drugs; rather the doctrine simply prevents patients from asserting strict liability claims against the manufacturer for failing to do so. So long as the manufacturers continue to provide physicians with adequate warnings, manufacturers will continue to receive the protection afforded under the "learned intermediary" doctrine. Information distributed to non-physicians would be superfluous and would have no bearing on the drug manufacturer's ability to defend itself against claims by non-physicians for failure to provide adequate warnings of a drug's risks.' (1989:1021)

Finally, on the issue of public policy, Milot concludes that rather than excluding pharmacists from the select class of "learned intermediaries" social and public policy might be leaning towards their inclusion. The continuing and developing definition of the pharmacist's professional responsibilities includes the provision of advising and counselling, using professional judgment, the provision of information on generic substitution and the clarification and expansion of the doctor's existing warnings. Further, the advocacy of the use of the public policy arguments employed by the *Leesley* court negates the public policy argument concerning

the consumer's right to know (1989:1022-1023).

Bailey (1991:487) questions the efficacy of the warning which the plaintiff sought. He wonders whether an arthritis sufferer would forgo treatment of arthritis symptoms because of a 1% chance of gastrointestinal bleeding even if provided with this information. Further the language contained in the warning provided by the drug manufacturer was virtually unintelligible except to those versed in the drug product rhetoric. Bailey is of the view that the simple provision by the pharmacist to the patient of drug product information supplied by the product's manufacturer might result in less useful information than if the pharmacist had chosen to highlight particular information relating to drug-drug interaction or possible side effects. This latter course of action would, of course, leave the pharmacist open to potential liability for not mentioning other side effects.

Raffath (1992: 67) submits that the *Leesley* opinion, and the academic reaction to it, provides the first indication that the trend in holding that pharmacists have no duty to warn may be changing. Laizure (1992:524) is of the view that the *Leesley* case is a good example of the expansion by the courts of the learned intermediary doctrine to shield the dispensing pharmacist as well as the manufacturer from liability.

In *Adkins v Mong* ((1988) 425 N.W. 2d 151), the plaintiff brought an action against the defendant pharmacy alleging that as a result of the defendant's negligence he became addicted to several narcotic substances. The Court of Appeals of Michigan began by referring to its own earlier decision in *Stebbins v Concord Wrigley Drugs Inc.*, in which it had held that a pharmacist has no

duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face and neither the doctor nor the manufacturer has required that any warning be given to the patient by the pharmacist. The ruling in *Stebbing* was enough for the present court to hold that the defendant had no duty to warn the plaintiff of the potential side effects of the substances it was dispensing to the plaintiff in accordance with the prescriptions all of which were valid on their face. Although a pharmacist owes a duty properly to fill lawful prescriptions, and, based on the principles in *Stebbins* and *Troppi v Scarfi* is held to a very high standard of care in performing this duty, a pharmacist would not be liable for correctly filling a prescription issued by a licensed doctor.

The plaintiff had also alleged that the defendant pharmacist owed the plaintiff the additional duty of maintaining detailed and accurate patient records, and a corresponding duty to identify addicted patients and their over-prescribing doctors either independently or through the combined efforts of other local pharmacists. The Court of Appeals submitted that, by analogy, the plaintiff would also argue that the pharmacist who identifies the addicted patient of an over-prescribing doctor would then be obligated to act on the information and refuse to fill the prescription, warn the patient, or notify the doctor. The court noted that other jurisdictions which had been presented with the same theory had overwhelmingly rejected it in favour of the more limited duty described in *Stebbins*. The court agreed with the analyses of the courts in *Psyz*, *Jones v Irvin*, and *Eldridge v Eli Lilley & Co* in also favouring such a rejection, and in so doing also distinguished the decision in *Hand* as it had done in *Stebbins*.

Overall, therefore the Court of Appeals found that there existed no legal duty on the part of a

pharmacist to monitor and intervene with a patient's reliance on drugs prescribed by a licensed treating doctor.

In *Ferguson v Williams* ((1988) 374 S.E. 2d 438) a patient had taken a prescription drug, after being advised that it was safe to do so, but which caused him to have an anaphylactic reaction resulting in his death. An action was brought by the patient's wife.

After distinguishing the decision in *Batiste v American Home Products*, the court held:

'While a pharmacist has only a duty to act with due, ordinary care and diligence, this duty, like all others, expands and contracts with the circumstances. Here, it is alleged that the defendant ... undertook to dispense not only drugs, but advice also. While a pharmacist has no duty to advise absent knowledge of the circumstances ... once a pharmacist is alerted to the specific facts and he or she undertakes to advise a customer, the pharmacist then has a duty to advise correctly'((1988) 374 S.E. 2d 438 at page 440)

Brushwood (1991:40) submits that the court clearly believed that a warning concerning the cross-sensitivity of aspirin and Indocin would not have been required of the pharmacist had the question not been asked by the patient. Further Brushwood argues that the information that the plaintiff alleged that the patient failed to receive was risk assessment information because it related to a decision whether or not to use the drug. It was arguable, therefore that the provision of such information was beyond the scope of the pharmacist's responsibilities:

'Yet, the rationale for distinguishing between risk assessment and risk management information is based in large part on the pharmacist's knowledge. Pharmacists usually do not know idiosyncratic characteristics of an individual patient, but they do know peculiar characteristics of a particular drug. Therefore, it makes sense to require that pharmacists give warnings regarding drug-specific information, but it does not make sense to require that pharmacists give warnings regarding patient-

specific information.' (1991:40-41)

McCormick (1992:245) submits that the decision in *Ferguson* exemplifies the recent judicial trend, as evidenced by cases like *Batiste*, for the courts to hold pharmacists to a more stringent standard of care with respect to the prescriptions they fill. He argues that while there are justifications for limiting the liability to which a pharmacist is exposed, it is wrong for any court to hold, as a matter of law, that a pharmacist never has a duty to warn customers of the inherent risks of a medication. McCormick argues that a court, in making a determination of whether a pharmacist has a duty to warn, should look to the circumstances surrounding the case in order to ensure that a patient's right to be informed of health risks is not jeopardized.

McCormick is of the view that cases such as *Batiste* and *Ferguson* include the pharmacist as a learned intermediary and submits that this is a sensible approach to take given the pharmacist's extensive training in pharmacology and pharmacokinetics, resulting in the acquisition of detailed knowledge of a drug's properties and propensities. As a result, pharmacists are more likely to be more knowledgeable than doctors with respect to drug products. Further the patient, by seeking advice from the pharmacists, is demonstrating that he or she is not placing a primary reliance on the doctor. Rather the patient is seeking the advice of a professional, perceived to be an authoritative source of information.

McCormick also argues that if the foreseeability, burden and public policy tests propounded in cases like *Leesley* were applied on a case by case basis, it would not necessarily result in pharmacists escaping liability. The expert testimony in both *Leesley* and *Ferguson* had shown that had the pharmacists been performing their duties with due care and diligence, they should

have realised that the prescribed medication posed significant health risks, without assuming too much of a burden.

McCormick finally submits that the decision in *Ferguson* did not violate public policy by holding that the pharmacist might be liable for failure to warn. The state legislature had included pharmacists within its definition of health care providers, and thereby pharmacists assumed the legislative duty to provide care in accordance with the standards of practice of the pharmacy profession. Equally the policy of the American Pharmaceutical Association clearly stated that the pharmacist must warn patients of the potential side effects of prescription medications. These requirements, according to McCormick, reinforce the view that public policy is being served by requiring a pharmacist to warn patients:

‘The judicial trend which is seen in *Ferguson* does not suggest that pharmacists must warn all customers of the potential side effects of their medications. Rather, it suggests that the duties of a pharmacist are not limited to counting pills. If a customer seeks the learned guidance of a pharmacist, *Ferguson* requires the pharmacist to inform the customer in a manner commensurate with his pharmaceutical training and expertise.’ (1992:231)

In late 1989, the Supreme Court of Washington issued an opinion that addressed most of the issues raised during the previous five years of pharmacist malpractice litigation. In the years preceding this case, many state courts had considered whether to depart from precedent and recognize an expanded standard of practice for pharmacists. The opinion from the case of *McKee v. American Home Products, Inc.*, ((1989) 782 P.2d 1045) serves as a primer on the arguments against expanded pharmacist liability up until that time. In a five to four split opinion, a majority

of the court rejected the argument that a pharmacist owes a patient a duty to detect and rectify problems with drug therapy. The court justified this holding by pointing to three public policy issues: (1) The need to recognize doctor primacy in health care, (2) The burden to pharmacists of expanding responsibilities without limits, and (3) The potential costs of an expanded duty for pharmacists. This three part rationale has served as the basis of a line of legal authority, developed in numerous judicial opinions that has rejected expanded responsibilities for pharmacists. An argument, such as this one, that advocates recognition of increased legal responsibilities for pharmacists, must address these standard reasons for judicial rejection of expanded pharmacist responsibilities.

The plaintiff, brought an action against the prescribing doctor, the drug manufacturer and the defendant pharmacists, seeking damages for physical and psychological injuries allegedly sustained as a result of her becoming addicted to a prescription drug which she had been taking for ten years. The plaintiff alleged that the pharmacists were negligent in selling her the drug for such an extended length of time without warning her of its adverse side effects, and were negligent in failing to give her the manufacturer's package insert.

The Washington Supreme Court began its analysis of the merits of the case by stating its view that:

“[r]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the doctor-patient relationship and interfere with ongoing treatment.” ((1989) 782 P.2d 1045 at page 1051)

This perspective reflects the traditional view of medical practice, emphasising doctor primacy.

The majority in *McKee* supported this traditional view of doctor primacy by stating that:

“proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition.” ((1989) 782 P.2d 1045 at page 1051)

The majority view also relied heavily on precedent derived from the learned intermediary doctrine under which a manufacturer of drug products has a valid defense to an allegation that it failed to directly warn a patient of a drug’s risk, if an adequate warning was provided by the manufacturer to the doctor. This doctrine assumes that, as between manufacturer and doctor, the doctor is best able to meet the responsibility to provide warnings directly to patients because the manufacturer already has fulfilled a responsibility by providing information to the doctor, and the manufacturer lacks the capacity to convey information to the patient, with whom it has no direct relationship.

The second justification offered by the majority opinion in *McKee* for upholding a traditional view of pharmacist duty was that

“[i]mposing a duty such as McKee urges would, in essence, require the pharmacist to question the doctor’s judgment regarding the appropriateness of each customer’s prescription.” ((1989) 782 P.2d 1045 at page 1053)

In effect, this argument assumes that every prescription issued by a doctor is so problematic that pharmacists must question all prescriptions. Under this reasoning, to require that a pharmacist

raise concerns about the use of an appetite suppressant over ten years, when scientific data indicate the drug is effective only for a matter of months and is prone to causing adverse effects the longer it is used, is to also require that pharmacists raise similar concerns about the most routine prescriptions that pose no obvious threat of harm.

The final justification offered by the majority opinion in *McKee* for not imposing a duty to detect and rectify problems with drug therapy is related to economic efficiency. The court stated:

“The Legislature can better assess the relative costs and benefits involved, and determine what form any warnings should take.” ((1989) 782 P.2d 1045 at page 1055)

Reflecting its importance in the jurisprudence on the question of pharmacist responsibility and the duty to warn, the decision in *McKee* has been the subject of extensive analysis. Brushwood (1993), after reviewing many of the arguments and issues outlined above, concludes that:

‘The medication-using public would be best served by a legal approach to pharmacy practice that requires action to prevent medication-related harm when (1) the pharmacist has knowledge of a problem with drug therapy, (2) there is a foreseeable (to the pharmacist) adverse outcome, and (3) the pharmacist has the capacity to prevent the adverse outcome without disrupting the delicate balance of relationships in health care.’ (1993:406)

Brushwood believes that such an approach is consistent with Washington state law, the law from other jurisdictions (*Hand*, *Riff*, and *Dooley*) and consistent with the new federal legislation imposing expanded requirements on pharmacists. Turning to the first of the three conditions inherent in the proposed legal approach to pharmacy practice, he believes that the knowledge condition, relating to pharmacological knowledge of drugs, and medical and personal knowledge of patients, and already the basis for determining a doctor’s

responsibilities is also relevant and appropriate for determining the basis of pharmacist responsibilities.

The foreseeability condition, according to Brushwood, limits the circumstances under which a pharmacist must communicate to a patient a known problem with drug therapy. He submits that the materiality rule, concerning the relationship of risk to harm, which already applies to doctors, should also be extended to pharmacists. Finally, the capacity condition requires converting capabilities into performance, recognising that there are limits to what a pharmacist can do. Within those limits, pharmacists should promote the idea of primary responsibility for patient welfare. However, just as the learned intermediary doctrine provides a defence to the manufacturer who has provided a warning to the doctor, pharmacists would be protected from liability where they have warned the doctor or taken other action for the patient's benefit.

Green (1991:1476) is of the view that the Supreme Court of Washington erred in failing to recognise a pharmacist's duty to warn:

'The court in *McKee* failed to recognize that pharmacists are no longer limited to licking, sticking, counting and pouring. Rather, pharmacists are taking on greater responsibility in the health care setting ... The current trend of cases indicates that, as pharmacists take on an increased role in patient care, they should face increased risk of litigation.' (1991: 1476)

The justifications offered by Green for the expansion in liability relate, primarily, to the parallel extension of the pharmacist's professional role towards counselling, the provision of drug information, and increased patient and doctor interaction. In addition, the increased

emphasis on the patient's right to make a decision whether or not to take a medicinal drug product, dictates that pharmacists should provide a sufficient amount of information about those products to patients. The objective would be to enhance the ability of the patient to make an informed decision, even where the decision might be to abandon the treatment. Further, it would be appropriate for the courts to impose a positive duty on pharmacists to provide drug information to patients in the form of imposing a duty to warn.

Raffath (1992:68) focuses on the narrowness of the majority verdict and emphasises that there were four dissenting judges who had thought that the jury could have found, based on the plaintiff's evidence, that the failure to warn breached a duty of care. Bailey (1991:492) submits that the case demonstrates the caution with which the parties must proceed in asserting a theory of negligence with respect to the pharmacist's duty to warn.

Other jurisdictions did consider the potential for an expansion of pharmacist responsibility. In *Dooley v Everett* ((1991) 805 S.W. 2d 380), the plaintiff suffered a series of cerebral seizures due to the interaction of two prescription drug products which had been prescribed for him. The plaintiff sued both the prescribing doctor and dispensing pharmacist, alleging a failure in a duty to warn of the potential interaction. In the Court of Appeals of Tennessee, Judge Lewis began by confirming that it was not a legitimate function of the court to make policy, which was a role properly exercisable by the legislature. However the judge did not believe that the court would be entering into the realm of policy making if it determined that the summary judgment in favour of the defendants was not appropriate. After reviewing the necessary elements of an action in negligence in Tennessee, including the meaning of 'duty' and

‘standard’ of care, the judge confirmed, relying on *Batiste v American Home Products*, that the pharmacist has a duty to act with due, ordinary, care and diligence in compounding and selling drugs.

Further, and applying the Supreme Court of Tennessee’s ruling in *Wood v Clapp* ((1856) 36 Tenn. (4 Sneed) 65), on the issue of the nature of the duty owed by professionals, the judge submitted that professionals are judged according to the standard of care required by the profession. The pharmacist is a professional, (confirmed by the state legislative provisions regulating the practice of pharmacy) who has a duty to the patient to exercise the standard of care required by the pharmacy profession in the same or similar communities as the community in which he practices his profession.

However the question to be determined was whether the duty to discover and warn patients of potential drug interactions was included within the general scope of the duties which a Tennessee pharmacist owes his or her customers. The judge considered each of the cases cited by the defendant including the decision of the Court of Appeals of Tennessee in *Laws v Johnson*, and concluded that none of the cases dealt with the situation, such as existed in the present case, where the plaintiff had produced an expert opinion that the pharmacy had breached the standard of care owed by the pharmacy to the patient.

Further the court considered the recent extension of the ‘learned intermediary doctrine’ to the pharmacist’s duty to warn under a negligence theory, in cases such as *Leesley v West*, *Ingram v Hooks* and *Eldridge v Eli Lilly*, all noted above. Judge Lewis thought that these cases could

be distinguished:

‘Here the focus is on the pharmacy’s duty to its customer. The case does not involve a relationship between the drug manufacturer and the patient or the physician and the patient. Here the question is whether the scope of the duty owed by the pharmacist to the customer includes a duty to warn. The fact that the pharmacy owes its customer a duty in dispensing prescription drugs is without question. [The defendant] simply argues that the duty to warn of potential drug interactions is not a part of its duty. The plaintiffs have introduced expert proof disputing this assertion. Therefore, whether the duty to warn of potential drug interaction is included within the pharmacist’s duty to his customer is a disputed issue of fact preventing the granting of summary judgment.’ ((1991) 805 S.W. 2d 380 at page 386)

Laizure (1992:519) notes that the decision in *Dooley* ‘has caused a veritable swivet in the pharmaceutical industry’. This decision led the Tennessee courts to join a minority of jurisdictions in rejecting the premise that the pharmacist has no duty, as a matter of law, to warn or intervene in the face of a questionable drug prescription.

However, Laizure notes one or two disquieting aspects of the judgment in *Dooley*. The affidavit produced in the case – the expert proof referred to above – indicated that the pharmacist, once aware of a possible interaction, should either call the prescribing doctor or advise the patient to be alert for side effects or to seek monitoring by the doctor. According to Laizure, because drug interactions vary greatly in clinical significance, based on the probability that they will occur and the resulting effects of the interaction, the question of when the pharmacist has a duty to intervene is raised. Further, another issue is whether the pharmacist is required to intervene each time the same interactive drugs are dispensed. These questions remained unanswered by the Tennessee court.

Further, Laizure is of the view that the professional standard of care is, by its nature, a subjective factual determination. She thinks that it is unfortunate that the *Dooley* court did not provide a definitive answer for whether the standard includes a duty to detect and warn of potential drug interactions. However she concludes that the outcome of cases like *Dooley* reflects the expanding scope of the practice of pharmacy and the expectations of both the public and the pharmacy profession that the pharmacist will take an active clinical role as health care professional.

Lewis (1992:75) argues that the decision in *Dooley* (like the decision in *Riff*) cut through the argument that avoiding pharmacist interference in the doctor-patient relationship is a valid reason for not imposing a duty to warn. Day & Marks (1991), (the authors were, incidentally, the lawyers who represented the plaintiffs in *Dooley*) discuss, in detail, the legal background to the case from a practitioner's perspective. They indicate that they distinguished the cases from all of the other jurisdictions by arguing that in all but two of these, the plaintiff had argued for a global duty to warn without giving the court the benefit of expert testimony on the issue. They had argued (successfully as it turned out) that those cases were properly dismissed because competent expert testimony was required to create a genuine issue of material fact on the issue of whether the pharmacist had a duty to warn.

Further they give detailed analysis of the arguments which they put forward on the question that imposing a duty on the pharmacist would interfere with the doctor-patient relationship. This issue was not dealt with in detail by the court itself. Day & Marks had argued that any

doctor can be held to be liable for failing to detect an error made by another doctor and such a holding does not interfere with the doctor-patient relationship. Further, and while there may be exceptions, any reasonably prudent doctor will not object to having another health care professional review his or her work. Finally, the rejection of a duty to warn would allow the profession of pharmacy to abdicate its responsibility to use a reasonable level of knowledge, training and experience to serve its patients. In turn, patients, who through their taxation support pharmacy schools and community pharmacies expect and deserve pharmacists to use their best efforts to protect them from injury:

‘Any rule of law to the contrary is nothing more than a judicial grant of immunity at the expense of individual patients, their families and society as a whole.’
(1992:116)

Williams (1992:2788) believes that the decision in *Dooley* is part of a recent shift in social policy requiring pharmacists to counsel their patients on how to minimise the adverse effects of medications. That social policy was also evident in the enactment of legislation by individual states and by the federal government on the duty to counsel. Williams submits that, as a conflict exists in the courts as to the extent of the duty to warn which should be imposed on the pharmacist, the task and challenge for pharmacy should be to resolve the issue.

The resolution offered by Williams is as follows:

‘If a pharmacist knows (or should know) of a risk, and there is a reasonably foreseeable possibility of the adverse effect occurring, then he or she must warn the patient. If there is a risk, but the pharmacist has no knowledge of it (or could

not be expected to have knowledge of it), or if the pharmacist knows (or should know) of a risk, yet harm to the patient is not reasonably foreseeable, then there is no requirement for a warning.’ (1992:2788)

Williams is also of the view that the practical burden imposed by the extension of duty may not be as great as some pharmacists might think. The extension of the duty does not require that every patient is told every fact about every drug. However he is also of the view that the change in role for pharmacists cannot be brought about by the courts alone:

‘Social change cannot be produced by the courts alone. Other institutions must respond to the judicial initiative if meaningful change is to occur. It is reasonable for practicing pharmacists and pharmacy educators, administrators and professional groups to take up the initiative that recognizes and empowers the duty to warn. Not only will the profession continue in its high level of public esteem, but the trauma of litigation will be minimized.’ (1992:2789)

Brushwood (1996:10) places *Dooley* at the beginning of a second wave of expanded duty cases against pharmacists. The first wave cases, including *Jones v Irvin* and *Eldridge v Eli Lilly* had recognized a hypothetically expansive duty for pharmacists, but with the courts refusing to impose a duty. The reason, according to Brushwood is that the mid 1980s was not an era during which the judiciary had been receptive to an expansion in liability:

‘The “malpractice crisis” (whether perceived or real), focused criticism on the judicial system as being unrestrained and unrealistic in its expectations of health care practitioners. Stung by severe criticism, judges were reluctant to expand liability during this period, because they were afraid that expansion might create another crisis and generate more criticism. The fact that pharmacotherapy had become more complex, and that pharmacists had become more responsible, mattered little. The principle of high expectations for pharmacists was often cited in legal opinions, but the result ... was to impose low expectations.’ (1996:10)

According to Brushwood, the second wave of expanded duty cases, of which *Dooley* was a good example, was responsible for taking a major step towards implementing earlier legal principles into a modern context. The second wave cases succeeded by establishing fact-based exceptions to the general rule of no duty. An expansion of pharmacist duty was the result but based on compelling facts rather than recognised principles.

Cases like *Dooley* recognised the potential for the expansion of pharmacist liability, but, in Brushwood's opinion, that had little to do with a general understanding of pharmacists and their professional relationship with patients:

'... it had more to do with an analysis of isolated incidents and the capacity of one individual to prevent harm to another. The general rule of "no-duty" persisted throughout the second wave of judicial decisions. The list of exceptions to the rule became lengthy, but the exceptions did not become the rule.' (1996:11)

A later case which had closely followed the reasoning of Brushwood's 'first wave' of expanded duty cases was that of *Fakhouri v Taylor* ((1993) 618 N.E. 2d 518). The plaintiff had brought an action for the wrongful death of a relative who had allegedly died as a result of an overdose of Imipramine, a psychiatric drug. The action was brought against the doctor who had prescribed the drug, the pharmacy at which the prescriptions for the drug were dispensed and two of the pharmacy's employees who had actually filled the prescriptions.

In the Appellate Court of Illinois, Justice O'Connor began by confirming that the issue before the court on appeal was whether pharmacists have a duty to warn their customers of prescribed dosages of medication in excess of the manufacturer's recommended limits. The

plaintiff's representatives had asked the court to distinguish the cases of *Leesley v West* and *Eldridge v Eli Lilley* on the basis that the Appellate Court of Illinois had taken a different and opposite view in *Jones v Walgreen*. As noted above, *Jones* was the most significant case, decided in the early period from 1852 to 1932, on the appropriate legal standards defining the role of pharmacists in drug distribution.

In turn, the Appellate Court of Illinois thought that the decision in *Jones* itself could be distinguished, on its facts. In *Jones* the pharmacist had difficulty in understanding the prescription in question and had filled it with a dangerous drug not indicated in the prescription. The Appellate Court in *Jones* had held that when doubt exists as to which drug is intended, a pharmacist has a duty to take all reasonable precautions to avoid filling the prescription with the wrong drug. In the case before it, Justice O'Connor stated, the plaintiff alleged that the defendants did nothing more than fill the prescriptions as ordered by the doctor.

The Appellate Court in *Fakhouri* agreed with the conclusions reached in *Leesley* and *Eldridge*:

'Determining which medication is to be utilised in any given case requires an individualized medical judgment, which, in our opinion, only the patient's physician can provide. That physician, having prescribed the drug, presumably knows the patient's current condition, as well as the patient's complete medical history. To impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship, *without* the physician's knowledge of the patient. Furthermore, ... the duty of the manufacturer runs to the physician and not to the patient ... Therefore, it is illogical and unreasonable to impose a greater duty on the pharmacist who properly fills a prescription than is imposed on the drug's manufacturer.'
(1993) 618 N.E. 2d 518 at page 521)

Similarly, the Appellate Court could not support the contention that the legislative provisions relating to the administration of the pharmacy profession in Illinois supported the imposition of the duty advocated by the plaintiff. The court in *Eldridge* had rejected such a contention and so would this court.

As noted above, Brushwood (1996:9) is of the view that the decision in *Fakhouri*, like that in *Eldridge* and *Jones v Irvin*, was typical of the ‘first wave’ of expanded duty cases brought against pharmacists – recognizing a supposed expansive duty for pharmacists but refusing to impose it in practice.

In *Kintigh v Abbott Pharmacy and others* ((1993 503 N.W. 2d 657), the plaintiff had a chronic chemical dependency, and over a number of years had consumed vast amounts of codeine medications from the defendants, who were twelve pharmacies and twenty-two individual pharmacists. In his complaint, he alleged that each of the pharmacists dispensed the addictive substances in violation of several specific control requirements of statutes, administrative regulations, and published ethical standards. As a result, he alleged that he developed and furthered a dependency and addiction to codeine and other controlled substances.

Before the Court of Appeals of Michigan, the majority (Judge Weaver, Judge Michael and Judge Kelly) were quickly and easily able to dispose of the issue:

‘Plaintiff asserts that the pharmacists owed him a duty to refrain from dispensing to him ... nonprescription controlled substances. We disagree. The claim is so clearly unenforceable as a matter of law that no factual development could possibly justify a right of recovery ... This Court has previously rejected the theory that a pharmacist owes a customer a legal duty to monitor drug usage, *Adkins v Mong* ... We find the pharmacists owed no duty to plaintiff to discover his addicted status; failing knowledge of that, they had no duty to refuse to sell to him. ((1993 503 N.W. 2d 657 at page 658)

Interestingly, a more detailed and comprehensive dissenting judgment was delivered. Judge Shelton, after reviewing the elements of an action in negligence, and the legislative controls which were exercised over the sale of controlled substances, turned to the nature of the duty which is owed by pharmacists to their patients:

‘... they owe a duty of care imposed upon them by the nature of their relationship with their patient. The patient who comes to a pharmacist for ... controlled substance is there for care and is there because our law provides that the only place the patient can obtain care in that form is from a licensed pharmacist. When the law bestows such a monopoly of care on a health professional, public policy and the common law require that the professional exercise that entrusted responsibility with the care common to the profession and be responsible for the consequences of a failure to do so. ((1993 503 N.W. 2d 657 at page 662)

The judge thought that the majority’s reliance on the ruling in *Adkins v Mong* was ‘cavalier’. He submits that *Adkins* did not involve a blanket rejection of the theory that a pharmacist owes the customer a legal duty to monitor drug usage. *Adkins* was concerned with prescription medications and the court had held that the doctor stands as the ‘gatekeeper’ between the patient and medically necessary, but potentially harmful, drugs. For Judge

Shelton, where the case, as the one before him, involved controlled substances, only the pharmacist could stand as ‘gatekeeper’ between the patient and such potentially harmful drugs:

‘The holding of *Adkins* is indeed consistent with a finding that the entrustment of the “gatekeeping” power carries with it a duty of reasonable care. With regard to [controlled] substances, if this Court does not recognize a duty of care by the pharmacist to the patient, then no one in the health care system will have any responsibility to the patient for the distribution of such addictive chemicals.’ ((1993 503 N.W. 2d 657 at page 662)

Brushwood (1996:11) states that:

‘Beginning in 1994, a third wave of expanded duty cases against pharmacists began to reject the no-duty rule developed by the first wave cases and continued (with exceptions) by the second wave cases. This rejection of prior case law was based on the recognition of a new principle of pharmacist duty. It was not based on factual exceptions to a general rule of no duty. In developing this new approach to pharmacist duty, the third wave cases have clearly distinguished themselves from the second-wave cases. They adopted a rationale virtually identical to the original approach to pharmacist duty from the earliest days of American jurisprudence. Under the rationale of the third-wave cases, a pharmacist is recognized as having a relationship of trust with patients to whom medications are dispensed. Within this relationship, a pharmacist is expected to use the level of care warranted by the circumstances.’

The first of these ‘third-wave’ cases is *Hook’s Superx Inc v McLaughlin* ((1994) 642 N.E. 2d 514). In *Hook’s* the Supreme Court of Indiana established that when a patient is having a prescription for a potentially addictive drug refilled at an unreasonably faster rate than that prescribed, the pharmacist has a duty to exercise professional judgment and to cease refilling the prescription pending direct and explicit directions from the prescribing doctor.

The plaintiff (and his wife for themselves and on behalf of their two children) brought an action against the defendant pharmacy under the theory that the pharmacy had breached its duty of care by failing to stop filling the prescriptions because the pharmacists knew or should have known that the plaintiff was consuming the drugs so frequently that it posed a threat to his health. The Indiana Court of Appeals ((1994) 632 N.E. 2d 365) concluded that no duty existed and that imposition of a duty on pharmacists to monitor drug therapy would be contrary to public policy because it would undermine the physician-patient relationship. Brushwood (1991:10-11) submits that the decision of the Court of Appeals in *Hooks*, like that in *Dooley v Everett*, recognised the potential for expanded pharmacist liability, although the general rule of 'no duty' persisted.

However *Hooks* did not end there. On appeal to the Supreme Court of Indiana, the most important issue was whether pharmacists are under a duty to refuse to fill validly-issued prescriptions that pose a threat to the welfare of the patient.. On the question of the existence of the duty - the more important question - the court followed its previous policy of using a three part analysis to determine the issue; namely, the relationship between the parties, the foreseeability of harm and public policy issues. Each of these three factors was considered important in determining whether to expand pharmacist duties as a matter of law. In essence, the court reasoned that it would not make good legal precedent to expand pharmacist duties to include the duty to monitor and intervene if the relationship between pharmacist and patient is not of the kind that should give rise to an expanded duty, if harm to the patient is not reasonably foreseeable to a pharmacist, or if public policy concerns (such as health care costs and patient confidence in physicians) militate against recognising such an expanded duty.

On the issue of relationship, the court reaffirmed that it is well established that the law recognizes that the relationship between the pharmacist and customer is one which gives rise to a duty under traditional order-processing circumstances, such as liability for dispensing the wrong medicine or imposing a requirement that the pharmacist inform the patient of warnings included in the prescription. In these circumstances the pharmacist was under a duty to follow the prescriber's instructions as written in the prescription. The court also determined that the relationship between the pharmacist and customer is a direct contractually-based one independent of the doctor and patient relationship. Pharmacists possess expertise regarding the dispensing of prescription drugs, and reliance is placed on them by customers for that expertise. All of these factors were sufficient for the court to conclude that the relationship between pharmacist and patient is sufficiently close to justify imposing a duty on pharmacists to monitor drug use and intervene when a problem becomes evident. Thus, the court ruled that it would be good legal precedent to require that one who has knowledge use that knowledge for the benefit of one who lacks the knowledge. This sort of dependency-responsibility relationship is one justification for expanding pharmacists' duties.

Turning to the factor of foreseeability, the court determined that it was not disputed that an individual who consumes sufficient quantities of addictive substances may become addicted to them and that such an addiction carries with it certain foreseeable consequences. As such the court was satisfied that, for the purposes of determining whether a duty exists, the risk of the plaintiff's addiction was foreseeable from the series of events which took place. Under the court's analysis, it would be good legal precedent to require that one who can anticipate harm to another intervene to prevent that harm. Thus, the ability of pharmacists to predict bad outcomes

from drug therapy is a second justification for expanding pharmacists' duties.

The final factor to be considered in determining the existence of a duty on the part of the pharmacist was that of public policy. The court considered three policy considerations to be at stake - preventing intentional and unintentional drug abuse, not jeopardizing the doctor/patient relationship and avoiding unnecessary health care costs. The purpose of these considerations was to determine whether public policy should, or should not, favour the recognition of a duty for pharmacists.

On the first issue the court determined that there are a variety of explanations why a pharmacy customer might have a prescription for a dangerous drug filled at a rate unreasonably faster than that prescribed; of which the development of an addiction to the drug or the improper disposal of the drug were two. Both of these explanations give rise to a strong public policy interest in preventing intentional and unintentional drug abuse. That public policy interest was reflected in the enactments of the state legislature. For example, the Indiana Code empowered a pharmacist to exercise professional judgment and refuse to honour a prescription where he believed in good faith that honouring the prescription might aid or abet an addiction or habit. This demonstrated that public policy concerns about proper dispensing of prescription drugs and preventing drug addiction might be paramount to policy concerns about interfering with the doctor-patient relationship. A doctor-patient relationship that is causing a drug addiction or diversion needs to be interfered with.

The court confirmed that the responsibility for warning patients about drug side effects lies with doctors. However the court reasoned that the imposition of a duty to cease filling prescriptions in certain circumstances would not lead to the development of an adverse relationship between the pharmacist and doctor for three reasons - first, the pharmacist possessed the power through statute; second, doctors remained ultimately responsible for the proper prescription of medication and recognition of a duty on the part of pharmacists would not replace the doctor's obligation to evaluate a patient's needs; finally, the recognition of a legal duty would encourage pharmacists and doctors to work together in considering the best interests of their customers and patients.

A final public policy concern related to the possibility of an increase in health care costs if a duty were to be imposed on pharmacists. If health care costs were to rise as the result of recognizing an expanded duty for pharmacists then public policy might not favour the recognition of such a duty. The defendant had argued that recognition of the expanded duty would require pharmacies to buy expensive new technologies, thus driving up the cost of health care.

The fact that there was evidence that the defendant pharmacy operated a computer-based information system which revealed the plaintiff's entire prescription history on screen at each new prescription or refill, negated the argument that the imposition of the duty further increased health care costs. The costs for computerization of the pharmacy had already been incurred and would not increase with the recognition of a pharmacist duty. Thus the public policy of holding down health care costs was not at odds with recognition of the duty.

The court concluded that consideration of the three relevant factors of relationship, foreseeability and public policy were convincing in the imposition of a duty on the pharmacist. Having determined the existence of that duty, the court had to determine the appropriate standard of care to be applied. In this regard, the court could see no reason why the traditional negligence standard should not be applied. This would mean that the pharmacist must take the degree of care that an ordinarily prudent pharmacist would exercise under the same or similar circumstances. What would amount to due care would be a question of fact to be determined under the circumstances of each case. However issues to be considered would include the frequency with which the pharmacist filled prescriptions for the customer, any representations made by the customer, the pharmacist's access to historical data about the customer and the manner in which the prescription was tendered.

The court was quick to make clear that the imposition of this standard did not mean that the filling of prescriptions faster than prescribed did not necessarily amount to a breach of a duty. There were circumstances in which it would be prudent for a pharmacist to refill a prescription faster than prescribed, for example in the days following surgery. However those circumstances would be rare and would be easily identifiable by a skilled pharmacist. The court was also anxious to emphasize that pharmacists were not to be regarded as insurers against a customer becoming addicted to medication legally prescribed by doctors. Good outcomes need not be guaranteed, but best efforts are absolutely required.

Mullan and Brushwood (1996:310) indicate that the ruling in this case makes it clear that a valid prescription is not sufficient in itself to permit a pharmacist to argue successfully that all responsibilities to the patient have been met by accurately filling that prescription. Just as

pharmacists have a duty to detect invalid prescriptions and to intervene to prevent their being filled, pharmacists have a duty to detect valid prescriptions that pose a threat to patient welfare and to intervene to protect the patient from such prescriptions. The pharmacist's duty to the patient is independent of the doctor's duty to the patient. Pharmacists are primary health care providers who must do what is right for patients because public policy weighs heavily in favour of an actively patient-oriented pharmacy profession.

Pharmacists should decide what is appropriate on the basis of what they know of a patient's medication use and what they know about the effects of medications when used in the way the patient is using them. This is the foreseeability test relied on by the court in the present case. Often the pharmacist will be the only health care professional who knows of a potential problem, because it may be only the refill pattern that enables one to know.

The outcome of the case helps to clarify pharmacists' duties in the dispensing of controlled substances. The earlier Indiana Court of Appeals opinion, had held that the defendant pharmacy had met its duty to the patient by asking the prescriber about the appropriateness of the therapy. While the Supreme Court opinion does not discuss the single telephone call by the pharmacy to the prescriber during the several months of propoxyphene use by the patient, the opinion indicates that this single telephone call was considered to be insufficient to meet the pharmacy's obligations.

As we shall see in the next chapter, the requirement for prospective drug-use review under the Omnibus Budget Reconciliation Act of 1990 reinforces this approach to drug therapy. Under a federal mandate, most states have promulgated rules that require pharmacists to review patient

records for evidence suggesting drug abuse or misuse. This requirement has been made applicable to both new and refill prescriptions in some states, while in other states the language is ambiguous as to whether refills are included. The result of *Hooks* makes it clear that monitoring of refills is a duty of pharmacists, and that failure to do so exposes pharmacists to liability.

A parallel third-wave ruling was issued by the Arizona Court of Appeals in *Lasley v Shrake's Country Club Pharmacy* ((1994) 880 P.2d 1129). The plaintiff had been treated by his doctor for a period of 30 years for clinical depression, the treatment including the regular issue of prescriptions for Doriden and codeine. All of the prescriptions were dispensed by the defendant pharmacists. The plaintiff alleged that the defendants had breached a duty to exercise the degree of care, skill and learning expected of reasonable prudent pharmacies and pharmacists in the profession. The allegation added that the standard of care for a pharmacist includes obligations to advise a customer of the highly addictive nature of a prescribed drug and of the hazards of ingesting two or more drugs that adversely interact with one another. The plaintiff added that a pharmacist should advise the prescribing doctor if it appears that the patient is taking an addictive drug in quantities inconsistent with the manufacturer's recommended dosage guidelines.

In the Court of Appeals of Arizona, Presiding Judge McGregor began by analysing the components of a negligence action. Turning to the specific issue raised by the appeal, the judge noted that the Arizona courts had not considered whether the scope of a pharmacist's duty of reasonable care includes an obligation to warn patients of possible adverse effects of prescribed medications. However other jurisdictions had done so, and the judge took the opportunity to review the existing jurisprudence. He thought that two distinct approaches had emerged.

Some courts, as evidenced by the cases of *Leesley v West*, *Ingram v Hook's Drugs Inc*, and *Stebbins v Concord Wrigley Drugs*, had held that no duty to warn of possible side effects exists, as to impose such a duty would place the pharmacist between the doctor, who knows the patient's physical condition, and the patient and would interfere with the doctor-patient relationship. Other courts, as evidenced by the cases of *Jones v Irvin*, *Pysz v Henry's Drug Store*, *Fakhouri v Taylor*, *Eldridge v Eli Lilley*, *Adkins v Mong* and *McKee v American Home Products*, had held that pharmacists have no duty to warn the patient or the doctor where the doctor prescribes excessive dosages of a drug, on the basis that the doctor, not the pharmacist, has the duty to prescribe drugs properly and to warn the patient of any dangers from taking the medication. Imposing a duty on pharmacists would compel them to second guess every prescription doctors write if the pharmacists wished to escape liability.

The Court of Appeals of Arizona rejected the analysis relied on in these cases, arguing that the existence of a duty could not be determined on the basis of the specific facts of a situation:

'It is better to reserve 'duty' for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal; standard of what is required to meet the obligation. In other words, 'duty' is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty [if it exists] is always the same – to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty'((1994) 880 P.2d 1129 at page 1132)

The court preferred the reasoning in *Dooley v Everett*, *Hand v Krawoski* and *Riff v Morgan*

Pharmacy. On the basis of these decisions, the court could not say, as a matter of law, that the defendant did not breach the standard of care for the duty which it owed to the plaintiff. It had earlier established that standard as higher than that of the ordinary prudent person, arguing that health care providers and other professionals are held to a higher standard when the alleged negligence involves the defendant's area of expertise. As such the case would have to be remitted to the lower court for further deliberation.

Cruz (1995) has argued that criticism of the reasoning in the case for injecting an element of uncertainty into the already confused area of negligence by unnecessarily broadening the definition of duty, is unfounded, because the model advocated in *Lasley*, and alternative models, are based on misinterpretations of legal treatises describing the concept of duty. Further, Cruz is of the view that case specific conduct is not the only factor which the courts will use in determining liability. Other factors, such as the public policy objectives in lowering health care costs and ensuring patient safety, will continue to play a part in the determination of whether a duty exists or not. As clinical pharmacy services, including periodic counselling and review of a patient's drug treatment, do actually reduce health care costs, courts may be convinced by such evidence to find for a legal duty to warn.

Cruz also submits that the court in *Lasley* failed to recognise that these cases can be distinguished by ascertaining the specific objective in patient counselling. Drawing on the work of Brushwood, Cruz submits that patient counselling can be either risk management or risk assessment. In risk management the pharmacist (or doctor) instructs the patient on the proper use of the prescribed medication and provides drug specific information as to common adverse reactions and

dangerous interactions with other drugs. In risk assessment, on the other hand, the doctor is solely responsible for involving the patient in the selection of a drug or treatment. As risk management is generally accepted to be one of the pharmacist's responsibilities, and as the claims of lack of warning (counselling on drug usage or alerting to the dangerous propensities of Doriden or codeine) in *Lasley* could be considered to be risk management claims, the case could have been decided on that basis. Alternatively, if the claim could be classified as risk assessment (failure to advise the plaintiff to terminate the treatment or refusal to fill the prescription), the appeal could have been dealt with that on that basis.

In *Pittman v The Upjohn Company*, ((1994) 890 S.W. 2d 425) an action was brought on behalf of the plaintiff who had sustained permanent brain damage after taking medication prescribed for a relative in the mistaken belief that it was a different drug. The action was taken against the drug's manufacturer, the prescribing doctor and the pharmacy where the prescription had been filled. It was alleged that each of the defendants had a duty to warn of the dangerous properties of the prescribed drug and the potential deadly consequences of its being consumed by someone other than the person for whom it was prescribed. The judgment of the Tennessee Court of Appeals examined the liability of each of these defendants in turn.

In its discussion of the manufacturer's liability, the court recognised that drug manufacturers have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products. This included a requirement to market and distribute the

products in a way which minimised the risk or danger. However the court also recognised that under the "learned intermediary doctrine" the manufacturer of an unavoidably risky prescription drug has no duty to warn patients directly and can fully discharge its duty to warn by providing the doctor with adequate warnings of the risks associated with the use of its drug. The question of the adequacy of a warning was one of fact to be decided in accordance with certain criteria.

The package insert provided by the manufacturers of the prescribed drug, Micronase, contained the following warning:

Information for Patients: Patients should be informed of the potential risks and advantages of Micronase and of alternative modes of therapy. . .The risks of hypoglycaemia, its symptoms and treatment and conditions that predispose to its development should be explained to patients and responsible family members.

On the basis of this and other information in the package insert, the court concluded that the manufacturer's warning to the doctor and the pharmacist was sufficient to refute the plaintiff's assertion that the manufacturer's warning was inadequate.

The court then considered the allegations against the doctor. The doctor contended that there could be no duty to the plaintiff because the plaintiff was not a patient of the doctor. The court noted that while the doctor-patient relationship is an essential element of a medical malpractice action, a doctor may owe a duty to a non-patient for injuries caused by the doctor's negligence if the injuries were reasonably foreseeable. An example was given of how a doctor might have a duty to warn members of the family of a patient who has an infectious disease that they are at risk of contracting the disease because transmission of the organism is reasonably foreseeable. Were

the plaintiff, non-patient's injuries foreseeable in the present case?

The question was framed in terms of the likelihood that an adult houseguest of the doctor's patient would take the prescribed drug accidentally. If a reasonable person could foresee this as a possibility then the law would impose a duty of reasonable care, care commensurate with the risk. The court concluded that the circumstances of the case did not support the plaintiff's insistence that he was among the persons likely to be harmed and was therefore entitled to protection at the hands of the doctor. Consequently, the doctor's duty to warn did not extend to the plaintiff because of the absence of a patient-doctor relationship and the lack of foreseeability of harm to him. The pharmacy had two main arguments in its defence. It agreed with the doctor's argument that it owed no duty to a non-patient who improperly used a drug dispensed by it and also that it had fulfilled the only duty owed to its patient by filling the prescription according to the doctor's order. The court's response to these arguments was that if the only duty owed by the pharmacy were to fill the prescription correctly then there would be no duty owed to a non-patient because, obviously, the pharmacy would have no higher duty to a non-patient than to a patient. However the court stated that a pharmacist is a professional who has a duty to his or her patients to exercise the standard of care required by the pharmacy profession in the same or similar communities in which the pharmacist practices. The court noted that the increased complexity of pharmacotherapeutics and accompanying adverse drug reactions and drug interactions have resulted in an expanded role for pharmacists as drug therapy counsellors. The court also observed a trend towards patient-oriented clinical pharmacy practice.

As for the pharmacy's duty to the patient, the court concluded:

The record shows that the duty owed [the patient] was greater than merely filling the physician's prescription correctly. As indicated by the evidence in the record, Micronase posed a danger to [the patient] even if taken according to the physician's order. The pharmacy customer was not aware of that danger because she had not been advised by either the physician, who prescribed the unavoidably unsafe drug or the pharmacy which dispensed the drug. A significant factor affecting the pharmacy's duty was the knowledge that no warning had been given by the physician. Under these circumstances, it was reasonably foreseeable that [the patient] was at risk of injury. Consequently the pharmacy, as well as the physician, owed her the duty to warn. ((1994) 890 S.W. 2d 425 at 435)

Thus, the court rejected the pharmacy's argument that its only duty was correctly to process the prescription.

Having established that the pharmacy had a duty to warn the patient, the court had to consider whether this duty extended to the plaintiff who was not a patient. The court adopted the same rationale towards the pharmacy that it had toward the doctor because the dangers posed by glyburide were equally foreseeable by the doctor and the pharmacist. Consequently the duty to the patient did not extend to the non-patient because of the lack of foreseeability of the harm that occurred.

As has been seen, in a number of recent cases, the courts have held that pharmacists have a duty to patients beyond technical accuracy in prescription processing. The decision in *Pittman* continues that trend but is exceptional in that the court clearly understood the responsibilities shared by the medical and pharmacy professions in drug therapy and presented a carefully considered analysis of the arguments for and against pharmacist liability for failure to warn a

patient about the potential adverse effects of a dispensed medication. It is also the only decision to have considered thoroughly the responsibilities of the pharmaceutical manufacturer, the prescribing practitioner and the pharmacist together in one concise piece of analysis.

Of particular interest was the court's reference to the "information for patients" section of the package insert. The conclusion is that where such a section is included in a package insert, the doctor and pharmacist ignore it at their peril. In addition, the fact that the patient had not been warned about potential problems by the doctor was a significant factor affecting the pharmacist's duty. It reinforces the view that liability need not stop when the prescription leaves the hands of the doctor, even when the doctor has been negligent. It may extend into and be the cause of the negligence of others. Harm to the patient was judged to be just as foreseeable by the pharmacist as it was by the doctor. Finally it was of interest that the court referred to the standards of practice adopted in the profession. Once the appropriate standard had been identified the court was persuaded that the defendant pharmacy should have done more to prevent possible harm to the patient.

However this judicial acknowledgement of development of pharmacist responsibility is subject to a number of limitations. First, if a pharmacist provides the same or equivalent information to that contained in the "information for patients" section of a package insert then it is arguable that he or she has complied with the appropriate standard and has met his or her responsibility. Second, in this case the doctor had not counselled the patient and this fact increased the pharmacist's exposure to liability. Had the doctor counselled the patient and had the pharmacist known of this, then the pharmacist's exposure to liability would have been reduced. Third the comparison with

another pharmacy showed that the defendant pharmacy in this case was doing less than that pharmacy. Had the evidence shown that the defendant pharmacy was doing more than expected then that pharmacist's liability exposure would have diminished based on the comparison. The existence of a professional standard expands liability for those who practice below it but it limits liability for those who practice above it. Finally the decision of the Supreme Court of Tennessee is of binding authority in that state alone although it certainly applies as persuasive authority in others.

One of the most interesting, and surprising, recent cases regarding the pharmacist's expanded duty is the case of *Baker v. Arbor Drugs, Inc.*((1996) 544 N.W. 2d 727). Decided by the Court of Appeals of Michigan in early 1996, the Baker case departed from a clear line of precedent in the Michigan appellate courts. As noted above, in *Troppe v Scarf*, *Stebbins v Concord Wrigley Drugs Inc.*, *Adkins v Mong*, *Kintigh v Abbott Pharmacy*, all decided prior to *Baker*, courts in Michigan had been reluctant to recognize expanded responsibilities for pharmacists. While the pharmacist's duty to process prescriptions correctly was clear, Michigan courts had held that pharmacists had no duty to warn the patient of possible side effects of a medication or to monitor drug usage. The *Baker* opinion adopted a very different perspective on the issue.

In *Baker* the plaintiff had suffered a stroke and died after taking a prescribed medication which had interacted with another prescribed drug product which the plaintiff was already taking. A computer at the pharmacy where the plaintiff had his prescriptions dispensed detected a potential interaction between the previously prescribed tranycypromine and the newly

prescribed phenylpropanolamine. However, a pharmacy technician overrode the computer prompt, and a pharmacist filled the prescription without becoming aware that the patient was also using a drug with which the prescribed drug could interact.

Since the case arose in Michigan, there was reason to believe that the judiciary would hold that no pharmacist owes a patient any duty other than that of technical accuracy. Because of the prior Michigan case law, this case might have been one in which the appellate court would rule in favour of the defense on the “no duty” issue. However, statements made by the defendant pharmacy in their commercial advertising were of such significance that they altered the factual basis of the plaintiff’s claim and produced an unexpected result.

The defendant pharmacy had advertised that its computer system was designed in part to detect harmful drug interactions such as the one that led to Baker’s death. For example, one advertisement said:

“Do you know what happens when you bring your prescription to Arbor Drugs? First, it’s checked for insurance coverage and screened for possible drug interactions and therapeutic duplication. That’s done very quickly by the Arbortech Plus computer. Then your prescription is filled and labeled. That’s done very carefully, by your Arbor pharmacist. The bottom line? Your prescription is not just filled quickly, it’s filled safely. Only at the Arbor Pharmacies. You can’t get any better.”

Despite providing this assurance in its advertising, the defendant did not prevent the plaintiff’s drug interaction. The available technology was not used correctly, because the pharmacy technician overrode the interaction indicated on the computer.

In reversing summary judgment granted in favour of the defendant pharmacy by the trial court, the Michigan Court of Appeals held that the pharmacy “voluntarily assumed a duty to utilize the Arbortech Plus computer technology with due care.” (1996) 544 N.W. 2d 727 at page 731)

Citing prior case law for the precedent that a defendant can be held liable when it voluntarily assumes a function that it was under no legal obligation to assume, the court thus expanded pharmacist responsibilities in Michigan, beyond technical accuracy to include drug therapy monitoring with the assistance of computer systems.

In *Harco Drugs, Inc. v. Holloway*, ((1995) 669 S.R. 2d 878), the Supreme Court of Alabama affirmed a jury verdict against a pharmacy, based on the plaintiff’s allegation that the pharmacy had failed to initiate sufficient institutional controls over the manner in which prescriptions were filled. The court ruled that the jury could properly have concluded that the pharmacy had acted with reckless disregard for the safety of others. The plaintiff had received three incorrect refills of a prescription drug after a pharmacist had entered the name of the wrong drug into the plaintiff’s computerised pharmacy record.

On appeal, the key issue was the appropriateness of punitive damages, and the legal conclusion that the defendant pharmacy had acted “wantonly” toward the plaintiff. There are two general classes of damages that are awarded in a pharmacist malpractice case: compensatory damages and punitive damages. Compensatory damages are intended to restore a harmed person to the position they would have been in had the defendant not caused the person harm. A finding of carelessness or inattentiveness or sloppiness supports an award of compensatory damages. Under

the law, a person whose carelessness harms another must compensate the victim for the results of the carelessness. On the other hand, a person who has engaged in wanton misconduct must pay additional punitive damages, the purpose of which is to punish the one who does the harm, rather than to compensate the one to whom the harm is done.

“Wantonness” is defined in Alabama, and in most other jurisdictions, as “conduct which is carried on with a recklessness or conscious disregard of the rights or safety of others.” The standard of conscious disregard requires that one have knowledge that one’s conduct is causing harm, and that one does nothing to prevent the harm that one knows is occurring. It is this higher level of culpability, for knowingly causing harm, that warrants the imposition of punitive damages.

With this standard in mind, the Supreme Court of Alabama noted that the pharmacy’s management had evidence of numerous incidents of incorrectly filled prescriptions; however, it failed to share this information with the stores in the chain. The jury could have inferred, said the court, that although the incident reports were in the possession of the pharmacy, the pharmacy did not see fit to disseminate the information to all of its pharmacists as a matter of course, despite undisputed testimony that a misfilled prescription could be fatal. Instead of providing this information to all of its stores, a company representative merely encouraged the pharmacists once a year to “be careful.”

The court noted that, given knowledge on the company’s part that misfilling a prescription could be fatal, the jury could have found that there was a reckless disregard on the company’s part for

the safety of its customers in not disseminating the information to all the pharmacists in the chain.

In addition, the court pointed to the failure by the company to use supportive personnel to look at prescriptions in order to make sure that the prescriptions were being filled correctly. The company had conceded that having two people, a pharmacist and a clerk, look at a prescription would reduce the chances of making a mistake in filling that prescription. The company felt, however, that it would cost too much to adopt such a policy. Based on this review of the evidence, the court concluded that the jury could have properly determined that the company had acted wantonly in connection with its handling of its pharmacies. The jury verdict for punitive as well as compensatory damages was upheld in a majority opinion agreed to by five of eight justices.

In a vigorous dissenting opinion, three of eight justices explained why they would have overruled the punitive damages judgment. This minority view disclosed a version of the facts of the case that was distinct from the facts as described in the majority opinion. According to the minority opinion, the incident reports upon which the plaintiff relied in support of her argument had all been sent to the company's director of pharmacy operations for review. The director of pharmacy operations testified that he reviewed each report and counseled any pharmacist who misfilled a prescription as reflected in an incident report. Occasionally a pharmacist would be transferred to a store with less volume if the company believed that the pharmacist could perform better in a low-volume store. The company had terminated the employment of some pharmacists who it believed could not perform their duties.

In addition, the dissenters pointed out that the plaintiff had relied heavily on the fact that the company management had considered the implementation of a policy of having clerical workers verify prescriptions, but had rejected the idea. Yet, the director of pharmacy operations had testified that the use of supportive personnel for this purpose was discretionary with the pharmacists. While the use of supportive personnel to check the accuracy of pharmacists was not expressly required, it was not forbidden. The dissenters disagreed with the majority's opinion that the company's decision not to require a clerical worker to inspect the work of a professionally trained and licensed pharmacist could constitute wantonness. Nevertheless, although the minority dissenting opinion did not support the award of punitive damages, the rationale of the majority opinion resulted in affirmation of the punitive damages verdict.

On reconsideration, the Supreme Court of Alabama endorsed all of its previous holdings regarding the failure to maintain institutional controls. However, the new opinion clarifies the responsibility of an individual pharmacist when the pharmacist is presented with a prescription that is difficult to interpret:

'We believe that a prescription from an oncologist that a pharmacist believes to call for Tambocor, a heart medication used by cardiologists to treat arrhythmias or serious heart ailments, should cause her grave concern and necessarily prompt further inquiry. The extreme unusualness of a prescription from a cancer specialist supposedly calling for a dangerous heart medication, combined with the alleged illegibility of the prescription, is sufficient evidence of a reckless disregard of the safety of others to create a jury question as to whether [the pharmacy] acted wantonly. A jury could infer that [the pharmacy's] actions under those circumstances rose to the level of a conscious disregard for the safety of [the patient]. ((1995) 669 S.R. 2d 878)

In *Cafarelle v Brockton Oaks CVS, Inc* (Mass. Sup. Ct.No. 94-0414A, April 1996), an action was

brought by the parents of a thirteen year old girl, who had died from respiratory failure associated with a severe asthma condition which she had since infancy, against the defendant pharmacy. The plaintiffs alleged that the pharmacy negligently filled prescriptions by supplying medication to their deceased daughter, at a rate faster than that prescribed. They also alleged that the defendant should have refused to fill the prescriptions before the normal time and should have warned their daughter, her parents, or her doctor, that their daughter was overusing the prescribed medication and that such overuse was potentially dangerous. They further alleged that the defendant's conduct caused their daughter's death. The defendants claimed that, as a matter of law, they only had a duty accurately to fill the prescriptions and that they had no affirmative duty to warn of the dangers associated with overusing the prescription drug medication.

Justice Brady began his analysis of the legal arguments by noting that there were no Massachusetts cases on the issue of the nature of the duty owed by pharmacists to their customers. However he could receive assistance from a number of other state and federal court decisions on this, and similar issues.

The judge began by confirming that the general rule is that a pharmacist owes his customers 'a duty of ordinary care to conduct his business as an ordinary skilful pharmacist would under similar circumstances'. Because the drug distribution was inherently dangerous, due care for a pharmacist required the highest degree of prudence, thoughtfulness, vigilance, and exact and reliable safeguards. What the judge now wished to analyse was the issue of what constituted due care for a pharmacist.

Justice Brady began that analysis by categorising a number of different duties which were owed by pharmacists. The first of these was the duty to warn. The judge noted that the issue of whether a pharmacist owed a duty to warn customers of the potential dangers associate with prescribed medication was relatively new. Despite this, the judge analysed a comprehensive series of cases on the issue including *Fuhs v Barber* 140 Kan. 373, 36 P.2d 962 (1934), *Krueger v Knutson* 261 Minn 144, 111 N.W. 2d 526 (1961)), *Batiste v American Home Products Corp.* 32 N.C. App 1, 231 S.E. 2d 268 (1977), *Bichler v Willing* 397 N.Y.S. 2d 57 (1977), *McLeod v W.S. Merrell. Co.* 174 So. 736 (Fla. 1965), *Hand v Krakowski* 453 N.Y.S. 2d. 121 (1982), *Perkins v Windsor Hospital Corporation* 142 Vt. 305, 455 A.2d 810 (1982), *Psyz v Henry's Drug Store* (457 So. 2d 561 (Fla. Dist. Ct. App. 1984), *Jones v Irwin* (S.D. Ill. 1985), *Ingram v Hook's Drugs. Inc.* (476 N.E. 2d 881, Ind. Ct. App. 1985) *Riff v Morgan Pharmacy* (353 Pa. Super. 21, 508 A.2d 1247, 1252 (1986)), *Raynor v Richardson-Merrell. Inc.* 643 F. Supp. 238 (D.D.C. 1986), *Ealy v Richardson-Merrell Inc.* (Prod. Liab. Rep. (CCH) 11, 235 (D.D.C. 1987), *Makripodis v Merrell-Dow Pharmaceuticals. Inc.* (362 Pa. Super. 589, 523 A. 2d 374 (1987)), *Stebbins v Concord Wrigley Drugs. Inc.* (164 Mich. Apps. 204, 416 N.W. 2d 381 (1987)), *Adkins v Mong* (168 Mich. App. 726, 425 N.W. 2d 151 (1988)), *Ferguson v Williams* (92 N.C. App. 336, 341, 374 S.E. 2d. 438, 440 (1988)), *Frye v Medicare-Glaser Corp.* (219 Ill. App. 3d 931, 579 N.E. 2d 1255 (1991), *McKee v American Home Products* (113 Wash. 2d 701, 782 P.2d 1045(1989)), *Dooley v Everett* (805 S.W. 2d 380 (Tenn Ct. App. 1991)), *Pittman v Upjohn* (890 S.W. 2d 425 (Tenn. 1994)), and *Lasley v Shrake's Country Club Pharmacy Inc.*(179 Ariz. 583, 880 p.2d 1129 (1994).

Judge Brady also examined the caselaw relevant to three other categories of pharmacist duty – the duty to refuse to fill prescriptions, the duty to monitor customer’s prescriptions, and the duty in respect to filling a prescription faster than that prescribed. In relation to the first category, the judge noted that most courts had held that a pharmacist has a duty accurately to fill a legal prescription, while accepting that there may be times when a pharmacist feels that it is in the customer’s best interests not to fill the prescription. The judge thought that where doses prescribed are unusual, inquiry should be made to ascertain that there has been no error. However the judge did note the decision in *Eldridge v Eli Lilly* (138 Ill. App. 3d 124, 485 N.E. 2d 551 (1985)), where the court ruled that a pharmacist has no common law or statutory duty to refuse to fill a prescription simply because it is for a quantity beyond that normally prescribed or to warn the doctor of that fact.

In relation to the second category of case, the duty to monitor customer’s prescriptions, the judge reviewed the cases of *Kampe v Howard Stark Professional Pharmacy Inc.*, (841 S.W. 2d 223 (Mo. Ct. App. 1992)) and *Walker v Jack Eckerd Corp.*, (209 Ga. App. 517, 434 S.E. 2d 63 (1993)), finding that both cases had found that a pharmacist has no duty to warn the patient or notify the doctor that a drug is being prescribed in a dangerous amount, that the patient is being over-medicated or that various drugs in prescribed quantities could cause adverse reactions to the patient. These duties were part of the doctor’s responsibilities.

Hook’s Superx. Inc v McLaughlin (642 N.E. 2d 514 (Ind. 1994)), was, in the judge’s submission, an example of a case where the court’s finding that the pharmacist has a duty to monitor a patient’s acquisition of excessive medication and that the refusal to continue to refill a

prescription when presented with evidence of excessive consumption would not create an adversarial relationship between doctors and pharmacists would help to encourage greater cooperation between pharmacists and doctors to work in the best interests of their patients.

Support for the finding in *Hooks* could be found in the case of *Speer v United States* (512 F. Supp. 670 (N.D. Tex. 1981)) where the court had also held that the pharmacy had breached its duty to monitor the refills of the patient's prescriptions to ensure that the patient did not obtain excessive quantities of the subject drugs. The court had noted that the frequency of the refills by the patient, together with the large amount of tablets involved, should have alerted the pharmacy that there was a problem and the pharmacy staff should have refused to refill the prescriptions. Judge Brady also noted however that the Court of Appeals of Ohio had reached a different conclusion in *Larabee v Super X Drug Corporation* (No. CA-876 (Ohio Ct. App. June 24 1987), holding that the dangers associated with disobeying the directions of a prescription were as obvious to the patient as they were to the pharmacist.

Following this extensive review of the relevant caselaw, Judge Brady turned to the issue as presented in the case before him. He submitted that the defendant's computer system alerted the pharmacists that the plaintiff was getting the inhalers at improper intervals. Further the pharmacists were aware of the length of time the inhalers should have lasted if used properly. The risk of her overuse of medication was not only foreseeable but was actually foreseen. The pharmacies should also have known of the dangers associated with the overuse of the inhalers. In addition, the defendant pharmacy had admitted that when the pharmacy computer warns that the customer may be refilling the prescription too soon, the pharmacist has a duty to alert the

prescribing doctor and the patient that she may be over-using the medication. All of these factors allowed for the imposition of a duty of care:

'Recognizing that pharmacists have a duty towards their patients does not undermine the doctor-patient relationship. Doctors still have the ultimate responsibility to evaluate the patient's needs and to prescribe the appropriate medication. However, a pharmacist may be in the best position to know when a patient is refilling prescriptions at too fast a rate, and to alert the patient and the physician of that situation. In this way, pharmacists and physicians can work together to provide the best care available to all patients.' (Mass. Sup. Ct.No. 94-0414A, April 1996 at page 18)

The latest case to consider the extent of the pharmacist's duty to warn is *Horner v Spalitto* ((1999)1 S.W.3d 519). A patient had died after taking two prescription medications which had been dispensed by the defendant pharmacy and which had interacted with each other. In a lawsuit, the family of the deceased patient contended that the defendant pharmacy was negligent by filling the prescriptions for when it knew or should have known, that, based on the nature of the drug, the dosage and instructions provided with it, it would expose the patient to unreasonable risk of great bodily harm or death; and/or failing to do any investigation to ascertain whether or not the patient had a problem, or potential problem, with drug abuse or chemical dependence; and/or failing to question the fact that the patient was having two prescriptions for the same drug filled on the same day by; and/or allowing the patient to either take the prescription beyond the recommended daily dosage or to take the drug on a long-term basis when, in fact, it was recommended for only short-term use; and/or failing to ascertain what other prescriptions or other drugs the patient was taking at the time; and/or failing to provide any warning, either written or verbal, of the potential side-effects or adverse reactions to the drug or the dangers

created by taking it in conjunction with other drugs or pharmaceuticals.

The circuit court granted the defendant pharmacy's motion for summary judgment, saying, "The court . . . finds and concludes based upon the ruling enunciated in *Kampe vs. Howard Stark Professional Pharmacy, Inc.*((1992) 841 S.W.2d 223), that [Spalitto] was under no duty to the [Horner family] and that the specific acts of alleged negligence stated in the pleadings are not sufficient to sustain a submission to a jury." In *Kampe*, the Court of Appeals of Missouri had stated that:

"By properly filling legal prescriptions that contained no apparent discrepancies on their face, the pharmacy fulfilled its duty to appellant." ((1992) 841 S.W.2d 223 at page 227)

On appeal to the Court of Appeals of Missouri, the summary judgment of the circuit court was reversed and the case was remanded back to the circuit court for further proceedings.

Judge Spinden began by confirming that the case required the Court of Appeals to revisit the issue of what conduct is required of a pharmacist in fulfilling his or her professional professional duties. The judge was willing to reverse what had been said in *Kampe* because he was of the view that the *Kampe* court had caused the circuit court to apply the wrong standard by confusing duty with what specific functions that duty obligates a pharmacist to do.

'Kampe ruled that a pharmacist fulfills his professional duties when he accurately fills a prescription--that he has no duty to warn or to monitor. This miscomprehended duty. Duty is an obligation imposed by law to conform to a standard of conduct toward another to protect others against unreasonable, foreseeable risks ... In other words, Anthony Spalitto's duty was to exercise the

care and prudence that a reasonably careful and prudent pharmacist would exercise in the same or similar circumstances--that is, his duty was to endeavor to minimize the risks of harm to Horner and others which a reasonably careful and prudent pharmacist would foresee.

Kampe wrongly held that, as a matter of law, a pharmacist's duty will never extend beyond accurately filling a prescription. This may be a pharmacist's only duty in particular cases, but in other cases, a pharmacist's education and expertise will require that he or she do more to help protect their patrons from risks which pharmacists can reasonably foresee. We must leave to a fact-finder what this duty requires of a pharmacist in a particular case. We can say at this point only that a pharmacist, as is the case with every other professional, must exercise the care and prudence which a reasonably careful and prudent pharmacist would exercise.

To hold as Kampe did would denigrate the expertise which a pharmacist's education provides concerning drugs and their therapeutic use. The Kampe holding also failed to comprehend the role a pharmacist must play in making the valuable, but highly dangerous, service of drug therapy as safe and reliable as it can be.'
((1999) 841 S.W.3d 519 at page 522)

Judge Spinden indicated that he was confirmed in this finding by the recognition of the augmented professional role of pharmacists by the legislature in Missouri, both in the general legislative provisions relating to the regulation and administration of the practice of pharmacy, and in the further legislation introduced to comply with the requirements of OBRA-90, the federal government enactment designed to initiate new provisions for pharmacist counseling of patients. These latter provisions will be discussed in detail in the following chapter.

The judge was also of the view that the adoption of a greater role for pharmacists would not, as had been suggested, interfere with the doctor-patient relationship:

'Pharmacists have the training and skills to recognize when a prescription dose is outside a normal range. They are in the best position to contact the prescribing physician, to alert the physician about the dose and any contraindications relating to other prescriptions the customer may be taking as identified by the pharmacy records, and to verify that the physician intended such a dose for a particular patient. We do not perceive that this type of risk management unduly interferes

with the physician-patient relationship. Instead, it should increase the overall quality of health care ... The physician still is responsible for assessing what medication is appropriate for a patient's condition, but the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer's questions regarding consumption of the medication.' ((1999) 841 S.W.3d 519 at page 523)

Turning to the case of *McKee v American Home Products* which had been cited by the defendant in support of an argument against the extension of liability of pharmacists, the judge agreed that a prescribing doctor was in a superior position to judge the propriety of a particular patient's drug regime. However Judge Spinden was firmly of the view that this should not relegate the pharmacist to the role of simply being an order filler:

'This view does not recognize ... that the practice of pharmacy includes consulting with physicians and patients to share with them the pharmacist's expertise in drugs and their interactions. We disagree that a pharmacist's consulting with a physician about an unusual prescription would result in antagonism exceeding the potential public benefit. Pharmacists are trained to recognize proper dose and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer. Relegating a pharmacist to the role of order filler, as the Kampe court seemed to do, fails to appreciate the role recognized in [the state legislative provisions]. We reject the suggestion in Kampe that the only functions which a pharmacist must perform to fulfill his duty is to dispense drugs according to a physician's prescription.' ((1999) 841 S.W.3d 519 at page 524)

Edwin H. Smith, Presiding Judge, and Forest W. Hanna, Judge, concurred.

Brushwood (1996:13) notes that by the end of the twentieth century, pharmacists' legal duties are expanding in line with the profession's own expectations and outlook. He submits that the most recently decided cases, until that date *Hooks*, *Lasley* and *Pittman*, had added a new duty, to promote actively good therapeutic outcomes by counselling patients and empowering them to

protect themselves from harm. The active promotion of good therapeutic outcomes is necessary as the secondary responsibility of preventing bad outcomes is not sufficient to define the extent of the pharmacist's duty. Brushwood is of the view that:

'the new tradition of pharmacist duty is based on the rationale that pharmacists and patients have a relationship of trust, and that this relationship serves as the justification of a duty of care. The scope of the pharmacist's duty of care depends on the potential danger to the patient. If the patient is at a slight risk of harm, then the standard of care for a pharmacist is ordinary. If the patient is at a great risk of harm, then the standard of care for a pharmacist is extraordinary. This is not a new standard, of course. It is virtually identical to the nineteenth century standard. However, because drug therapy has become more complex now than it was then, the actions that must be taken to meet the standard of care are more complex now'

According to Brushwood, what the recent pharmacist expanded liability cases have done is to create a duty for pharmacists to use their skill and knowledge for the benefit of patients:

'Pharmacists have a duty to promote good outcomes for all who seek the pharmacist's services in the provision of pharmaceutical products and care. This duty arises out of public expectations that a patient can trust a pharmacist to care for the patient. In meeting this expanded duty, pharmacists use their knowledge to detect potential problems with drug therapy, and they use their skill to resolve the problems and prevent harm to the patient. This does not mean that pharmacists guarantee good outcomes from drug therapy. But it does mean that pharmacists guarantee that they will use the best of their ability to promote a good outcome.'

Brushwood was making these comments before the decisions in the pivotal cases of *Baker*, *Harco*, *Cafarelle* and *Horner* were handed down. As such, they take on a greater significance in that the predicted expansion of liability, and its associated rationale, is becoming a reality.

Conclusion

In the introduction to this chapter, its purpose was explained as the commencement of the process of analysing how the expanded role of pharmacists has been recognised by the **courts** in the United States of America.

An analysis of judicial attitudes towards pharmacist responsibility has shown distinct patterns or trends. As such, the analysis in this chapter has looked at three periods of judicial activity. The first, from **1852-1932**, analysed the early perspective on pharmacist responsibility, and has concluded that the early cases set the standards for pharmacists at a high professional level. The second, from **1932-1985**, evaluated a period of traditional legal analysis which resiled from the earlier expansion of pharmacist responsibility and restricted liability to technical inaccuracy in prescription processing. The third, and most recent period, from **1985 to present**, demonstrates that the judiciary may be returning to first principles and are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions. An analysis of the rationale behind the recognition of expanded legal duties for pharmacists will be carried out in chapter six.

Currently, judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. The movement towards a recognition of expanded responsibility must be viewed against a recent background of traditional legal analysis which had limited pharmacist responsibility to the accurate processing of prescriptions and which had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor. Finally, the recent judicial creativity in expanding pharmacist

responsibility has its basis in a series of very early cases, from as far back as the early nineteenth century.

The next chapter will undertake a similar analysis of how the expanded role of pharmacists has been recognised by the **legislature** in the United States of America. We have already seen that certain legislative provisions, recently enacted by both federal and state legislatures, are beginning to have a significant impact. The full extent of that impact will be examined next.

The Attitude of the Legislature to Pharmacist Responsibility in the United States of America

Purpose

The purpose of the last chapter was to analyse how the expanded role of pharmacists has been recognised by the **courts** in the United States of America. An analysis of judicial attitudes towards pharmacist responsibility had shown distinct patterns or trends. In the first period, from **1852-1932**, the early perspective on pharmacist responsibility was examined, and we concluded that the early cases set the standards for pharmacists at a high professional level. The second, from **1932-1985**, evaluated a period of traditional legal analysis which resiled from the earlier expansion of pharmacist responsibility and restricted liability to technical inaccuracy in prescription processing. The third, and most recent period, from **1985 to present**, demonstrated that the judiciary may be returning to first principles and are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions.

Currently, judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. The movement towards a recognition of expanded responsibility must be viewed against a recent background of traditional legal analysis which had limited pharmacist responsibility to the accurate processing of prescriptions and which had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor.

In addition, the recent judicial creativity in expanding pharmacist responsibility has its basis in a series of very early cases, from as far back as the early nineteenth century.

The purpose of this chapter is to seek to undertake a similar analysis of how the expanded role of pharmacists has been recognised by the **legislature** in the United States of America. In the previous chapter it was seen that certain significant legislative provisions, recently enacted by both federal and state legislatures, are beginning to have a significant impact. The full extent of that impact is what is to be examined in this chapter.

It will be noted below that the federal government has recently enacted a significant piece of legislation with important consequences for the professional roles of pharmacists and the manner in which pharmacy is practised. This legislation, the Omnibus Budget and Reconciliation Act 1990, or OBRA-90 for short, has been described as '**the most important pharmacy-related law of all time**'. (Brushwood 1994:176). It establishes that, as part of the conditions for participation in the prescription drug component of the programme known as Medicaid, individual states are required to adopt expanded standards of pharmacy practice.

The overall purpose of the chapter, therefore, will be to explore this legislation in all of its aspects. That objective can be achieved in a number of ways, as follows. In the United States of America, legislative control and legislative power lie with both the federal government or Congress, and with individual state legislatures. Initially, therefore, it will be important to examine, in very general terms, the scope and extent of federal and state

legislative control over the activities of pharmacists. As was noted above, OBRA-90 establishes that, as part of the conditions for participation in the prescription drug component of the programme known as Medicaid, individual states are required to adopt expanded standards of pharmacy practice. It is important to examine, therefore, although necessarily in general terms, what exactly the Medicaid programme is and why reforms to it were thought to be necessary. It is also important to note at this early stage that although the mandate imposed by OBRA-90 was initially restricted to pharmacy practice as part of the Medicaid programme, most state boards of pharmacy, responsible for the implementation of the new requirements, have extended the new duties to all aspects of pharmacy practice.

Quite clearly, OBRA-90 itself requires to be analysed in some detail. This will be achieved in a number of different ways. Firstly, the background to the legislation will be examined, together with an analysis of the reasons why the federal government thought it important to intervene, through the enactment of legislation, in an area of professional regulation which it had, until then, largely left to individual state legislatures.

Secondly, it will be important to audit the content of the provisions of OBRA-90 in detail, to confirm the intent of the federal government and to analyse the scope of the new duties which are imposed. This analysis will demonstrate that OBRA-90 imposes specific requirements on individual state legislatures to take action for the purpose of establishing expanded standards for pharmacists, if those states wish to continue to participate in the prescription drug component of the Medicaid programme. As such, and thirdly, it will be

appropriate to scrutinise the approach taken, in general, by the states to the enactment of OBRA-90, and to examine the response of two individual states, Florida and Missouri, in particular. The Florida legislation has many features in common with the new pharmacy practice acts of the remaining states of the United States. The state of Missouri has been also chosen for comparative purposes because the state provisions introducing the OBRA-90 requirements, have, as will be examined in detail below, been subject to judicial scrutiny in that state.

At the time of the implementation of the new legislative provisions, and reflecting their perceived significance for the future of the pharmacy profession in the United States, there was extensive analysis of the practical consequences of the new requirements. The chapter will include an examination of the content of that analysis for the purposes of comparing the perceived impact with the reality of implementation some ten years later.

The new legislative provisions have been in force for some ten years. As such, it will be appropriate to analyse the extent, nature and scope of the actual impact on the pharmacy profession, and its relationship with other members of the health care team and the patients with whom they interact.

Although the new professional pharmacy requirements are enshrined in legislation, those provisions, as with all legislative provisions, have been subject to interpretation by the judiciary. Despite the fact that the extent of judicial activity with respect to these new legislative provisions has been limited, the cases to date do give an insight on the limits

of the new duties. Further, the cases on the new obligations prompt a re-assessment of existing cases on the extent of the pharmacist's duty towards the patient. It will be argued that many of the cases, analysed in chapter four, which sought to restrict and limit the extent of the pharmacist's duty, prompt significant re-assessment in light of the new legislative requirements.

Finally, and in conclusion, it will be seen that the evidence analysed supports Brushwood's initial assessment of OBRA-90 as 'the most important pharmacy-related law of all time'. (Brushwood 1994:176). The contents of OBRA-90 reflect the modern context of pharmacy practice, recognise the requirement for an expanded role for pharmacists, identify the benefits for patients and health care inherent in such an expansion, provide regulatory control of it, and supply the judiciary with the legal basis upon which to undertake its own augmentation (and inherent recognition) of pharmacist professional responsibility.

A brief note on federal and state legislative power and federal and state control of the practice of pharmacy

As most readers will be aware, the supreme law of the United States of America is its written constitution. Legislative power at the federal level in the United States of America lies with the United States Congress, Article 1 of the U.S. constitution providing that all legislative power of the federal government will lie with the Congress. Article 1 also provides that Congress will have the power to make all laws necessary and proper for carrying out its responsibilities.

The U.S. Congress is made up of the Senate consisting of 100 members, and the House of Representatives, made up of 435 members. The process of enactment of legislation at the federal level has similar but not identical characteristics to the procedure for legislative enactment in the United Kingdom.

Proposals for legislation emanate from a number of different sources, including the President, on the advice of his cabinet members, lobby groups, individual citizens, members of Congress, and government officials. Once drafted, an individual bill must be introduced to Congress by a member of Congress, either a senator or representative, who becomes the bill's sponsor. Following the introduction of the bill to Congress, in either the Senate or House of Representatives, a procedure which is relatively formal and technical, the bill will go through the most significant stage of its enactment. As with the process for legislative enactment in the United Kingdom, the scrutiny of the bill before a congressional committee, is usually determinative of its eventual content and subsequent outcome. Bills cannot progress to a vote of the appropriate Senate or House without the agreement of a majority of the relevant congressional committee.

The congressional committees of the United States Congress have, however, more extensive powers than their United Kingdom equivalents. The congressional committees may hold public hearings, conduct investigations, and generally ensure, by operating closely with the bill's sponsor, that interests of special groups affected by the legislation are reflected in the eventual content of the legislation. It is at the congressional committee

stage of a bill that those with a particular interest in it, or who are likely to be adversely affected by its provisions, direct their efforts in safeguarding their interests.

However if the bill is approved by a majority of the congressional committee, the committee prepares and distributes a report outlining the bill's objectives, details of the rationale of the committee in endorsing the legislation, and indicating the major amendments which will be made to the existing scheme of law. Although the published report will represent the views of the majority of the relevant congressional committee, individual members, or groups of members of the committee, may issue additional opinions, which will be published together with the majority report. The published congressional committee report, together with any minority assessments, are often used by the courts when interpreting the relevant legislative provisions in order to assist in determining the legislature's purpose in enactment.

Following consideration and approval by the congressional committee, the bill is placed on a calendar for consideration by the full Senate or House. It has been argued that the precise placing of the bill on the calendar is of significance in that the majority leadership of the Senate or House, if it does not approve of the contents of the bill, may place it on the calendar close to the annual adjournment, thereby guaranteeing its failure for lack of time. However, if the bill is considered by the relevant chamber, it is again the subject of intense scrutiny debate and amendment.

Following consideration and progress through one chamber, the bill will be transferred for consideration by the other chamber of Congress. The bill will go through the same procedures as described above, necessitating further detailed consideration by the second chamber's committee. If significant differences emerge following consideration by the two chambers, a conference committee is formed to resolve the disagreements.

After the bill has been negotiated through both chambers of Congress it is sent to the President for signature and implementation into law. A bill will become law on the signature of the President or automatically after ten days, following failure by the President to sign the bill and return it to Congress. The President may exercise a veto over the bill in two ways. He can indicate that he disapproves of the contents of the legislation and refer the bill back to the appropriate chamber with his criticisms attached. In this situation, each chamber of Congress may only reverse the veto with a further two-thirds majority vote. A second, and more covert method by which the President can exercise a veto is to fail to sign and return a bill within the ten day period following its passage through Congress, in the knowledge that Congress will adjourn within that time period.

Each state of the United States of America has its own constitution which represents the supreme law for that particular state. The tenth amendment to the United States Constitution, part of the 1791 Bill of Rights, provides that the individual states will have power to legislate in all areas except those prohibited or given to the Congress by the

Constitution, thereby ensuring that each individual state has wide-ranging legislative power.

Each individual state has its own legislature which is shaped by the federal Congress model. The procedures for enactment of legislation at the state level also reflect the federal Congress practice although it is clear that state bills do not receive the same level and degree of scrutiny as their federal counterparts. Further, state bills do not usually have the same amount of documentation in the form of committee reports, public hearing summaries, opinions etc. It has been argued that the natural consequence is that a state statute's legislative history is often difficult to determine.

State and federal regulation of the practice of pharmacy

The main differences between state and federal regulation of the practice of pharmacy can be summarised as follows. State legislatures have formulated laws, practices and procedures which directly regulate the profession of pharmacy by imposing standards and models for professional practice. The federal government has enacted a wide range of legislation having as its primary purpose the control and regulation of the production, licensing and distribution of medicinal drug products. The indirect effect of this significant regulation is that those responsible for aspects of drug distribution, including pharmacists, are subject to legislative regulation.

The importance of federal intervention in the regulation of the production, licensing and distribution of medicinal drug products should not be under-estimated. Statutes such as the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, et seq 52 Stat. 1040) and the Controlled Substances Act (21 U.S.C. 801-970) provide mechanisms for ensuring that all medicinal drug products are safe and effective for use, are licensed appropriately, and are properly distributed (For the detail of these rules see Brushwood and Abood 1994: Chapters 2 & 3). As was noted above, inherent in this critical level of control is the further regulation of those with responsibility for a drug product's distribution. For example, the Drug Enforcement Administration has power to enter and inspect any place where controlled substance records are kept or persons registered under the Controlled Substances Act (21 U.S.C. 880).

Despite this, the federal government, until the enactment of OBRA-90, did not intervene to regulate professional standards for pharmacists. Rather the detail of such standards and the legislative source required for their implementation and enforcement has been left to individual states. In this respect alone, OBRA-90 is a unique piece of legislation.

All of the individual states of the United States of America have enacted legislation for the regulation of the pharmacy profession. In the state of Florida, for example, the legislation is contained in the Florida Pharmacy Act (Chapter 465 of Title XXXII Florida Statutes). The Florida Pharmacy Act has many features in common with the pharmacy practice acts of the remaining states of the United States.

The legislative purpose of the Act is stated to be to:

‘... to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.’ (Paragraph 002 of Chapter 465 of Title XXXII Florida Statutes)

Brushwood (2000:?) submits that many pharmacists misunderstand the purpose of the establishment of state regulation of the profession, in that many pharmacists believe that any regulation is designed to act against their interests. Brushwood argues that the misunderstanding occurs because pharmacists forget that the purpose of regulation is not the promotion of the profession’s interests but rather, and as the example from the Florida Pharmacy Act noted above illustrates, the protection of public health, safety and welfare.

The Florida Pharmacy Act creates an administrative agency called the Board of Pharmacy. In Florida it consists of nine members appointed by the Governor of the state and confirmed by the Senate. In Florida, seven of the nine members must be licensed pharmacists, resident in the state and who have been engaged in the practice of pharmacy for at least four years. At least one of the pharmacy members must be currently engaged in the practice of community pharmacy, and one must be currently engaged in the practice of institutional (hospital, nursing home) pharmacy. The remaining five pharmacy members may come from any practice setting. The remaining two members of the Board must be resident in the state, must never have been licensed as community pharmacists and must not have a connection with the practice of pharmacy, drug manufacture or wholesale.

Brushwood and Abood (1994:171) submit that as the appointment of a member to the Board of Pharmacy, in any state as well as Florida, is dependent on the sanction of the Governor, the appointments tend to be political. As a general rule, the pharmacist members tend to be independent community practitioners, and, occasionally, pharmacy owners. Brushwood notes that 'chain' pharmacists and others who do not own independent pharmacies have traditionally been under-represented on state boards of pharmacy.

Such had been the resentment felt at such a censure that the constitutionality of the practice was challenged in the case of *Rite Aid Corporation v Board of Pharmacy* (421 F. Supp. 1161 (D.N.J. 1976)). The New Jersey court ruled, however, that there was nothing in the state pharmacy board legislation to prevent chain pharmacists from becoming members of the state board and, further, there was no evidence of board selection bias. Brushwood notes that, as a result of this action, most state boards of pharmacy attempt to include at least one chain pharmacist and one hospital pharmacist on the board in an attempt to become more representative of the pharmacist community.

One important function for state boards of pharmacy is the grant and issue of licenses for both pharmacists and pharmacy premises. In the Florida Pharmacy Act, provision is made for the grant of licenses for pharmacists in paragraphs 465.007-465.013 and for pharmacies in 465.018-465.0196. State boards of pharmacy also retain a broad legislative discretion in the discipline of pharmacists and pharmacies. Disciplinary action can

include the suspension and revocation of licences and/or the imposition of civil remedies. In the Florida Pharmacy Act the appropriate provisions are paragraphs 465.015 and 465.016. The grounds for disciplinary action include obtaining a license through misrepresentation or fraud, permitting an individual who is not licensed to fill, compound or dispense a prescription, unfitness or incompetency to practice, unprofessional conduct, conviction of a crime, and continuing to practice while a license has been suspended or revoked. Provision is made, in paragraph 465.016(4), for the establishment of guidelines for the disposition of disciplinary cases involving specific types of violations.

A second and fundamental function of the state boards of pharmacy is to develop and implement professional standards of practice. In the Florida Pharmacy Act, provision is made for standards of practice in paragraph 465.0155. Practice standards become important in the assessment of whether a pharmacist has been in breach of a duty of care to a patient, and are frequently referred to by the courts when they are faced with the determination of that question. (see, for example, the comments of the court in *Pittman v Upjohn* (890 S.W. 2d, 425 at page 435, (Tenn. 1994)), the court in *Ingram v Hook's Drug Inc.* (476 N.E. 2d 881 at page 885, (Ind. App. 1985)), the court in *Dooley v Everett* (805 S.W. 2d 380 at page 385, (Tenn. App. 1991)), the court in *Fakhouri v Taylor* (618 N.E. 2d 518 at pages 521-522 (Ill. App. 1993)), and the court in *Nichols v Central Merchandise* (817 P. 2d 1131 at page 1132 (Kan. App. 1991)).

It is the practice standard aspect of the work of state boards of pharmacy which has been most directly affected by the intervention of the federal government through OBRA-90.

As Brushwood and Abood (1994:177) has noted, the standards of practice promulgated by state boards of pharmacy had traditionally focused on issues related to structure – the presence of a pharmacist when a prescription is being dispensed, the prominent display of a license in a pharmacy, the possession of the appropriate equipment for dispensing, for example. Following the enactment of OBRA-90, the focus of practice standards has switched to regulation based on process – the proper counselling of patients when a medication is dispensed, the maintenance of adequate patient medication records and the dispensing of equivalent and generic drugs, for example. It is the effect of OBRA-90 on pharmacy practice standards which will be explored in detail below.

State boards of pharmacy have their own national organisation – the National Association of Boards of Pharmacy (NABP). Its mission statement indicates that it is:

‘... the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing and enforcing uniform standards for the purpose of protecting the public health.’

The NABP’s main function is to control the administration of the standardised examination used by most individual states to measure professional proficiency for pharmacy licensure. Further, the NABP has an important role in the drafting and progression of archetype legislation and rules for use by individual states, following the development of particular policies and standards. It has already been noted that OBRA-90 required individual states to amend their existing pharmacy legislation to conform with the new professional requirements. As will be noted below, the NABP was

instrumental in the development of model rules (and further clarifications) to assist individual state boards to comply with this mandate. The NABP also has an important role in the supervision of the transfer of licenses between states and in the facilitation of inter-state disciplinary actions.

A brief note on the Medicaid programme

As noted above, OBRA-90 imposes specific requirements on individual state legislatures to take action for the purpose of establishing expanded standards for pharmacists, if those states wish to continue to participate in the prescription drug component of the **Medicaid** programme. It is important, therefore, to undertake a brief analysis of the nature and scope of this individual health care scheme, and its place within the health care system of the United States as a whole.

The last thirty years has seen a dramatic growth in the provision of spending on health care in the United States. From \$27 billion in 1960, it grew to \$898 billion in 1993, increasing at an average rate of more than 11% annually. As a result, health care was strongly represented in the overall economy, with health expenditures rising from 5.1% to 13.7% of the gross domestic product (GDP) between 1960 and 1993. During the years 1993-1998, however, the previously strong growth trends in spending on health care have declined. The average annual rate of health care spending between 1993 and 1998 was 5% with an overall annual 1998 expenditure of \$1.1 trillion. In a parallel way, health care's share of the GDP steadied, the 1998 share being measured at 13.5%. For the 281

million people residing in the United States, the average expenditure for health care in 1998 was \$4,094 per person, up from \$141 in 1960. (National Health Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA).

Health care in the United States of America is funded through a variety of private and public programs. Privately funded health care includes private health insurance and health services that are provided in the employment setting. As is well recognised, private health insurance coverage is an important issue in the United States. Private health insurance has largely been the choice of the majority of the population due to the expansion of employee benefits and the lack of legislative action by the federal government to provide wholly accessible publicly funded health care insurance. In the years 1974-1991, private funds accounted for 58 to 60% of all health care costs. By 1998, however, the private share of health costs had declined to 54.5% of the country's total health care expenditures. The share of health care provided by public spending increased correspondingly during the 1992-1997 period. (National Health Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA).

Public spending on health care is provided by the federal, state, and local governments. Publicly funded health care includes the Department of Defence and the Department of Veterans' Affairs health care programs for current serving and retired military personnel, non-commercial medical research, payments for health care under workers' compensation

programs, health programs under state-only general assistance programs, and the construction of public medical facilities. Other activities that are also publicly funded include maternal and child health services, school health programs, public health clinics, Indian health care services, migrant health care services, substance abuse and mental health activities, and medically related vocational rehabilitation services. These expenditures, however, only make up a small percentage of the overall cost of publicly funded health care. The largest shares of public health expenditures, however, are made by the **Medicare** and **Medicaid** programs.

As was noted above, the federal government, prompted by earlier state action, had considered the introduction of government health insurance in the periods immediately before and after the Second World War. By 1950, the federal government had, however, legislated to improve access to medical care for impoverished individuals who were receiving public assistance through social security payments. The federal government also recognised that the elderly, like the impoverished, also needed increased access to medical care.

In 1965, after considerable internal debate, the federal government introduced Title XVIII and Title XIX, to the Social Security Act thereby establishing **Medicare** and **Medicaid**. As will be noted below, Medicare was established to address the specific medical care needs of the elderly. Medicaid was established to provide a system of welfare medical care under public assistance. Initially, responsibility for administering the Medicare and Medicaid programs was entrusted to the Department of Health, Education, and Welfare, the forerunner of the current Department of Health and Human

Services (DHHS). Until 1977, the Social Security Administration (SSA) managed the Medicare program, and the Social and Rehabilitation Service (SRS) managed the Medicaid program. The Health Care Financing Administration (HCFA) assumed the responsibilities of both the SSA and SRS in that year.

In 1998, Medicare and Medicaid financed \$387 billion in health care services, representing one-third of the country's total health care bill and almost three-quarters of all public spending on health care.

As noted above, **Title XIX** of the Social Security Act is a joint federal/state entitlement programme called Medicaid that pays for medical assistance for certain individuals and families with low incomes and resources. The programme is jointly funded by the federal and state governments with the purpose of assisting individual states to provide medical assistance to eligible indigent persons. Medicaid is the largest source of funding for medical and health-related services for the poorest individuals in the United States of America.

Federal legislation has established a series of national guidelines within which individual states are permitted to establish their own standards for eligibility, determine the type, amount, duration, and scope of services, set the rate of payment for services and administer individual programmes. This range of discretion has meant that individual state policies for eligibility, services, and payment will vary considerably.

As was noted above, Medicaid is a joint federal/ state initiative with funding provided by both sets of government. While individual states have a wide discretion in determining

the extent of coverage and the financial criteria for Medicaid eligibility, they are required to provide Medicaid coverage for certain individuals who receive federally assisted income-maintenance payments in order to receive parallel federal funding. In addition, individual states also have the option of providing Medicaid coverage for certain other 'categorically related' groups and 'medically needy' groups. Parallel federal funding is also available for these groups of recipients. Finally, most states also have their own programmes to provide medical assistance for those needy individuals who do not qualify for Medicaid. These 'state-only' programmes do not receive parallel federal funding.

Individual states are permitted significant discretion in the range of services which they provide under their Medicaid plans. However, there is a federal requirement that individual state Medicaid programmes must offer medical assistance for certain basic services to most categorically needy individuals. These services generally include inpatient and outpatient hospital services, prenatal care, vaccines for children, physician services, nursing facility services for persons aged 21 or older, family planning services and supplies, rural health clinic services, home health care for persons eligible for skilled-nursing services, laboratory and x-ray services, paediatric and family nurse practitioner services, nurse-midwife services, federally qualified health-centre services, and early and periodic screening, diagnostic, and treatment services for children under age 21.

Other services, including a prescription drug service, may be provided on an optional basis. Currently all states provide the optional prescription drug service. The prescription drug service allows for reimbursement to the pharmacist for the cost of the medicinal

drug product, determined according to a prescribed formula, and a dispensing fee. As the dispensing fee is determined by individual state Medicaid agencies, it can, as a result, vary from state to state. The level of reimbursement for the cost of the medicinal drug product and the adequacy of the dispensing fee have both been the subject of litigation in the United States of America but with little success (*State of Louisiana v U.S. Department of Health and Human Services*, 905 F.2d 877 and *Pennsylvania Pharmaceutical Association v Department of Public Welfare*, 542 F. Supp. 1349).

Within the broad federal guidelines and certain limitations, outlined above, states are permitted to determine the amount and duration of services offered under their Medicaid programs. There may be restrictions, for example, on the number of days of hospital care or the number of doctor visits covered. There are two main restrictions which apply. Firstly the limits must result in a sufficient level of services to reasonably achieve the purpose of the benefits, and secondly, the limits on benefits must not discriminate among beneficiaries based on medical diagnosis or condition.

Individual states either pay health care providers directly on a fee-for-service basis, for the Medicaid services which they provide or pay for Medicaid services through various prepayment arrangements. States are permitted to exact coinsurance, or copayments on some Medicaid recipients for certain services. Certain Medicaid recipients, however, must be excluded from cost sharing, and all Medicaid recipients must be exempt from copayments for emergency services and family planning services. The federal government pays a share of the medical assistance expenditures under each State's Medicaid program. The share cannot, under the Social Security legislation, be lower than 50% or higher than 83%. In 2000, the share varied from 50% in ten states to 76.80% in

one state, and averaged 57% overall. The federal government also shares in each State's expenditures for the administration of the Medicaid scheme at a matching average of 50%.

In 1998, payments to health care vendors for 40.6 million Medicaid recipients averaged \$3,500 per person. Medicaid payments for services for 20.6 million children, who constituted 51% of all Medicaid recipients, averaged \$1,150 per child; for 8.6 million adults, who made up 21% of recipients, payments averaged \$1,775 per person, for 4 million elderly, constituting 11% of all Medicaid recipients, averaged \$9,700 per person; and for 7.2 million disabled, who constituted 18% of recipients, payments averaged \$8,600 per person. (National Health Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA).

As noted above, Title XVIII of the Social Security Act, headed "Health Insurance for the Aged and Disabled," is commonly known as **Medicare**. Medicare provides federal health insurance for most persons age 65 or over, and for certain individuals with a disability.

Medicare consists of two parts, hospital insurance (HI), also known as Part A, and supplementary medical insurance (SMI), also known as Part B. The Balanced Budget Act of 1997 established a further, third part of Medicare, called the Medicare+Choice scheme, and which is sometimes known as Part C. When Medicare began on July 1, 1966, approximately 19 million people were enrolled. In 2000, about 40 million people were enrolled in one or both of Parts A and B of the Medicare program, and 6.4 million of them had chosen to participate in a Medicare+Choice plan. (National Health

Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA).

HI is usually provided automatically, and free, to persons age 65 or over who are eligible for social security and certain retirement benefits. As noted above, certain other individuals with a disability are also covered. In 1999, the HI program provided protection against the costs of hospital and specific other medical care to about 39 million people (34 million elderly and 5 million disabled). HI benefit payments amounted to \$129 billion in 1999. (National Health Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA). The health care services covered under Medicare's HI program include in-patient hospital care, which includes inpatient prescription drugs, skilled nursing facility care home health agency care, and hospice care, subject to certain limits and restrictions.

The SMI scheme is available to all citizens age 65 or over, and all disabled persons entitled to coverage under HI, who voluntarily enrol in the scheme by payment of a monthly premium. Virtually everyone who is entitled to HI has chosen to extend coverage to SMI. The SMI scheme covers most medical expenses not covered by the HI scheme, but not prescription drug products. In 1999, the SMI scheme provided protection against the costs of doctor and other medical services to about 37 million people, at a cost of \$80.7 billion. (National Health Expenditure (NHE) estimates are from the National Health Statistics Group in the Office of the Actuary (OACT), HCFA).

The HI programme is financed primarily through a mandatory employment tax. Almost all employees and self-employed workers in the United States work in employment covered by the HI program and pay taxes to support the cost of benefits for elderly and disabled beneficiaries. The HI trust fund also receives income from a number of other sources. As noted above, the SMI programme is financed through monthly payments by those enrolled in the scheme (\$45.50 per beneficiary per month in 2000) and contributions from the federal government, at a ratio of 25% to 75%. The Medicare program covers 95 percent of the elderly population of the United States, as well as many individuals on social security because of disability. Medicare beneficiaries who have low incomes and limited resources may also receive help from the Medicaid program.

The background to the enactment of OBRA-90

Baker (1996:503-505) summarises a number of general factors which, he submits, influenced the introduction of the pharmacy provisions in OBRA-90. The first of these, already been identified in chapter three of this thesis, is the search by the pharmacy profession, since the early 1970s, for a new role, consistent with their education and knowledge:

‘Unwilling to be relegated to the simple functions of ‘count, pour, lick and stick,’ pharmacists increasingly counseled patients regarding their prescription medications ... Individual pharmacists, schools of pharmacy, and pharmacy organizations recognized that unless pharmacy developed new roles, highly educated professional pharmacists risked the perception that pharmacists were an expensive luxury.’ (1996:504)

According to Baker, one of the factors (also discussed in detail in chapter two of this thesis) which had precipitated pharmacists towards the identification of a new role was the loss by the pharmacy profession to the pharmaceutical industry of the former, unique professional role as a compounder and dispenser of medicinal drug products. Added to this, Baker argues, the public, from around the 1960s and 1970s began to participate more actively in decisions about their health. Not content to routinely accept taking medicinal drug products with unaccustomed and unexpected side effects, and armed with a new knowledge about the potential, both beneficial and pernicious, of drug therapy as part of their health regime, patients demanded more information regarding prescription and over the counter medications. The most accessible source of such guidance was going to be the pharmacist rather than the physician, the pharmacist having always been regarded by the public as an accessible, trustworthy and inexpensive source of advice on all aspects of health-related matters.

Baker submits that the mandate provided by the public for further, detailed information on the side effects of drugs, led those responsible for pharmacy education to recognise, *inter alia*, that pharmacy students would require a more comprehensive technical insight into the effects and side effects of drug products. That requirement was intensified by the fact that, due to the expansion of the pharmaceutical industry, and parallel investment in drug innovation and development, new and more potent drug products were reaching the public, increasing by degrees their requirement for knowledge as to how and when medication should be taken.

Baker also identifies that pharmacy competition changed during the 1970s and 1980s:

‘The established pharmacy industry, which competed increasingly on price, experienced a proliferation of new pharmacy outlets that could compete very effectively with lower prices. Deep discount pharmacies, grocery stores, and department stores recognised [that] pharmacy departments were ‘traffic builders’ and were willing to accept a lower profit margin. Mail order pharmacies found ways to sell at lower prices and were aided by the increasing development of the third-party-payer.’ (1996:505)

As noted above, the vast majority of the employed population in the United States receive their health care benefits as part of their employment contracts, with employers generally paying third party insurers a premium to assume the risk of the health care claims. The third party providers, according to Baker, also recognised the value of increased competition by persuading employers that employees’ requirements for prescription drug benefits could be realised through the provision of a limited selection of pharmacies participating in the scheme. The basis for this conclusion was the realisation that pharmacies had become so uniform in product and service delivery that few employees could differentiate between them and were rarely gaining any added value from their own individual pharmacy. The net result was further competition between pharmacies for places in the third party schemes.

Commercial competition was another factor forcing pharmacists to seek out different methods of distinguishing their products from those available in other pharmacies. Included in those methods was a recognition that services such as a patient counselling could provide the extra value which patients (including employees) were seeking:

‘Many pharmacists recognized a decrease in profits from utilizing only the dispensing function of pharmacies and therefore determined they needed to find a better way of using their specialized knowledge of drugs to enhance their professional recognition and earning power.’ (1996:504)

It was opportune that, at the same time that pharmacy was seeking to carry out this dual ambition of increased professional recognition and return to high profit yield, the federal government was at the time undertaking the task of reducing the increasing cost of the Medicaid scheme. Pharmacy leaders, according to Baker, were able to convince the government sub-committees that the increased use of drug reviews and counselling, the pharmacy profession’s driving aspiration, would lead to fewer hospitalisations, as previously non-compliant patients could be persuaded of the benefits of drug therapy as an alternative to more expensive medical interventions such as surgery. Who better to provide such services than the pharmacy profession?

Quick (1993) also emphasises the reduction in health care cost as a partial but significant factor in the introduction of OBRA-90. Pointing to 1993 statistics (1993:147, citing Nelson, 1993:56) revealing that 10-30% of all hospital admissions were the result of drug therapy problems, that at least 12000 deaths per annum associated with drug reactions and that as much as \$7 billion was spent in 1993 on providing care for those who suffered from some drug induced illness, Quick concludes that this enormous cost would concentrate the minds of those attempting to reduce the overall expenditure on health care in the country.

Gastineau (1993:313) refers to the same statistics, adding that by 1993, more than 125,000 Americans were dying each year as a result of drug therapy non-compliance (1993:313, citing Cardinale, 1993:38). Gastineau argues that patient non-compliance with medication, manifested by either a misuse or non-use of a prescribed medication, represented a significant problem in health care. Gastineau refers to the studies undertaken by Kawahara (1993), which estimated that the range for patient non-compliance was between 25% and 50% for the average patient at home, as evidence of the gravity of the problem. The cause of non-compliance includes mis-interpretation or mis-understanding of the directions for medication use, an individual's patient's self-belief about his/her condition and parallel requirement (or not) for medication, the failure to adjust to the requirements of the drug administration schedule, the occurrence of side effects of the drug therapy, and the inability to pay for the prescribed medication.

This, according to Gastineau, can lead to over or under-utilisation of a medication, administration at inappropriate times outside of the sanctioned regime, improper administration of the medication, use of the medication for improper purposes, or simple failure to have a prescription filled. The failures associated with non-compliance are often compounded when the expected favourable results of the drug therapy do not materialise, and unwarranted and uninformed adjustments in the therapy are made. Gastineau submits that the mandates of OBRA-90 have a twofold purpose –they are directed at remedying the problems associated with patient non-compliance to drug therapy, in order to diminish the cost of excessive medication and parallel unrequired hospitalisations:

‘The underlying concept of OBRA-90 is clear. The more informed a patient is about drug therapy, the more likely that patient will be compliant, thereby improving the results of the prescribed drug therapy ... The pharmacist, through effective counseling, can impact positively upon the patient’s ability to comply with prescribed medication regimens. Through appropriate counseling, the pharmacist is able to inform the patient about the safe and appropriate use of medications. Additionally, the pharmacist is able to obtain information regarding the patient’s medical history and determine any difficulty the patient is presently having, or may expect to encounter, as a result of ongoing use of medication. The pharmacist can then utilize this information to recommend simplified regimens, warn of potential side effects, or when appropriate, consult with the prescribing physician.’ (1993: 313-314)

The US Congress had been persuaded that the discovery and prevention of drug related problems would lead to increased patient compliance. In turn increased patient compliance would produce favourable drug therapy results, higher quality patient care, and, inevitably, reduced health care costs.

Gastineau believes that those responsible for enacting OBRA-90 had ‘astutely’ chosen the pharmacist as the member of the health care team who could deliver the ambitious goals of improved patient drug therapy and decreased health care costs. As noted above, Baker (1996:503) is of the view that it was the pharmacy profession who had persuaded Congress that through the use of drug reviews and mandated counselling (the new pharmacy professional requirements introduced by OBRA-90), the necessary objectives could be achieved.

Brushwood (1997) concentrates on the potential for the improvement in patient drug therapy as the major motivation for the introduction of the legislation, and undoubtedly,

its major benefit. Earlier (Brushwood (1996)) he had concluded that the importance of the role of drug therapy in medical treatment cannot be underestimated. While stating that, for the most part, modern drug therapy works well, he had agreed that problems do arise with drug therapy. Licensing and approval does not necessarily mean that a drug is problem free. Even proper diagnosis of a patient's condition, followed by the appropriate selection of a patient's medication, will not ensure a successful outcome from drug therapy. Toxicities and therapeutic failures can occur from either the chemistry of the drug, the chemistry of the patient, or both.

Returning to this theme in 1997, and drawing on the results both of government reports and private research on the issue, Brushwood submits that there is room for a significant improvement in drug therapy. One method of preventing drug-related problems, would be to reflect on an individual's drug therapy, and then consider both the outcomes which may occur and all available alternatives. By adopting this novel approach to drug therapy, pharmacists might be in a position to work with doctors to eliminate the frequency of poor consequences which currently result.

The reflective and outcome approach to drug therapy is novel and had not, by 1997, been grasped by either the pharmacy profession itself, or by those responsible for the regulation of medications. The regulatory authorities have concentrated, with immense success, on the medications themselves. Specific legislation was (and still is) in force which ensured that a drug product will not be licensed and put on the market until lengthy and rigorous scientific study shows that, on balance, the drug is more beneficial than

detrimental for the population as a whole. The process of drug evaluation is meticulous, with approval from the Food and Drug Administration only coming on the basis of substantial evidence, 'consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved' (21 U.S.C. 355(d) (1996)).

Brushwood submits that despite the rigour of the drug evaluation system:

'... specific unique responses that individual subjects have had to the drug are given little consideration ... The possibility that an approved drug may be unsafe and/or ineffective for the population, is reflected in the mandated product labelling that includes information concerning contraindications, precautions, and warnings that re related to the use of the drug. Safety is a relative concept, even for those drugs that are essentially risk free.'
(1997:479)

The traditional medicines use process continues to reinforce and intensify the possibility of drug therapy error. Although the position is changing (both in the United Kingdom and in the United States of America) the vast majority of drug products are the subject of further regulation and restriction by being legally classified as only available subject to the prescription of a health care professional, usually a doctor. This requirement introduces an element of subjectivity to a process which until then has relied on, and taken pride in, its objectivity. Brushwood argues that the decision that by a prescribing doctor that a drug will be safe and effective for a particular patient is different from the decision by the Food and Drug Administration that a drug will be safe and effective for the population as a whole. The key factors influencing a prescribing decision are his/her clinical impressions of the likely reaction of a particular patient to the proposed drug

therapy. Although prescribing doctors may be able to determine, and indeed may be told what are standard dosages and what are typical side effects of a particular drug product, they have to apply such factors to the peculiarities of an individual patient:

‘Physicians try to make rational prescribing decisions under conditions of uncertainty; but the profusion of promotional product information, the frequent introduction of new products, and the underestimation of the true toxicity of drugs, can interfere with attempts to make prescribing a systematic, objective exercise.’ (1997:480-481)

Prescribing of medications is not subject to regulatory control in the same way as drug development and marketing is subject to regulatory control. As noted above, the regulation of professions is in the hands of individual states rather than the federal government. The choice of unsuitable drug therapy by a health care professional is not usually the subject of a disciplinary action. The courts will only award damages in negligence when a prescribing health care professional makes a gross error of judgment. The net result is that regulation of the medications use process is strong on inputs (the medications) and weak on outcomes (drug therapy for individual patients).

The philosophy of pharmaceutical care gives the best opportunity to negate the failures associated with the traditional medicines use process. The promotion of positive outcomes in the drug use system will prevent many of the problems which the traditional medicines use process is creating. The practice of pharmaceutical care obliges the pharmacist to share responsibility for the design, implementation and monitoring of a therapeutic plan which seeks to achieve a set of desired therapeutic objectives. As an essential element of health care, the practice of pharmaceutical care must be carried out

in co-operation with patients and other professional members of the health care team. It is clear, however, that pharmaceutical care is provided for the direct benefit of the patient and the pharmacist must accept direct responsibility for the quality of that care.

Pharmaceutical care moves the practice of pharmacy beyond the traditional model where the primary function of the community pharmacist is to dispense prescriptions, to a new model where the pharmacist is involved in rational drug therapy. Within this new model, pharmacists, in their professional capacity, continue to function as experts in the dispensing of drugs but also collect/find and interpret evidence relating to specific clinical questions and provide information that permits patients to assess risk, enhance their autonomy, and develop their own medication practice.

As has already been noted, in the traditional medicines use process, the patient has a great deal of autonomy in deciding whether or not to take a drug, is largely unsupervised in making that decision and has no-one with the appropriate knowledge of their individual circumstances to assist them in making rational and careful decisions about self-administration and re-administration.

The community pharmacist is well placed to fill this void and assume a client-specific role with respect to decisions about drug taking. Pharmacists are highly trained in the science of drug therapy, are readily available in the community in which they live and are highly regarded and trusted by members of that community. As a result of this, pharmacists often have a greater access to information about the prescription process relating to a particular patient .

The pharmacist in this new role is still concerned with the initial choice of prescription and more concerned with patient outcomes, using patient-specific evidence to monitor and manage the patient's care. This role equates with the current expectations of the profession, applying existing knowledge of drug therapy in original and creative ways to improve patient outcomes.

The new role naturally requires co-operation with patients and other members of the primary health care team. However the pharmacist's intervention is provided for the direct benefit of the patient and the pharmacist must accept direct professional responsibility for the quality of that intervention.

The pharmacist in the pharmaceutical care system is less concerned with initial choice of prescription and more concerned with monitoring, management and patient outcomes. The pharmacist in such a system will use patient-specific evidence to monitor and manage the patient's care. Pharmaceutical care changes episodic drug therapy to coherent, continual care. Responsibility for patient outcomes is spread from the individual (doctor) to the team (all healthcare providers).

For Brushwood, the key to OBRA-90 is its potential to use the underlying philosophy of pharmaceutical care to change the medications use process for the better:

'OBRA-90 is the first comprehensive piece of legislation to take a systems view of the medication use process and attempt to ensure that the arduous and careful decisions made about drug safety at the early stages of drug

development are not defeated by careless, uninformed actions during the last stages of product use ... The OBRA-90 mandate establishes a systematic means of improving medication use. By adopting many of the underlying principles of pharmaceutical care, OBRA-90 has empowered pharmacists to use their full potential as health care professionals. Pharmacists are able to give added value to drug therapy by providing feedback to patients, physicians and others. Full participation by pharmacists closes the loop, so that each drug therapy experience builds on the last, and continuous improvement eventually produces the best results available.’ (1997:478 & 485)

Hartoum, Hutchinson & Lambert (1992) submit that there are many reasons why pharmacists should appreciate the need to provide essential patient-oriented pharmaceutical care. For these authors no reason was more convincing than the findings of three government reports issued by the office of the Inspector General for Health and Human Services on the contemporary state of pharmacy practice.

The first report, ‘The Clinical Role of the Community Pharmacist’ (OIG 1992), found that the role of the community pharmacist in managing drug therapy can be critical, with strong evidence that clinical pharmacy services add value to patient care and reduce the cost of health care utilization. The report recommended that the process of providing pharmaceutical care should be facilitated by the provision of further funding, and that improved standards of practice that address the components of clinical pharmacy should be developed. The second report, ‘State Discipline of Pharmacists’ (OIG 1990) included arguments for state boards of pharmacy to assume a leadership role in terms of filling the societal mandate of protecting the public health. Finally, the third report, ‘Medication Regimens: Causes of Noncompliance’ (OIG 1990), concludes that non-compliance with medication regimens increases the use of resources such as hospitals, nursing homes and

clinics and results in unnecessary related treatments. Educating patients represents the best way to improve compliance with drug therapy, a process entailing skills to gather data, individualise instructions, to prompt and support the patient, and to evaluate and follow up the patient's response to therapy to determine the success of the treatment in improving patient outcomes.

OBRA-90 What does it say and do?

No matter what has been said by academic commentators about the rationale and philosophy of OBRA-90 its overall purpose, and the justification for its implementation are well summarised in the legislation itself. In introducing one of the fundamental aspects of the new professional responsibilities (drug use review programs, to be discussed in detail below), the legislature gave a succinct summary of the intention behind the legislative provisions:

'... to educate physicians and pharmacists to identify and reduce the frequency and patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care, among physicians, pharmacists and patients, or associated with specific drugs or groups of drugs, as well as potential and actual adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.' (42 U.S.C. 1396r-8(g)(a)(A) (1990))

This summary of purpose section (and the other pharmacy provisions in OBRA-90) were drafted by Senator David Pryor, the main promoter of the legislation, and reflect his

earlier reasoning on the likely impact of the legislation. In an unpublished discussion paper he had offered the following reasons for the introduction of drug use review (the components of which will be discussed in more detail below):

‘Expenditures on pharmaceuticals represent only a small part of the total health care dollar in the United States, yet government and third party providers are paying increasingly more attention to how drugs are used because of their escalating costs;

In addition to the concern about high cost, there is some well-known evidence to suggest that improvements could be made in the way that drugs are utilised and monitored. Studies show that 7% of all hospitalisations are caused by drug-related side effects and that 28% of elderly hospitalisations are related to drug misuse;

Many Medicaid patients receive primary care in emergency rooms, or have multiple physicians or multiple pharmacists, resulting in fragmentation of health care delivery to this population. As a result, medication management of most Medicaid patients is almost impossible to perform. Technology has evolved to the point where the pharmacist can have access to a patient’s entire medication profile so that when necessary, the physician can be consulted and drug therapy problems avoided;

There is substantial evidence to suggest that Drug Use review in the inpatient setting and the managed care environment contributes to improving the quality of and increasing the cost effectiveness of drug therapy. While the evidence is less conclusive about DUR in the outpatient setting, properly structured, there is every reason to believe that outpatient DUR can be as successful;

Third party payers other than the federal government are becoming increasingly interested in methods to contain pharmaceutical program costs. While DUR can result in reduced expenditures for drugs, its primary focus should be to improve the quality of drug therapy received by patients;

The evolution of outpatient DUR programs in the United States represents an opportunity for the health professions to continue to exert significant influence over how drugs are used in Medicaid patients and other patients. There is increasing evidence to suggest that corporate benefit managers, large employers, and even pharmaceutical manufacturers are attempting to exert greater influence over the drug prescribing and utilization process. By

becoming proactive, health professionals can maintain and even increase their influence in determining how drugs are used in health care.'

It is important to note that OBRA-90, as the full title of the legislation – The Omnibus Budget Reconciliation Act 1990 – suggests, is not a piece of legislation solely about pharmacy and the role which the pharmacy profession will play in medication over-use and the reduction in the cost of health care. The legislation as a whole is about money, or rather the saving of money, and the pharmacy provisions, although significant in their substantive content, only form a small part of the overall Act.

It is also important to note that the provisions of OBRA-90 are directed towards the amendment and reform of, amongst other things, pharmacy participation in the Medicaid programme. As noted above, OBRA-90, in general terms, establishes that, as part of the conditions for participation in the prescription drug component of the programme known as Medicaid, individual states are required to adopt expanded standards of pharmacy practice. As such, it was arguable, at the enactment stage, that individual pharmacists had no obligations to meet under the legislation, and that individual states had no duty to alter their regulations, subject to the penalty of losing participation in the Medicaid scheme. Two factors destroyed these arguments immediately. The first was that the Medicaid scheme is so crucial to the overall health care system in the United States of America, as evidenced by the statistics noted above, that no individual state could choose to voluntarily remove itself from participation. The second is that those responsible for the development and implementation of professional standards of practice recognised that the standards imposed for pharmacists under the provisions of OBRA-90 were so appropriate

that they ought to be extended to all aspects of pharmacy practice. This aspect of OBRA-90 will be discussed in more detail below.

The provisions of OBRA-90 which are of significance to pharmacy may be summarised under three main headings – **rebates**, **demonstration projects** and **drug use review**. In fact, it is only the third of these, **drug use review**, which has a direct impact on pharmacy practice standards and the provisions relating to drug use review will be discussed in greater depth below. It is important to note the provisions relating to **rebates** and **drug use review** as these aspects of OBRA-90 have an indirect effect on the practice of pharmacy by providing additional funding for the payments to pharmacists, including payments for the additional drug use review responsibilities.

Rebates

Under the provisions of paragraph 1396r-8(a)-(e) of OBRA-90, manufacturers of drug products, participating in the Medicaid programme, are obliged to prepare details of the average manufacturer's price and best price for a drug product. The 'average manufacturer's price' is defined by the legislation as the price that wholesalers pay to the manufacturers for drug products distributed to the retail pharmacy class of trade. The 'best price' is defined as the lowest price available from the manufacturer to any wholesaler, retailer, non-profit agency or governmental entity within the United States, inclusive of any discounts etc.

Once the two prices have been calculated, drug manufacturers are under a duty to provide pharmaceuticals to the Medicaid scheme at the best price. This usually mandates the manufacturer to provide a rebate to individual Medicaid agencies, representing the difference between the average and best prices.

Demonstration projects

Paragraph 1396r-8 of OBRA-90 permits the establishment of a number of what are termed 'demonstration projects'. The purpose of such projects are twofold – to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists to provide drug use review services and to assess the efficiency and cost-effectiveness of prospective drug use review provided on an on line computerised basis and in face to face consultation. The purpose of the demonstration projects is to provide evidence to the government agencies as a basis for determining future funding priorities.

Drug use review

As noted above, the provisions relating to drug use review (on drug use review in general see Smith (1992)) in OBRA-90 are the most significant for the practice of pharmacy and necessitate examination in detail. Paragraph 1396r-8(g)(A) of OBRA-90 obliges individual states, who wish to continue participation in the Medicaid programme, to establish a drug use review programme for outpatient drugs in order to assure that

prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results.

Under the provisions of paragraph 1396r-8(g)(A)(2), each drug use review programme must have the following requirements:

(i) Prospective Drug Review

There are three main elements to a prospective drug use review, as follows:

(a) Screening Prescriptions

OBRA-90 provides that each state plan must provide for a review of drug therapy before each prescription is filled or delivered to an individual, typically at the point of sale or point of distribution. The review must include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with non-prescription or over the counter drugs) incorrect drug dosage or duration of treatment, drug-allergy interactions and clinical abuse/misuse.

(b) Patient Counselling

OBRA-90 provides that, as part of the state's prospective drug use review programme, state law must establish standards for the counselling of individuals by pharmacists. The minimum counselling requirements are set out in the legislation as follows:

'The pharmacist must offer to discuss with each individual, or caregiver of such individual, (in person, wherever practicable, or through access to a telephone service which is toll-free for long distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, including the following:

the name and description of the medication;

the route, dosage form, dosage, route of administration, and duration of drug therapy;

special directions and precautions for preparation, administration and use by the patient;

common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

techniques for self-monitoring drug therapy;

proper storage;

prescription refill information;

action to be taken in the event of a missed dose'

The requirement to counsel individual patients is abrogated when the patient exercise his/her right, guaranteed under the legislation to refuse counselling.

(c) Documenting information

OBRA-90 provides that a reasonable effort must be made by the pharmacist to obtain, record and maintain a minimum amount of information about an individual patient, including the name, address, telephone number, date of birth or age, gender; individual history where significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; pharmacist comments relevant to the patient's drug therapy.

(ii) Retrospective Drug Use Review

OBRA-90 provides for the establishment, in each state, of a Drug Use Review Board (known as the DUR Board). The DUR Board is made up of health care professionals who have recognised knowledge and expertise in the clinically appropriate prescribing, or dispensing of outpatient drugs, drug use review, evaluation, and intervention or medical quality assurance. While the DUR Board is meant to be interdisciplinary, in reality, it is made up of doctors and pharmacists. The major function of the DUR Board is to undertake the retrospective drug use review programme. The purpose of this programme is to review the data concerning the use of medications accumulated by pharmacists as part of the prospective drug use review and compare this data with criteria and standards on ideal medications use and model drug therapy already developed by the DUR Board.

Specifically the legislation states that the programme shall:

‘... on an ongoing basis, assess data on drug use against explicit pre-determined standards ... including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds.’

(iii) Educational Programmes

As noted above, the DUR Board, as part of its ongoing retrospective drug use review, may identify problems with drug therapy. As part of its mandate to introduce remedial strategies, the DUR Board may recommend educational programmes. The objective of these educational programmes is to improve drug therapy by improving the method by which medications are used. Educational programmes can take a variety of different formats, ranging from one to one contact with an individual pharmacist or doctor, identified as having a specific problem with aspects of drug therapy, or general instruction for groups of health care professional on general patterns of drug mis-therapy.

What is the rationale behind drug use review?

The impact of drug use review on pharmacy practice and procedure, and its consequences for individual pharmacist liability, both anticipated and real, will be discussed in greater

detail below. It might be useful, however, to reflect in general terms, on the rationale and purpose of the drug use review scheme as a whole, and its individual components in particular.

Drug use review is not a new concept for the pharmacy profession. As Smith (1992:70) concludes, drug use review has been an integral part of pharmacy and health care for some time. Smith submits that drug use review has never become 'institutionalised': that is, had never become a formal part of the professional practice of pharmacists in their interactions with patients. The key to OBRA-90 is that it provides the opportunity, through mandating pharmacists to participate in all of its components but particularly in prospective drug use review, to institutionalise drug use review as an integral aspect of health care.

Brushwood and Abood (1994:158) submit that while each of the individual components of drug use review are significant in themselves, all three functions are elements of a continuous quality improvement cycle, all are ongoing, and all are necessarily inter-related. Further, although a great deal of attention has been devoted to the pharmacist's involvement in prospective drug use review, the other two elements, retrospective drug use review and educational programmes, are equally important.

The system is cyclical. The prospective drug use review programme is to give pharmacists the opportunity to reflect on drug therapy and to apply their knowledge about appropriate medication use. The prospective drug use review programme produces new,

up to date data about the dispensing of medications. This date may then be used by the DUR Board in its function of retrospective drug use review, allowing it to determine whether existing and identified problems with drug therapy have been removed or diminished, and whether new problems have been identified. If new problems have been identified, these may be addressed through educational programmes. The three part drug use review cycle then continues. Brushwood submits that, theoretically, the continuous application of the drug use review cycle would eventually identify and eliminate all problems with drug therapy, leaving behind a perfect drug use system. Perfection, though will not be achieved, due to the parallel, continuing entry to the system of new drugs, new pharmacists, and new patients.

What of the individual components of drug use review?

Palumbo (1992), gives a comprehensive analysis of the rationale and purpose of the retrospective drug use review programme. He argues that the programme will focus on an ongoing periodic examination of professional practice to identify, amongst other things, inappropriate or medically unnecessary care among pharmacists, doctors and patients. The evaluation should concentrate on prescribing appropriateness, principally with regard to dosage, length of therapy, drug-drug interactions and duplicate therapy. As noted above, in retrospective drug use review, orders for specific drugs are measured against specific criteria and any differences with the criteria are recorded and summarised.

Palumbo argues that criteria are an essential aspect of any drug use review programme, providing a specific description of how prescription drugs should be prescribed. However, there appears to be a great deal of confusion with regard to the use of measurement 'criteria', as advocated by OBRA-90 and 'standards', which is the term that has traditionally been used in Medicaid and other laws, as the elements against which the quality of any medical service should be compared. Palumbo welcomes the fact that the development of criteria by those responsible for the administration of the Medicaid scheme, as non-proprietary and readily available. Further, Palumbo argues that pharmacists, as members of the DUR Board, must actively participate in the retrospective drug use review process, by assisting in the development of suitable criteria, and as individual pharmacists, they must be diligent in co-operating by reporting problems with the use of the criteria.

Palumbo also analyses the impact of the new educational programmes or interventions. As noted above, following retrospective drug use review, the DUR Board may identify patterns of drug prescribing which are inappropriate. If this is the case, the DUR Board is empowered to initiate educational programmes to remedy the situation. Palumbo argues that such interventions might take the form of a letter to an individual pharmacist or prescriber, or a series of more general educational programmes designed for groups of pharmacists and prescribers. Palumbo warns pharmacists of the potential adverse consequences of failing to respond to DUR Board's recommendations with respect to educational programmes.

Of the three individual components of drug use review, - retrospective drug use review, educational programmes, and prospective drug use review, - the latter impacts most directly on the day to day professional activities of pharmacists, and their interaction with patients and other health care professionals. As such, this element of drug use review has received the most attention in the professional literature, both in terms of its underlying philosophy and, more importantly, its impact on individual practices and procedures and individual liability, if and when such practices and procedures fall below the required standard. This aspect will be discussed in more detail below.

Both Brushwood and Abood (1994:160) and Palumbo (1992:) argue that the overall objective of prospective drug use review is to promote the solution of drug therapy problems via a comprehensive review of the patient's prescription at the point of dispensing. The pharmacist is under a duty to evaluate the appropriateness of medication prescribed for the patient in parallel with other information known about the patient. While, and as was noted above, prospective drug use review has three separate components, all three are continuous and ongoing, and are necessarily inter-related (Brushwood, Catizone, & Coster 1992:4).

For Palumbo, prospective drug use review:

'represents the most significant opportunity and challenge to pharmacists. It codifies the integral role of the pharmacist in the delivery of health care services, detailing activities which many but not all pharmacists had been conducting prior to OBRA-90' (1992:4)

Portner and Fitzgerald (1993) in their detailed article on the opportunities provided by OBRA-90, agree that the new requirements contained in the prospective drug use review programme, while providing a challenge to pharmacists, also represent an opportunity to provide quality care for patients, communicate in a more constructive manner with prescribers, and add value to professional practice. Gastineau (1993:315) argues that prospective drug use review has several purposes, including the requirement to assess a patient's drug therapy and resolve any potential problems before dispensing any prescription, ensuring that all the essential information concerning a patient's medical history has been obtained, and requiring pharmacists to provide patients and their prescribers with information regarding medications so that patients can improve their compliance, avoid medication errors, and increase the probability of favourable drug therapy.

It is clear from this analysis that the purpose and rationale of drug use review is to use existing but untapped expertise in drug therapy evaluation to permit patients to improve their compliance with drug therapy regimes, avoid medication errors and increase the likelihood of success with their health care.

How have the requirements of OBRA-90 been implemented?

OBRA-90 required individual states to adopt expanded standards of pharmacy practice by 1 January 1993, if those states wished to continue to participate in the prescription drug component of the Medicaid programme. As noted above, individual states have the

responsibility for developing and implementing legislation for the purposes of the Medicaid scheme and for professional practice standards for pharmacists. As the OBRA-90 mandate had implications for both the Medicaid scheme and for professional standards, any amending state legislation would have to straddle both of these objectives.

It has already been noted that the state boards of pharmacy have their own national organisation – the National Association of Boards of Pharmacy (NABP). As part of its mission statement of assisting its member boards and jurisdictions in developing, implementing and enforcing uniform standards for the purpose of protecting the public health, the NABP produced detailed guidance on the requirements imposed by OBRA-90, the meaning of individual words and phrases in the legislation, and produced draft legislation for consideration by the state boards of pharmacy for enactment (NABP 1992 and Catizone 1992).

OBRA-90, although containing specific mandates, is drafted in general terms, and gives considerable discretion to individual states to implement the provisions as they wish. It is important to recall that the provisions provide a mandate related to continued participation in the Medicaid scheme, and impose no additional requirements on states who do not wish to continue with participation in that scheme, no extra duty with respect to health care outside of the Medicaid scheme, and impose no additional demands on individual pharmacists. It will be noted below, however, that the majority of states have taken the OBRA-90 mandate extremely seriously, and have imposed requirements covering all patients which impose new duties on all pharmacists.

An excellent summary of the implementation of OBRA-90 is provided by the National Association of Boards of Pharmacy in its 1993 document 'Patient Counselling Requirements – a State by State Compilation of Statutory and Regulatory Provisions Enacted in Response to the Mandates of the Omnibus Budget Reconciliation Act 1990' (NABP 1993). The NABP confirms that OBRA-90 had given 'significant latitude' to individual states for the establishment of patient counselling standards to fulfil OBRA-90's mandate. That latitude had resulted in a diversity of individual state requirements, all of which are reported in detail in the compilation. However it is important to note that the diversity is often in the detail of the individual requirements imposed by the state's interpretation of the federal legislation. What is clear is that the majority of the states (44/52) were satisfied that the new requirements were of sufficient importance to be extended to all prescriptions and were to apply to all interactions between pharmacist and patient.

For comparative purposes, two examples of how OBRA-90 has been implemented in individual states can be extracted. The first relates to the state of Florida. This state has been chosen both because it was the subject to a review of existing pharmacy standards above, and because the provisions introducing the OBRA-90 requirements are comprehensive.

Following the enactment of OBRA-90, the following new rules were drafted pursuant to paragraph 465.0155, the Standards of Practice section, of the State Pharmacy Act:

'REQUIREMENT FOR PATIENT RECORDS

- (1) A patient record system shall be maintained by all pharmacies for patients to who new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:**

 - (a) full name of the patient for whom the drug is intended;**
 - (b) address and telephone number of the patient;**
 - (c) patient's age or date of birth**
 - (d) patient's gender;**
 - (e) a list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the twelve months immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;and**
 - (f) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.**
- (2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.**
- (3) A patient record shall be maintained for a period not less than twelve months from the date of the last entry in the profile record. This record may be a hard copy or computerized form.**
- (4) Patient records shall be maintained for prescriptions dispensed subsequent to the effective date of this regulation.**

PROSPECTIVE DRUG USE REVIEW

- (1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:**
 - (a) over-utilization or under-utilization**
 - (b) therapeutic duplication;**
 - (c) drug-disease contraindications;**
 - (d) drug-drug interactions;**
 - (e) incorrect drug dosage or duration of drug treatment;**
 - (f) drug-allergy interactions;**
 - (g) clinical abuse/misuse**
- (2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.**

PATIENT COUNSELLING

- (1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of drugs to the patient or the patient's agent is not made at the pharmacy, the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's' record and personally discuss matters which will enhance or optimize drug therapy with each patient or the agent of each patient. Such discussion shall be in person, whenever practicable, or by toll free telephone communication and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:**
 - (a) the name and description of the drug;**
 - (b) the dosage form, dose, route of administration, and duration of drug therapy;**
 - (c) intended use of the drug and expected action (if indicated by the prescribing health care practitioner);**
 - (d) special directions and precautions for preparation, administration, and use by the patient;**
 - (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;**

- (f) techniques for self-monitoring drug therapy;
 - (g) proper storage;
 - (h) prescription refill information;
 - (i) action to be taken in the event of a missed dose; and
 - (j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
- (2) Patient counseling, as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).
- (3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

The Florida legislation does not limit these new requirements to those participating in the Medicaid scheme but extends them to all patients.

The state of Missouri has also been chosen for comparative purposes and because, the state provisions introducing the OBRA-90 requirements, have, as will be examined in detail below, been subject to judicial scrutiny in that state.

In Missouri, the following paragraphs, 220-2.190, were inserted into the state legislation relating to the State Board of Pharmacy (4 CSR 220):

'PATIENT COUNSELING

- (1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or

caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

- (2) Pharmacies shall maintain appropriate patient information to facilitate counseling. This may include but shall not be limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of their drugs prescribed.
- (3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include but shall not be limited to written information leaflets, pictogram labels, video programs, and the like.
- (4) Patient counseling, as described in this rule, shall not be required for inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications.
- (5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation.

As in Florida, the state provisions in Missouri are extended to all patients and all prescriptions.

The initial reaction of the pharmacy profession to the new professional requirements

The pharmacy profession's reaction to the enactment of OBRA-90 was one of almost universal welcome and endorsement, reflected in the plethora of professional literature

published in the period before and after implementation, and which was designed to assist pharmacists in meeting and managing their new responsibilities.

Portner & Fitzgerald (1993), in a comprehensive analysis of the benefits of the new legislation, encouraged pharmacists actively to implement the drug use review programme of OBRA-90 and view the new requirements as the impetus to enhance professional responsibilities and financial gains and to facilitate growth in the profession. The opportunities identified by the authors, as provided by OBRA-90, include the future provision of quality care, through focusing on outcomes, documenting activities, communicating with prescribers, data collection and the prevention of drug therapy 'crashes'; opportunities in cost containment and health care reform; opportunities in risk management; the scope for further financial rewards, financial stability, increasing job satisfaction; the preparation for new roles including nondistributive roles; and opportunities for adding value:

'OBRA '90 presents many opportunities to practicing pharmacists. To justify our clinical services and interventions to patients, reimbursers, and prescribers, we must document activities and collect data. We can use our extensive knowledge base to improve patient compliance and reduce the costs of medications and related health care. As pharmaceutical care suggests, pharmacists must take responsibility for patient outcomes that include clinical, economic, and patient well-being components.' (1993:74)

As was noted above, the National Association of Boards of Pharmacy was instrumental in the development of model rules to assist individual state boards to comply with the mandate of OBRA-90. In addition, the NABP has been responsible for providing detailed guidance to members of the pharmacy profession on the rationale and purpose of the new

legislation, and on the specific responsibilities which it creates. The NABP published a series of articles in October 1992 to reflect this objective.

In the first, 'OBRA 90: What It Means to Your Practice', Brushwood, Catizone & Coster give an extensive overview of the implications of OBRA-90 for professional pharmacy practice, by analysing all aspects of the three main components of the new legislative requirements. In urging the pharmacy profession to identify with, and accept the challenge offered by OBRA-90 the authors conclude:

'The United States Congress has identified pharmacists as health care professionals who can help solve existing problems with the quality and cost of drug therapy. This is a tremendous opportunity, not a horrendous burden. Pharmacists must rise to the occasion and show that the trust placed in them by Congress has not been misplaced ... Pharmacists have been 'at the crossroads' of expanded practice for the past two decades, during which there have been false alarms when the correct direction to turn has been apparent, but the turn has not been taken. Now is the time to turn toward pharmaceutical care. The federal government and the State Boards of Pharmacy are behind it and will continue to be as long as pharmacy does not disappoint those who have so much faith in the profession. By accepting the challenge of OBRA 90, pharmacists can assure their status as highly respected, highly rewarded and highly valuable professionals for many years to come.' (1992:10)

In the second and third articles sponsored by the NABP, 'Drug Use review Under OBRA 90' and 'OBRA90: Patient Counseling – Enhancing Patient Outcomes', Palumbo, Hatoum, Hutchinson and Lambert, analyse, in detail the specific components of drug use review process and the patient counselling mandate, and give detailed guidance to pharmacists on strategies for implementing the new programmes in to day to day

practice. In so doing , the authors also provide significant support for the objectives of the legislation and crucial motivation for the profession to adopt its ideals:

‘Drug use review when properly used, can be a powerful tool in ensuring the appropriate prescribing of medications and, therefore, optimal patient care ... Pharmacists must maintain their leadership and involvement in the DUR process so that optimal pharmaceutical care can be achieved with minimal governmental interference in their particular practice.

Pharmacists are educated and trained to function effectively as experts in pharmacotherapy in the health care team ... Pharmacists need to assume greater responsibility and accountability, show interest not just in the physical dispensing of drugs, or in the provision of drug related information, but show where the drug is going, how it is to be consumed, the eventual patient outcome and the cost effectiveness of the entire process ... Accountability means accepting responsibilities, doing the best a pharmacist can do to meet his or her primary care obligations for the benefit of patients ...Patient counseling represents the visible opportunity for pharmacists to share their knowledge of pharmacotherapy and assure responsibility for patient outcomes while demonstrating the level of caring that is demanded by today’s assertive health care professional.’ (1993:8-10)

The fourth article in the NABP series introducing OBRA-90, ‘OBRA 90: Implementation and Enforcement’, by Richard Abood, gives further guidance to pharmacists on the enforcement machinery for a failure to meet the requirements of the legislation. Abood notes that in most states, as was the intention of the federal law, the implementation and enforcement of OBRA 90 is the joint responsibility of the state Medicaid agency and the state board of pharmacy. In most states, as the survey of state practice above demonstrated, the main obligations of the drug use review process have been written into the state pharmacy practice act giving responsibility for implementation and enforcement of these provisions to the state board of pharmacy. Abood is clear about the implications of a failure to comply with the terms of the state pharmacy practice act – a violating

pharmacist might face disciplinary proceedings by the state board of pharmacy, the state Medicaid agency or both. A finding of guilt by the state Medicaid agency would result in an ejection from the Medicaid programme. A breach of the provisions of the state pharmacy act could result in licence suspension, revocation and/or the imposition of fines for both the pharmacy and pharmacist involved. Abood notes, however, that in the early stages of implementation, however, the most likely first intervention by state authorities will be through educational programmes provided by the state DUR board after the board has identified, through the retrospective drug use review programme, that problems have arisen. Further, the most likely first intervention for violation of the prospective drug use review programme, including the patient counselling requirement. Abood was of the view that disciplinary proceedings would be reserved for intentional violations, situations where educational interventions or warnings had failed to have a positive effect or where the pharmacy cannot substantiate an activity through documentation.

Although analysing OBRA-90 from the perspective of discipline and censure, Abood mirrors his colleagues in asserting that the pharmacy profession should view the new legislative requirements as an opportunity rather than a problem:

‘Pharmacists, however, should not criticize, but rather assist state boards of pharmacy and state Medicaid agencies in their complex assignment of implementing OBRA 90. Pharmacists should also make every attempt to practice according to OBRA’s standards, thereby confirming pharmacy’s vital role in health care. (1993:8)

Abood repeated this advice, and call for acceptance in the further guide to compliance with the requirements of OBRA-90, published in 1993, with Jellin and Ponedal (Abood, Jellin and Ponedal 1993).

West and Smith (1993) concentrate on the potential of OBRA-90 to increase individual pharmacist liability, and this aspect of their article will be discussed in more detail below. The authors, however, also analyse the impact of the legislation on pharmacist-doctor and pharmacist patient relationships. In relation to the former, the authors are of the view that while the initial reaction of the American Medical Association to the new pharmacist duties was negative, an attitude based largely on a conviction that the new legislative requirements would interfere with, and damage the patient-doctor relationship, OBRA-90 would have the beneficial effect of promoting more professional co-operation between doctors and pharmacists. West & Smith are of the view that it is in the interests of both professions to ensure collaboration throughout the process. The authors report that reaction from patients to the new counselling requirements had been mixed but suggest that increased patient education would lead to a demand rather than a request for the appropriate information.

Quick (1993) submits that, in addition to the new responsibilities and potential liabilities that pharmacists will face as a result of the implementation of OBRA-90, there remains the possibility that counselling by pharmacists will create conflicts between themselves and other health care providers, particularly prescribing doctors. Further, the requirement for all information obtained from patients under the mandated counselling requirements

to remain confidential, will require pharmacists to adopt new practices and procedures, including the re-adaptation of the physical environment of the pharmacy.

The National Association of Boards of Pharmacy, as noted above, produced its own information pack on the patient counselling and drug use review requirements of OBRA-90 (NABP 1992). Other professional organisations also assisted in the process of promoting and guiding the introduction of the new requirements. The American Pharmaceutical Association, the national organisation representing the interests of the pharmacy profession, published in 1994 a detailed practical guide to the implementation of OBRA-90, describing the legislation as a method of effecting pharmaceutical care (AphA 1994). The guide is detailed, with seven chapters devoted to all aspects of OBRA-90. In addition to providing practical assistance to individual pharmacists, the AphA are keen to stress the importance of the legislation for the future of the profession. Roger Davis, in chapter 6 of the guide, 'Beyond Patient Counseling: Creating Broader Opportunities Through OBRA-90', reflects on the importance of the legislation in pointing the way for the pharmacy profession in the future:

'Pharmacists practicing in the coming decades are likely to find themselves in new roles. They may be much more involved in the direct delivery of care to patients, including making independent judgments. Pharmacists also may play an essential role in assessing the outcomes of drug therapy, using technologically advanced laboratory tests and other evaluators. Pharmacy practice in the future will require a more direct approach to patient care, to ensure rational and effective drug therapy management. Pharmacists may become the core facilitators in a multifaceted system of care in which practitioners share responsibility for patient outcome and authority to implement care decisions. The opportunity for pharmacists to practice in this integrated fashion has been clearly initiated by OBRA-90.' (Davis 1994:63)

Finally, the American Society of Hospital Pharmacists, representing, as the title suggests, the interests of hospital pharmacy, produced its own guidance to the impact of the requirements of OBRA-90 on the practice of pharmacy in the hospital and other institutional environments (AJHP 1991). While recognising that the greater impact will be on the practice of pharmacy in the community environment, and that hospitals and other institutional would be only likely to be affected by OBRA-90 in terms of the impact which it would have on drug budgets, the ASHP nonetheless recognised that the provisions in the legislation are certainly helpful in assisting the pharmacy profession to move forward.

What was the potential impact of OBRA-90 on pharmacist liability?

The purpose of this thesis is to look at the issue of pharmacist liability, and to analyse how changes in the pharmacy profession's role and purpose over time have impacted on that question. As has been noted above, OBRA-90 has been described as the most significant pharmacy law of all time, expanding as it does, pharmacy practice standards in an unprecedented manner. As such, it is essential to examine how this important new law impacts on the question of individual pharmacist liability. That analysis will take two forms. To begin with, it will be useful to go back to the date of implementation to review what commentators were saying about the likely impact of OBRA-90 on pharmacist liability. That will be the focus of this aspect of the chapter. Later, the speculation on the potential for liability may be measured against the reality of the situation, some seven years later.

It is important to note that the mandate imposed by OBRA-90 had the potential to impact on individual pharmacist liability in two main ways. Firstly, and as was noted above, in most states, as was the intention of the federal law, the implementation and enforcement of OBRA-90 is the joint responsibility of the state Medicaid agency and the state board of pharmacy. In most states, as the survey of state practice above demonstrated, the main obligations of the drug use review process have been written into the state pharmacy practice act giving responsibility for implementation and enforcement of these provisions to the state board of pharmacy. As such, a violating pharmacist might face disciplinary proceedings by the state board of pharmacy, the state Medicaid agency or both. This liability aspect of OBRA-90, which might also be described as professional administrative responsibility, and which relates to the pharmacist's duty to the profession, will be discussed in more detail below.

The second impact of OBRA-90 on individual pharmacist liability may be to expand the scope of the duty owed by the pharmacist in negligence. The last chapter of this thesis demonstrated that judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability in negligence based on an expansion of the pharmacist's new roles and functions. When OBRA-90 was enacted, many commentators speculated on the effect which the legislation, and its inherent expansion of pharmacy practice standards, would have on the current trend of expansion of pharmacist responsibility. It is this aspect, which focuses on the pharmacist's responsibility to the individual patient, which will be examined in the next section.

Brushwood (1998:184, 1997:493) refers to two cases which, he submits, propose that individual state appellate courts will defer to the language of OBRA-90 as contained in the state pharmacy practice acts. The first of the cases is *Huggins v Longs Drug Stores* (862 P.2d 148 (Cal. 1993)). The plaintiffs in this case were the parents of a child who had suffered the ill effects of an overdose caused by a dispensing error. The pharmacist had negligently entered the wrong instructions for the medication dosage on the prescription label. The child's action for damages for the damage caused by the negligence was settled. The parents contended that the defendant pharmacist, by providing the dosage amounts, assumed a duty to them because he knew or ought to have known that they would have to administer the prescription to the child, the child being too young to do so himself, and would do so in accordance with the pharmacist's direction.

The Californian Court of Appeal agreed that the action of a pharmacist, in providing incorrect dosage under circumstances making it necessary for a caregiver to administer the medication, would constitute negligence directed at the caregiver who did so administer the medication:

'The duty of care assumed by pharmacists supplying prescriptions to those who are to administer them includes not only the provision of correct medication but just as importantly the direction of appropriate dosage to be administered.' (862 P.2d 148 (Cal. 1993), 84)

The court also thought that there should be no general public policy consideration to insulate from liability a pharmacist who provides instructions for a prescription intended

for an infant and who negligently mis-states the dosage, setting in motion a process which results in death or serious injury to the child. Rather, the court held that a parent or close relative who, as a caregiver, relies upon the directions and administers the prescription should be allowed recovery under these circumstances.

The court did think that there should be some limit, based on public policy considerations, on the conditions upon which recovery should be permitted. The court thought that recovery should be restricted to parents and close relatives, because, in common experience, it was more likely that they will suffer a greater degree of emotional distress from negligently caused pain and suffering or death than others not so related. Further, there should be a requirement of knowledge on the part of the pharmacist and serious injury to the child. In order to assume a duty to the parents, the pharmacist would either have to know, or be in a position that he/she ought to have known, that the medication was for administration to a child or other person so incapacitated. The court thought, finally, that requiring serious injury or death to the loved one would also be appropriate and necessary. The court thought that to allow recovery to a person who learns after the fact about what might have been would lead to liability out of all proportion to the degree of fault.

Although the decision in *Huggins* was given prior to the enactment of OBRA-90, Brushwood submits that the finding the court that the pharmacist has a duty to consult with the agents of patients, such as the parents of a small child, or the carers of an elderly patient, and that the purpose of the consultation is to ensure that the pharmacist's advice

is used constructively and appropriately for the benefit of the patient, even if the patient, him or her self would be unable to understand the advice, is evidence that the court recognised the principles of OBRA-90 (1997:493).

Certainly it is arguable that the court in *Huggins* was continuing the trend of an expansion of pharmacist responsibility, based on the 'duty to warn' principle, and based on an expansion of pharmacist role and function. The advice and guidance which the court held to be appropriate is advice which falls into the category of 'warning', and the decision strengthens the evidence, outlined in the previous chapter, that the courts have begun to recognise expanded responsibilities. As outlined above, the drug use review requirements of OBRA-90, and in particular the duty on pharmacists to undertake prospective drug use review, including prescription screening and patient counselling, are analogous to the type of activity mandated by the court in *Huggins*. The patient counselling requirement includes a duty to counsel as to the route, dosage form, dosage, route of administration, and duration of drug therapy. The court clearly required that the prescription is screened, and that the patient, and in this case the patient's surrogate, is counselled on problematic aspects of the drug therapy, including dosage strength and administration. It is arguable that had the OBRA-90 requirements been in force at the time the prescription was presented for filling, and had the pharmacist complied with those requirements, the problem with the overdose would never have occurred.

The second case referred to by Brushwood, as providing evidence of state court compliance with the language of state pharmacy acts implementing OBRA-90 is *Walker*

v Jack Eckerd Corporation (434 S.E. 2d 63 (Ga. Ct. App. 1993)). In this case, the defendant pharmacist was alleged to have negligently dispensed, in a period of one year, fifteen separate refills of a prescription drug called 'Blephamide' pursuant to a prescription marked "PRN". As the court noted, a prescription marked "PRN" can be refilled 'as needed' over a lengthy time period, usually not over one year. The plaintiff developed glaucoma, and alleged that the problem was caused by the excessive prescription of the Blephamide. The development of glaucoma is a well recognised and well documented side effect of prolonged use of Blephamide. Before the Court of Appeals of Georgia, it was argued, *inter alia*, that the defendant pharmacist was in breach of a legally recognised duty in failing to warn or in failing to refuse to refill the prescriptions.

The Court of Appeals ruled that, on the basis of preserving, without the interference of third parties, a trusted doctor-patient relationship, the fact that patients have different reactions to and tolerances for drugs, the fact that the severity of a patient's condition may warrant a different level of risk acceptance, that the public policy of the state was for reducing frivolous malpractice actions against professionals, and moreover, that all of these factors were best monitored and evaluated by doctors, there was no duty on the pharmacist to warn a patient or notify the doctor that a drug is being prescribed in dangerous amounts, that the patient is being over-medicated or that various drugs in their prescribed quantities could cause adverse reactions. In arriving at this conclusion, the court approved of the comments made on the question by the court in *Jones v Irvin* (602 F.Supp 399 at page 402, cited above). Further the court approved of the additional finding

in *Jones* that it is the duty of the prescribing doctor to know the characteristics of the drug being prescribed, to know much can be given to each patient, to elicit information from the patient concerning other drugs being taken, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drugs, to monitor the patient's dependence on the drug and to tell the patient how and when to take it.

In addition, the court in *Jones* had found that it was the duty of the drug manufacturer to notify the doctor of the other drugs which the patient is taking, and that it was the duty of the drug manufacturer to notify the doctor of any adverse side effects or other precautions which must be taken in administering the drug. The court in *Walker* agreed with the court in *Jones* that to place these duties on the pharmacist would only serve to compel the pharmacist to second guess every prescription which a doctor orders in order to avoid liability.

It is important to note that, in arriving at these conclusions, the Court of Appeals in Georgia, had cited before them, and had analysed in depth, almost every authority, including the conflicting authorities, relating to the common law duty of pharmacists regarding the warning of patients and the refusal to fill prescriptions, including those referred to in chapter four above. As such, the finding of no duty to warn is authoritative. It is important to remember, however, that the court specifically qualified the precedential value of its finding by reminding itself that its ruling was not a mandatory authority for any case arising after the implementation of OBRA-90:

‘In adopting this view we are aware that effective January 1, 1993, the Georgia State Board of Pharmacy imposed certain new drug review and patient counselling rules on pharmacists ... this case is not intended to serve as a controlling precedent for cases involving pharmacists’ duties after January 1 1993. ‘

Brushwood argues that the OBRA-90 requirement that a pharmacist screen for medication overuse would suggest that the pharmacist in *Walker* would be held to be accountable after the implementation of OBRA-90. Such a conclusion is wholly reasonable. The Court of Appeals of Georgia undoubtedly had the full details of OBRA-90 cited before it. It is submitted that had the court formed a view that the new legislation would have made no difference to its finding on no duty to warn, it would have expressly made provision for this in its judgment. The fact that the court had undertaken such an extensive analysis of all of the duty to warn cases in arriving at its initial finding, and then moderated that authoritative conclusion, gives strength to Brushwood’s argument that a different conclusion would have been arrived at, had the case been decided post OBRA-90 implementation (1997:493).

OBRA-90 will not only re-define the nature of the duty of care owed by pharmacists, but will also have an influence over determining the standard of care. As noted above, practice standards become important in the assessment of whether a pharmacist has been in breach of a duty of care to a patient, and are frequently referred to by the courts when they are faced with the determination of that question. Brushwood is of the view that following the implementation of OBRA-90, when courts analyse pharmacy statutes and

regulations for evidence of a standard of care, they are likely to find more compelling and stringent mandates:

‘Courts that might otherwise have read ambiguous statutory or regulatory definitions of “the practice of pharmacy” ... will find in the statutes and regulations new language that clarifies what it means to be responsible as a pharmacist. Courts that inventory the pharmacy laws ... will find the missing piece that previously was left out of the pharmacy laws. Courts ... that relied on a limited description of pharmacist responsibility under administrative rules, will see that the responsibility has expanded ... if the pattern of the past in relying on statutes and regulations as some evidence of the standard of care continues into the future, judicial rulings should adjust to an expanded standard, because the statutes and regulations reflect an expanded standard, as mandated by OBRA-90.’ (1997:501)

The individual components of drug use review will, according to Brushwood, expand pharmacist liability in three main ways. Firstly, the requirement that pharmacists screen all prescriptions gives an exposure to liability where a problem occurs which would have been prevented by appropriate screening. Secondly, the requirement that a pharmacist offers to discuss common, severe side effects or adverse effects, including ways to avoid such effects and the action to be taken if they do occur, will lead to liability when an avoidable side or adverse effect takes place. Thirdly, the requirement that pharmacists document information relating to an individual’s drug therapy, mandates the pharmacist to record potential problems and their resolution, as the failure to do so will also increase exposure to liability.

Brushwood concludes that, in order to avoid liability under the new regime, pharmacists will have to become problem solvers. That requires pharmacists to determine, at an early stage, what action is required for the benefit of the patient. It also mandates pharmacists

to document all aspects of the care which was provided to the patient. Finally, the pharmacist must enable the patient to recognise problems which may arise in the future, and must also instruct the patient as to the appropriate action when a problem develops. (1997:501)

West and Smith (1993) were of the view that the prospective drug use review programmes, mandated by OBRA-90, would have an effect on pharmacist liability because of the additional duties imposed. The authors suggested that the new requirement imposed on a pharmacist to make a reasonable effort to obtain a patient's individual history was an example of the potential for increased exposure to liability. They noted that under a traditional analysis of the patient-pharmacist relationship, and traditional analysis of pharmacist liability, the pharmacist had no duty to know a customer's condition or history, and therefore no duty to warn the patient based on any information related to condition or history.

Under the new mandate, pharmacists are required to know about condition and history, so that a pharmacist with access to individual patient information may be held to be liable for a failure to warn, because the pharmacist might have a more comprehensive knowledge of the individual drug therapy:

'... the requirement of maintaining patient profiles concerning individual medical history places additional liability on pharmacists, because this arguably gives the pharmacists the information needed to determine what warnings would be appropriate for a particular patient, absent direction from the prescribing physician. If the physician fails to issue the proper warnings, ... the pharmacist will be obligated to do so under OBRA, not

withstanding the common law's holdings (until then) to the contrary.'
(1993:138)

West & Smith are of the view that cases such as *Irwin v Hook's Drugs* (476 N.E. 2d 881 (Ind. Ct. App. 1985)), where the court had noted that there was no allegation that the pharmacist had any prior knowledge of the plaintiff's medical history or condition; *McKee v American Home Prods. Corp.* (782 P. 2d 1045 (Wash. 1989)), where the court had noted that neither the manufacturer nor the pharmacist had the medical education or knowledge of the medical history of the patient which would justify a further imposition of duty; and *Ramirez v Richardson-Merrell* (628 F. Supp. 85 (E.D. Pa. 1986), where the court had held that the duty to warn of the hazards associated with a prescription should lie with the prescribing doctor as the doctor was more familiar with the appellant's condition and medical history, would all be completely changed by the mandate of OBRA-90.

West and Smith are also of the view that the patient counselling requirements of OBRA-90 will also have the effect of increasing pharmacist exposure to liability. Under the traditional analysis, the pharmacist has no responsibility for warnings. The OBRA-90 mandate will increase the knowledge available to a pharmacist about the patient, the patient's condition and the patient's medical history. In the authors' view, this increased knowledge and expanded knowledge may be sufficient to establish a duty that the pharmacist should know what warnings are necessary and appropriate for a particular patient. Further, the pharmacist may be the subject of a cause of action for a failure to counsel to the appropriate standard.

West and Smith conclude that the pharmacist's traditional insulation from liability, based on the learned intermediary doctrine, applied almost universally by the courts, might be swept away by OBRA-90, but that this was not necessarily a bad thing:

'In a sense, OBRA recognizes pharmacists as professionals rather than as retail providers of consumer products. Consequently, along with professional recognition comes potential liability, traditionally reserved for others in the medical profession. Pharmacists may have to interject themselves into the doctor/patient relationship not only to improve the quality of pharmaceutical care, but also to protect themselves from liability for failing to serve as the "safety supervisor" of prescription medications' (1993:143)

Baker (1996) is of the view that the real outcome of OBRA-90 will be its effect on the determination of the minimum standard of pharmacy. He is also of the view, and in agreement with both Brushwood and West & Smith, that the series of cases which had held that a pharmacist has no duty to warn on the basis of public policy, may have to be re-evaluated. According to Baker, courts, such as those in *Jones v Irvin* (602 F.Supp. 399 (S.D. Ill. 1985)), *Ingram v Hook's Drugs Inc.* (476 N.E. 2d 881, (Ind. Ct. App. 1985) and *Lasley v Shrake's Country Club Pharmacy, Inc.* (880 P. 2d. 1129 (Ariz. Ct. App. 1994)), which had viewed the legal duty of pharmacists as a matter of public policy, may have the matter taken out of their hands by OBRA-90.

The decision in *Walker v Jack Eckerd Corp.* (434 S.E. 2d 63 (Ga. Ct. App. 1993)), showed that other cases such as *Ingram* and *Hooks SuperX Inc. v McLaughlin* (642 N.E. 2d 514 (Ind. 1994) would have to be decided differently after the implementation of OBRA-90. The state legislation implementing the OBRA-90 requirements in Indiana, the

state where *Ingram* and *Hooks* were decided, was drafted in such a way that a pharmacist abiding by its drug review standards, would have to counsel about common adverse side effects or interactions, their avoidance and the action necessary should they occur. Such action would have alerted the pharmacist to the problems which arose in *Ingram* and *Hooks*.

Baker cautions that the courts should recognise that the duty imposed by OBRA-90 is only a limited duty, and only involves the pharmacist in performing a drug use review rather than a drug use assessment. The duty of determining what medication is to be taken remains with the prescribing doctor and, submits Baker, OBRA-90 does not involve the pharmacist in second-guessing that decision. The pharmacist's duty is to determine how that medication can best be taken for the patient's benefit. Baker concludes, however, that OBRA-90 is an important advance for the pharmacy profession:

'The role of the pharmacy in providing medical care, and thus the pharmacist's duty is still evolving ... As new roles for pharmacists become mainstream, the legal duties of the pharmacist and the minimum standards will naturally expand ... The current duty of pharmacists is set by the OBRA 90 type-regulations. It is important that courts not lag too far behind or leap too far forward. The standards of any profession are set by the profession; pharmacy has set its minimum standards and they are found in OBRA 90'.
(1996:518)

Gastineau (1993), after reviewing, in detail, the common law approach to the pharmacist's duty to warn, including those cases analysed above in chapter four, concludes that, as a general rule, a pharmacist who properly filled a prescription could usually escape liability, regardless of the harm caused to the patient, as long as the

medication dispensed conformed precisely to the prescribing doctor's prescription. Gastineau, however, is of the view that the enactment of OBRA-90 could radically alter that position by expanding the pharmacist's responsibilities, and refocusing the practice of pharmacy into a new direction. The refocusing is from a practice with a product disbursement orientation to a clinical practice responsible for reducing potential drug therapy problems.

Gastineau is of the view that although the requirements imposed by OBRA-90 have the potential to increase the liability of pharmacists, there are many steps which the pharmacist can undertake to avoid such liability arising. These include the requirement to have a thorough knowledge of each patient, in order to meet OBRA-90's screening mandate. This will necessitate the conduct of an interview with each patient before a prescription is dispensed, and, further, will require the pharmacist to maintain adequate documentation which contains relevant information about patients and the pharmacist's comments regarding the patient's drug therapy. In turn, the development of comprehensive and accurate patient profiles will assist the pharmacist in acquiring the information needed to perform the mandated screening and counselling functions of prospective drug use review. Proper documentation also assists in protecting the pharmacist from an allegation of a failure to counsel or an omission to counsel properly.

Gastineau, like many of his professional colleagues, is keen to stress the advantages of OBRA-90 and to encourage the profession to accept its ideals and objectives:

'The mandates of OBRA 90 should be seen as a challenge to the professionals that practice pharmacy. The challenge is to lead the practice of pharmacy into a new direction that will allow the pharmacist the time and opportunity to effectively and cost efficiently counsel every patient. Pharmacists must arise to the occasion and meet this challenge head on. In doing so, the pharmacist must assume greater responsibility and accountability. The pharmacist must refocus the priorities of the profession from being a dispenser of medication to becoming a drug therapy counselor who is concerned about where the drug is going, how it is to be consumed, the ultimate patient outcome of the drug therapy, and the cost effectiveness of the whole process.' (1993:325)

Quick (1993) identifies that the mandated requirement to counsel patients may give rise to possible liability where the counselling is inaccurate and the patient is harmed as a result. The compulsory nature of the counselling function only serves to increase the risk of error – the more often the pharmacist counsels, the more likely that a mistake will be made. The existing protection of a pharmacist from liability, on the basis that the pharmacist does not make decisions regarding which drugs a patient should take or the correct dosage, is swept away by the requirement that a pharmacist take the primary responsibility for initiating counselling about the use of drugs. Quick also suggests that the new mandate requiring pharmacists to take appropriate steps to avoid or resolve drug misuse or abuse might result in a contravention of the civil rules on defamation. This might arise where a pharmacist makes a false allegation of drug abuse based on a wrong conclusion about the patient's drug regime. This latter extension of liability has not been raised by the other commentators on the liability implications of OBRA-90, and, it is submitted, such conduct would already be covered by the pharmacist's existing duty of confidentiality (Mullan 2000: Chapter 14).

Quick submits that pharmacists can reduce the potential for increased liability by comprehensively documenting each patient counselling session undertaken, a task which she accepts would not be easy, due to pressures of time, and lack of familiarity with individual patients and their medical history. Further, pharmacists would have to be careful to ensure that the counselling given to an individual patient was sufficiently comprehensible to that patient. The counselling standard to be adopted under OBRA-90 would be likely to be greater than that of ensuring that an average patient would understand the nature of the information and advice being given.

Patane (1993), in taking a different view of the benefits associated with OBRA-90, begins with an analysis of the cases which had held, consistently, that pharmacists have no duty, at common law, to warn or counsel patients. The author notes, however, that the decision in *Frye v Medicare-Glaser Corp.* (219 Ill. App. 3d 931, 579 N.E. 2d 1255 (1991)), was indicative of the possibility of a departure from the traditional 'no duty to warn' theory and had increased the pharmacist's duty in a manner similar to OBRA-90.

As was noted above in chapter four, in *Frye*, the Illinois Supreme Court had held that, as a general rule, the pharmacist had no affirmative duty to provide a warning to the patient. However, once a pharmacist undertakes to provide a warning, it must be complete and accurate. On the facts of the case, the pharmacist had placed a label on a dispensed medication which warned of certain, but not all, of the possible side effects and interactions associated with the medication. One of the omitted warnings was that the consumption of alcohol could intensify the effect of the drug. The patient took the

medicine after consuming alcohol and subsequently died. The Illinois Supreme Court held that the pharmacist was negligent in failing to warn about the possible side effects of the alcohol.

Patane submits that a major *reality* of OBRA-90 is the potential increase in pharmaceutical malpractice claims. He argues that a major *problem* with OBRA-90 is that it ignores decades of common law:

‘Some extremely well-founded and sound reasoning is lost. With the exception of *Frye*, courts have declined to hold pharmacists to duties such as those implemented by OBRA ... because they reasoned that physicians were better suited and trained to diagnose their patients. Courts did not want to interfere with the doctor-patient relationship by having an equally knowledgeable pharmacist cast doubt upon a doctor’s ability. Essentially, courts made a policy decision in this regard.

OBRA, state legislation, and *Frye*, however, contradict this tradition by viewing pharmacist as a safety mechanism. Rather than place the correct duty upon a physician to ensure he properly examines, diagnoses, and prescribes medication for patients, the law places the legal burden upon the pharmacist. This burden is one that is both harsh and undue.’ (1993: 187-188)

Although he recognises the argument that patients may receive better care as a result of the additional counselling and review mandated by OBRA-90, Patane submits that patient review has never been the duty of the pharmacist, but has rather been reserved for the doctor. The fears expressed by the courts, as analysed above in chapter four, that recognising that a pharmacist has a duty to counsel, amounts to second-guessing, or doubting the ability of the doctor, and amounts to an intrusion into the doctor-patient relationship, become, according to Patane, a reality.

The author does also accept that the pharmacist has the qualifications and training to undertake the responsibilities mandated by OBRA-90, but submits that the new duties are excessive and burdensome, and impinge too greatly on the pharmacist's resources. Further, the new legislation relieves doctors of a series of duties to which they should be strictly held, which did not seem to be an appropriate outcome from a law seeking to improve health care.

Holleran (1995) submits that even before the implementation of the OBRA-90 requirements, the courts were beginning to recognise its likely impact. Cases such as *Walker* and *Lasley*, already referred to above, were indicative that the regulations implementing OBRA-90 would provide a new avenue of pharmacist liability. More specifically, the reasoning employed by the courts which had omitted to impose a duty to warn on pharmacists because that would require pharmacists to have knowledge of the patient's specific medical history, and would force pharmacists to interject into the doctor-patient relationship, had been negated by the new legislative requirements:

'OBRA 90 and its progeny have codified various elements of the practice of pharmacy, thereby setting statutory benchmarks that all pharmacists must meet. These benchmarks or practice requirements can arguably be identified as legal "duties" owed by pharmacists to their patients.' (1995:50)

Holleran is clear that the new duties imposed by OBRA-90 have a clear link to new liabilities. Failure to counsel, and failure to obtain a complete medical history, with

resultant, avoidable harm to the patient, are two examples of breach of a new legal duty owed by pharmacists to their patients.

Holleran gives the most detailed guidance of any of the commentators noted above on how pharmacists might avoid civil liability under OBRA-90. In summary, his main recommendations involve a specific documentation system, (with examples of the relevant documents being provided) to comply with the requirements for counselling, recording and maintenance of patient history and profiles, and cataloguing of screening of prescriptions. Holleran is of the view that the establishment of a mechanistic or systematic practice of documentation assists a pharmacist to establish a prudent and accurate professional practice. The establishment of a routine practice is time consuming at the outset but will, in the long run, provide a barrier against the wave of civil liability which inevitably will result.

Fitzgerald (1996) is of the view that the decision in *Harco Drugs, Inc. v. Holloway*, ((1995) 669 S.R. 2d 878, and analysed in depth in chapter four above), in which the Alabama Supreme Court had held that a pharmacist has a duty to enquire into the appropriateness of a prescription from an unusual source, is an example of how the drug use review requirements imposed by OBRA-90 expand the pharmacist's duty to evaluate. Failure to evaluate, according to OBRA-90 standards, results in censure by the courts, and the imposition of liability. Fitzgerald argues that while the OBRA-90 legislation attempts to define the range of items which a pharmacist must consider when undertaking

drug use review, the decision in *Harco* shows that this list is not comprehensive and must be viewed as a minimum standard which pharmacists must achieve:

‘Pharmacists should view the DUR process, and all aspects of pharmacy practice as continually evolving and changing. Standards such as those established by OBRA ’90 should be viewed as minimum standards subject to routine expansion in the best interests of the patient. The Alabama Supreme Court opinion ... represents a clear example of such expansion.’

Blackwell, Szeinbach, Garner and Smith (1996), in analysing the nature of the legal duty which is owed by pharmacists to their patients, have no doubt that the implementation of OBRA-90 has an impact on the ability of a plaintiff to establish a duty of care. OBRA-90, according to the authors, increases a pharmacist’s potential liability exposure immensely. This is because the pharmacist, since the implementation of the new legislative requirements, has a specific duty to warn the patient on a wide variety of matters such as potential contraindications, side effects, abuse, disease interactions, etc:

‘... if a plaintiff patient in a negligence action proves that the attending defendant pharmacist violated the mandates of OBRA ’90 by failing to warn the plaintiff patient of a known contraindication, side effect, abuse and so on, the patient is deemed to have satisfied the elements that (1) a duty existed and (2) the attending pharmacist breached the duty.’

It is clear from this analysis of what commentators were saying about the likely impact of OBRA-90 on pharmacist liability, that there was no doubt that the universal response was that OBRA-90 had the potential to increase that liability. As will be seen below, although the response of the courts has been slow, that potential has indeed become reality. Almost every commentator on this question of increased liability, has been eager to play down

the reality of the issue, both by giving positive advice on the practical steps which can be taken to avoid liability and to emphasise the opportunities presented by OBRA-90 for the profession of pharmacy. Those benefits include the increased participation of pharmacy in health care, the recognition of the professional responsibilities of pharmacists and the expertise which they bring to the resolution of problems in drug therapy, and the enhanced welfare of patients who profit directly from the pharmacist's increased interaction with them. Below, the speculation on the potential for liability may be measured against the reality of the situation, some seven years later.

OBRA-90 – How has the pharmacy profession reacted?

OBRA-90 has been in force for some seven years, at the time of writing. In that time, the pharmacy profession has had time to react to the implications of this new law, and a series of articles has sought to analyse the impact which OBRA-90 has made on the practice of pharmacy.

Reutzel, Wilson, Mickel, Lee, Anderson, Gray, Borkowski, Manasse, & Cooksey (1993) sought to answer the question 'Inner-city pharmacies: can they meet the OBRA '90 mandates?' Visits were made to 21 pharmacies in two poor Chicago neighbourhoods. Pharmacists reported that Medicaid reimbursement policies resulted in: (1) prescribing patterns that have no consistent therapeutic or economic rationale; (2) dispensing of expensive drugs, some of which are then sold on the street or to other pharmacies; and (3) dispensing of unnecessary and often expensive legend drugs when other legend drugs and

generics or over-the-counter products would perform just as well. On the positive side, 76% of the pharmacies possessed computerized patient-profile systems, and 72% maintained background information on their prescribers. These results suggested to the authors that OBRA-90's mandates should contribute toward improving the Medicaid program, but that implementation was likely to be difficult and uneven.

Hansen & Ranelli (1994) sought to examine, amongst other things, pharmacists' willingness to assume further professional responsibilities. The results showed that pharmacists tended to agree that all three of the OBRA-90 mandates will be beneficial. Fifty-six percent favoured the prospective DUR requirements, while 68 percent favoured the patient counselling requirements and 66 percent favoured the information-recording requirements.

Allan, Barker, Malloy, & Heller (1995) attempted to analyse the nature and frequency of dispensing errors and quality of patient medication counseling in 100 randomly selected community pharmacies. Analysis of 100 prescription orders dispensed detected 24 dispensing errors, of which 4 were clinically significant. Oral counseling was provided to 64 of the patients, covering an average of 3 of the 14 categories of drug information that OBRA-90 required pharmacists to consider when counselling patients. In addition to prescriber's label instructions, pharmacists provided written counselling information, including auxiliary labels and receipts, to 98% of the patients, but it covered only an average of six OBRA-90 categories. The results suggested to the authors that problems

with the quality of community pharmacy medication counseling and dispensing accuracy required immediate attention.

To begin assessing the impact of New York state regulations enacted to implement patient counseling mandated by OBRA-90, Rumore, Feifer & Rumore (1995), distributed an anonymous questionnaire to 300 New York City pharmacists and pharmacy interns in 1993. A sixty-five per cent response rate was achieved. The opinions of interns and pharmacists differed on whether the counseling requirement had been implemented correctly. The interns' responses were overwhelmingly negative, but the majority of pharmacists responded positively. Time, personnel, and expense constraints were most frequently cited as barriers to implementation. Half of the respondents mentioned that patients had to wait for counseling. More often than not, the offer to counsel originated with the pharmacist (51%). Interns (19.5%), technicians (12%), and clerks (17%) offered counseling less frequently.

Approximately 35% of patients chose not to supply counseling information. Reasons most usually cited for not accepting counseling included the patient being in a hurry, chronic therapy, and that the patient already knew about the medication. A list of items discussed each time a prescription is dispensed revealed little agreement on what constitutes counseling. The authors concluded that their results were consistent with other studies, including that by Reutzel, Wilson, Mickel, Lee, Anderson, Gray, Borkowski, Manasse, & Cooksey (1993), described below, and illustrated the difficulties faced as the law is implemented and interpreted.

Perri, Kotzan, Pritchard, Ozburn, & Francisco (1995) undertook two separate studies in Georgia. The first study measured, by direct observation, pharmacists' compliance with the mandates of OBRA-90 before (December 1992) and after (June 1993) the law took effect in January 1993. Eight chain and four independent pharmacies participated in the first study. Observation was made during three phases – collecting patient information, performing prospective drug utilization review, and conducting patient counselling. The results of the observational phases were then compared between the pre and post OBRA-90 periods. The second study assessed patient awareness, experience, and degree of co-operation with pharmacists in complying with OBRA-90. A representative sampling of patients answered questions by telephone.

Findings from the pharmacy study indicated more streamlined information gathering, more time devoted to prospective drug utilization review, and a 29% increase in counselling frequency in the post-OBRA-90 period. The authors concluded that some of the changes might be due to increased computer sophistication but agreed that the improvement in counselling frequency might be due to a recognition by pharmacists of the importance of patient communications in improving patient care and ultimate health outcomes. The patient survey indicated a lower frequency of counselling than was reported in the pharmacy study. In addition patients appeared willing to supply information to pharmacists when they viewed it as a way to improve the care they receive.

Pugh (1995) surveyed 416 Medicaid pharmacy providers in Virginia for the purpose of estimating the potential impact of OBRA-90 on their professional day to day practice. The survey was designed to measure which drug use review activities were being performed by pharmacists before OBRA-90 took effect. Pharmacists were asked to provide information on the scope and range of clinical/cognitive services which they provided, including prospective DUR screening, patient medication profiling services, and patient counselling. Pharmacists were also asked to define the factors which they regarded as potential barriers to implementation of the OBRA-90 requirements. The results of the survey showed that the majority of the respondents were already performing several of the required drug use review activities. Almost all of those responding agreed that full compliance with the OBRA-90 requirements required more time to process each prescription order. Other barriers to full compliance which were identified included lack of time to counsel patients adequately, lack of patient-specific information and no compensation for offering clinical/cognitive services. The author concluded that compliance with the prospective component of the OBRA-90 drug use review programme would require major changes in the practice of pharmacy in the state of Virginia. She also thought that the process of change was likely to evolve slowly as a result of informational, professional and monetary barriers.

In an editorial for the journal *American Pharmacy* in February 1995, Vicky Meade asked the question 'OBRA '90: How has Pharmacy Reacted?' (Meade 1995). Meade concludes that, although hard data on the issue was scarce, the balance was towards a positive

reaction from the pharmacy profession. The author, noted, however, that there was evidence to suggest that the increased financial cost to a pharmacy of introducing the OBRA-90 requirements was a major factor in the profession's reaction to the new duties. Meade also identified two potential further problem areas for pharmacy – increased legal liability and disciplinary actions from state boards for failure to comply with patient counselling. While the evidence showed that few disciplinary actions had been taken by state boards of pharmacy for failure to comply with OBRA-90, as time moved on state boards were beginning to take a more hard-line attitude. Where disciplinary actions had been commenced, the evidence showed that the main bases for discipline were a failure to counsel and failure to detect drug-related problems through prospective screening. One member of a state board of pharmacy reported to Meade that dispensing errors were a strong signal of non-compliance with counseling regulations.

Meade also submits that the evidence to date showed that the increased professional responsibility required by OBRA-90 exposed pharmacists to the threat of liability claims. She adds, however, that compliance with the requirements of OBRA-90, including the maintenance of adequate records of patient counselling and other interventions that involve potential drug therapy problems, can actually lead to a decrease in liability, as significant proof of a reasonable effort and detecting and intervening with such drug therapy problems. The lack of clarity over the issue of documentation is a worrying aspect of compliance with OBRA-90 according to Meade, adding her encouragement to members of the profession to document as accurately as possible, preferably on computer, no matter how time-consuming such an intervention might be. Finally, Meade

reports that since the implementation of OBRA-90, pharmacists have grappled with ways to educate the public to accept the pharmacy profession's expanded role and to be patient about the additional time needed for counselling and drug use review. Overall, however, the profession was responding positively to the new legislative requirements, with evidence showing that patients were becoming more compliant with their medication regime, when given more information about their diseases and medications.

Barnes, Riedlinger, McCloskey, & Montagne (1996) sought to identify which barriers have been most significant to community pharmacists in their ability to comply with the OBRA-90 regulations during its first year of implementation in Massachusetts. Barriers that were considered most significant to pharmacies surveyed in their ability to implement OBRA-90 regulations were excessive workload, lack of financial compensation, and patients' attitudes. Of least significance were inadequate knowledge about drugs, inadequate references, and store layout. Almost fifty percent of the responding pharmacists indicated that OBRA-90 regulations had not affected or changed their practice. Twenty-five percent of the pharmacists believed that their practice was less rewarding after OBRA-90, and about twenty percent believed it was more rewarding. The authors concluded that community pharmacists in Massachusetts were making an attempt to comply with OBRA-90, but there were specific barriers that were affecting their ability to do so. The OBRA-90 regulations appear to have had little impact on the practice of most community pharmacies. Community pharmacy management needed to examine (1) expanded roles of supportive personnel to give pharmacists more time to

spend counseling patients, (2) reimbursement mechanisms for cognitive service, and (3) approaches to educating patients about these changes in the pharmacy profession.

Lyons, Rumore, & Merola (1996) sought to assess if patient information needs are being met following the efforts to educate patients about drug therapy through the inclusion in OBRA -90 of the requirement for pharmacists to offer counselling to all patients receiving prescription drugs. Seventy-five per cent or more of those responding to the survey in New Jersey indicated that they been given the medication name, the reason prescribed, and were told how often to take the medication and the duration of therapy. Less than fifty per cent of respondents received information concerning storage conditions, over-the-counter or prescription only interactions, what happens to the body if a dose is missed and how to avoid side-effects. The authors concluded that although information was reaching the majority of patients who responded, there were still some gaps between that which they considered to be important and information actually received.

Muirhead (1996) reports that since the OBRA-90 mandate for pharmacists to offer prescription drug counselling to Medicaid patients became effective, the amount of drug information given to patients had risen. Drawing on the results of a collaborative study undertaken by the Health Care Financing Administration and the Food and Drug Administration, Muirhead was able to report that 61% of patients were receiving a written communication from a pharmacist indicating how much of their medication they

should take and how often. This finding contrasted with a finding in 1982 that only 16% of patients received a written communication from a pharmacist concerning the use of their medication. Further, 33% of patients stated that they received oral counselling from a pharmacist regarding how they should take their medication. This contrasted with a finding in 1982 that 23% of patients were given such verbal instructions.

Ukens (1997) reports that the annual number of drug related deaths that could have been prevented by counselling had decreased to zero in North Carolina. An analysis of the data showed that a total of 90 deaths possibly linked to drugs were reported to the North Carolina pharmacy board from 1992, when the state introduced the reporting requirement, through to 1996. Of the 90 deaths reported, 12 might have been prevented by patient counselling. However, the number of such deaths had steadily declined as more pharmacists adhered to the OBRA-90 mandate. The number of such deaths decreased from five in 1992 to zero in 1996.

Scott & Wessels (1997) undertook an assessment of the OBRA '90 regulations on the counseling practices of community pharmacists in Nebraska by conducting a survey of 166 randomly selected community pharmacies throughout Nebraska. Only 44.6% of those responding reported that time devoted to patient counseling had increased as a result of OBRA-90. Chain pharmacists generally devoted more time to counseling after OBRA-90 became effective than did independent community pharmacists. Scott & Wessels concluded that while more than three out of four pharmacists felt adequately prepared for mandated patient counseling, fewer than half reported that time devoted to

counseling had increased. Although the profession was moving toward the standard of pharmaceutical care, many pharmacists were not yet counseling as the law requires.

Erickson SR, Kirking DM, Sandusky M (1998) also sought to assess pharmacist counseling under OBRA-90 but from the Medicaid recipient's perspective in Michigan. Specifically, their study was designed to (1) assess pharmacists' compliance with counseling requirements, (2) assess recipients' level of satisfaction with the information provided during counseling and whether the information provided increased their comfort level in taking medication correctly, and (3) determine relationships between variables associated with pharmacist counseling and recipient satisfaction and comfort level.

408 Medicaid recipients in Michigan who received new prescriptions during a one-week period in November 1995 were surveyed. Only 104 (25.5%) of those surveyed indicated that someone offered counselling for their new prescription, and only 62 (15.2%) indicated they knew of the requirement to be offered counselling. Those who were counselled were satisfied with the amount, quality, and way the information was presented, and were more likely to assign a higher level of importance to pharmacist counseling. The majority of those responding indicated high levels of ease in using their medications safely, with those who were counseled expressing a higher level of satisfaction. The authors concluded that from the perspective of the Medicaid recipient, pharmacies are failing to offer counseling for most new prescriptions. The results indicated that counselling improves measures of recipient satisfaction in using

medications safely and enhances the level of importance patients assign to pharmacist counseling.

Gebhart (1998) reviews a series of reports and studies in seeking to answer the question, 'Five Years Later is OBRA '90 Working?'. The results of a survey, undertaken in 1996 by the American Pharmaceutical Association showed that patients were being told why they were taking their medication (84%), how to take it (94%), what to do if they missed a dose (76%), how to store the product (76%), potential drug-drug interactions (79%), drug-food interactions (79%), drug-alcohol interactions (87%), and side effects (88%). It was noted, however, that the vast majority of this information was being provided by a computer print-out, rather than by individual oral counselling from a pharmacist.

Gebhart also reports on a further study undertaken by the journal *Drug Topics* which found widespread agreement on the barriers to counselling, including reimbursement, lack of consumer demand, and failure to enforce by the state boards of pharmacy. Others had responded that the lack of consumer demand was due to a failure by the pharmacy profession to educate patients on the value of drug information. Gebhart reports that one state, Mississippi, had grasped the reimbursement issue by providing payment for pharmacists for counselling Medicaid patients, recognising that there were significant economic gains to be achieved from a relatively modest initial investment. The state of North Carolina had invested heavily in patient education, realising that patient counselling was a public health and safety issue. The result was that patients were demanding more of their pharmacists. In addition, the state board of pharmacy was

treating violation of the new requirements as an offence meriting suspension of the pharmacy licence. The state was able to demonstrate that the parallel approach of patient education and strict enforcement was having a direct effect on the saving of patient lives, as evidenced in the report of Ukens, noted above.

Ukens (1998) reports on a survey undertaken of over one thousand pharmacists in New York, which ominously, reported that two thirds of those surveyed would not enter the profession again. Among the reasons cited for the dissatisfaction with their career path was the increased workload associated with the implementation of the OBRA-90 regulations. This dissatisfaction was expressed, however, in terms of a frustration at not being able to undertake the new professional responsibilities, which were welcomed, in an appropriate manner. Ukens reports that the pharmacists surveyed were also committed to changing the situation in the expectation of achieving career satisfaction.

Cardinale (1999) cites the Ukens New York survey referred to above, in reporting on a further examination of the pharmacy workplace survey undertaken by the George Washington University of over thousand members of the American Pharmaceutical Association. The results, says Cardinale, were more upbeat than those of the New York survey. There was a higher overall job satisfaction than that found in other professional groups including other health care professionals. Further, the survey reported a high percentage of compliance with the counselling requirement mandated by OBRA-90.

The study by Franic, Pathak, & Mott (1999) aimed, amongst other things to assess the level of pharmaceutical care delivered by pharmacists. Patients in a community setting in Columbus Ohio who had been prescribed antihypertensive medication and their pharmacists were selected for study participation. An analysis of the matching surveys of pharmacists and patients indicated that nearly all pharmacists counselled patients and two thirds of pharmacists counselled and monitored drug therapy. According to the authors this was consistent with providing the minimal OBRA-90 requirements, and suggested that pharmacists are aware of patient clinical outcomes and therefore, are in an excellent position to improve patient outcomes by making appropriate drug therapy changes.

It will be seen from this analysis of the impact of OBRA-90 on the professional practice of pharmacy that the reaction from the pharmacy profession has been mixed. While welcoming the potential of the new law to enhance the standing of the profession, increase pharmacist participation in drug therapy and improve the health care of individual patients, the profession has also, and somewhat naturally, focused on problematic aspects of the new requirements. These include a series of practical barriers to implementation, including lack of time to carry out new functions, and lack of positive reimbursement for the work which is to be carried out. In addition, the profession has reacted to the warnings given by the commentators that OBRA-90 has the potential to increase civil liability. For the most part, the profession is willing to accept the further comforting words of the commentators that appropriate compliance with the new legislative requirements can also mean no increase in liability, but many worries also remain.

OBRA-90 and liability – what has been the reality?

It was noted above that the mandate imposed by OBRA-90 had the potential to impact on individual pharmacist liability in two main ways. Firstly, in most states, as was the intention of the federal law, the implementation and enforcement of OBRA-90 is the joint responsibility of the state Medicaid agency and the state board of pharmacy. In most states, as the survey of state practice above demonstrated, the main obligations of the drug use review process have been written into the state pharmacy practice act giving responsibility for implementation and enforcement of these provisions to the state board of pharmacy. As such, a violating pharmacist might face disciplinary proceedings by the state board of pharmacy, the state Medicaid agency or both. This liability aspect of OBRA-90, which might also be described as professional administrative responsibility, and which relates to the pharmacist's duty to the profession, is the focus of this section.

Fitzgerald (1994) provides the first evidence of the impact of OBRA-90 on the pharmacist's professional administrative responsibility. The results of a survey of state boards of pharmacy conducted in January 1994 showed that at least 17 states had reported disciplinary actions for failure to comply with OBRA-90, such violations often having been detected following undercover inspections by state inspectors checking compliance. Fitzgerald reports disciplinary actions ranging from informal reprimands, warnings and corrective actions to formal licence suspension and civil fines. The main

reason for the imposition of a censure were failure to counsel and failure to detect drug related problems through prospective screening.

Meade (1995), after reviewing the research undertaken by Fitzgerald, indicates that the main reason for the lack of action by state boards, until then, was their policy of permitting pharmacists to have a period within which to adjust to the new professional requirements and implement them into everyday practice. Meade reports that state boards of pharmacy were warning that the adjustment period had ended, and that they would move from a policy of encouraging voluntary compliance to a policy of strict enforcement where voluntary compliance was not working. Meade gives an example of how the state boards will react to obvious violations. She cites an example of disciplinary action which was taken against a pharmacy in Iowa. The pharmacy was found to have too few staff members to maintain patient records and provide counselling. The pharmacy was fined \$25000 and was placed on probation for three years. The terms of the probation were that the head pharmacist was required to submit monthly reports to the board and to notify the board immediately if staffing levels fell below a minimum standard. Several months later, after several customers had complained about dispensing errors, the pharmacy was disciplined again, was fined a further \$25000, was required to have a minimum staffing level, and the head pharmacist himself was placed on probation for two years and was fined \$2500.

Brushwood (1997) submits that Meade's reports, as noted above, provide evidence of the occurrence of disciplinary action against pharmacists for a failure to comply with the

OBRA-90 standard. The findings of Brown (1997), however, suggest that state boards' enforcements of the counselling laws has been minimal. Brown found that state pharmacy boards had played an active role in explaining and urging pharmacist compliance with the patient counselling laws, through the conduct of specific education activities. In 38 states, boards had either distributed newsletters, presented information at professional association meetings, or provided information during inspection visits on the topic of OBRA-90.

The state boards were, however, slow to take enforcement action with respect to violations of OBRA-90. Boards had made little use of the previously popular tactic of board representatives and inspectors visiting pharmacies, posing as patients, in order to assess compliance with the counselling laws. Only 17 states had reported such visits and then usually only in response to a specific complaint. Most states had relied on formal inspection visits as their main form of compliance evaluation but these were conducted with varying degrees of frequency. Brown is of the view that such formal visits offer limited opportunities for assessing the extent and adequacy of counselling. Finally, the state boards had taken few formal disciplinary actions involving violations of patient counselling laws. Of the 354 actions taken during the previous year by 23 boards, 208 or 59% were in just three states.

The major obstacles which state boards identified as limiting the successful implementation of the patient counselling laws were limited reimbursement for counselling services, lack of patient demand for counselling, and lack of sufficient

resources, particularly staff, to carry out the practical work. Brown recommends that further research is carried out on the usefulness of written information offered to patients receiving new prescriptions, and argues that there should be a facilitation of the production of guidelines and objectives, as part of the state's efforts to enforce the patient counselling mandate. Responses to the research findings, published in the final report, from both professional medical, and patient groups, suggested that there was support for stronger action in ensuring that patients are adequately counselled.

As noted above, the second anticipated impact of OBRA-90 on individual pharmacist liability was to expand the scope of the duty owed by the pharmacist in negligence. The last chapter of this thesis demonstrated that judges in the United States were beginning to recognise the wider responsibilities of pharmacists and potential liability in negligence based on an expansion of the pharmacist's new roles and functions. When OBRA-90 was enacted, many commentators, as noted above, speculated on the effect which the legislation, and its inherent expansion of pharmacy practice standards, would have on the current trend of expansion of pharmacist responsibility. It is this aspect, which focuses on the pharmacist's responsibility to the individual patient, which will be examined in this section.

Brushwood (1996:184) rightly reports that litigation in any sphere takes a long time, and that the actual impact of OBRA-90 on civil liability might not be evidenced for some years. Certainly if the corroboration was to come through the reports of the appellate courts, it would take a period of time for such cases to be heard and reported. By 2000,

however, there exists evidence that the expected expansion of civil liability resultant on the implementation of OBRA-90 has become a reality. That evidence comes from a number of sources. Firstly, Baker (1999) in a report of a study of claims taken against pharmacists between 1989-1997, was able to categorise causes of claims as follows:

Cause of Claim	Percentage
Wrong drug	49.3
Right drug but wrong strength	25.9
Right drug but wrong directions	7.7
<i>Failure to conduct a drug review</i>	6.0
<i>Failure to provide counselling</i>	5.6
Personal injury	3.4
Excessive refills	0.9
Failure to dispense with safety caps	0.8
Generic substitution	0.7

Two of these categories have been italicised as, prior to the implementation of OBRA-90 they would not have featured on a similar list of categories of cause of claims against pharmacists. Under a traditional analysis of pharmacist duty, the courts would not have recognised that a pharmacist had any duty to conduct a drug review or to counsel. It is arguable that a third cause, that is the giving of the right drug but the wrong directions, is also an OBRA-90 related category but, on balance, this would also have fallen into the category of technical error which was recognised under the traditional analysis. The fact

that, by 1997, close to 12% of all claims against pharmacists were for causes related to the new duties imposed by OBRA-90 demonstrates the extent of the impact of the legislation.

Support for the significant impact of OBRA-90 is also to be found in the report by Ukens (1999) that a jury in Texas had entered a verdict of three million dollars in damages against a pharmacist for failure to warn about potential adverse reactions which resulted in a young boy's death from drug induced hypereosinophilic syndrome. The young boy was taking a drug for attention deficit hyperactivity disorder, and had the prescription for it refilled on four occasions. The allegation was a failure to warn about the possibility of an adverse allergic reaction to the drug, which had in fact materialised, and went unrecognised. Ukens notes that the pharmacist in the case had given evidence that while she had been trained to give adverse drug reaction information, she felt that she was not required to do so. Ukens notes that the implementation of the OBRA-90 counselling mandate requires pharmacists to counsel patients about a wide variety of matters, including potential adverse reactions. The implications of a failure to do were obvious from the substantial award made.

Ukens (1998) also reports that those lawyers representing a group of patients involved in litigation with respect to warnings about contraindications associated with the use of an anti-obesity medication. The lawyers reported that they would be citing state pharmacy practice standards and the OBRA-90 counselling regulations in any action against pharmacists, adding that the standards relating to patient records, checks for dosage and

duration of drug therapy all create a higher duty of care. The lawyers were clear that violations of those standards raised a civil cause of action.

Abood (1999) reports that OBRA-90 is firmly in the hands of the legal profession. By that he means that ten years after the implementation of the legislation, the courts were beginning to hold pharmacists to new standards of care. Abood was prepared to go as far as stating that a failure to comply with the new practice requirements, particularly the requirement to conduct patient profiles or counselling, amounted to negligence *per se*, with the plaintiff not having to prove the existence of a duty, merely breach and damage caused. This required pharmacists to ensure that they had the correct mechanism, pharmacy practice protocols, in place to protect against the increased liability.

As Brushwood recognised, the most significant factor in measuring the impact of OBRA-90 on civil liability would be the extent to which the courts, and particularly the appellate courts, after analysis of the relevant duties, endorsed the opinion that failure to carry out the OBRA-90 mandates, and resultant harm, formed the basis of a cause of action for which damages would be recoverable.

It has already been concluded that even prior to the implementation of OBRA-90, judges in the United States were beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. The movement towards a recognition of expanded responsibility was viewed against a recent background of traditional legal analysis which had limited pharmacist responsibility to the accurate processing of

prescriptions and which had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor. There was a strong view that the implementation of OBRA-90 would reinforce the movement towards enhanced pharmacist responsibility, even in those jurisdictions which had endorsed the traditional approach of no duty to warn.

As has already been noted, the decision in *Walker v Jack Eckerd Corporation*, analysed above, paved the way for judicial endorsement of OBRA-90. In that case, the Court of Appeals in Georgia had cited before them, and had analysed in depth, almost every authority, including the conflicting authorities, relating to the common law duty of pharmacists regarding the warning of patients and the refusal to fill prescriptions, including those referred to in chapter four above, and had concluded that the pharmacist concerned had no duty to warn. It is important to remember, however, that the court specifically qualified the precedential value of its finding by reminding itself that its ruling was not a mandatory authority for any case arising after the implementation of OBRA-90.

Judicial endorsement of OBRA-90 became full-blown reality in the case of *Horner v Spalitto*((1999)1 S.W.3d 519). The facts were outlined in detail in chapter four above.

In the Court of Appeals of Missouri, Judge Spinden was clear that the pharmacist's duty was to exercise the care and prudence that a reasonably careful and prudent pharmacist would exercise in the same or similar circumstances. That is, the duty was to attempt to

minimize the risks of harm to the patient and others which a reasonably careful and prudent pharmacist would foresee. The judge had thought that the lower court had wrongly held that, as a matter of law, and based on a traditional analysis of pharmacist duty expounded for decades in the Missouri courts, that a pharmacist's duty would never extend beyond accurately filling a prescription:

'This may be a pharmacist's only duty in particular cases, but in other cases, a pharmacist's education and expertise will require that he or she do more to help protect their patrons from risks which pharmacists can reasonably foresee. We must leave to a fact-finder what this duty requires of a pharmacist in a particular case. We can say at this point only that a pharmacist, as is the case with every other professional, must exercise the care and prudence which a reasonably careful and prudent pharmacist would exercise.'

To hold [that a pharmacist has no duty beyond technical accuracy in filling a prescription] would denigrate the expertise which a pharmacist's education provides concerning drugs and their therapeutic use. [That] holding also failed to comprehend the role a pharmacist must play in making the valuable, but highly dangerous, service of drug therapy as safe and reliable as it can be.' ((1999) 841 S.W.3d 519 at page 522)

The judge was clear that despite the OBRA-90 mandate, a pharmacist has a duty, at common law, beyond technical accuracy. In so doing he was prepared to set aside existing Missouri law, which on the basis of a traditional legal analysis was prepared to hold to the contrary. This aspect of the judgment is in keeping with a current judicial trend of expanding pharmacist responsibility.

One of the factors which permitted the judge to abandon existing jurisprudence was the recognition of the augmented professional role of pharmacists by the legislature in Missouri, both in the general legislative provisions relating to the regulation and

administration of the practice of pharmacy, and in the further legislation introduced to comply with the requirements of OBRA-90, the federal government enactment designed to initiate new provisions for pharmacist counseling of patients.

After analysing the further legislation, introduced in Missouri to comply with the requirements of OBRA-90, which were reproduced above, the judge thought that the legislative provisions recognised the role of pharmacists which he had identified above. Further the specific requirements in Regulation 4 C.S.R. 220-2.190, reproduced above, which mandated a pharmacist to offer to discuss with each customer or their caregiver information about the safe and appropriate use of the medication based on the pharmacist's review of available patient information, recognised that:

'Pharmacists have the training and skills to recognize when a prescription dose is outside a normal range. They are in the best position to contact the prescribing physician, to alert the physician about the dose and any contraindications relating to other prescriptions the customer may be taking as identified by the pharmacy records, and to verify that the physician intended such a dose for a particular patient. We do not perceive that this type of risk management unduly interferes with the physician-patient relationship. Instead, it should increase the overall quality of health care ... The physician still is responsible for assessing what medication is appropriate for a patient's condition, but the pharmacist may be in the best position to determine how the medication should be taken to maximize the therapeutic benefit to that patient, to communicate that information to the customer or his physician, and to answer any of the customer's questions regarding consumption of the medication.' ((1999) 841 S.W.3d 519 at page 523)

Turning to the case of *McKee v American Home Products* (113 Wash. 2d 701, 782 P. 2d 1045 (Wash. 1989)), which had been cited by the defendant in support of an argument against the extension of liability towards pharmacists, the judge agreed that a prescribing

doctor was in a superior position to judge the propriety of a particular patient's drug regime. However the judge was firmly of the view that this should not relegate the pharmacist to the role of simply being an order filler:

'This view does not recognize ... that the practice of pharmacy includes consulting with physicians and patients to share with them the pharmacist's expertise in drugs and their interactions. We disagree that a pharmacist's consulting with a physician about an unusual prescription would result in antagonism exceeding the potential public benefit. Pharmacists are trained to recognize proper dose and contraindications of prescriptions, and physicians and patients should welcome their insights to help make the dangers of drug therapy safer. Relegating a pharmacist to the role of order filler, as the Kampe court seemed to do, fails to appreciate the role recognized in [the state legislative provisions]. We reject the suggestion in Kampe that the only functions which a pharmacist must perform to fulfill his duty is to dispense drugs according to a physician's prescription.' ((1999) 841 S.W.3d 519 at page 524)

It is submitted that the decision in *Horner* closes the circle on the judicial expansion of the civil liability of pharmacists. The analysis undertaken in chapter four had shown that, in certain jurisdictions, judges were prepared to be creative in recognising an enhanced role for the pharmacy profession, while assigning responsibility where the new role was performed carelessly. A limited duty, based on technical accuracy, was already beginning to disappear, as the judiciary discovered that pharmacists are more than dispensing mechanics, and have a significant role to play in the outcomes of drug therapy.

The decision in *Horner* adds further persuasion to those jurisdictions clinging to a limited duty legal analysis. *Horner* demonstrates, as *Walker* had suggested, that the mandates of OBRA-90 confirm a new role for pharmacists, new duties arising from that role, and new liabilities where the pharmacists fails to implement the mandate. Prior to the

implementation of OBRA-90, the state of Missouri had been reluctant to expand pharmacist responsibility, and had failed to recognise the reality of modern pharmacy practice. The analysis in *Horner* sweeps away the existing jurisprudence and acknowledges that the new legislative requirements provide the basis of an extended analysis. The Court of Appeals of Missouri has reminded those state appellate courts that had refused to recognise a duty to warn (and the pharmacists practicing in those states), that the implementation of OBRA-90 necessitates a re-analysis of the profession of pharmacy, its practices and procedures, the contributions which it makes to drug therapy, and the appropriate sanction when the relevant standards are not met.

Conclusion

Is OBRA-90 the ‘most important pharmacy-related law of all time’? The cynic would argue that the analysis, undertaken above, of the reasons why the legislation was introduced, demonstrates that the new legislation has little to do with recognising professional roles, enhancing pharmacy practice standards, and improving the outcome of drug therapy for patients. Rather, the exercise was a misanthropic manipulation of public health care funding.

That suspicion betrays the further facts that the financial limitation was only one of the objectives of the federal government which had also sought to improve patient compliance with drug regimes. It was the pharmacy profession which sought to convince the government sub-committees that the increased use of drug reviews and counselling,

the pharmacy profession's driving aspiration, would lead to fewer hospitalisations, as previously non-compliant patients could be persuaded of the benefits of drug therapy as an alternative to more expensive medical interventions such as surgery. Further, the implementation programmes of individual states recognised that the new practice requirements should not be limited to interactions by pharmacists with the significant, though necessarily limited, group of Medicaid patients. OBRA-90, according to the states, was not only good economically, it was good for health care.

OBRA-90 places a legislative coating on a series of developments within and without the pharmacy profession. The aspirations of the profession towards a recognition of its contribution to health care, the role of the pharmacist within the health care team, and the ability of the profession to adapt, and re-evaluate its benefit to drug therapy, developed in a cohesive and structured manner over a period of three decades, had necessitated a parallel acknowledgement by the judiciary of the relevance of that role.

As will be explored in the final chapter of this thesis, it is a necessary and welcome implication of a move towards expanded responsibility that it brings with it the potential for expanded liability should the responsibility be exercised in a careless fashion. It is necessary because the traditional legal standard which insisted that pharmacists are only liable for mechanistic errors is legally inappropriate to the expanded role. It is welcome because the imposition of legal liability to perform a role gives greater authority to a claim to have that role.

What OBRA-90 does is to strengthen pharmacy's grip on its entitlement to professional recognition. Enshrining the new role in legislation has provided the impetus for the profession to take further steps forward. The additional analysis in this chapter has shown that the profession has largely welcomed the latest development, agreeing that it provides a specific endorsement for pharmacy's future. Further, as the decisions in *Walker* and *Horner* have shown, OBRA-90 has provided the necessary sanction for the appellate courts in those jurisdictions which had creatively clarified pharmacy's role in health care, and has provided the stimulus for those jurisdictions eager to do so, but which has been constrained by decades of traditional legal analysis.

Much work with respect to OBRA-90 remains to be done. As was evident above, the state boards of pharmacy have to re-evaluate their stance with respect to achieving full implementation of the legislation through administrative, disciplinary action. Further, the skilful analysis undertaken in *Horner* requires specific support from the appellate courts of other jurisdictions. While the profession retains an element of uncertainty about aspects of the role of OBRA-90 in its future, a majority of the profession remain convinced that the legislation builds on and continues the process of new role recognition, the placing of professional responsibility in a modern context, and strengthens the view that the determination of pharmacy standards by the profession itself is appropriate.

Pharmacist Responsibility in the United Kingdom

Purpose

Chapter four of this thesis analysed judicial attitudes to pharmacist responsibility in the United States of America. That critique showed that in recent years the judiciary are returning to first principles, are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions, and are resiling from the earlier restriction of liability to technical inaccuracy in prescription processing. Chapter five contained a parallel examination of the perspective of the legislature on the nature and form of the relationship between pharmacist and patient, by evaluating, in detail, the policy source, legislative content and practice implications of the enactment of OBRA-90.

The developments analysed in chapters four and five could not, and did not happen in isolation. The aspirations of the pharmacy profession towards a recognition of its contribution to health care, the role of the pharmacist within the health care team, and the ability of the profession to adapt, and re-evaluate its benefit to drug therapy, developed in a cohesive and structured manner over a period of three decades, has necessitated a parallel acknowledgement by the judiciary of the relevance of that role. In turn, the judiciary, in order to achieve that endorsement, have had to re-evaluate and criticise pre-existing and well-established ideas of professional responsibility and duty, re-assess entrenched health care relationships and re-determine existing legal principles underlying both. The purpose of the final chapter will be to examine and to analyse the basis for the judiciary's re-assessed principles of responsibility and duty.

The contents of OBRA-90 also reflect the modern context of pharmacy practice, recognise the requirement for an expanded role for pharmacists, identify the benefits for patients and health care inherent in such an expansion, provide regulatory control of it, and supply the judiciary with the legal basis upon which to undertake its own augmentation (and inherent recognition) of pharmacist professional responsibility. Again, that required the legislators to criticise existing health care practice, be innovative in their vision for health care, and confirm the benefit in involving the profession of pharmacy in a new and varied health care scheme.

In summary, therefore, the changes evidenced in the United States of America required a re-evaluation by the legislators and the judiciary of existing ideas on professional relationships, responsibilities, and duties. The conditions for change have been present in that jurisdiction for some time – an uncertain, self-conscious but persistent profession advocating reform; a recognition by health care policy makers of the value of re-defining professional-patient relationships and the nature of health therapy; and an obsolete set of legal principles based on an out-of-date and limited concept of duty, inappropriate to a profession's desire for progress and a governmental permissive response.

The purpose of this chapter is to evaluate whether the pre-determinants are present in the United Kingdom for a similar re-examination of professional relationships, responsibilities, and duties to take place. It will be noted that the judiciary in the United Kingdom has not been as active and forthright as their counterparts in the United States of America in defining, and re-defining

pharmacist professional responsibility. It is not that the judiciary has been inactive. Pharmacists in the United Kingdom, as with their colleagues in the United States of America, are expected to carry out their various professional roles, and the duties and obligations which arise from them, in a careful and reliable manner. Pharmacists are under a legal duty to act professionally and responsibly, and the extent and limits of that legal duty, have been defined, in part by the judiciary (1).

It will be noted below that the judiciary in the United Kingdom, in carrying out the essential function of defining the pharmacist's legal duty to act professionally and responsibly, have, to date, limited liability to technical inaccuracy in prescription processing. While there has been no overt reference in the United Kingdom cases to parallel judicial trends in the United States, the pattern of restriction of duty follows the U.S. trend, in the analysed period from 1932-1985, in limitation of liability. It is important to remember, however, and as has been noted above, that since 1985, the judiciary in the United States of America has sought to re-assess its attitude toward professional responsibility. It will be seen that the conditions are also right for a similar re-assessment by the United Kingdom judiciary.

Any examination of the issue of pharmacist professional responsibility in the United Kingdom must include an exploration of the implications of a failure to act in a professional and

¹ The legislature has in the United Kingdom has been proactive in the regulation of the profession of pharmacy. This regulation includes the enactment of legislation on the classification and distribution of medicinal products, the provision of pharmaceutical services in the National Health Service, and the management and control of the pharmacy profession through the Royal Pharmaceutical Society of Great Britain. For the detail of this legislation see Mullan (2000), Appelbee and Wingfield (1997) and Merrills and Fisher (1997)

responsible manner with respect to the sale and distribution of medicinal products. It is quite clear that a significant proportion of medical negligence claims are directly related to errors in prescribing, monitoring or administering medicinal products (2). Such failures and poor outcomes from drug therapy often lead to legal action and an attempt to discover who or what is responsible for the harm which has been done to the patient.

Quite clearly there are a number of participants in the drug distribution business who may be responsible for such harm. The principle agents in the procedure are the manufacturer of the drug, the doctor, and the pharmacist. A patient who has suffered harm as a result of a failure from drug therapy may consider litigation against any one, or combination, of these individuals. Indeed, statistics do show an upward trend in litigation by patients for such failures. In turn, an individual manufacturer, doctor or pharmacist, sued by a patient, may lay the blame for the failure of the drug therapy at the door of one of the other participants in the drug distribution process. As such, the professional responsibility of a pharmacist for the distribution of drug products may only be understood by exploring the parallel responsibility of the manufacturer and doctor.

The manufacturer and prescribing doctor in the United Kingdom have negotiated a position of virtual immunity from liability for failures in drug therapy. Cases against manufacturers of drug products for compensation for injuries caused by defects in those drug products do not tend to be successful in the United Kingdom. As will be seen below, this is largely to do with the problems

² The extent and nature of current medical negligence claims and the direct relationship with errors in prescribing, monitoring or administering medicinal products will be explored in

of proving breach of a duty and causation. The 'informed intermediary' doctrine absolves many manufacturers of liability where they can prove that adequate warnings were provided to a third party intermediary. While there is some potential for the erosion of the 'informed intermediary doctrine' it is unlikely to result in increased manufacturer liability. Further, the inclusion of the 'state of the art' defence in the reforming consumer protection legislation is likely to exacerbate rather than lessen the problems.

Equally, cases against prescribing doctors of drug products for compensation for injuries caused by failure to warn about drug products do not tend to be successful, unless the error falls into the 'gross' category as outlined in some of the cases to be examined below. The reason for that is largely to do with particular analyses of the law on doctor liability, and in particular the lack of recognition of informed consent. While again there may be room for alternative interpretations of the current jurisprudence on doctor liability, these may only serve to increase the potential responsibility and duty of the pharmacist.

Disturbingly for the pharmacy profession, attention therefore focuses on the final participant in the drug distribution process - the dispensing pharmacist. For most patients, the pharmacy is the place where they are likely to actually receive their drug products. Under the current classification of medicinal drug products, pharmacists have responsibility for the distribution of all classes of drug product and have sole responsibility for the distribution of one of these. That prerogative is the result of long standing negotiation by the pharmacy profession. Pharmacists

more detail below.

should be rightly proud of this unique role which they play in the provision of drug therapy as part of health care. Further recognition of this unique role is to be found in the fact that increasingly, medicinal drug products are being de-regulated from the more restrictive category of 'prescription only' and being moved in the pharmacist-exclusive 'pharmacy' category.

However the role carries significant legal implications. The patient who purchases general sale list or pharmacy medicines from a pharmacist does so under a sale of goods contract. All of the general principles of contract law are applicable to such contracts and certain specific legal consequences for pharmacists arise from that fact. More importantly all of the principles of sale of goods law are also applicable to such sales with the result that pharmacists may find themselves strictly liable for the consequences of the breach of an implied term in the contract. Liability under contract law is strict and pharmacist may not be absolved by blaming the defect on others in the drug distribution process.

The lack of a contractual relationship between a pharmacist and patient in relation to prescription only medicine drug products under the National Health Service means that the patient who is injured by a defect in a drug product, and who alleges that the fault for that injury lies with the prescribed drug product, must sue in tort. That form of action is also appropriate for a patient who alleges injury as a result of a failure to warn of the dangers of a drug product or adequate guidance for its safe use. An analysis of a number of cases below confirms that the relationship between pharmacist and patient is one which gives rise to the imposition of a duty of care, including specific duties with respect to prescribed drug products. The net result is that the

pharmacist must be aware that he or she should not tacitly accept what they see, or perceive to see, on the written prescription before them. They are under a legal duty of care to draw on their skill and knowledge of drugs to inquire into the surrounding circumstances of the case. In addition to technical accuracy, the law will consider that a pharmacist, as a professional, has sufficient knowledge, through education and training and supply of information by the manufacturer, to counsel patients about drug therapy. In addition the pharmacist has a duty to provide such counselling and a failure to do so which results in injury to the patient will result in liability.

The implications of this analysis have, initially, to be of concern to the pharmacy profession in the United Kingdom. Should the judiciary in the United Kingdom continue to preserve immunity for the drug manufacturer and prescribing doctor for failures in drug therapy, should the policy of de-regulation of prescription only medicines proceed, should the patterns of increased litigation for failures in drug therapy be maintained, and should the judiciary be convinced that an extension of pharmacist professional responsibility, based on a re-definition of duty, is appropriate, then the profession is ready for targeting by a voracious legal profession disposed to responding to the claims of its clients.

It is submitted, however, that the pharmacy profession is in a position to influence the future development of legal expectations of pharmacists. As will be noted in detail in the final chapter, legal expectations of pharmacists are expanding, at least in part because drug therapy has begun to cause problems on a scale that has not occurred before. As experts on drug therapy,

pharmacists can detect potential problems with a patient's medication use, and can interact with the patient and/or the patient's doctor, to resolve the potential problem and protect the patient from harm. The purpose of allowing pharmacists a virtual monopoly over prescription drug and pharmacy drug distribution is to serve the public interest. Technical accuracy by pharmacists is no longer sufficient to provide adequate protection to the public. Drug therapy monitoring is an additional essential responsibility for pharmacists, because the public expects pharmacists to provide protection from potential problems such as drug-drug interactions. Pharmacists have represented that this service is available, and they have undertaken to provide the service to the public. More than a mere gratuitous exercise, drug therapy monitoring is a cornerstone of pharmaceutical care, the focus of expanded pharmacy practice. The principles of pharmaceutical care have been incorporated into judicial opinions that have recognized a responsibility for pharmacists to intervene for the patient's benefit when a problem with drug therapy becomes evident.

However the pharmacist's responsibility for drug therapy monitoring and education of prescribers and patients is limited by the inability of pharmacists to guarantee good outcomes from drug therapy. Pharmacists can be attentive to the need for good therapeutic outcomes, and they can promote good outcomes by caring for patients. In this sense, caring for patients requires that pharmacists think about a patient's drug therapy, apply available knowledge to the solution of potential problems, and intervene to promote good therapeutic outcomes. By accepting responsibility for the outcomes of drug therapy, pharmacists can justify the public trust placed in them as the managers of the country's medications.

The role of the pharmacy profession in influencing the future development of legal expectations of pharmacists is to emphasise its willingness to assume full responsibility for knowledge based drug therapy monitoring but also to argue that a limit has to be placed on that responsibility by judicial recognition that the pharmacist's role cannot be risk elimination because that would mean the end of all drug therapy. Rather, the pharmacist's role requires using available knowledge to minimise the risk of foreseeable adverse consequences to the patient.

The classification and re-classification of medicinal drug products

Before any analysis of the professional responsibility of pharmacists in the United Kingdom can be undertaken, it is important to say something about the legal classification of medicinal drug products. The reasons why such a description is necessary are manifold. The pharmacy profession has negotiated a virtual monopoly over the distribution of certain categories of medicinal drug product. Monopoly carries with it the advantages of unchallenged exploitation for commercial gain, and regulatory recognition of a dependence on the professional expertise of pharmacists as managers of medications as an integral part of drug therapy. Monopoly also demands responsibility in its exercise and that responsibility now includes a duty, based on public (including governmental) expectation, to provide protection from potential problems from the drug products, necessary for the implementation of drug therapy and over which they have a bargained dominance in supply.

Part of the rationale behind the passing of the Medicines Act 1968 was the control of the retail sales of medicines (3). The method by which the aspiration towards the regulation of the retail sale of medicines was to be achieved was the restriction of the supply of medicines through pharmacies. There are, of course, a number of exceptions to that general rule. Certain drug products have been classified as capable of being sold, with reasonable safety, to members of the public, without the supervision of a pharmacist. Certain other medicines may be sold by a hospital or health centre where there is no pharmacy under certain restricted circumstances. Other drug products may be supplied directly by a doctor to a patient, either in an emergency situation, or because of the particular geographical location of the health care practice.

Those medicinal products which in the opinion of the appropriate Ministers can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist are known as general sale list (GSL or OTC) medicines and are listed in the General Sale List Order. The sale or supply of GSL medicines is not restricted to pharmacies. These drug products may be sold or supplied from other shops, subject to certain legislative requirements. Further details on these, and other, legislative requirements relating to GSL medicines, are provided in Mullan 2000:Chapter 8).

Prescription only medicines (POM) may only be sold or supplied in a registered pharmacy, by or under the supervision of a pharmacist, in accordance with the prescription of a doctor, or other health care professional. Such drug products are described in the various pieces of secondary

3 Other purposes of the Act were to regulate the licensing and identification of all medicinal drug products. See Mullan 2000

legislation. The rationale behind such a restriction is that the use of such products in treatment needs to be supervised by a doctor or other health care professional because they may produce a toxic reaction or physical or psychological dependence, or may endanger the health of the community. There are detailed regulations on the nature and form of registered pharmacies, the training and accreditation of registered pharmacists and the form of valid prescriptions, all of which are described elsewhere (Mullan 2000: Chapter 5).

Pharmacy (P) medicines are a default category in that all medicines which are not GSL or POM are automatically P medicines. They must be sold in a registered pharmacy by or under the supervision of a pharmacist. Incidentally, a retail pharmacy business must be under the personal control of a pharmacist so far as it concerns the sale of all medicinal products, including products on the general sale list. Again, full details of the legislative requirements relating to P medicines are provided elsewhere (Mullan 2000: Chapter 8).

The categories of medicinal drug product do not remain static. The nature of the legislation which established them permits movement of drug product from one category to another. That movement is often precipitated by a variety of factors, including, but not restricted to, the dynamics of the drug product itself. In recent years, there has been a significant trend towards the de-regulation of prescription only medicines and their re-classification with the pharmacy and over-the counter categories.

Blenkinsopp and Bradley (1996) explore some of the reasons behind the drive for changes to the classification of medicinal drug products. The greatest motivation for change was noted to be an expansion of the primary care medicinal drug products bill. That has led policy-makers to advocate a shift in responsibility for primary health care from the medical professions to the patient. The patient, as a consumer, has welcomed increased autonomy in health care choice, as part of an overall drift towards consumerism. In turn, pressure on the primary health care market, the traditional outlet for the pharmaceutical industry, has led that sector of commerce to re-evaluate its future interests:

‘Self care and medication with non-prescription medicines are seen by governments throughout the world as a means of shifting some of the responsibility and cost of health care from government and third party payers onto consumers. Increasing scrutiny of NHS prescribing costs has pressurised pharmaceutical companies to protect their markets. Reclassification of a drug not only creates potential new business in the non-prescription market-place but can also promote an existing branded medicine that is also available on prescription.’ (1996:629)

Thomas and Noyce (1996) also recognise the potential for a considerable saving in the National Health Service primary care drugs bill by an increased de-regulation of prescription only medicinal drug products. Their research showed a potential saving of 71% in the annual budget of a single general practitioner’s practice. Ryan and Yule (1990) had shown that making certain medicinal drug products available from a pharmacy without a prescription had resulted in substantial benefits by reducing costs to consumers and saving general practitioners’ time. The research of Bradley and Blenkinsopp (1996) had demonstrated that more prescription only drug products had been switched to pharmacy and over-the-counter status in 1994 and 1995 than had substituted in the previous decade. The authors, while acknowledging that the primary motivation

for change was a reduction in the NHS drugs bill, indicate that the trend towards the de-regulation of prescription only medicines was likely to continue.

Bradley and Blenkinsopp argue that the movement towards category substitution is a natural consequence of advances in drug regulation policy. The primary motivation for drug licensing and control is patient safety. While safety in drug *manufacture* can be achieved through the strict control of development, testing and production, safety in drug *use* may be achieved through patient education. The increased provision of both general health and drug specific information to patients permits and encourages the de-regulation of drug products. De-regulation would be particularly appropriate for conditions for which long-term or recurrent drug treatment is required, which, in turn, would permit the shifting of drug costs from the central health system to the individual patient.

There is evidence that governmental endorsement of the policy of de-regulation, based on an aspiration towards a reduction in the NHS drugs bill, and which is the key factor identified by all of the researchers noted above in the current and expanding trend of category substitution, is likely to continue. The Pharmaceutical Industry Competitiveness Task Force was established in March 2000 to bring together expertise and experience of the pharmaceutical industry leaders in the United Kingdom with Government policy makers to identify and report to the Prime Minister on the steps required to retain and strengthen the competitiveness of the United Kingdom business environment for the pharmaceutical industry. Although the Task Force has the primary objective of the protection of the commercial interests of the pharmaceutical industry, its findings

(PICTF 2001) reflect the current concerns on the promotion of de-regulation of medicinal drug products.

The Task Force identified that patients were increasingly seeking reliable and balanced information about their health needs and recognised that Government health policy encouraged better information, and saw clear benefits to public health if patients are well informed by accurate, balanced material:

‘Concordance is a new approach to the prescribing and taking of medicines. It involves a range of strategies to determine whether, when and how medicines are taken, and seeks two outcomes – health gain in terms of the pharmacological intention of the treatment and health gain in terms of patient satisfaction. Industry and Government are committed to working together, and with others, to explore ways of improving the efficiency and effectiveness of medicines taking in the United Kingdom.’ (PICTF 2001: 6.15)

One key method by which efficiency and effectiveness of medicines taking could be improved was the streamlining of the processes for reclassifying medicines from prescription-only to pharmacy.

One half of the membership of the Pharmaceutical Industry Competitiveness Task Force was made up by representatives, from the highest level, of the pharmaceutical industry. As was noted above, the pharmaceutical industry has a distinct interest in controlling the process by which medicines are classified and re-classified, and the parallel development of specific markets for specific products. When the Government introduced its policy of promoting self-care, with corresponding de-regulation of prescription only products, the pharmaceutical industry responded

by recognising that while the existing market – prescription only medicines within the National Health Service – might be restricted, a new, innovative, wide ranging and potentially more lucrative market – pharmacy and over-the-counter medicines to the public at large – might be developed. As such, the pharmaceutical industry has been industrious in the promotion of the health care policy of self-care, with its inherent emphasis on the promotion of over-the counter and pharmacy medicines.

Evidence of the enterprise of the pharmaceutical industry in the patronage of the policy of self-care is to be found in the work of the Proprietary Association of Great Britain (PAGB). The PAGB is a national trade organisation representing manufacturers of non-prescription medicines. Since its inception the PAGB has sought to emphasise the system of responsible self-medication in order to permit consumers to participate more fully in managing their own health. In the past six years, however, the PAGB has been actively and aggressively promoting the concept of self care and self medication, evidenced by a plethora of published research (4) emphasising the benefits of the policy in relieving pressure on the National Health Service by re-focusing doctors' time on the most needy patients, capitalising on the expertise of the pharmacist, and offering consumers greater freedom, choice and convenience when self-caring for episodes of ill health.

The PAGB have worked closely with the Government, general practitioners, the pharmacy profession, and consumer organisations in spreading the message concerning the advantages of a system of self-care. In a 1996 symposium, organised by the PAGB (PAGB 1996), the Government's Deputy Chief Medical Officer stated that:

‘... individuals can contribute to their own health in many ways ... sensible self-medication has a significant part to play in the treatment of ... ailments ... an important element ... is the availability of a range of effective medicines which can be supplied without the need for a prescription.’ (PAGB 1996:5)

The then President of the Royal Pharmaceutical Society said:

‘In every country in the world with a developed pharmaceutical service we see Governments deciding that more medicines should be available without the need for a medical prescription. It is bound to be good economic sense to allow self-medication for self-limiting conditions provided that there is adequate control and appropriate professional advice is available at the point of supply. Recent developments in countries like New Zealand, the United States of America and Denmark have demonstrated not only that a wider range of effective medicines can be released from prescription-only control, but also that pharmacists will continue to act very responsibly and professionally in the supply of medicines which have been so released ... I want to make it very clear that I believe that an increasing number of products could and should be transferred from POM to P and that the mechanism for effecting this change needs, to put it mildly, “speeding up”.’ (PAGB 1996:15)

At the same symposium, the Assistant Director of the Consumers’ Association made it clear that the increased awareness of the consumer of individual rights in respect of health care, and a parallel challenge to the requirement to have to purchase drug products on prescription, necessitated a re-evaluation of existing health care policy, health care relationships and the further provision of appropriate and effective information in order to empower the consumer (as patient) even further. The PAGB, in agreeing with this last sentiment, added that the increase in a desire for individual autonomy in health care necessitated the establishment of a structure whereby individuals could exercise that independence. That structure included the requirement

⁴ See the successive Annual Reports of the PAGB published since 1995

for a shift in the cost of health care treatment from the state to the individual patient, which, in turn, required increased de-regulation of medicines:

‘This is not something that manufacturers have dreamt up because they had nothing better to do. It came out of research of consumers and their expectations of OTC products. Moving modern, safe and effective ingredients out of the prescription arena and into individuals’ hands is a real step towards achieving greater self-control ... consumers want and are ready to handle many conditions themselves.’ (PAGB 1996:43)

By 2000, the PAGB was continuing to promote the policy of self-care. In its 2000 Annual Report, the President of the PAGB re-emphasised the increased awareness by the public of the benefits of self-care, indicated by the placing of the issue by the Government at the centre of its policies designed to make people more self-sufficient in terms of their own health-care. According to the PAGB, consumers are broadly in tune with government policy, willing to self-medicate and thereby saving the National Health Service up to 14% of its annual budget.

It is clear that the Government policy towards self-medication, actively promoted by the pharmaceutical industry may be having the desired effect. Statistics produced by the PAGB in its 2000 Annual Report show a 7.4 % increase in the sales of over-the-counter medications between 1998 and 1999, worth over £106 million to the industry. Further figures show a saving to the National Health Service of some 6 billion pounds in 1995 through the increased use of medicines.

What are the implications of these developments in the re-classification of medicinal drug products for the pharmacy profession? Blenkinsopp and Bradley (1996) identified the drive by the pharmacy profession for an increased role in medicines management and use as a precipitative factor in the push towards the re-classification of medicinal drug products. The authors submit that the constant support of the Royal Pharmaceutical Society for re-classification is motivated, in part, by a recognition that a welcome side-effect of such a move would include further support for the ambitions of the profession to obtain recognition of a new role.

Blenkinsopp and Bradley submit that there is no evidence to support the allegations of some general practitioners (Morley, Jepson, Edwards and Stillman (1983)) that the commercial environment of the pharmacy would motivate pharmacists to always recommend a sale of a medicine when approached for health care advice. Such business constraints should, say some general practitioners, preclude pharmacists from being members of the primary health care team, let alone have increased responsibility for medicines management and use. The authors conclude that the profit motive theory has no substance in practice where pharmacists, in a significant minority of cases, make no recommendation for the sale of medicine but re-refer the patient to the general practitioner.

Bond and Bradley (1996) also agree that the shift to self-care, as evidenced by the drive towards the de-regulation of medicinal drug products, has distinct implications for the future of the pharmacy profession. In particular, the new health care policy will strengthen the pharmacist's position as a member of the primary health care team. The authors are firmly of the view that

health care policy makers specifically identified the pharmacy profession as a key resource in the promotion of the initiative of rational and cost effective prescribing, in order to make a contribution towards the overall, increasing expenditure on health care. For the initiative to be successful, submit the authors, there will have to be a re-alignment of the membership of the primary health care team, a recognition of the potential contribution of each team member towards effective health care, a re-definition of certain aspects of professional practice, and increasing co-operation between health care team members.

Bradley and Blenkinsopp (1996) identify the key challenges for the pharmacy profession following the widening of the scope for self-medication. These include the possibility of greater profits through increased medicine sales; the creation of a closer professional relationship with general practitioners and the development of a more constructive interaction with the patient, for the patient's benefit. Each of these remains a challenge, according to the authors, because they involve a re-negotiation of existing relationships and a re-definition of current health care practices. The authors hope that the professions involved can rise to the challenge presented as the result would be that the patient would get the best possible advice, both on diagnosis from the doctor and on medication from the pharmacist.

As was noted above, the purpose of this chapter is to evaluate whether the pre-determinants are present in the United Kingdom for a re-examination of professional relationships, responsibilities, and duties similar to that which has taken place in the United States of America. Chapters four and five had shown that the changes evidenced in the United States of America

required a re-evaluation by the legislators and the judiciary of existing ideas on professional relationships, responsibilities, and duties. Certain of the conditions for change, which had been present in that jurisdiction for some time, included an uncertain, self-conscious but persistent profession advocating reform and a recognition by health care policy makers of the value of re-defining professional-patient relationships and the nature of health therapy.

Quite clearly, as the analysis above has shown, those conditions are also present in the United Kingdom. Here, the health care policy makers are committed to a parallel reduction in health care costs through the promotion of the benefits of self-care, including a de-regulation of medicinal drug products. The policy makers have recognised the potential of the pharmacy profession as a significant promoter and catalyst for the new policy. In turn, the pharmacy profession continues its own policy of aggressive self-promotion as the key member of the primary health care team with the expertise, experience and capacity to carry forward the strategy. Finally, the scheme requires the re-negotiation and re-definition of existing relationships, roles and practices.

In the United States of America, the circle has been closed by the re-definition by both the legislature and the judiciary of existing ideas on professional relationships, responsibilities, and duties. That required a critical analysis of existing health care practice, an innovative vision for health care, and a confirmation of the benefit in involving the profession of pharmacy in a new and varied health care scheme. Whether that circle will be closed in the United Kingdom remains to be seen. It is clear, however, that the pharmaceutical industry will continue to favour the policy of self-care with its inherent de-regulation of medicinal drug products, for two main reasons.

Firstly, it makes little commercial difference to the large drug manufacturers. Indeed, and as was noted above, the de-regulation of drug products results in increased OTC sales, thereby maximising profits. Secondly, de-regulation places yet another litigation defensive barrier between the drug manufacturers and the ultimate consumer of their products. Not, it is arguable, that they need such a barrier. As has already been noted, litigation against drug manufacturers for failures in drug therapy does not tend to be successful, largely due to the successful implementation of the informed intermediary doctrine. Even though there is some potential for the reform of this doctrine, it is likely to lead to increased rather than decreased pharmacist responsibility.

The re-categorisation of drug products, however, has distinct implications for the allocation of responsibility for failures associated with those drug products. Re-categorisation as a P drug product, the pharmacy's profession's monopolised classification, or as an OTC drug product, a highly desired classification for the profession, has the potential for further exposure to increased liability, particularly through the law of contract.

It is equally clear that the medical profession (although there may be exceptions) will largely remain ambivalent towards the new strategy of promoting self-care. On the one hand, and because it involves a re-negotiation of the roles and responsibilities of the members of the primary health care team, the medical profession, which often sees itself as leading that team, will be wary of relinquishing any existing responsibility and of promoting the interests of what are perceived as lesser members of the health care team, particularly those with competing

commercial interests. As was noted above, there are those within the medical profession who refute any claim by the pharmacy profession to be members of the primary health care team. On the other hand, the drive towards self-care, by implication, means a reduction in professional responsibility, and a parallel decrease in liability. Not that the medical profession requires any decrease in liability. As was noted above, cases against prescribing doctors of drug products for compensation for injuries caused by failure to warn about those products do not tend to be successful, largely because of specific analyses of the law on doctor liability, and in particular the lack of recognition of informed consent.

Disturbingly for the pharmacy profession, attention therefore focuses on the final participant in the drug distribution process, the dispensing pharmacist, and the implications of this analysis have, initially, to be of concern to the pharmacy profession in the United Kingdom. Blenkinsopp and Bradley (1996) identified pharmacists' anxieties about increased responsibility as a factor with the potential to inhibit the re-classification of drug products. What needs to be examined is whether the further factors are present which would lead the judiciary in the United Kingdom to continue to preserve immunity for the drug manufacturer and prescribing doctor for failures in drug therapy, and to convince it that an extension of pharmacist professional responsibility, based on a re-definition of duty, is appropriate.

Responsibility for failures in drug therapy

It is quite clear that a significant proportion of medical negligence claims are directly related to

errors in prescribing, monitoring or administering medicinal products. In turn, the severity of injury caused by medication errors, or failures in drug therapy as we shall term it, are equally significant, and can include permanent injury or death.

The recent report of the Comptroller and Auditor General (HC 403 Session 2000-2001) into the handling of clinical negligence claims in England concluded that some 8% of all clinical negligence claims are based on drug complication defined as:

- drugs administered to a person with known allergies or to a person on known other medication;
- drugs administered inappropriately ;
- no information provided to patient on side effects of medication;
- failure to listen to patient's concerns.

The report also showed that the rate of new claims per thousand finished consultant episodes rose by 72% between 1990 and 1998, that by 31 March 2000 there were an estimated 23000 claims outstanding; that the estimated net present value of outstanding claims at 31 March 2000 was £2.6 billion, up from £1.3 billion at 31 March 1997, and that the largest volume of claims arises where the claimants allege that negligence has led to a fatality. The report also shows that clinical negligence is not an issue for England alone. As at March 2000, provisions to meet outstanding claims were £2.6 billion for England, £38 million for Scotland, £111 million in Wales and £100 million in Northern Ireland.

In many ways these figures are startling. In reality, however, they show that drug therapy is not error free and that there are significant implications for failures in drug therapy. They also demonstrate that litigation and in particular medical litigation is on the increase, resultant on an increase in consumer awareness, and a parallel drive by the legal profession to pursue claims on their behalf. The figures also show that litigants, especially that 8% pursuing claims resultant on drug complication, will pursue whichever participant in the drug distribution process is thought to be appropriately responsible for the failure in drug therapy. Finally, increased litigation will inevitably result in increased appeals. As will be known, it is at the appellate stage that the possibility of significant judicial intervention will occur, and re-definition of professional responsibilities will take place.

Brushwood (1996:439) also concludes that the importance of the role of drug therapy in medical treatment cannot be underestimated. He states that, for the most part, modern drug therapy works well. However, problems do arise with drug therapy. Licensing and approval do not necessarily mean that a drug is problem free. Even proper diagnosis of a patient's condition, followed by the appropriate selection of a patient's medication, will not ensure a successful outcome from drug therapy. Toxicities and therapeutic failures can occur from either the chemistry of the drug, the chemistry of the patient, or both.

It is generally accepted that there are three main types of drug defect - manufacturing defects, design defects and marketing defects. Manufacturing defects are caused by errors which arise

during the production process and may affect all, some or only one drug product. Contamination of the drug with another product would be a good example of a manufacturing defect. Design defects arise because the design process itself is imperfect although the manufacturing process is not. Such a defect will necessarily affect all drug products manufactured to the design. Marketing defects arise because of a failure to give an adequate warning of the dangers of the product or adequate guidance for its safe use.

Such failures and poor outcomes from drug therapy often lead to legal action and an attempt to discover who or what is responsible for the harm which has been done to the patient. Quite clearly there are a number of participants in the drug distribution business who may be responsible for such harm. The main participants in the procedure are the manufacturer of the drug, the doctor, and the pharmacist. A patient who has suffered harm as a result of a failure in drug therapy may consider litigation against any one, or combination, of these individuals.

In turn, an individual manufacturer, doctor or pharmacist, sued by a patient, may lay the blame for the failure of the drug therapy at the door of one of the other participants in the drug distribution process. As such, the professional responsibility of a pharmacist for the distribution of drug products may only be understood by exploring the parallel responsibility of the manufacturer and doctor.

Responsibility of manufacturer for drug therapy failure

The manufacturer's initial role in the drug distribution process is to develop the drug product through a variety of stages - discovery, test, trial and licence. The manufacturer's secondary role is to market the drug product to health care professionals and patients and the final role is to distribute and/or sell the drug product to patients. Distribution and sale may be undertaken either directly through over the counter or pharmacy medicine sales, or via a health care professional through prescription only medicine disbursement.

It is important to note, therefore, that the manufacturer does not have direct distribution contact with the patient. Over the counter and pharmacy medicine sales are usually conducted by a pharmacist or other distributor with legal authority to sell. Prescription only products are distributed through two intermediaries - the prescribing health care professional and the dispensing pharmacist. This has a direct consequence for the patient's remedies, against the manufacturer, should the product be defective and cause injury. The interjection of an intermediary (or two) necessarily affects the legal relationship between patient and manufacturer.

Direct liability becomes indirect liability and the patient loses the advantage of consequential, no-nonsense legal remedies, such as would be available under the sale of goods legislation. The right to make a product liability claim in contract is confined to an injured person who actually buys the goods him or herself. The contract claim can be brought against the supplier of goods only. In contract, there would, as between buyer and seller, normally be implied conditions and warranties as to the quality of the goods. Liability arises even though there is no fault. However

the rules of privity of contract would prevent anybody other than the contracting party from relying on them. The patient who is injured by a defective drug product is not without a legal remedy against the manufacturer, but has to enter the minefield of tortious, and other remedies, in order to establish liability.

It is important to note that the common law in the United Kingdom treats drug products in precisely the same way as other consumer products. There is no separate body of law to deal with liability for injuries caused by defective pharmaceutical products and this has direct consequences for the form of action taken by those injured by defective drug products. A patient injured by a defective drug product is therefore in exactly the same legal position as a consumer injured by a defect in the consumer product which they have purchased.

In the United Kingdom manufacturers of products, including drug products, have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products, according to the principles first set out in *Donoghue v Stevenson* ([1932] AC 562). This judgement has been subject to significant interpretation, analysis and application since 1932. It is clear that products will now include drug products and the duty also extends to any container or package in which it is distributed and to any labels, directions or instructions for use which accompany it (*Watson v Buckley* [1940] 1 All ER 174, *Holmes v Ashford* [1950] 2 All ER 76 and *Vacwell Engineering Co Ltd v BDH Chemicals Ltd* [1971] 1 QB 88).

In *Donoghue v Stevenson*, Lord MacMillan was of the view that a manufacturer's liability should end when he/she had parted with the product. It is now accepted (Newdick 1988) that this is a narrow view and that manufacturers are under specific duties to issue adequate warning notices after putting the product into circulation, and, if necessary, to issue a recall programme. The licensing rules on medicinal drug products (Mullan 2000: Chapter 4) also impose a requirement that there exists an adequate recall programme.

Lord Atkin's original analysis of the nature of the duty owed by manufacturers contains the words 'with no reasonable possibility of intermediate examination'. It is generally accepted that an intermediate examination, may absolve the defendant manufacturer from liability where it can be shown that the examination ought to have revealed the defect or, importantly in relation to drug products, provide a warning which will allow the consumer to use the product safely. For such a defence to 'bite', there must, at least, be the probability that an intermediate examination will take place, a fact which the plaintiff need not prove. It has already been noted that, in the drug distribution process, drug products will pass from the manufacturer, through the hands of at least one, and possibly two, intermediaries.

As part of the general duty of care, the manufacturer is required to provide adequate information about the product, including warnings, so that the product may be used safely. If the manufacturer supplies an adequate and proper warning to the user of the product and the user ignores the warning then the manufacturer will be under no liability to the user. The question of what is an adequate and proper warning will be determined according to criteria such as the nature of the

product, the degree of hazard inherent in it and the location and prominence of the warnings.

In the United Kingdom, a manufacturer may discharge the duty to supply information and warnings by supplying the information or warning to an intermediary. In the case of *Holmes v Ashford* ([1950] 2 All ER 76), Lord Justice Tucker made these comments about the supply of warnings to an intermediary:

"In my view, if [the manufacturers] give a warning which if read by [an intermediary], is sufficient to intimate to [the intermediary] the potential dangers of the substance with which he is going to deal, that is all that can be expected of them. I think that it would be unreasonable and impossible to expect that they should give warning in such form that it must come to the knowledge of the particular customer who is going to be treated ... The most that can be expected of the manufacturers of goods of this kind is to see that [the intermediary] is sufficiently warned."([1950] 2 All ER 76 at page 80)

How do these general principles apply to the specificity of drug products? There is no authoritative judicial pronouncement on this issue but several leading academic commentators in the United Kingdom have made it clear that in the field of medicinal products - at least those medicinal products available on prescription - the manufacturer's duty to warn is discharged by the provision of information to intermediaries – the ‘informed intermediary doctrine’ (Miller & Lovell (1977) and Clark (1989)).

The ‘informed intermediary doctrine’ has been judicially recognised in the United States of America for some time. A good summary of the current position in that jurisdiction is to be found in the case of *Pitman v The Upjohn Company* (1994 Westlaw 663372 [Tenn. 1994]). In its

discussion of the manufacturer's liability, the court recognised that drug manufacturers have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products. This included a requirement to market and distribute the products in a way which minimised the risk or danger.

However the court also recognised that under the "informed intermediary doctrine" the manufacturer of an unavoidably risky prescription drug has no duty to warn patients directly and can fully discharge its duty to warn by providing the doctor with adequate warnings of the risks associated with the use of its drug. The question of the adequacy of a warning was one of fact to be decided in accordance with certain criteria.

As noted above, although there is no authoritative judicial pronouncement on this issue, it can be concluded that, at present, and in general terms, the 'informed intermediary doctrine' applies in the United Kingdom. The manufacturer of an unavoidably risky prescription drug has no duty to warn patients directly and can fully discharge its duty to warn by providing the doctor with adequate warnings of the risks associated with the use of its drug.

It is submitted that the informed intermediary doctrine applies to prescription medicinal drug products alone. A manufacturer of over the counter medicinal drug products has a duty to warn the ultimate consumer of those products, the patient, of any risks associated with the use of the drug. This is because there is no intervening intermediary to whom the duty to warn can be delegated. It could not be said, for example, that a retailer of over the counter medications, such

as a garage or small shop owner has any duty to warn the consumer or patient of any risks associated with the drug use. The situation may be slightly different with pharmacy only medicines. Although these are also available for direct sale, they must be sold in a registered pharmacy by or under the supervision of a pharmacist. Consumers cannot get their hands on pharmacy only medicines without the permission of a pharmacist. It is submitted that a drug manufacturer remains under a duty to warn the consumer directly about any known risks associated with that drug's use. It is arguable, though, and this will be explored in more detail below, that the pharmacist supervising the sale, is also under a duty to warn the consumer.

Evidence supporting the 'informed intermediary doctrine' is to be found in the legislation which controls the licensing of drug products in the United Kingdom. Under s. 96 of the Medicines Act 1968, the licence holder of a drug product may not promote a drug product to doctors through advertisements or other representations unless those doctors have been provided with a copy of the pharmaceutical manufacturer's data sheet about the drug product in the prescribed form within the preceding fifteen months. As such, the doctor will be compulsorily supplied with information about drug products by the drug manufacturer and indeed, is likely to obtain further information about the drug product from other authoritative sources.

As was noted above, the rationale behind the classification of certain medicinal drug products as prescription only, is that the use of such products in treatment needs to be supervised by a doctor or other health care professional because they may produce a toxic reaction or physical or

psychological dependence, or may endanger the health of the community. A patient cannot obtain a prescription only drug product unless a relevant health care professional, using his/her knowledge, training, clinical experience and acquired subjective and objective evidence from the patient, assesses the patient's health care problem and develops and implements a therapeutic plan to alleviate the difficulty, involving the writing of a prescription for a prescription only drug product.

The health care professional's knowledge, training and clinical experience will necessarily include information and expertise in the practice and expected outcomes of drug therapy. That knowledge may have been acquired through initial and continuing education, clinical practice or, importantly, through the marketing endeavours of the manufacturers of drug products. The essential point is that it is the prescribing doctor who chooses the therapy for the patient.

As has been noted in detail above, it is arguable that the maintenance of a classification of medicinal drug products as prescription only flies in the face of a modern thinking on health care. The current drive is towards the promotion of the policy of self-care which includes a strategy of de-regulation of prescription only drug products. The drug manufacturer's duty to warn, discharged by the provision of information to intermediaries, is, for the moment, restricted to those drug products supplied for distribution as prescription only. With increased de-regulation of prescription only products comes a parallel diminution of the manufacturer's duty to warn, and a potential increase in the duties of other health care professionals. This latter aspect will be explored in more detail below.

The informed intermediary doctrine currently restricts the drug manufacturer's duty to provide the *doctor* with adequate warnings of the risks associated with the use of its drug. The theory behind the doctrine is that it is the doctor who has the knowledge, training and clinical experience, including information and expertise in the practice and expected outcomes of drug therapy, to assess the risk associated with the dispensing of a particular drug or not. As a corollary, the theory holds that the ultimate consumer of the drug product, the patient, has no such basis for risk assessment, is uneducated in the outcomes of drug therapy, and is untrained in risk assessment. Giving a warning directly to the patient would be of little value as the patient would be unable to do anything with it. As a result, the best protection for patients is to take risk assessment directly out of their hands.

It is submitted that the basis for restricting the informed intermediary doctrine to the provision of warnings to doctors also rankles with current theories on health care, for a number of reasons. Firstly, the patient, as a health care consumer, wants to be more directly aware of the therapeutic plan which has been developed, and ardently wishes to participate directly in choices which are to be made about continuing health care. In a 1997 consumer survey of self-medication for the Proprietary Association of Great Britain, BMRB International found that the wider availability of over-the counter medicines was being matched with an increased public demand for more information about treatments and medicines. Further 80% of those surveyed agreed that they should visit their general practitioner less and seek alternative forms of advice about minor illnesses (BRMB 1997).

Secondly, the argument that it is the doctor who is in the best position, because of knowledge, training, and experience, to undertake risk assessment with respect to drug therapy is to ignore totally the greater education, training and credentials of the pharmacist in carrying out this task. Pharmacists are experts on drug therapy, and can directly detect potential problems with a patient's medication use through drug therapy monitoring. The increased complexity of drug therapy means that the general practitioner, already under constant and increasing pressure to maintain expertise in all other areas of clinical practice, cannot be expected to sustain an understanding of the intricacies of every new drug therapy and its appropriate use in the health care of individual patients. Drug therapy monitoring is an additional, essential and newly developed responsibility for pharmacists who have represented to other health care professionals and to the public that this service is available, and they have undertaken to provide that service.

Thirdly, the current basis for restricting the informed intermediary doctrine to the provision of warnings to doctors, for the protection of patients, is to ignore the growing subtlety of the patient, through increased knowledge and awareness to manage their own health care, including their own drug therapy. As was noted above, Bradley and Blenkinsopp (1996) argue that safety, the current basis for the restriction of certain drug products to the category of prescription only, is not simply an intrinsic feature of the drug, but can also be achieved by providing better information to the patient.

Fourthly, the exclusion of patients from decisions with respect to their health care, and the

continuing promotion of a paternalistic theory that the doctor knows best, flies in the face of current thinking on respect for patient choice, the right to self-determination, and patient autonomy. That thinking has found its way into judicial opinions in the United Kingdom, where it forms the basis of the current jurisprudence on consent to medical treatment.

Thus it is settled law in the United Kingdom that an adult patient with sufficient mental and physical capacity may withhold consent to medical treatment. This principle is based on the concept of the right to self-determination. The judgement of Robins JA in the Canadian case of *Malette v Shulman* ((1990) 67 DLR (4th) 321 (Ont CA)) in which he clearly set out the legal basis for the maintenance of the principle of self-determination and the legal consequences of treating contrary to the wishes of a competent adult, is most usually cited as the basis for the current United Kingdom cases:

'The right of self-determination ... obviously encompasses the right to refuse medical treatment. A competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternate form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community. Regardless of the doctor's opinion, it is the patient who has the final say on whether to undergo the treatment. The patient is free to decide, for instance, not to be operated on or not to undergo therapy or, by the same token, not to have a blood transfusion. If a doctor were to proceed in the face of a decision to reject the treatment, he would be civilly liable for his unauthorised conduct notwithstanding his justifiable belief that what he did was necessary to preserve the patient's life or health.'

In the United Kingdom case of *Re F* ([1990] 2 AC 1 at 72), Lord Goff fully approved this principle:

"I start with the fundamental principle, now long established, that every person's body is inviolate."

Further support for this view was apparent in *Airedale NHS Trust v Bland* ([1993] 1 All ER 821 at 866) where Lord Goff repeated his earlier remarks:

"First, it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that, an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so ..."

The principle is probably best summarised by Butler-Sloss LJ in *Re T* ([1992] 4 All ER 649 at 664-665):

"A man or woman of full age and sound understanding may choose to reject medical advice and medical or surgical treatment either partially or in its entirety. A decision to refuse treatment by a patient capable of making the decision does not have to be sensible, rational or well considered...Doctors therefore who treat such a patient against his known wishes do so at their peril."(⁵)

These are potent statements and one might expect that they would be rigidly applied. To a certain extent that has been the case and the effect has often been striking, for example in the cases of *Secretary of State for the Home Department v Robb* ([1995] 2 WLR 722), and *Re C (Refusal Of Medical Treatment)* ([1994] 1 All ER 819).

While it is equally clear that the appellate courts have been prepared to dilute the strength of their

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5. The consequences of that peril lie in the potential for a civil suit for trespass to the person or negligence and/or a variety of criminal charges.

statements in a number of specific situations where the courts are determining that the right to self-determination might be abrogated for a variety of reasons, for example in the cases of *Re S*, (*Adult: Refusal of Treatment*) ([1993] Fam 123), *Re T* (*Adult: Refusal Of Treatment*) ([1993] Fam 95), *Re KB* (*adult*) (*mental patient: medical treatment*) (19 BMLR 144) *B v Croydon District Health Authority* (22 BMLR 13), the principle of self-determination, the right to personal autonomy, and the requirement for consent to medical treatment, is well recognised in United Kingdom law.

It is arguable that a further legal principle, such as the informed intermediary doctrine, which emphasises that it is for the prescribing doctor, based on perceived greater knowledge, training and experience, to choose the therapy for the patient, and which implies that the patient does not have the requisite capacity to comprehend and accordingly participate in the decision-making process leading to the choice of treatment, runs contrary to accentuated rights to self-determination.

Fifthly, in other jurisdictions, there has been some recognition of a requirement to modify the extent of the existing rule so as to require manufacturers of prescription only medicinal products to provide a warning directly to the patient. The modification of the rule has been proposed with respect to prescription only medicinal drug products with particular characteristics, for example, oral contraceptives and vaccines. In *MacDonald v Ortho Pharmaceutical Corporation* (475 NE 2d 65 (1985) (Mass), *Davis v Wyeth Laboratories* (399 F 2d 121 (9th Cir, 1968)), *Reyes v Wyeth Laboratories* (498 F 2d 1264 (5th Cir 1974)), *Stephens v G.D. Searle & Co* (602 F Supp 379

(Mich) (1985)), *Lukaszewicz v Ortho Chemicals* (510 F Supp 961 (Wis) (1981)), the courts held that the manufacturer had a duty to warn the patient directly.

These latter United States cases were reviewed by the Ontario Court of appeal in *Buchan v Ortho Pharmaceuticals (Canada) Ltd* ((1986) 54 OR (2d) 92). Although the point was not directly at issue in the substance of the appeal, the judgement refers in detail to the philosophy of requiring a manufacturer of prescription only drug products to provide a warning directly to the ultimate consumer, the patient:

‘There can be little doubt that oral contraceptives have presented society with problems unique in the history of human therapeutics. At no time have so many people taken such potent drugs voluntarily over such a protracted time for an objective other than the control of disease ... Furthermore, unlike the selection of an appropriate drug for the treatment of illness or injury where patient involvement is typically minimal or non-existent, consumer demand for oral contraceptives prompts their use more often than doctors’ advice. The decision to use the pill is one in which consumers are actively involved; more frequently than not, they have made the decision before visiting a doctor to obtain a prescription.

For these reasons ... I am of the view that oral contraceptives bear characteristics distinguishing them from most therapeutic, diagnostic and curative prescription drugs. The *rationale* underlying the informed intermediary doctrine does not hold up in the case of oral contraceptives. Manufacturers of this drug should be obliged to satisfy the general common law requirement to warn the ultimate consumer as well as the prescribing physicians. To require this would not be to impose any real burden on drug manufacturers or to unduly interfere with the doctor-patient relationship as it exists with respect to the prescription of this drug. What is more, appropriate warnings conveying reasonable notice of nature, gravity and likelihood of known or knowable side-effects and advising the consumer to seek further explanation from her doctor of any information of concern to her, would promote the desired objective of ensuring that women are fully apprised of the information needed to balance the benefits and risks of this form of birth control and to make informed and intelligent decisions in consultation with their doctors on whether to use or to continue to use oral contraceptives.’

While the judge uses the term 'characteristics' of oral contraceptives, he is not in any way referring to anything concerned with the clinical composition of the drugs. Rather he is referring to other factors such as the particular use for which they are sought, the active participation of the patient in assessing the risks associated with their use, and the freedom of choice exercised by the 'patient' in seeking their prescription in the first place. It is suggested that participation in risk assessment, freedom of choice and informed consent are characteristics which are now associated with other types of drug therapy.

It is submitted, therefore, that it is opportune for the judiciary to re-examine the current bases for the restriction of the manufacturer's duty to warn of the risks associated with prescription only medicinal drug products, through the provision of information to the doctor alone. The submission is not that the manufacturer should be absolved of any duty to warn. That proposition would fly in the face of all of the current jurisprudence on product liability which correctly holds that all manufacturers of products have a duty to exercise ordinary and reasonable care not to expose the public to an unreasonable risk of harm from the use of their products. What is suggested is that the range of individuals to whom warnings, or more correctly adequate information for safe and appropriate use, should be extended to include a further intermediary, the pharmacist, and the ultimate consumer, the patient.

That proposed extension would not prove to be too burdensome for the drug manufacturer, who, it is submitted, would remain largely unfazed by any proposed changes. As it presently stands, the drug manufacturer has significant duties with respect both to the labelling of relevant

medicinal products, and to the provision of information leaflets with the packages of such medicinal drug products. The net summary of the current law (for the detail of these rules, see Mullan 2000: Chapter 9), resultant on amendments passed after enactment of several European Union directives, means that the containers and packages of all medicinal products, whether in the category of POM, P or OTC, must be clearly labelled to show certain particulars, and that such products must not be supplied unless a leaflet containing specified information is enclosed in, or supplied with, the package.

Containers, packages, labels and leaflets are all currently supplied by the drug manufacturers to both pharmacists and patients alike, and it is true to say that drug manufacturers have taken to their new duties with respect to the identification of medicinal drug products with rigour. Their response to any proposed extension of the duty to warn others, aside from the doctor, is that they are doing it anyway. The content of the information leaflets, supplied by the drug manufacturers to pharmacists and patients, reflects that which is currently given to doctors, under the present restricted duty to warn. Such information has consistently been held to be adequate for the assessment of risk to be carried out. Indeed the nature of the warnings given with certain drug products is such that no consumer would ever consider using them. Miller & Lovell (*Product* (1977) suggest that the manufacturer's legal position (even under a system of strict liability) will seldom be better when it can show that the patient's safety expectations were directly qualified by supply of a patient-oriented package leaflet. Again, this would reinforce a conclusion that the drug manufacturers would see any proposed extension of the categories of person to whom a warning would have to be given, as unproblematic.

Drug manufacturers would, therefore, see no obvious interference with their current virtual immunity from liability for failures in drug therapy, even if the proposed extension of duty to warn was to happen. What are the implications, however, for pharmacists, if they were suddenly to be included in the category of person, or intermediary, to whom a manufacturer of a prescription only drug product had a duty to give a warning? It is submitted that such a proposal ought to be warmly welcomed by the pharmacy profession as amounting to recognition of the vital role which it performs in monitoring drug therapy. It would provide reinforcement that it is the pharmacist, with the relevant knowledge, training and experience, who has the greater ability to detect potential problems with a patient's medication use, and to interact with the patient and/or the patient's doctor, to resolve the potential problem and protect the patient from harm. It accords with the current expectations of the pharmacy profession which has held out to the public, and other health care providers, that it is willing to provide this type of service for public benefit. It strengthens public endorsement of the community pharmacist as an authority in drug therapy.

The potential downside is that the proposed interjection of the pharmacist as a drug manufacture's intermediary increases pharmacist responsibility, and by analogy, increased liability for failure to exercise that responsibility to the appropriate standard. Under the current doctrine, the doctor who fails to act as an intermediary and pass on the warning to the patient, remains liable for the consequences of that omission. It will be seen below that it may be difficult to prove that a prescribing doctor is under a duty, under the current interpretation of the

principles of informed consent, to provide detailed and complex warnings about every risk associated with the drug therapy. That does not negate the principle, however, and should the informed intermediary doctrine be extended, to include the pharmacist as intermediary, it does open up further avenues of liability.

It is worth noting, in concluding an analysis of the manufacturer's responsibility for failures in drug therapy, that their existing immunity, under the informed intermediary doctrine, is strengthened by the further difficulties which plaintiffs meet in proving breach and causation in negligence.

Newdick (1988:457) outlines the degree or standard of care which is expected of manufacturers of products at common law:

'Negligence does not require standards of absolute product safety from manufacturers. The extent of their duty to guard against defects has depended on a consideration of the nature of the risk presented by an activity, in terms of its likelihood and severity and the probable effectiveness of precautions. The greater the danger, the more that must be done to avoid or minimise it. If a particular manufacturer possesses more extensive knowledge of the risks presented by an undertaking than his competitors, he will be judged according to the more demanding standards of his own knowledge. On the other hand if he has less knowledge, he may be required to employ consultants to assist in the identification, or management, of the danger.'

Newdick reinforces this view by stating that a manufacturer must keep abreast with leading developments and with increasing development comes an increasing obligation to remain familiar. In relation to particularly dangerous products, there may be a positive obligation to

discover knowledge, particular to that product. Finally, Newdick is of the view that, while a manufacturer might have regard to the standards currently adopted in the industry, adherence to those standards will not absolve liability where they have become outmoded.

In many cases, the task of proving that a defendant drug manufacturer did not reach the appropriate standard may be a difficult one for the plaintiff. It is difficult as it involves a detailed investigation of the defendant's processes of manufacture design and testing, a comparison with industry standards, and a contrast with procedures adopted by other producers in the same field. The plaintiff will need to employ an expert witness(es) who can analyse these processes and procedures and pinpoint any lack of care which may have caused the defect in the product and therefore caused the injury. If the plaintiff is unable to prove a breach of duty he/she may have to bear the loss without compensation, unless there is another available legal basis for the claim.

Brazier (1992) is of the view that a plaintiff's greatest difficulty in any claim against a drug company for a drug defect injury will be in proving that the drug caused the injury. The link between cause and effect in other product liability cases can be established clearly and quickly. With drug products, there may be significant delay in effect. Brazier notes that delay in effect is only one of the plaintiff's problems. The plaintiff may have difficulty in showing that the injury was caused by the defect in the drug taken rather than arising from some natural cause.

Newdick (1988) points to a second problem in causation which relates to the identification of the manufacturer of the drug product alleged to be defective and alleged to have caused the injury.

That problem often arises because the drug has been prescribed under its generic, rather than its brand-name, or because a number of different brand name drugs have been prescribed over a period of time. Newdick states that the courts take a strict view of the establishment of liability in these cases. The plaintiff must prove his/her claim on the balance of probabilities. The production of two defendants, when it is clear that only one is responsible, defeats the claim.

Further, plaintiffs who were supposed to have been assisted by the introduction of a form of strict liability for injury caused by defective products through the passing of the Consumer Protection Act 1987 in Great Britain and the Consumer Protection (Northern Ireland) Order 1987 in Northern Ireland, are finding that those aspirations are ill-founded.

As is well known, the legislation makes it clear that liability arises where damage is caused, either wholly or partly, by a defect in a product. The definition of 'product' in the legislation is sufficiently wide to include drug products. The legislative provisions state that a product will be regarded as defective when the safety of the product is not such as persons generally are entitled to expect. Further guidance is given as to the factors which will be relevant in deciding whether a product is defective, which include the presentation of the product, including instructions and warnings;

Brazier (1992:177) has suggested that the issue of determining when a drug product falls within the definition of defective will be far from easy. Newdick (1988) is of the view that serious difficulties attach to a test which describes the defectiveness of a drug in terms of warnings and

reasonable expectations. Current definitions of defectiveness are constructed to deal with all types of consumer products while drug products present particular difficulties in relation to risk and effects.

Newdick (1988) believes that there is an over-emphasis on the role of warnings and that it is unreasonable to assume that a patient has consented to the risk in question. He states that an examination of the broad categories of risks which may be presented by drugs, and the professional obligation to warn, suggest that the current tests are 'too crude and arbitrary'. The notion of defectiveness then necessarily leans towards the concept of fault, which the new legislation was trying to eliminate.

The greatest problem associated with the new legislation is that the defendant in a case under the consumer protection legislation has a number of possible defences, including the 'development risks defence' which provides that, given the state of scientific and technical knowledge at the time the product was put into circulation, no producer of a product of that kind could have been expected to have discovered the defect if it had existed in his/her products while they were under his/her control.

The United Kingdom was instrumental in having this defence included in the final draft of the relevant European Directive (Brazier 1992:180). Member States were eventually allowed to derogate from it, if they wished. The United Kingdom, like most EU countries has included the

defence in its enacting legislation.

The Royal Commission on Civil Liability and Compensation for Personal Injury, the 'Pearson Commission' (Great Britain 1978) and the Law Commission (Law Commission 1977) had argued against the inclusion of such a defence. It has been suggested that the Government of the day was persuaded by counter-arguments from industry, particularly the pharmaceutical industry (Brazier 1992:180). Those counter-arguments included the claims that innovation would be discouraged and that the cost of insurance against development risks would be astronomical.

The defence was considered recently by the European Court in a case brought against the United Kingdom by the European Commission (*European Commission v United Kingdom* [1997] All ER(EC) 481). The European Commission contended that the wording of the provisions including the defence in the UK legislation, which was different to the wording contained in the original Directive, introduced a subjective assessment by placing an emphasis on the conduct of a reasonable producer, having regard to the standard precautions in use in the industry in question. This had the effect of broadening the ambit of the defence in that the original wording was based on an objective test. The net effect was to reduce the strict liability imposed by the Directive into liability for negligence.

The Court of Justice rejected the Commission's arguments. The Court was of the view that, on its proper construction, the 1987 legislation placed the burden of proof on the producer but placed no restriction on the state of scientific and technical knowledge which was to be taken into

account. Neither did it suggest that the availability of the defence was dependent on the subjective knowledge of a producer taking reasonable care in the light of the standard precautions taken in the industrial sector in question.

The Court was of the view that the Directive, as originally drafted, did raise difficulties of interpretation, which would have to be resolved by the national courts. The courts of the United Kingdom were obliged by the 1987 legislation to interpret the relevant provisions in conformity with the Directive. This finding is placing the emphasis on the national courts to define the ambit of the 'development risks' defence through an interpretation of the relevant national provisions. That interpretation has not yet taken place and until it does, academic comment on the ambit of the defence can only remain conjecture. It has been suggested, however, (Ferguson 1992:63) that an action based on a failure to warn of drug-induced side effects, which were undiscoverable at the time of supply, would be most unlikely to succeed.

Responsibility of doctor for drug therapy failure

Although the position is changing, the doctor (as general practitioner) will be the primary source of health care advice for the vast majority of patients. The doctor's role in health care practice is to use his/her knowledge, training, clinical experience and acquired subjective and objective evidence from the patient, to assess the patient's health care problem and to develop and implement a therapeutic plan to alleviate the difficulty. Knowledge, training and clinical experience will necessarily include certain information and expertise in the practice and expected

outcomes of drug therapy. That knowledge may have been acquired through initial and continuing education, clinical practice or, importantly, through the marketing endeavours of the manufacturers of drug products.

The development of the therapeutic plan will often involve the writing of prescriptions for prescription only drug products. Occasionally it may also involve the actual distribution of prescription only drug products, either in an emergency situation, or because of the particular geographical location of the health care practice. However, it is clear from the statistics, that the therapeutic plans for the alleviation of health care problems frequently involve the writing of prescriptions for prescription only drug products, and that the vast majority of drug products distributed in the National Health Service are done so by prescription.

Again, although the position is changing, the doctor's expectations of the patient are to assist the implementation and outcome of the therapeutic plan by presenting the prescriptions to be dispensed and to take the prescribed drug product as instructed. The doctor's expectations of the pharmacist are to interpret the contents of the prescription, check its validity, dispense the prescription and give appropriate verbal or written instructions as to how to take the medicine.

It is important to note, therefore, that while the doctor has direct clinical contact with the patient, it is often the case that he/she does not have direct drug distribution contact. The sale of drug products on a general sale list and the sale of pharmacy medicines are usually conducted by a

pharmacist or other distributor with legal authority to sell. Prescription only drug products are distributed through an intermediary - the dispensing pharmacist. It will be seen below that this fact may have a significant impact on the distribution of responsibility for responsibility for defective drug products and failures in drug therapy.

In turn, the doctor acts as an intermediary between the manufacturer of the drug product and the patient. It has already been noted that the fact of the presence of an intermediary between manufacturer and patient (consumer) has led to the development of the rule that a manufacturer may discharge the essential element of the duty to provide adequate information about the product, including warnings, so that the product may be used safely, by the provision or supply of that information to the intermediary.

It is a clear fact that patients may consult with their doctor on a private basis, or through the National Health Service. The vast majority of patients choose the latter option. Two main questions arise from this. The first is whether the legal relationship between a doctor and patient who is being treated within the National Health Service is contractual in nature. The second relates to a similar analysis of the legal relationship between doctor and patient outside of the National Health Service.

In the important case of *Pfizer Corporation v Ministry of Health* ([1965] AC 512), the House of Lords held that, where services are being provided pursuant to a statutory obligation, there is no contractual relationship (Bell (1984)).

Lord Reid summarised the position:

‘ The appellant’s argument is that when the patient pays [the prescription charge] and gets the drug there is a sale of the drug to him by [the doctor] or the chemist and that [the prescription charge] is the price ... But in my opinion there is no sale in this case. Sale is a consensual contract requiring agreements, express or implied. In the present case there appears to me to be no need for any agreement. The patient has the statutory right to demand the drug on payment of [the prescription charge] ... And if the prescription is presented to a chemist he appears to be bound by his contract with the appropriate authority to supply the drug on receipt of such payment. There is no need for any agreement between the patient and either [the doctor] or the chemist, and there is certainly no room for bargaining ... It appears to me that any resemblance between this transaction and a true sale is only superficial.’ ([1965] AC 512 at page 536)

The reasoning in *Pfizer* was followed in *Appelby v Sleep* ([1968] 2 All ER 265). This view of the legal relationship between doctor and patient under the National Health Service was accepted by the Pearson Commission (Great Britain 1978). At paragraph 1313, it was noted:

‘Under the National Health Service ... there is no contract between patient and doctor and a plaintiff must rely on an action in tort.’

It is equally clear that a contract exists between the doctor and patient who is seeking treatment on a ‘private’ basis or whose health care is being paid for by someone else, such as an insurance company or employer. Difficulties arise in determining the precise nature and scope of the contractual relationship.

The contract will also have terms, express and implied. In the medical contract scenario, the express terms *might* be found in a consent form, signed by both parties. Two cases - *Eyre v Measday* ([1986] 1 All ER 488) and *Thake v Maurice* ([1986] 1 All ER 497) have discussed the nature of terms to be implied in contracts between doctors and patients. In *Eyre v Measday*, Lord Justice Slade defined one such implied obligation as follows:

‘... I think that there is no doubt that the plaintiff would have been entitled to assume that the defendant was warranting that the operation would be performed with reasonable care and skill. That, I think, would have been the inevitable inference to be drawn, from an objective standpoint ... The contract did, in my opinion, include an implied warranty of that nature.’ ([1986] 1 All ER 488 at page 495)

In *Thake v Maurice* Lord Justice Neill was of the view that in a contract to perform a vasectomy operation, the defendant was subject to an implied duty to carry out the operation with reasonable care and skill.

One interesting aspect of the nature and scope of contracts between patients and doctors which has been discussed by the United Kingdom courts is whether there is an obligation, express or implied, that the success of the therapeutic procedure will be guaranteed. Kennedy & Grubb rightly draw the distinction between a requirement that a contract be performed properly - meaning, probably, with the inclusion of an implied term that it will be carried out with reasonable care and skill - and the demand of a doctor that he/she guarantee success.

The courts in the United Kingdom have not been prepared to find that a doctor has guaranteed a particular result. In *Thake v Maurice*, Lord Justice Nourse stated:

‘ ... a professional man is not usually regarded as warranting that he will achieve the desired result. Indeed, it seems that that would not fit well with the universal warranty of reasonable care and skill, which tends to affirm the inexactness of the science which is professed. I do not intend to go beyond the case of a doctor. Of all sciences medicine is one of the least exact. In my view a doctor cannot be objectively regarded as guaranteeing the success of any operation or treatment unless he says as much in clear and unequivocal terms.’([1986] 1 All ER 497 at page 512)

Other jurisdictions have allowed plaintiffs to obtain damages for breach of contract where the doctor has guaranteed a particular result and has failed to achieve it. In *Sullivan v O'Connor* ((1973) 296 NE 2d 183 (Cal Sup Ct)), a cosmetic surgery case in California, the court allowed the plaintiff to recover damages for breach of contract, but stressed that recovery would not be automatic in every case. There was a difference between statement of opinion and firm promises.

In *LaFleur v Cornelis* ((1979) 28 NBR (2d) 569 (New Brunswick)), a Canadian cosmetic surgery case, the plaintiff succeeded in establishing a breach of contract as well as succeeding in an action for negligence. The court found that the terms of the contract had been clearly established between the parties. There was no need to consider the implications of an implied warranty of success, as the defendant surgeon had expressly indicated that the proposed surgery would be successful.

As noted above, the patient who is treated within the National Health service has no contractual

legal relationship with the doctor. To succeed in gaining compensation for injuries alleged to have been caused by an error of the doctor, the National Health Service patient plaintiff will have to sue in the law of tort. In general terms, patients injured by an error of the doctor usually allege one of two things. The first is that the doctor has been careless in diagnosis and treatment. This could mean that, in the development and implementation of the therapeutic plan, the doctor has omitted to take relevant evidence into account, or has missed relevant symptoms, or has not checked medical records, or has failed to keep up to date with recent developments in therapy, or has carelessly written a prescription.

The second allegation is usually that the patient has not consented to the therapeutic plan which the doctor has devised and implemented. Here the patient often alleges that he/she was unaware of the risks involved with the therapeutic plan, had not consented to those risks, and would not have proceeded with the therapeutic plan had the risks been known.

A doctor owes a patient a number of duties in tort in relation to the development and implementation of therapeutic plans. So, for example, the doctor has a duty to diagnose and treat correctly (*Barnett v Chelsea and Kensington Hospital Management Committee* [1968] 1 All ER 1068). A doctor who fails to carry out these duties in a careful manner, or who fails to act, will be liable in negligence and will have to pay compensation to any patient injured as a result. The concept of duty in medical negligence has been recognised by the courts for some time, at least as far back as *R v Bateman* ((1925) LKKB 791).

The action in medical negligence is not without its problems. While the existence of a duty of care will usually be conceded by a doctor, hospital or health authority sued by a patient, difficulties arise in establishing the appropriate standard of care, that the doctor was in breach of that standard and that the injury was caused by the careless act or omission in question. Some of those difficulties, and the further defences which might be asserted by the doctor, have been outlined in the discussion of the manufacturer's duty of care above.

It will be noted in detail below that there are two significant cases relating to a doctor's duty of care and the writing of prescriptions - *Dwyer v Roderick and others* ([1983] 80 Law Society Gazette 3003), and *Prendergast v Sam & Dee Ltd* ([1989] 1 M.L.R. 36). It is clear from these cases, that the law, through the tort of negligence, will readily impose liability on doctors (and other health care professionals) who have been careless in their professional work. Although the implications in these cases may seem obvious from the facts, their seriousness should not be underestimated by those health care professionals involved.

As noted above, the allegation by an injured plaintiff may often be that he/she has not **consented** to the therapeutic plan which the doctor has devised and implemented. Here the plaintiff often alleges that he/she was unaware of the risks involved with the therapeutic plan, had not consented to those risks, and would not have proceeded with the therapeutic plan had the risks been known.

Consent lies at the heart of all medical treatment. As has already been noted, it is settled law that

an adult patient with sufficient mental and physical capacity may withhold consent to medical treatment. The consequences of that peril are a civil suit for trespass to the person or a variety of criminal charges. Doctors, and other health care professionals, are therefore under a duty to ensure that the patient has consented to the proposed therapeutic plan. Where the design and implementation of the therapeutic plan involves drug therapy, through the actual supply of drug products, or, more usually, the writing of a prescription for prescription only drug products to be dispensed by someone else, the doctor will have to be sure that a valid consent is forthcoming.

Ferguson (1996:68-69) puts the problem quite well:

'Ideally the doctor will have spent some time ... outlining to the patient the diagnosis, proposed treatment, and any important hazards associated with that treatment. In medical cases we are not, generally, faced with a complete lack of consent ... In an ideal world the doctor could be relied upon to ensure that the patient is given relevant warnings and risk information. The reality is likely to fall short of this; not infrequently, patients leave their doctors' surgeries without knowing what has been prescribed for them. It is clear that there would have been minimal discussion of any risks associated with the medication in such cases.'

In the discussion of the civil liability of the manufacturer for defective drug products, it was noted that the manufacturer of an unavoidably risky prescription drug has no duty to warn patients directly and can fully discharge its duty to warn by providing the doctor and pharmacist with adequate warnings of the risks associated with the use of its drug.

If the "informed intermediary doctrine" discharges the duty of the manufacturer towards the patient, the focus then turns to the doctor (and potentially the pharmacist) who has been supplied

with the information. To begin with, what should a doctor in the United Kingdom do with the wide variety of information which has been supplied to him or her? The law in the United Kingdom takes the same view about the supply of information to patients by doctors about drug use as it does about the supply of information about all forms of medical treatment.

The famous case of *Bolam v Friern Hospital Management Committee* ([1957] 2 All ER 118) makes it clear that a doctor will not be negligent if he or she acts in accordance with a practice which is in accordance with a responsible and competent body of relevant medical opinion. The rule concerning the supply of information concerning medical treatment was clearly set out by the Court of Appeal in *Sidaway v Governors of the Bethlem Royal Hospital*:

‘What information should be disclosed and how and when it should be disclosed is very much a matter of professional judgement, to be exercised in the context of the doctor's relationship with a particular patient in particular circumstances.’ ([1984] 1 QB 493 at page 512.

The reasoning was confirmed on appeal to the House of Lords ([1985] All ER 643). Applying this general principle about the supply of information concerning all medical treatment to the specificity of adequate information or warnings about drug use, a potential plaintiff would need to show that the provision of information is not in accordance with accepted, responsible and competent practice within the medical profession.

As it currently stands such a task may be onerous. In the case of *Blyth v Bloomsbury Health Authority* ([1993] 4 Med LR 151), the plaintiff had seen a consultant in relation to her pregnancy.

It was established that she had no, or insufficient immunity to rubella. The proposal was that although it was too late to vaccinate her against rubella at that stage of her pregnancy, it was necessary to do so after the birth of her baby in order to protect her and the baby against the risk of infection. In addition, since the vaccine itself could cause adverse symptoms to a foetus should she become pregnant again within three months, it was necessary that she should have some contraceptive protection during this period. The plaintiff had a previous history of problems with Minilyn a combined pill, containing oestrogen and progesterone.

The general practice at the hospital during this period was to prescribe Depo-Provera for the purpose of long-term contraceptive protection. It was a progesterone only contraceptive and it was thought that it would not have the same adverse consequences as the Minilyn which she had used previously. The plaintiff alleged that she had been insufficiently informed and advised about the possible side-effects of Depo-Provera when she was in hospital; that if she had been informed about the possible side-effects more fully, she would not have agreed to take the Depo-Provera injection and that she suffered from manifold side-effects as a result of the injection of the Depo-Provera.

The Court of Appeal held that the duty owed to the plaintiff by her doctor was to use her professional judgement to decide what information to give to the patient *even* where the patient asks specific questions about specific treatments. In determining whether the doctor has exercised that judgement correctly he or she is to be judged against the standards of the profession as laid down in *Bolam* and *Sidaway*.

It is submitted that this routine adherence to the *Bolam* test carries with it difficulties and complexities. The test was originally formulated to assist in the determination the standard in negligence in relation to diagnosis and treatment. The extension of its application across all aspects of medical procedures, (including the disclosure of risk and the provision of advice and information - *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871), to a variety of treatments - from sterilisation to persistent vegetative state - and across forms of action to trespass to the person and consent has elevated it from a rule of thumb to a rule of law (Grubb 1988:121 at page 137). Control of the decision-making process is firmly in the hands of the medical profession whose views and opinions are determinative of the extent of the legal duties which they owe to their patients. There is a lack of recognition by the courts that it is for them to determine legal standards.

In other jurisdictions the tide of opinion may be turning against the necessary application of the test to all medical cases. Strong misgivings have been voiced about the weight to be attached to the importance of the medical profession's opinions and convictions. It is regrettable that the courts in the United Kingdom have not taken the opportunity to review these apprehensions and seek to apply a modified test.

In a series of cases, the appellate courts in Australia have firmly put the *Bolam* test in its rightful place and have refused to systematically apply it in that jurisdiction. In *F v R*, ((1983) 33 SASR 189) King CJ had the following to say about the issue (at page 194):

'Practices may develop in professions ... not because they serve the interests of the clients, but because they protect the interests or convenience of members of the profession. The court has an obligation to scrutinise professional practices to ensure that they accord with the standard of reasonableness imposed by law ... The ultimate question, however is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community'

The judge had approved the judgment of the Supreme Court of Canada in *Reibl v Hughes* ((1980) 114 DLR (3d) 1 which had adopted a similar approach. The Australian courts continued to develop this theme in *Rogers v Whitaker* ([1992] 67 AJLR 47). Applying a series of cases, (6) the High Court of Australia was clear in its view of the applicability of *Bolam*:

'Further, and more importantly, particularly in the field of no-disclosure of risk and the provision of advice and information, the *Bolam* principle has been discarded and, instead, the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard...'([1992] 67 AJLR 47 at page 51)

While the case of *Bolitho v City & Hackney HA* ((1993) 13 BMLR 111 (CA)) demonstrates, in a limited way, that there is a growing acknowledgment by the courts in England that the question of the determination of the appropriate standards is for them alone, it is time that the matter was clearly settled and explicitly declared.

Any proposals to dilute the current dominant and pervasive application of the principles in *Bolam*

6. F v R supra, *Albrighton v Royal Prince Alfred Hospital* [1980] 2 NSWLR 542, *Battersby v Tottman* (1985) 37 SASR 524 and *E v Australian Red Cross* (1991) 27 FCR 310.

(and *Sidaway*), must include a revision of its present application to the specificity of adequate information or warnings about drug use. It is clear that a routine adherence to a principle that it is for those providing information about drug use to determine its content, adequacy and relevance, according to established principles of professional practice, and to deny the recipient of the information the opportunity to seek clarification or elaboration, runs contrary to current thinking on autonomy, choice, and enablement.

That proposal for change, however, may cause an initial degree of alarm amongst the pharmacy profession. Earlier, it was submitted that the category of person to whom information should be given, particularly information about prescription only medicinal drug products, by drug manufacturers, as part of the informed intermediary doctrine, should be extended to include pharmacists. Currently, the only recipient of the information, the prescribing doctor, is permitted, by the principles in *Bolam* and *Sidaway*, to decide how to impart that information to the patient. A submission that there should be an abrogation of the application of the principles in *Bolam* and *Sidaway*, in respect of the use made by prescribing doctors of the information which they receive, must equally be applied to pharmacists, in their proposed new role of recipients of drug-use related information.

The *Bolam* test is being criticised precisely because of the weight which is attached to the importance of the medical profession's opinions and convictions. Any new test must be stronger than the current routine adherence to established practices and procedures. The pharmacy profession

might counter that while it accepts and desires a new responsibility as recipient and distributor of drug-use related information, it too might wish to self-determine the extent and effect of its distributive powers, according to its professional practices and procedures. To take that view is to take a narrow view. The medical profession is being critically reviewed because its practices and procedures are too paternalistic, and have no place in a consumer society placing emphasis on individual choice and participation.

The pharmacy profession has stressed that increased consumer participation in health care has led to a (currently unmet) demand on health care services that can be alleviated, in part, by the increased use of the profession in drug use monitoring for the patient's benefit. The provision of drug-related information as an integral part of drug monitoring, and positive health care, requires a standard greater than that of established, routine practice and procedure. The pharmacy profession must accept that any new role in drug therapy monitoring needs a re-evaluation of standards of professional practice. Current standards are inappropriate to any proposed new role. It will be seen, in the final chapter, that the pharmacy profession is in a position to influence the future development of legal expectations of pharmacists. The role of the pharmacy profession in influencing the future development of legal expectations of pharmacists is to emphasise its willingness to assume full responsibility for knowledge based drug therapy monitoring but also to argue that a limit has to be placed on that responsibility by judicial recognition that the pharmacist's role cannot be risk elimination because that would mean the end of all drug therapy. Rather, the pharmacist's role requires using available knowledge to minimise the risk of foreseeable adverse consequences to the patient.

It is equally arguable, for the many reasons outlined above, that the retention of the doctor as the sole intermediary for the purposes of the informed intermediary rule is no longer justified. Without repeating the arguments again, the strongest justifications for widening the range of person to whom relevant drug product information should be given are the increasing complexity of drug therapy, the availability of an alternative expert source for drug therapy monitoring and enabling the patient to exercise autonomy in health care decision making.

General practitioners remain highly sceptical of the ability of other health care team members to provide the range of health care needed for individual patients; are unwilling to relinquish control of patients whom they see as their own; and do not subscribe to the theories that self-medication is an appropriate direction for health care (Thomas and Noyce 1996, Bradley 1995).

As was noted above, this scepticism reflects the doctors' perception of the respective roles of themselves, pharmacists and patients in health care. Within the traditional medicines use process a doctor's decision to prescribe will be based on science or clinical experience which is not necessarily information about the patient at hand and rarely involves the active involvement of the patient who is given limited information about the proposed therapy. Further, the pharmacist's role in the traditional medicines use process is dependent on the writing of a prescription and the decision by a patient to have it dispensed. even then the pharmacist's role is limited to interpretation, dispensing and the provision of limited information and instruction. at that stage in the traditional medicines use process the pharmacist's responsibility ends.

Bradley and Blenkinsopp (1996) are clear that in the prevailing climate of health care, such attitudes will have to change:

'Doctors cannot ignore or discourage prior self-medication, and knowledge of such medication is essential ... The patient empowerment that flows from de-regulation can be seen as a good thing. Doctors who encourage and support responsible self-medication will be seen by their patients as a more acceptable source of independent advice. The role of the doctor will then evolve to one of a collaborator with patients in the management of their health problems rather than an exclusive controller of access to medicines ... The alternative approach of fighting to retain control over access to medicines will mean that, as patients gain more and more access to the means to treat their own illnesses, doctors will be rejected as a source of help and advice ... A more optimistic scenario envisages greater co-operation between doctors and pharmacists to ensure that their patients get the best possible advice, both on diagnosis from doctors and on medication from pharmacists.'

The comments of the authors accord with the philosophy for the future of pharmacy, already discussed in chapter four, that of pharmaceutical care. The practice of pharmaceutical care obliges the pharmacist to share responsibility for the design, implementation and monitoring of a therapeutic plan which seeks to achieve a set of desired therapeutic objectives. As an essential element of health care, the practice of pharmaceutical care must be carried out in co-operation with patients and other professional members of the health care team. It is clear, however, that pharmaceutical care is provided for the direct benefit of the patient and the pharmacist must accept direct responsibility for the quality of that care.

Pharmaceutical care moves the practice of pharmacy beyond the traditional model where the primary function of the community pharmacist is to dispense prescriptions, to a new model where the pharmacist is involved in rational drug therapy. Within this new model, pharmacists, in their professional capacity, continue to function as experts in the dispensing of drugs but also collect/find and interpret evidence relating to specific clinical questions and provide information that permits patients to assess risk, enhance their autonomy, and develop their own medication practice.

When patients obtain their medicines they may choose not to take the drug at all or to take it in a certain way based on their own individual social and familial circumstances. The patient has a great deal of autonomy in deciding whether or not to take a drug, is largely unsupervised in making that decision and has no-one with the appropriate knowledge of their individual circumstances to assist them in making rational and careful decisions about self-administration and re-administration.

The pharmacist is well placed to fill this void and assume a client-specific role with respect to decisions about drug taking. Pharmacists are highly trained in the science of drug therapy, are readily available in the community in which they live and are highly regarded and trusted by members of that community. As a result of this, pharmacists often have a greater access to information about the prescription process relating to a particular patient.

The pharmacist in this new role is less concerned with the initial choice of prescription and more concerned with patient outcomes, using patient-specific evidence to monitor and manage the patient's care. This role applies existing knowledge of drug therapy in original and creative ways to improve patient outcomes. Pharmaceutical care changes episodic drug therapy to coherent, continual care. Responsibility for patient outcomes is spread from the individual (doctor) to the team (all healthcare providers).

The new role naturally requires co-operation with patients and other members of the primary health care team. However the pharmacist's intervention is provided for the direct benefit of the patient and the pharmacist must accept direct professional responsibility for the quality of that intervention.

Of course, the extension of the categories of intermediary carries with it the already stated warning of a further extension of liability

Responsibility of pharmacist for drug therapy failure

What is clear, in fact, from the above analysis is that the pharmacist, unlike the other two participants in the drug distribution process, has direct distributive contact with the patient in relation to all three categories of medicinal drug product. The pharmacist may recommend and/or sell GSL medicines, has direct control over the sale and supply of P medicines, and is directly responsible for the distribution of the vast majority of POM medicines. It is clear that such an

allocation of responsibility has direct legal consequences for the pharmacist. Some of these consequences are discussed below.

It is already well-established in United Kingdom law that the relationship between the pharmacist and the patient is one which gives rise to a duty of care in certain circumstances. In *Collins v Hertfordshire County Council and Another* ([1947] 1 KB 598), a patient in a hospital, while undergoing an operation, was killed by an injection of cocaine which was given by the operating surgeon in the mistaken belief that it was procaine. The operating surgeon had ordered procaine on the telephone, but the resident house surgeon has mis-heard procaine as cocaine. The resident house surgeon had orally asked the pharmacist to make up a cocaine with adrenaline mixture, described by Mr Justice Hilbery, the trial judge, as a dosage and mixture that 'nobody has ever heard of injecting ... into anybody' ([1947] 1 KB 598 at page 633).

It was shown, on the facts, that the pharmacist was without doubt aware that the solution was for injection as part of the operative procedure on the patient. Significantly, it was also shown that the hospital's procedures, relating to orders for dangerous drugs, had been totally ignored. These procedures included the requirements that oral instructions for the ordering of drugs was not permitted and that all prescriptions for dangerous drugs had to be initialled by a medical officer and the number of doses specified. Those requirements had not been complied with, resulting in a dangerous and negligent system. Both the resident house surgeon and the hospital pharmacist had contributed to the danger and the negligence.

In *Dwyer v Roderick and others* ([1983] 80 Law Society Gazette 3003), Dr Ian Roderick wrote a prescription for Mrs Joan Dwyer, who had complained to him of severe headaches, for a pain-killing drug which was successful in the treatment of migraine. The drug, ergotamine tartrate (Migril), is extremely dangerous if not taken in proper doses. It can produce gangrene. Dr Roderick did not prescribe the drug in the proper doses. Mrs Dwyer took the prescription to the pharmacy of Cross Chemists (Banbury) Ltd. There she was given ergotamine tartrate in a container displaying the exact dosage as recommended and prescribed by Dr Roderick.

Mrs Dwyer began to take the drug as directed and rapidly became very ill. During this time she was seen by a partner of Dr Roderick, Dr Jackson, who called to see Mrs Dwyer from his own home and therefore did not have her medical notes with him. He gave evidence that he was unaware that Mrs Dwyer was taking ergotamine tartrate. He stated that he had examined drugs that were on her bedside but had not seen ergotamine tartrate. By the time the mistake was discovered Mrs Dwyer was suffering from gangrene and her toes had to be amputated. As a result she became permanently crippled.

In the High Court, Mr Justice Stuart-Smith noted that negligence was admitted by Dr Roderick who had written the prescription and by the pharmacy which had dispensed it. There were therefore two main issues to be decided. Firstly, the judge had to decide whether any further liability lay with Dr Jackson. In an attempt to limit its liability the pharmacy had joined Dr Jackson as another defendant. The judge held that the overwhelming likelihood was that on Dr Jackson's first visit to Mrs Dwyer a bottle containing ergotamine tartrate was by her bedside. Dr

Jackson had persuaded himself, during the eight years which it took for the case to come to trial, that he could not have known that the plaintiff was taking the drug.

Having decided that Dr Jackson had also been negligent, the judge had to decide what the proper apportionment of liability should be. Accordingly the judge awarded damages of £100,000 against Dr Roderick, Dr Jackson and the pharmacy to be apportioned as to 45% to Dr Roderick, 15% to Dr Jackson and 40% to the pharmacy.

On appeal, the Court of Appeal reversed the decision of the High Court in relation to the liability of Dr Jackson. Lord Justice May took the view that after the passage of eight years it was inevitable that however truthful a witness might be trying to be, at least part of his evidence would be inaccurate. By agreement, the pharmacy accepted liability for the 15% liability which had rested on Dr Jackson. In the end, therefore, Dr Roderick's initial gross negligence only cost him 45% of the blame with the pharmacy accepting the remaining 55%.

In *Prendergast v Sam & Dee Ltd* ([1989] 1 M.L.R. 36), Dr Stuart Miller wrote a prescription for Mr Prendergast, who was asthmatic with a chest infection, prescribing three Ventolin (salbutamol) inhalers, 250 Phyllocontin (aminophylline) tablets, and 21 Amoxil (amoxycillin) tablets. It was accepted to be a commonplace combination of drugs for a patient with asthma and a chest infection.

Mr Prendergast took the prescription to the pharmacy of Sam & Dee Ltd, where it was dispensed

by a pharmacist, Mr Peter Kozary. Mr Kozary dispensed the inhalers and Phyllocontin correctly, but instead of the Amoxil he had dispensed Daonil (glibenclamide), a drug used for diabetes to reduce the sugar content in the body. Mr Prendergast was not a diabetic and as a result of taking a large dose of the Daonil suffered permanent brain damage and symptoms of hypoglycaemia.

In the High Court, Mr Justice Auld dealt firstly with the position of the pharmacist, Mr Kozary. Mr Kozary had argued in his defence that the word Amoxil on the prescription was unclear and was capable of being read as Daonil. The “A” could be mistaken for a lower case “d” and the “x” for “n”. His lordship, therefore found it necessary to consider Dr Miller’s handwriting. While the question would always be one of general impression, in his view, the word Amoxil on the prescription was capable of being read as Daonil.

Assuming, however, that the writing was not clear, the judge was of the opinion that there were sufficient other indications to put Mr Kozary on enquiry that something was wrong. More particularly, it was known that Daonil was made only in 5mg strengths, while the word Amoxil was always followed by “250”. Mr Kozary’s defence that he thought that Dr Miller had mixed Daonil up with another diabetic drug which was taken in 250mg was confirmation of the need for the prescription to be checked with the doctor.

Secondly, the dosage of 250mg was normal for Amoxil, but high, and unusually high for Daonil. This fact combined with the assumed knowledge that the taking of Daonil was dangerous for

non-diabetics should have put Mr Kozary on his guard. Finally, Mr Prendergast had paid for the drugs on collection when it might have been expected that a diabetic would have been entitled to free drugs.

Accordingly, the judge concluded that had Mr Kozary been paying attention when he dispensed the drugs he should have known that something was amiss with the contents of the prescription and should have checked these with the doctor. He had not been paying attention and therefore fell below the standard of care and skill expected of a professional pharmacist and had been negligent. There had been sufficient information on the prescription as a whole and in his dealings with the patient to put him on enquiry.

Mr Justice Auld then turned to the position of Dr Miller. He first made it clear that if Dr Miller owed a legal duty of care to his patient and had been in breach of that duty it would be no defence to his liability to rely on the already established liability of Mr Kozary. The judge indicated forcefully that a doctor did owe a duty to his patient to write a prescription clearly and of sufficient legibility to allow for possible mistakes by a busy pharmacist who might be distracted by other customers. Having already established that in his opinion the word Amoxil on the prescription could have been read as Daonil, Dr Miller had been in breach of his duty to write clearly and had been negligent. Such liability could not be excused by the argument that there had been sufficient information on the prescription to put Mr Kozary on his guard. Dr Miller's negligence had contributed to the negligence of Mr Kozary, although the greater proportion of the responsibility lay with Mr Kozary.

Accordingly, Mr Justice Auld awarded damages of £119,302 plus interest against Mr Kozary, his pharmacist, and Dr Miller, the proper apportionment of which was that Dr Miller was 25% liable and Mr Kozary 75% liable.

On an appeal by Dr Miller to the Court of Appeal, Lord Justice Dillon was of the view that the chain of causation from Dr Miller's bad writing was not broken and the consequence of his writing a word which could reasonable be read as 'Daonil', even with the other factors, including the reference to the 250mg as the dosage, was not enough to make it beyond reasonable foreseeability that Daonil would be prescribed. The Lord Justice was also reluctant to interfere with Mr Justice Auld's apportionment of liability.

Although the implications in the above cases may seem obvious from the facts, their seriousness should not be underestimated by those health care professionals involved. In each of these cases the courts were prepared to hold that pharmacists possess expertise regarding the supply of medicinal products and reliance is placed on them by patients for that expertise. The cases confirm that the relationship between pharmacist and patient is one which gives rise to the imposition of a duty of care.

Although liability was also imposed on the prescribing doctor in each of these cases, they both demonstrate that liability need not stop when the prescription leaves the hands of the doctor, even when the doctor has been grossly negligent. It may extend into and be a cause of the negligent

mistakes of others. The net result is that the pharmacist must be aware that he or she should not tacitly accept what they see, or perceive to see, on the written prescription before them. They are under a legal duty of care to draw on their skill and knowledge of drugs to inquire into the surrounding circumstances of the case. In this respect the finding of the judge in *Prendergast* that the pharmacist should have noticed that the patient paid for the drugs is noteworthy. If there is any doubt in the pharmacist's mind then the prescription should be checked by the prescribing doctor.

It goes without saying that the implications of careless conduct are significant, and that specific sanctions flow from a failure to carry out professional roles. As it currently stands pharmacists must pay close attention to the significance of professional responsibility and the tort of negligence. However, in each of the above cases, the facts show that there was an error on the face of the prescriptions which the pharmacist ought to have detected and rectified by querying the contents of the prescription or by refusing to dispense it. Technical accuracy is what the United Kingdom courts appear to be asking of the pharmacist. To that extent, the attitude of the courts in the United Kingdom towards pharmacist responsibility, reflects the approach taken by the United States judiciary in the period from 1932-1985, as analysed in chapter four.

In chapter four, it was noted that in the subsequent period, from 1985 to the present, the judiciary in the United States resiled from its earlier restrictive attitude and was prepared to extend pharmacist responsibility by recognising a new duty to warn. Is the pharmacist in the United Kingdom under any duty to give warnings about drugs which are correctly prescribed and the

appropriate therapy for those drugs?

It has already been noted that those precise issues were at the heart of the recent United States' case of *Pittman v The Upjohn Company* (1994 Westlaw 663372 [Tenn. 1994]), which was discussed in detail in chapter four. In this case the Supreme Court of Tennessee affirmed that the manufacturer, doctor and pharmacist were not liable to the plaintiff on the particular facts. However it also clearly recognised that each of those defendants had a duty to provide warnings about potential problems with drug therapy.

The court stated that a pharmacist is a professional who has a duty to his or her patients to exercise the standard of care required by the pharmacy profession in the same or similar communities in which the pharmacist practices. The court noted that the increased complexity of pharmacotherapeutics and accompanying adverse drug reactions and drug interactions have resulted in an expanded role for pharmacists as drug therapy counsellors. The court also observed a trend towards patient-oriented clinical pharmacy practice.

As for the pharmacy's duty to the patient, the court concluded:

'The record shows that the duty owed [the patient] was greater than merely filling the physician's prescription correctly. As indicated by the evidence in the record, [the drug] posed a danger to [the patient] even if taken according to the physician's order. The pharmacy customer was not aware of that danger because she had not been advised by either the physician, who prescribed the unavoidably unsafe drug or the pharmacy which dispensed the drug. A significant factor affecting the pharmacy's duty was the knowledge that no warning had been given by the physician. Under these circumstances, it was reasonably foreseeable that [the patient] was at risk of injury. Consequently the pharmacy, as well as the physician,

owed her the duty to warn.' (1994 Westlaw 663372 [Tenn. 1994] at page 435)

Thus, the court rejected the pharmacy's argument that its only duty was to correctly process the prescription. The pharmacy had a duty to warn the patient.

It was noted above that in each of the UK pharmacist liability cases, the facts show that there was an error on the face of the prescriptions which the pharmacist ought to have detected and rectified by querying the contents of the prescription or by refusing to dispense it. The issue was one of technical accuracy. Is the pharmacist in the UK under any duty to give warnings about drugs and the appropriate therapy for those drugs?

There is a number of compelling reasons why it can be concluded that such a duty would be imposed in this jurisdiction. The imposition of a duty of care in such circumstances would accord with current pharmacy practice. As has been noted in detail, the pharmacy profession in the United Kingdom has been seeking a move away from a mechanistic role in the drug distribution process towards an increased responsibility for patient care through patient counselling, drug therapy and patient education. The practice of pharmaceutical care is now obliging the pharmacist to share responsibility for the design, implementation and monitoring of a therapeutic plan which seeks to achieve a set of desired therapeutic outcomes.

This trend is evidenced in recent pronouncements of the Royal Pharmaceutical Society of Great Britain, amendments to the Society's Code of Ethics (Royal Pharmaceutical Society 2001), adoption of particular standards of practice, Council Statements and vigorous debate on the

issue through the pages of the professional journals (for example, Roberts (1988), Salkind, Balon, Evans and Greene (1989), Taylor & Harding (1989), Ford (1989), Harding & Taylor (1990)) .

It is a necessary and indeed welcome implication of such a move that expanded responsibility implies the potential for expanded liability should the responsibility be exercised in a careless fashion. It is necessary because the current legal standard which states that pharmacists are only liable for careless, mechanistic errors is legally inappropriate to the expanded role. It is welcome because the imposition of legal liability for failure to perform a role gives greater authority to a claim to have that role.

Further an expanded duty, including a duty to warn, reinforces an earlier submission that the pharmacists should be included in the category of individual to whom a drug manufacturer should be obliged to provide drug-use information. As was noted above, the inclusion of the pharmacist as an intermediary is appropriate, both to satisfy consumer demand for increased drug-use information, and to exploit the potential of the professional pharmacist as a drug-therapy monitor for the patient's benefit. The current drug manufacturer intermediary, the prescribing doctor, distributes drug-use information to an inappropriate standard. The pharmacy profession's aspirations to intermediary status must be matched by alternative, more apposite standards. Those could, and should, include a duty to give warnings about drugs and the appropriate therapy for those drugs.

It can be concluded that the law will consider that a pharmacist, as a professional, has sufficient

knowledge, through education and training and supply of information by the manufacturer, to counsel patients about drug therapy, has a duty to provide such counselling and that a failure to do so which results in injury to the patient will result in liability. That was the conclusion of the court in *Pittman* and it is submitted that a similar conclusion would be reached by the courts in the United Kingdom.

There is a growing recognition by those members of the legal profession who advise those who have been harmed by drug products that pharmacists have legal and professional responsibilities beyond the careful filling of prescriptions as written towards the adoption of responsibility for drug therapy. In a recent unreported case, (*Grove v Addis-Jones and another* Court of Appeal 24 March 1995, LEXIS Transcript) the plaintiff brought an action, amongst a series of actions, against a pharmacy. Her allegation was that a pharmacist had been negligent in making up and supplying prescriptions for the drugs Mudocren and Priadel at the same time and on the same day, since any competent pharmacist ought to have known that if taken at the same time by the patient they would cause a dangerous rise in the serum lithium level which, on the facts, was the cause of her admission to hospital in a comatose state. Similar claims were made against her general practitioner and others.

The fact that the actions were eventually dismissed on procedural grounds should not disguise the recognition by the plaintiff's legal advisers that pharmacists have duties and responsibilities beyond the filling of prescriptions and that liability for failure to perform these expanded roles

may result in the award of damages. Absent the procedural issues in this case, the plaintiff's lawyers were prepared to argue the substantive point before the courts. Argument about the potential expansion of a duty of care before a judge is often persuasive of that judge imposing it.

An important factor for the court in *Pittman* was the inclusion of an "information for patients" section in the drug's package insert. The conclusion for pharmacists in the United States from the court's analysis of the significance of the insert is that to ignore the contents of the insert is perilous. The question of the inclusion of package inserts has taken on a greater significance in the United Kingdom since the alteration in the rules regarding the provision of information leaflets with drug products, as outlined above.

Pharmacists have been concerned about the practical questions which arise from this change in the law - whether each patient receiving stock from a split original pack should be entitled to an information leaflet; whether an information leaflet must be supplied if stock is dispensed from a bulk pack; whether multiple copies of leaflets will be available or whether photocopying of leaflets will be permitted. Pharmacists should also be concerned about the legal implications of this change in the law. What is clear is that if leaflets containing information and warnings are supplied by manufacturers to pharmacists in order that the pharmacist might pass on the information to patients then a failure to provide the information attracts the potential for liability should that failure result in injury. If patient information leaflets are supplied by the manufacturer they should be passed on to the patient and their contents noted and explained to the patient at the time of delivery. To that extent, the conclusions of the court in *Pittman* regarding the peril of

ignoring package inserts is as applicable in this jurisdiction. Equally, however, a recognition of a legal duty to forward information leaflets to the patient reinforces the pharmacist's objective of acknowledgement as a further intermediary between the drug manufacturer and patient.

The discussion so far has concentrated on the pharmacist's duties with respect to the distribution of prescription only medicinal drug products. The conclusion has been that the pharmacist has a duty beyond technical accuracy in the processing of a prescription, is under a duty to counsel patients about drug therapy, which includes a duty to pass on drug manufacturer supplied warnings and other information, and that a failure to do so which results in injury to the patient will result in liability. It is clear, however, that the pharmacist has an important role to play with respect to the sale and distribution of the two other categories of medicinal drug product. It has negotiated a monopoly over the sale and supply of one of these categories and a ready market in the sale and distribution of the other.

It is clear that the sale of general sale list medicines and pharmacy medicinal products are subject to the laws and principles applicable to the sale of all other consumer products. To begin with, this means that the sale is subject to the normal rules of contract law (7). A detailed analysis of all of those rules is beyond the scope of this thesis. However it is clear that liability may attach to the pharmacist under such general principles.

7 It is clear that there can be no liability in contract for injuries caused by a defective drug product distributed to the patient via a prescription.. To repeat what was said earlier, in the important case of *Pfizer Corporation v Ministry of Health* ([1965] AC 512, the House of Lords held that, where services are being provided pursuant to a statutory obligation, there is

For example, pre-contractual discussions may take place in relation to the sale and supply of medicinal products as would happen in relation to other consumer products. A customer might ask the pharmacist for advice in relation to the choice of a medicinal product and specify that it is required for a particular purpose or for a particular individual. In turn, the pharmacist may make statements or representations concerning the product and its uses, prior to sale. For example, a pharmacist may state that a particular drug product is safe for use, or that it will provide a remedy for a particular ailment. If the pre-contractual statement turns out to be untrue, and the patient is injured as a consequence, he/she may seek a remedy in contract from the pharmacist.

Much will turn on the classification of the pre-contractual statement and much will depend on the injured party proving difficult aspects of breach or misrepresentation. However, misrepresentation, if proved, may cover statements made recklessly, carelessly and even innocently. It is also important to remember that liability in contract law is strict. Once the breach or misrepresentation is proved, then damages are payable for all of the consequences of the breach, subject to the rules on remoteness. Damages will be payable for physical or psychological injury, for example, consequent on the breach or misrepresentation. As such, the action for misrepresentation or breach of contract is an attractive one for a plaintiff patient.

The pharmacist's potential liability as a retailer of goods does not stop with general principles of contract law. In order to redress the imbalance in contracting power between the seller and buyer in a consumer sales contract, Parliament has intervened to offer protection to the seller. This has resulted in the passing of the Sale of Goods Act 1979 which received significant amendment

no contractual relationship.

through the Sale and Supply of Goods Act 1994. Again, a detailed analysis of the provisions of these important Acts of Parliament is beyond the scope of this thesis. For the moment, there are some aspects of sale of goods law worthy of consideration.

Pharmaceutical goods are clearly within the definition of 'goods' for the purposes of the legislation and include the container or packaging in which the products are supplied (*Gedding v Marsh* [1920] 1 KB 668), and any instructions which are provided (*Wormell v RHM Agriculture (East) Ltd* ([1986] 1 All ER 769). The provisions of the Sale of Goods Act 1979 have significant consequences for pharmacists as retailers of general sale list and pharmacy medicines. A patient who purchases general sale list or pharmacy medicines does so under a sale of goods contract and is entitled to all of the protection which the legislation provides. Injury as a result of a defect in a general sale list or pharmacy medicine drug product will allow the patient to sue for breach of the sale of goods contract. The cause of action will usually be breach of one, or a number of the implied terms. Damages will be payable for physical or psychological injuries suffered if they are consequential on the breach.

It is very important to stress that liability is strict under such an action. A pharmacist may well claim that the drug product was sold to the patient in the same form and structure as it arrived in the pharmacy and that any defect was attributable to another defendant. Such a claim will not excuse the individual contractual liability of the pharmacist to the patient. However it may allow the pharmacist to sue the party alleged to have been responsible for the defect in the drug product, or join them as a co-defendant in the action taken by the patient.

The pharmacy profession in the United Kingdom has considered the specific issue of the sale of non-prescribed medicines pharmacy and general sale list medicines. As part of the practice advice which supplements the Royal Pharmaceutical Society's Code of Ethics, there is a requirement that there should be a written protocol in each pharmacy covering the procedure to be followed in that pharmacy when a medicine is supplied or advice on treatment of a medical condition is sought. In addition, each member of staff whose work in a pharmacy includes the sale of medicines should have completed a course at NVQ level in retail operations.

Further, as part of the general legal advice offered by the Royal Pharmaceutical Society of Great Britain, it is suggested that medicines sales protocols should comply with certain standards outlined in the Standards of Good Professional Practice. These include standards on the request for advice on treatment of symptoms or a condition, request for a medicine by name, the pharmacist's involvement in the sale of non-prescribed medicines, special purchasers or users and medicines requiring special care.

The fact that these issues are addressed may go some way towards the assessment of whether a pharmacist has acted recklessly or carelessly in making pre-contractual statements in relation to the sale of non-prescribed medicines. Further, the supply by the pharmacist to the patient of the drug manufacturer's leaflet relating to the drug product, will also have a direct bearing on the defence of any pharmacist sued for misrepresentation. However, the fact of acting carefully, and in conformity with a profession's accepted standards, or the passing on of

information from another source, will generally be of no defence to the general action for breach of contract and for breach of the terms of a contract, implied under the sale of goods legislation.

The action in contract relates most closely to manufacturing and design drug defects, leading to problems inherent in the drug product itself which could not have been identified. As was noted above, manufacturing defects are caused by errors which arise during the production process and may affect all, some or only one drug product. Contamination of the drug with another product would be a good example of a manufacturing defect. Design defects arise because the design process itself is imperfect although the manufacturing process is not. Such a defect will necessarily affect all drug products manufactured to the design.

For all of these reasons, the action in contract is attractive to the plaintiff injured as a result of a manufacturing or design defect in a pharmacy or over the counter medicinal drug product sold to him/her by a pharmacist. Moreover, the potential for pharmacists to be sued in contract, for manufacturing and design defects in medicinal drug products is likely to increase with the further de-regulation of prescription only drug products, as described above.

Marketing defects, on the other hand, arise because of a failure to give an adequate warning of the dangers of the product or adequate guidance for its safe use. The action in contract may not be appropriate for failure in drug therapy due to an omission to give a warning of the dangers

associated with it. The question then arises as to whether pharmacists owe a duty to warn in the civil law of tort with respect to the provisions of warnings with respect to pharmacy and over the counter medicinal drug products?

As was noted above, an important factor in concluding that pharmacists owe a duty to counsel patients about drug therapy, and that a failure to do so which results in injury to the patient will result in liability, with respect to prescription only drug products is the inclusion of a manufacturer produced information leaflet in the drug's package. The duty to counsel includes, but certainly is not restricted to, a duty to pass on drug manufacturer supplied warnings and other information. The conclusion for pharmacists is that to ignore the contents of the insert is perilous.

It is submitted that the same principles certainly apply to pharmacy and potentially apply to over the counter medications, even though these are normally supplied through a sale of goods contract. It is clear that the manufacturer of over the counter medicinal drug products has a duty to warn the ultimate consumer of those products, the patient, of any risks associated with the use of the drug. This is because there is no intervening intermediary to whom the duty to warn can be delegated. As was noted above, it could not be said, for example, that a retailer of over the counter medications, such as a garage or small shop owner has any duty to warn the consumer or patient of any risks associated with the drug use. The manufacturer presently fulfils this duty to warn by the inclusion of a warning leaflet with the product when sold.

The manufacturer also owes a duty to warn the ultimate consumer of pharmacy medicines about any known risks associated with that medicine's use. Again this duty is fulfilled through the provision of appropriate warning leaflets. Although these medicines are also available for direct sale, they must be sold in a registered pharmacy by or under the supervision of a pharmacist. Consumers cannot get their hands on pharmacy only medicines without the permission of a pharmacist. It is arguable, therefore, that the pharmacist supervising the sale is also under a duty to warn the consumer.

The basis for this conclusion has to be twofold – the exclusivity of the market for such drugs, and the potential for the pharmacist to exploit this market to influence sales. It is clear that the patient purchasing a pharmacy medicine will usually do so after a recommendation from the pharmacist. That recommendation will be based on a number of factors including, but not restricted, to the pharmacist's education, knowledge, training, and experience, but may, it is also accepted, include commercial considerations including the potential to increase profits. Sanction of the distribution of prescription only drug products, based on monopoly of distributive role, and founded on the pharmacist's education, knowledge, training and experience, forms the basis for the establishment of a duty of care on the pharmacist with respect to the diligent performance of that role. That duty of care now includes a duty to warn of risks associated with prescription only drug products and their appropriate use, reinforced by the requirement to pass on manufacturers' warnings.

It is submitted, therefore, that pharmacists are under a duty to warn patients of any known risks

associated with pharmacy only medicines. That conclusion is reinforced by the findings, noted above, that the pharmacy profession has recognised the requirement for the establishment of protocols with respect to the sale of such medicines. Further, if leaflets containing information and warnings about those medicines are supplied by manufacturers to pharmacists in order that the pharmacist might pass on the information to patients then a failure to provide the information attracts the potential for liability should that failure result in injury. The contents of patient information leaflets should be noted and explained to the patient at the time of delivery.

It is arguable that an extension of the pharmacist's duty in this respect will make little difference to the consumer patient who purchases a pharmacy medicine from the pharmacist under a contract for sale, and is injured as a result of a defect in that drug product. As was noted above, the action in contract is attractive to the patient plaintiff. It was also noted, however, that the contract action may not be appropriate where the defect which caused the injury was a marketing defect, arising because of a failure to give an adequate warning of the dangers of the product or adequate guidance for its safe use. In all respects a pharmacy drug product may be safe, correspond with its description, and be of satisfactory quality. It is the failure to warn of its potential interaction with other drug products, or of other known characteristics of the individual patient which renders it unsafe. These specific features of drug product and individual patient are what pharmacists are promoting that they know and implement best, and better than the drug manufacturer. It is appropriate, therefore, that duties with respect to them are recognised and enforced.

Conclusion

At the outset it was indicated that the purpose of this chapter was to evaluate whether the pre-determinants are present in the United Kingdom for a re-examination of professional relationships, responsibilities, and duties with respect to the sale and distribution of medicinal drug products to take place. It is concluded that the answer to this question has to be yes. In summary, and based on the analysis undertaken above, these pre-determinants are:

A The move towards the re-classification of medicinal drug products

It is clear that health care-policy makers have adopted a policy which seeks to de-regulate medicinal drug products, particularly by re-categorising prescription only drug products as pharmacy medicines. The justification for adopting this approach is largely based on a drive to reduce health care costs, but with the further objective of enhancing consumer choice, and meeting consumer demand for more active participation in health care. The policy is government led, drug manufacturer sponsored, and pharmacy profession endorsed. It has distinct practical and legal implications, including the potential for increased pharmacist responsibility.

B An increase in medical negligence claims

The statistics analysed above have shown that the number, type and cost of medical

negligence claims are on the increase. Further, the incidence of drug complication as a cause or category of medical negligence claims shows a parallel marked acceleration. Finally, the legal profession is ready to satisfy the demands of its clients for actions against health authorities for failures in drug therapy.

C The virtual immunity of drug manufacturers from liability for failures in drug therapy

The manufacturers of medicinal drug products have negotiated a substantial exemption from liability for failures in drug therapy, largely based on the current interpretation of the informed intermediary doctrine. While it is appropriate for a re-interpretation of this doctrine to take place - based on factors such as increased patient participation in health care, greater awareness by the patient of the health care dynamics, the recognition that other health care professionals, such as pharmacists, are more appropriate intermediaries, competing jurisprudential principles such as respect for, and advancement of individual autonomy, and the experience of other jurisdictions – the re-interpretation will result in an appropriate extension of duty and responsibility for the pharmacist.

D The inapplicability of permitting the medical profession to define and determine access to information about drug use as part of health care treatment

As was noted at C above, it is time to extend the category of health care team member

deemed appropriate to impart drug use information as part of health care to include the pharmacist. It is equally apposite to re-define the legal principles which determine the standards to be applied in the utilisation of drug use information. Both factors increase pharmacist responsibility.

E The appropriateness of extending pharmacist responsibility for drug therapy monitoring, in any event.

It is clear that it is time for a re-definition of pharmacist role and responsibility, despite other developments. Such a re-definition is suitable because it equates with the prevailing aspirations of the profession, as it recognises the pivotal position which the pharmacist occupies in the delivery of drug therapy, and because current legal standards, restricted to technical accuracy are inappropriate to the pharmacist's key role.

The potential for increased liability is likely to increase with the adoption of new roles and responsibilities. The pharmacy profession is to be complimented for the in depth analysis which has taken place on the future role for pharmacists, as an integral member of the health care team, providing essential care for patients. It is important that legal standards recognise and welcome that role, place pharmacist responsibility in the modern context, strengthen the view that, in part, the determination of pharmacy standards by the profession itself is appropriate and present a carefully considered analysis of arguments for and against pharmacist liability for failure to warn.

The potential for an expansion of judicial recognition of pharmacist responsibility for patient care beyond the routine careful filling of prescriptions as written may alarm some within the pharmacy profession but it is submitted that it should be seen as a positive development, primarily because it is reflective of the realities of current pharmacy practice. The cautious pharmacist might counter that the analysis is speculative or conjectural and that no case has yet been taken against a pharmacist in the United Kingdom in such circumstances.

The evidence has shown that legal advisers are bringing actions for, *inter alia*, failure to warn and that this trend will mean that the issues will soon be discussed and deliberated upon in the higher courts. A prudent and responsible profession does not wait for the negative imposition of liability and the award of damages before thinking about its role, function and purpose in the health care system. All aspects of the pharmacist's expanded role need to be examined and the legal aspects included with the aim of realising that careful and conscientious practice means no liability. In this latter respect, it is interesting to note that the pharmacy profession in the United Kingdom has not undertaken, as yet, an extensive examination of the legal aspects of the pharmacist's expanded role, through the publication of discussion papers or journal articles. This is despite the fact that such analysis has been undertaken in the United States of America, as the evidence in chapters four and five has shown, and despite the fact that the other characteristics of the extended role - professional, social, commercial, - have all been subject to extensive scrutiny. It is clear that there is a place for a parallel examination to take place.

Pharmacy has concluded a prime position for the profession in the provision of health care, drug

therapy, and in relationships with individual patients. Other health care professionals, with similar roles, have taken steps to define the appropriate standards should failures in health care occur. It is appropriate that pharmacy conducts a similar analysis. As was noted in the introduction, the role of the pharmacy profession in influencing the future development of legal expectations of pharmacists is to emphasise its willingness to assume full responsibility for knowledge based drug therapy monitoring but also to argue that a limit has to be placed on that responsibility by judicial recognition that the pharmacist's role cannot be risk elimination because that would mean the end of all drug therapy. Rather, the pharmacist's role requires using available knowledge to minimise the risk of foreseeable adverse consequences to the patient. How and why that might be achieved will be the subject of the final chapter.

Conclusion – a limited new duty for pharmacists

In chapter one of this thesis, it was seen that the pharmacy profession has a long, detailed and distinguished history. The profession's historical development has been dependent upon the historical development of other members of the health care team - in particular the general medical practitioner - and the evolution of a drug development and distribution system. Chapter one also noted that the roles and functions of the pharmacist have changed and have been refined to cope with greater changes within the health care system as a whole. It was concluded that by the middle of the twentieth century, the pharmacist's role within the health care system was crucial - a professional recognised as having essential expertise and knowledge and without whom the health care plan would not be complete.

Yet within thirty years that position and role would be questioned and doubted by a number of participants in the health care process and even by pharmacists themselves. Chapter two of the thesis sought to review the reasons why the pharmacist was to adopt particular functions and roles within the health care system in the late twentieth century. It showed that the principal reasons why the community pharmacist has become a dispenser of pre-packaged, pre-labelled medicines and drug products prescribed by medical practitioners was the advent of the National Health Service and the spectacular growth of the international research-based pharmaceutical industry. The review of the history of the NHS showed that the period from the 1940s to the 1980s saw the service changing radically the provision of health care within the United Kingdom. In a parallel and almost as a corollary to the birth of the NHS, the evolution of the pharmaceutical industry had the most

significant technological and scientific impact on the practice of medicine within the NHS structure. Those two determinants had forced community pharmacy into accepting and relying on certain roles and functions as providers of health care. From a distinguished profession, highly trained in the manufacture and compounding of medicinal drug products, exercising absolute autonomy in health care practice, and with a central role in national health care provision, the profession had spiralled into a limited distributor of pre-prepared medicinal drug products, and despite retaining a graduate status, with little or no independence of judgement.

Chapter three showed that the analysis undertaken by the pharmacy profession has resulted in agreement that pharmacists need to adopt some sort of new or "extended" role. That role should be one which builds upon the existing expertise of the pharmacist in relation to drugs and drug therapy (the basis of their technical training) but which would see the pharmacist becoming more actively and directly involved in patient care. As a result, pharmacy is expanding into new areas beyond those traditionally expected of the profession and, it is now accepted that the term 'pharmaceutical care' is appropriate to define pharmacy's new mission.

The pharmacy profession's requirement for a new mission arrived at an opportune moment. As was shown in chapter six, a number of other important factors were also mandating a re-examination of professional relationships, responsibilities, and duties with respect to the sale and distribution of medicinal drug products, and by implication, a re-evaluation of the pharmacy profession's role within that process. The move towards the re-classification of medicinal drug products by health care-policy makers, in a drive to reduce health care costs, enhance consumer choice, and meet

consumer demand for more active participation in health care; the increase in medical negligence claims and the parallel willingness of the legal profession to satisfy the requirements of the victims of drug complications; the virtual immunity of drug manufacturers from liability for failures in drug therapy; the inapplicability of permitting the medical profession to define and determine access to information about drug use as part of health care treatment; and the appropriateness of extending pharmacist responsibility for drug therapy monitoring, are all determinants which lead to the requirement for such a re-evaluation.

Chapter five showed that the legislature in the United States of America was prepared to introduce a new law – OBRA-90 - which sought both to improve and limit health care spending and recognise professional roles, enhance pharmacy practice standards, and improve the outcome of drug therapy for patients, by bettering patient compliance with drug regimes. It was the pharmacy profession which sought to convince the U.S. government sub-committees that the increased use of drug reviews and counselling, the pharmacy profession's driving aspiration, would lead to fewer hospitalisations, as previously non-compliant patients could be persuaded of the benefits of drug therapy as an alternative to more expensive medical interventions such as surgery. Further, the implementation programmes of individual states recognised that the new practice requirements should not be limited to interactions by pharmacists with the significant, though necessarily limited, group of Medicaid patients. OBRA-90, according to the states, was not only good economically, it was good for health care.

OBRA-90 had placed a legislative gloss on the series of developments within and without the pharmacy profession. The aspirations of the profession towards a recognition of its contribution to health care, the role of the pharmacist within the health care team, and the ability of the profession to adapt, and re-evaluate its benefit to drug therapy, developed in a cohesive and structured manner over a period of three decades, had necessitated a parallel acknowledgement by the judiciary of the relevance of that role.

An analysis of judicial attitudes towards pharmacist responsibility, undertaken in chapter four, has shown distinct patterns or trends. The analysis in that chapter had looked at three periods of judicial activity. The first, from **1852-1932**, analysed the early perspective on pharmacist responsibility, and has concluded that the early cases set the standards for pharmacists at a high professional level. The second, from **1932-1985**, evaluated a period of traditional legal analysis which resiled from the earlier expansion of pharmacist responsibility and restricted liability to technical inaccuracy in prescription processing. The third, and most recent period, from **1985 to present**, demonstrated that the judiciary may be returning to first principles and are recognising the necessity to apply standards appropriate to the pharmacist's new roles and functions.

Currently, judges in the United States may be beginning to recognise the wider responsibilities of pharmacists and potential liability based on that expansion. The movement towards a recognition of expanded responsibility must be viewed against a recent background of traditional legal analysis which had limited pharmacist responsibility to the accurate processing of prescriptions and which

had ascribed responsibility for drug therapy evaluation, selection, advice and assessment to the doctor. However what the analysis of the judiciary's attitudes towards the introduction of the OBRA-90 requirements has shown is that OBRA-90 has provided the necessary sanction for the appellate courts in those jurisdictions which had creatively clarified pharmacy's role in health care, and has provided the stimulus for those jurisdictions eager to do so, but constrained by decades of traditional legal analysis.

The conclusions from the earlier chapters can be put quite simply. Until very recently, drug therapy was relatively uncomplicated, the available drugs were relatively few in number, and drugs were rarely identified as causing problems for the patients who used them. Patients were protected by the comprehensive knowledge of a single doctor who supervised and managed all therapies for the patient, including drug therapy. Times have changes dramatically. The complexity of modern pharmacotherapy makes it virtually impossible for any one type of practitioner to be aware of the subtleties of every class of medications. Human physiology can be manipulated by exotic chemicals that are difficult to understand. The drugs that are being prescribed today are not only more complicated, they are more numerous. To claim expertise in drug therapy, one must now have a greater depth of understanding of a larger number of subjects.

In addition, medical specialties have evolved, and patients seek treatment from multiple health care providers, none of whom has a complete record of the patient's treatments from the others, and none of whom is able to fully appreciate the significance of what the other has done for the

patient. The complexity of drug therapy, the vast numbers of new and different drugs, and the prescriber's lack of access to a complete medication history, combine to increase the likelihood that a serious drug-drug interaction will occur.

The changes outlined above have resulted in an expectation, particularly on the part of the public, but also on the part of health care policy makers, that pharmacists have a responsibility to detect problems with prescribed medications, and that to fail in this responsibility is a direct threat to the public health. The new expectations of drug therapy and the parallel anticipations of the participants in drug therapy have created a new duty on the part of the pharmacist, to intervene and promote the patient's best interests. That duty is in addition the pharmacist's existing technical responsibilities, for example, with respect to the correct dispensing of a drug, the labelling of a medication container or the accurate processing of a prescription order. Pharmacist intervention to protect patients is a widely accepted and obvious duty of pharmacists.

In this chapter, it is argued that this perspective is a reasonable one. Pharmacists ought to detect and prevent problems with drug therapy, particularly obvious problems like drug-drug interactions. The public should be disappointed if a profession, a government-sanctioned monopoly, has the ability to improve the public health but fails to do so. In turn, courts (and a legislature) that refuse to recognize expanded responsibilities for pharmacists, and that fail to impose corresponding expanded liabilities for the failure to meet a responsibility, are perpetuating an outdated view of pharmacy practice based on an incomplete understanding of the medication use system. There are solid policy reasons for imposing a higher standard for pharmacists that

includes, but goes beyond, mere technical accuracy in order processing.

Focusing on three representative cases, already referred to in chapter four, the arguments for and against expanded legal expectations of pharmacists will be reviewed. In the first section, a critique will be made of the frequently offered rationale for concluding that pharmacists are primarily vendors of a product who have little to offer as providers of a valuable health care service. In the second section, it will be explained how a new perspective on pharmacy practice can elevate the pharmacist's role as a provider of pharmaceutical care, based at least in part on public expectations of the profession. In section three, it will be shown how expanded duties for pharmacists can evolve, even in jurisdictions that have been reluctant to endorse such an expansion. Finally, it will be concluded that there are limits to what pharmacists can reasonably be expected to do, and that a judicial system exploring the subject of expanded pharmacist responsibility should be aware of those limits.

The traditional view of pharmacist duty

As was noted in chapter four, in late 1989, the Supreme Court of Washington issued a decision that addressed most of the issues raised during the previous five years of pharmacist malpractice litigation. In the years preceding this case, many state courts had considered whether to depart from precedent and recognize an expanded standard of practice for pharmacists. The decision in the case of *McKee v. American Home Products, Inc.*, (1989) 782 P.2d 1045 (Wash. 1989)) serves

as a guide to the arguments against expanded pharmacist liability up until that time. In a five to four split opinion, a majority of the court rejected the argument that a pharmacist owes a patient a duty to detect and rectify problems with drug therapy. The court justified this holding by pointing to three public policy issues:

- (1) The need to recognize doctor (or physician) primacy in health care;
- (2) The burden to pharmacists of expanding responsibilities without limits; and
- (3) The potential costs of an expanded duty for pharmacists.

This three part rationale has served as the basis of a line of legal authority developed in numerous judicial opinions, as analysed in chapter four, that have rejected expanded responsibilities for pharmacists. An argument, such as the one advanced in this thesis, that advocates recognition of increased legal responsibilities for pharmacists, must address these standard reasons for judicial rejection of expanded pharmacist responsibilities.

Doctor primacy

The Washington Supreme Court began its analysis of the merits of the case by stating its view that

“[r]equiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment.” (1989) 782 P.2d 1045 (Wash. 1989) at page 1051)

This perspective reflects the traditional view of medical practice. Under this view, the doctor-patient relationship is virtually sacred, and few considerations are of greater value than the promotion of that relationship. Even protecting the patient's health by providing information about medications to the patient through a pharmacist is a lesser concern than is non-interference with the doctor-patient relationship.

Under the traditional approach to medication prescribing, the analysis and assessment of subjective and objective evidence is done by the doctor, and a therapeutic plan is constructed on the basis of that evidence. According to the standard medical model of patient care, the doctor's decision to prescribe is based on science or clinical experience, and does not necessarily reflect experience with the particular patient who is being cared for. It is impossible to know how a particular patient will react to any drug that the patient has not yet used, despite scientific knowledge of how most patients generally react to the drug. Individual physiologic variation leads to a high degree of uncertainty. Approval of a drug as safe and effective does not mean that every person can use the drug safely and effectively. A doctor's diagnostic expertise is still required to determine which patients are those for whom therapy with a particular drug should be initiated.

In addition to initiating drug therapy, the doctor, in the traditional role, also has clear professional responsibility to coordinate care provided by other health care providers. The doctor is likely to

view the patient's loyalty as being directed toward the doctor rather than toward the co-ordinated health care team. Practicing within the traditional medical model of care, allied health care professionals view themselves as having a duty to the doctor to do what is necessary to assist the doctor in meeting the doctor's duty to the patient.

The doctor's responsibility for care includes a duty to make good decisions about prescribing medications; a duty to communicate with patients about prescribed medications; a duty to caution patients on how to use a prescribed medication properly and a duty to warn of the possibility of addiction to prescribed drugs. The majority in *McKee* supported this traditional view of doctor primacy by stating that:

“proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition.” (1989) 782 P.2d 1045 (Wash. 1989) at page 1051)

This analysis reflects decades of traditional judicial analysis of health care roles and the primacy of the medical profession in determining the patient's best interests. For example in the case of *Jones v Irvin* ((1985) 602 F. Supp 399), already analysed in detail in chapter four, the court had the following to say about pharmacist interference in the functions conventionally associated with the medical profession:

‘...a pharmacist has no duty to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts, that the customer is being over-

medicated, or that the various drugs in their prescribed quantities could cause adverse reactions to the customer. It is the duty of the prescribing physician to know the characteristics of the drug he is prescribing, to know how much of the drug he can give to his patient, to elicit from the patient what other drugs the patient is taking, to properly prescribe various combinations of drugs, to warn the patient of any dangers associated with taking the drug, to monitor the patient's dependence on the drug, and to tell the patient when and how to take the drug. Further it is the duty of the patient to notify the physician of the other drugs the patient is taking. Finally it is the duty of the drug manufacturer to notify the physician of any adverse effects or other precautions that must be taken in administering the drug ... Placing these duties on the pharmacist would only serve to compel the pharmacist to second guess every prescription a doctor orders in an attempt to escape liability' ((1985) 602 F. Supp 399 at page 402)

The majority view in *McKee* also relied heavily on precedent derived from the learned intermediary doctrine under which a manufacturer of drug products has a valid defence to an allegation that it failed to directly warn a patient of a drug's risk, if an adequate warning was provided by the manufacturer to the doctor. As was noted in the previous chapter, this doctrine assumes that, as between manufacturer and doctor, the doctor is best able to meet the responsibility to provide warnings directly to patients because the manufacturer already has fulfilled a responsibility by providing information to the doctor, and the manufacturer lacks the capacity to convey information to the patient, with whom it has no direct relationship.

The *McKee* court's deference to doctor primacy is an effective argument, particularly in a time of managed care when the character of the core relationships between doctors and patients has already been placed at risk. To urge that a pharmacist, or anyone else, should challenge the doctor-patient relationship would be a useless threat to a rich tradition of caring. Such nostalgia is

not the only reason to value highly the doctor-patient relationship. Good outcomes from health care depend, at least in part, on good relationships between health care providers and patients. Clearly no pharmacist should speak or act in a way that disparages a patient's doctor. Mutual trust between doctor and patient is at least as important as clinical skills and technology in meeting patient needs. It goes without saying that all pharmacists should act in ways that promote this trusting relationship. The fact that pharmacist activities for a patient's benefit may be counterproductive if done poorly supports a policy of requiring that these activities be done well; not a policy of refraining from beneficial action.

A pharmacist should convey important information to a patient, in a manner that does not cast aspersions on the patient's doctor. Effective interpersonal communication is a function of both the content of the message conveyed, and the process through which the information is conveyed. Accurate information that is inappropriately worded does not promote quality patient care, it impedes care. Pharmacists should be attentive to both accuracy and professional courtesy in discussing drug therapy with patients. In practice, this is not a difficult standard for pharmacists to meet. It is no more difficult to be cautious in the manner of one's communications than it is to be accurate in the content of what one communicates. To ask that pharmacists communicate with patients, and refrain from negative talk about doctors during this discussion, is a reasonable request with which pharmacists can easily comply.

Perhaps the *McKee* court was concerned that any advice given by a pharmacist to a patient regarding the potential risks of drug therapy necessarily constitutes detracting of the doctor, irregardless of the manner that is used by the pharmacist to convey the information. The *McKee* court actually went beyond deciding that a pharmacist need not provide warnings to patients, and actually ruled that a pharmacist should not provide warnings to patients. This is a huge and unnecessary step. In theory, complete reliance on doctors may seem appropriate. When a patient is being prescribed a medication for years, however, and the medication is effective only for weeks, a conclusion that pharmacists ought not to talk with the patient about potential risks (not just that pharmacists need not do so to avoid liability) seems particularly stubborn.

The simple fact of a warning being provided by a pharmacist to a patient may indicate that the doctor was wrong to have prescribed the medication. Do patients expect their drug therapy to be completely risk-free, such that the mere mention of possible problems and how to detect and/or avoid them casts doubt on the integrity of the person who prescribed the therapy? The answer to this question would seem to be "no." Most patients are sophisticated enough to understand that all drugs have risks. To the extent that a patient has been informed of a risk by the doctor, and is later reminded of the risk by a pharmacist, there would be no interference with the doctor-patient relationship. In fact, the relationship would be enhanced through the pharmacist's confirmation that the doctor's information is significant and relevant. If a patient has not been told of a risk by a doctor, and hears of the risk for the first time from a pharmacist, then there is a strong likelihood that the patient will heed advice of the pharmacist and use the drug in a way that

reduces the risk. Better outcomes occur when risks are minimized, and good outcomes contribute to a productive and valuable doctor-patient relationship.

The *McKee* court, and other courts that have adopted similar views, may have been concerned that a patient would be given information by a pharmacist and afterward choose not to use a prescribed medication. If this were to occur, then the patient could be harmed by the absence of necessary therapy, and the doctor-patient relationship could suffer from a lack of confidence by the patient in the doctor (although it would seem more likely that the pharmacist-patient relationship would be adversely affected). It would be very unfortunate for a pharmacist to provide a patient with inaccurate information, or with accurate information expressed in an inappropriately alarming way, after which the patient failed to use a necessary medication due to unfounded concerns about the medication. Pharmacists should be held accountable when such rare events occur.

On the other hand, the provision of accurate information by a pharmacist, in a sensitive and professional manner, would virtually always assist the patient in making his or her independent assessment of the risks and benefits of drug therapy. It is difficult to imagine a situation in which a patient would “know too much” about the drug therapy the patient is using. The traditional “Doctor knows best” approach to drug therapy may fail to recognize that patients have the right to make informed decisions about the medications they use. The decision not to use a prescribed medication may be a good one from the patient’s perspective, even though it is bad from the doctor’s perspective. For example, the informed decision to not use a narcotic analgesic as

frequently as it has been prescribed may increase the pain a patient experiences but reduce the chances of the patient developing an addiction. Surely the decision to use medication in this way is the patient's decision, not the doctor's, and accurate information about the potential for addiction would be appropriately given by a pharmacist to the patient.

The provision of information to the patient can be justified as a necessary step in empowering the patient to make his/her own decisions about risks to him/herself. The value of the doctor-patient relationship is high, but not as high as is the value of the patient's health, or the value of the patient's autonomous right of action. Respect for the doctor-patient relationship is important, but not because it promotes doctor primacy. Patient primacy is far more important, and correct information provided in a sensitive way to a patient by a pharmacist promotes patient primacy, irregardless of what a doctor may or may not have done.

The *McKee* court overemphasizes the importance of doctor or physician primacy. Pharmacists can provide accurate information to patients, in a manner that does not disparage the doctor. If patients develop their own effective (for them) medication use behaviors based on this information, then the system has not failed; it has succeeded.

The *McKee* court's citation of the learned intermediary doctrine as authority for doctor primacy is misplaced. The learned intermediary doctrine does not impose an affirmative duty, thus is it not really a doctrine at all. It is a defence, used by a pharmaceutical manufacturer who has been

alleged not to have directly warned a patient of adverse effects that can be caused by the manufacturer's drug. In asserting this defence, the manufacturer is allowed to show that it has met its duty to the patient by providing a warning to the doctor. As was noted in the *McKee* judgements, the logic of the learned intermediary defence is that doctors, not pharmaceutical manufacturers, can individualize warnings for patients; and that doctors, not pharmaceutical manufacturers, are proximate to patients. This same logic does not apply to exempt the pharmacist from a direct duty to the patient. Unlike pharmaceutical manufacturers, pharmacists are proximate to patients and they have the ability to know individual patient characteristics. Furthermore, the learned intermediary rule is not a "no duty" argument at all. It simply permits a manufacturer to show that a recognized duty to a patient has been met indirectly by providing information to the doctor. For these reasons, reliance on the learned intermediary defense as support for doctor primacy, and for a "no duty" argument regarding pharmacists and warnings to patients, is not well taken.

The slippery slope

The second justification offered by the majority opinion in *McKee* for upholding a traditional view of pharmacist duty was that

"[i]mposing a duty such as McKee urges would, in essence, require the pharmacist to question the physician's judgment regarding the appropriateness of each customer's prescription." (1989) 782 P.2d 1045 (Wash. 1989) at page 1053)

In effect, this argument assumes that every prescription issued by a doctor is so problematic that pharmacists must question all prescriptions. Under this reasoning, to require that a pharmacist raise concerns about the use of an appetite suppressant over ten years, when scientific data indicate the drug is effective only for a matter of months and is prone to causing adverse effects the longer it is used, is to also require that pharmacists raise similar concerns about the most routine prescriptions that pose no obvious threat of harm. The facts underlying this conclusion simply cannot be accepted. Fortunately, doctors prescribe medications so well that in the vast majority of circumstances they are perfectly safe and there is no need for pharmacist action, other than to reinforce what the doctor has already told the patient.

The court evidently feared that the pharmacist solution to the problem of doctor misjudgment would be worse than the problem itself, because pharmacists would constantly be challenging doctors over non-problems. It would not be likely to be this way. While there is always a temptation to fix something that does not need fixing, pharmacists can be expected to be good stewards of their own time. To think that pharmacists will welcome opportunities to unnecessarily pester doctors with pointless questions about patients whose drug therapy is perfectly safe and effective is to fail to recognize the realities of modern pharmacy practice. Time is at a premium. This is not to say that there would never be an unfounded concern raised by a pharmacist. But it supports the notion that a landslide of pointless and irrelevant contacts by pharmacists with doctors would be unlikely. Recognition of a pharmacist duty to protect the patient in the *McKee* case

would not have required questioning of every customer's prescriptions; it would have required questioning only when the risk was high and the benefit low, as was the case with the patient in the *McKee* case.

The *McKee* court may have recognized that "each prescription" is in fact not really problematic, because two paragraphs later in the opinion, the court downsized the extent of the intrusion into medical practice that would supposedly be caused by an expansion of pharmacist duties.

"The duty which McKee urges would result in the pharmacist second guessing numerous prescriptions to avoid liability. This would not only place an undue burden on pharmacists, but would likely create antagonistic relations between pharmacists and physicians." (1989) 782 P.2d 1045 (Wash. 1989) at page 1053)

It is certainly more accurate to argue that pharmacists would need to address concerns regarding "numerous" prescriptions, than it is to predict that "each" prescription would present such problems. However, the court is probably still overstating the extent of the problem of poor prescribing by doctors, and thus it is probably also overstating the potential difficulties that would arise from the solution of requiring that pharmacists request clarification.

The court's concerns regarding increasing burdens on pharmacists, and the possibility of antagonism between pharmacists and doctors, are hardly relevant to a discussion of patients' rights and professional responsibilities. It is always burdensome to provide care for a person to whom one owes a duty, but that burden is born willingly as a component of the role one accepts, and to

which one has made a commitment in becoming a professional person. That there might be professional disagreements between doctors and pharmacists is obvious, but it is equally obvious that disagreements can be handled respectfully (see Mullan and Weinstein 1996, Mullan 1996 and Mullan 2000), and that working together toward the common goal of patient safety could lead to as much collegiality as antagonism. There would likely be good days and bad between pharmacists and doctors, just as there are good days and bad days between any two people who work together. Protecting the public health is more important than promoting courtesy in the workplace.

The slippery slope that pharmacists might slide down if they misconstrue a duty to disclose to patients important and necessary information is that they might also believe there to be a requirement that pharmacists disclose unimportant and unnecessary information. Pharmacists might over warn patients just to make sure that they are not accused of under warning. The *McKee* court states:

“Moreover, unnecessary warnings to the patient could cause unfounded fear and mistrust of the physician’s judgment, jeopardizing the physician-patient relationship and hindering treatment.” (1989) 782 P.2d 1045 (Wash. 1989) at page 1053)

This is above all a call for standards in patient counseling by pharmacists, so that patients receive optimal information (a level of information between minimal and maximal). Such standards do exist. For example, the scientific references cited in United States’ federal law for prospective drug use review (see chapter five) specify what information is important for all patients to receive

when a drug has been prescribed for them, and what sorts of patients should receive special information if their condition or other aspect of their care requires individualized information.

Pharmacists need not fear accusations of under warning if they have met the standard, thus there should be no need to over warn with unnecessary warnings. Fear that a beneficial activity might be done poorly is not a sufficient reason for retreating from the activity. If an activity is worth doing, then the means should be found for doing it well.

Economic efficiency

The final justification offered by the majority opinion in *McKee* for not imposing a duty to detect and rectify problems with drug therapy is related to economic efficiency. The court stated:

“The legislature can better assess the relative costs and benefits involved, and determine what form any warnings should take.” (1989) 782 P.2d 1045 (Wash. 1989) at page 1055)

Such deference to the legislature is not an unreasonable approach. There are costs involved with the provision of warnings to patients by pharmacists, and these costs should be considered when deciding whether or not to expand pharmacist duties in the area of patient education. All too often the adversarial nature of litigation obscures the broader implications of a ruling that involves only two parties. Of course, the value of an educated medication-using public is significant. Educated patients have better therapeutic outcomes, and they are inclined to accept responsibility for their

own decisions about medication use. The costs of pharmacist warnings would have to be very high to outweigh these significant benefits.

In deferring to the legislature, the court recognized that issues of public policy should be resolved in a systematic fashion. Legislatures have the ability to discuss the relative merits of proposed changes in the law, and to adopt a change only after careful consideration of the implications of the change. As was described in detail in chapter five, subsequent to the *McKee* case, an important change in the law occurred, in which United States Congress determined that it would be good policy to require states to expand pharmacy practice standards as a condition of participation in the Medicaid program. Most states in the United States of America have now included in their laws requirements for the provision of warnings by pharmacists to patients, in addition to other requirements, consistent with the federal initiative. As was concluded in chapter five, with this change in the law, there should come a change in judicial reluctance to recognize expanded responsibilities for pharmacists. The barrier of economic efficiency has been overcome through recognition by United States Congress that the advantages of warnings to patients by pharmacists outweigh the disadvantages.

An expanded view of pharmacist duty

Following the *McKee* case, the next case in which a state supreme court thoroughly considered the arguments relating to an expanded legal duty for pharmacists was the case of *Hooks SuperX, Inc.*

v. McLaughlin ((1994) 642 N.E. 2d 514 (Ind. 1994). In the Supreme Court of Indiana, the most important issue was whether pharmacists have any duty to refuse to fill validly issued prescriptions that pose a threat to the welfare of the patient. The judgements in this case analyse the concept of duty based on three factors. In essence, the court reasoned that it would make good legal precedent to expand pharmacist duties to include the duty to monitor and intervene if:

- (1) the relationship between pharmacist and patient is of the kind that should give rise to an expanded duty;
- (2) harm to the patient is reasonably foreseeable to a pharmacist; or
- (3) public policy concerns (such as increased health care costs and diminished patient confidence in doctors) in favor of recognizing such an expanded duty.

The relationship factor

The court in *Hooks-SuperX* reaffirmed that the law recognizes the relationship between pharmacist and patient is one that creates a duty under traditional prescription-processing circumstances. Pharmacists are clearly liable for dispensing the wrong medicine or for failing to inform the patient of warnings included in the prescription. The court noted that the relationship between the pharmacist and the patient is a direct one, independent of the doctor-patient relationship. The court

recognized that pharmacists possess expertise in the dispensing of prescription drugs and that reliance is placed on them by patients for that expertise. All of these factors combined led the court to conclude that “the relationship between the pharmacist and customer is sufficiently close to justify imposing a duty” ((1994) 642 N.E. 2d 514 (Ind. 1994) at page 517) to monitor drug use and intervene when a problem becomes evident.

The court recognized that in evaluating the relationship of one party to another, it is necessary to first identify the characteristics of the two parties. A relationship is forged from the identities of the individuals in the relationship; thus people relate to each other only in ways that reflect their own personal, or professional, characteristics. The *Hooks-SuperX* opinion noted that a pharmacist is a person who knows about drugs, and that a patient is a person who needs information about drugs. Given these individual characteristics, it is logical to conclude that the pharmacist-patient relationship is one in which the pharmacist has a duty of information provision. Under this analysis, the duty of a pharmacist expands and contracts, based on the pharmacist’s knowledge. A knowledge-based duty would serve as the foundation for requiring some action by pharmacists, but not for requiring unlimited action. Pharmacists would have a duty to warn patients of known risks, but there would be no duty to warn of risks that are not known. Thus, the answer to a question of pharmacist duty would begin with a determination of pharmacist knowledge. The availability of knowledge would define the minimum that could be expected of a pharmacist, and the unavailability of knowledge would set limits on what could be expected of a pharmacist.

Knowledge, by itself, is not a sufficient foundation for a duty of pharmacists to patients. For there to be a duty to intervene to protect patients from known adverse effects, it is necessary that pharmacists foresee harm to patients.

The foreseeability factor

Turning to the factor of foreseeability, the court found it undisputed that an individual who consumes sufficient quantities of addictive substances may become addicted to them, and that such an addiction carries with it certain foreseeable consequences. The court was satisfied that, for the purpose of determining whether a duty exists, the risk of the plaintiff's addiction was foreseeable from the events that took place. Under the court's analysis, it would be good legal precedent to require that one who can anticipate harm to another intervene to prevent that harm. Simply knowing of a potential adverse effect would not be sufficient to require a pharmacist to provide a warning to a patient; it would also be necessary for the pharmacist to foresee harm to the patient.

The foreseeability requirement takes the pharmacist's duty from the realm of the hypothetical into the realm of the practical. A known but relatively unlikely adverse effect would not require a warning, because it would not be foreseeable. Under this approach, a pharmacist's duty to warn requires first that the adverse effect to be known, and second that there be foreseeable negative consequences for the patient if a warning of the adverse effect is not given. Many adverse effects

are known of, because they have occurred at some time in the past, and at that time they were associated with the use of a medication. However, the incidence of the adverse effect may be so low that it is not realistically foreseeable. Although McLaughlin's addiction to propoxyphene was foreseeable under the circumstances, many adverse effects would not be foreseeable.

Public policy considerations

The final factor considered in determining the existence of the duty for pharmacists was that of public policy. The court considered three public policy considerations to be at stake:

- (1) preventing intentional and unintentional drug abuse;
- (2) not jeopardizing the physician-patient relationship; and
- (3) avoiding unnecessary health costs.

The purpose of considering these factors was to determine whether public policy should or should not favor recognition of the duty.

On the first issue, the court recognized that there are a variety of reasons why a patient might try to have a prescription for a potentially harmful drug refilled at a rate higher than that prescribed, of which an addiction to the drug and diversion of the drug for an illicit purpose were two. Both of these explanations for continual and far too frequent refills give rise to a strong public policy

interest in preventing intentional and unintentional drug abuse. This public policy interest is also reflected in legislative provisions which permit a pharmacist to exercise professional judgment and refuse to fill a prescription when the pharmacist believes in good faith that filling the prescription might aid or abet an addiction or habit. These legislative provisions demonstrate that public policy concerns about proper dispensing of prescription drugs and preventing drug addiction are paramount to policy concerns about interfering with the doctor-patient relationship. A doctor-patient relationship that is causing drug addiction or diversion needs to be interfered with. As a matter of policy, pharmacists should be required to act to prevent intentional and unintentional drug abuse.

Next, the court reasoned that, as a matter of public policy, the imposition of a duty to cease filling prescriptions in certain circumstances would not lead to the development of an adverse relationship between pharmacists and doctors. The court offered three separate reasons for this conclusion:

- (1) pharmacists already have authority to intervene through statute;
- (2) doctors remain ultimately responsible for the proper prescription of medications, and recognition of a duty on the part of pharmacists would not replace the doctor's obligation to evaluate a patient's needs; and

(3) the recognition of a legal duty would encourage pharmacists and physicians to work together in considering the best interests of their patients.

Public policy should encourage collaboration to protect the public.

The last public policy concern reviewed by the court related to the possibility of an increase in health care costs if the duty in question were to be imposed on pharmacists. The court implied that, if health care costs were to rise as the result of recognizing the expanded duty then public policy might not favor the recognition. The defendant had argued that recognition of the expanded duty would require pharmacies to buy expensive new technologies, thus driving up the cost of health care. But the defendant pharmacy already had a computer-based information system that showed the plaintiff's entire prescription history on the screen at the time of each fill or refill. The cost of computerizing the pharmacy had already been incurred and would not increase with recognition of the expanded pharmacist duty. Thus the public policy of holding down health care costs was not at odds with recognition of the duty.

The court concluded that all three relevant factors (relationship, foreseeability, and public policy) supported imposition of the expanded duty on pharmacists. While any of the three factors could individually have justified the decision, the collective force of the three was compelling. The ruling in this case makes it clear that a valid prescription is not sufficient in itself to permit a pharmacist to successfully argue that all responsibilities to the patient have been met by accurately

filling that prescription. Just as pharmacists have a duty to detect invalid prescriptions and to intervene to prevent their being filled, pharmacists also have a duty to detect valid prescriptions that pose a threat to patient welfare and to intervene to protect the patient from such prescriptions.

Rationale for expanded pharmacist duties

As was noted in detail in chapter five, consistent with the rationale of the *Hooks-SuperX* opinion, courts across the United States of America have begun to recognize expanded responsibilities for pharmacists. To escape liability for negligence, it is still necessary for pharmacists to process orders accurately, but it is no longer sufficient to be technically accurate. Pharmacists must competently monitor drug therapy and thoroughly discuss drug therapy with patients if they wish to assure that they have avoided exposure to legal liability. The imposition of a duty to monitor and discuss drug therapy coincides with the emerging role of the pharmacist as a primary health care provider within pharmaceutical care.

The emerging judicial view of the pharmacist-patient relationship was summarized by Judge Pittman of the United States District Court for the Southern District of Alabama, in the opinion from the case of *Griffin v. Phar-Mor, Inc.* (790 F.Supp. 1115 (S.D.Ala. 1992)) Judge Pittman stated:

“The relationship between a pharmacist and a client is one in which the client puts extreme trust in the pharmacist. Pharmacists possess important specialized knowledge that is possessed by few, if any, non-pharmacists, and it is this specialized

knowledge that puts patients in the position of having to put complete trust and confidence in a pharmacist's skill.” (790 F.Supp. 1115 (S.D.Ala. 1992 at page 1118)

Judge Pittman then described the specific responsibility of pharmacists to educate patients about their medications:

“The importance of the particular facts does not need to be explained in any great detail. In general, it is important that a person know the type of medicine the person is taking. For example, a person may be allergic to a particular medicine, or a person may need to inform another doctor of what medications the person is taking. Also, and this is another thing that patients depend on pharmacists to provide, a person needs to know the type of medicine he or she is taking so that the person can know what activities (i.e., drinking alcohol or dairy products) to avoid while taking the medications.” (790 F.Supp. 1115 (S.D.Ala. 1992 at page 1118)

The responsibility of pharmacists to convey such information is important, in fact it is potentially life-saving, and the cost of providing this information is not great.

The Supreme Court of Tennessee has described the drug information responsibility of pharmacists using similar language. In the opinion from the case of *Pittman v. The Upjohn Co.*, (890 S.W. 2d 425 (Tenn. 1994) that court quoted with approval rules of the Tennessee Board of Pharmacy, which state as follows:

“A pharmacist should, on dispensing a new prescription, explain to the patient or the patient's agent the directions for the use and a warning of all effects of the medication or device that are significant and/or potentially harmful.” (T.C.A 63-10-102 (1994))

The disclosure standard recognized by this language relates to both the content of the information to be given by a pharmacist to a patient, and the process through which the information is to be provided. Accurate and complete information must be provided in a way that will promote appropriate medication use.

One of the most interesting, and surprising, recent cases regarding the pharmacist's expanded duty is the case of *Baker v. Arbor Drugs, Inc.* (544 N.W. 2d 727 (Mich. App. 1996) already described in detail in chapter five. Decided by the Court of Appeals of Michigan in early 1996, the *Baker* case departed from a clear line of precedent in the Michigan appellate courts. Prior to *Baker*, courts in Michigan had been reluctant to recognize expanded responsibilities for pharmacists. While the pharmacist's duty to process prescriptions correctly was clear, Michigan courts had held that pharmacists had no duty to warn the patient of possible side effects of a medication or to monitor drug usage. The *Baker* judgments adopted a very different perspective on the issue, based in part on the compelling facts of the case.

The facts of the *Baker* case, briefly, are that the patient, Baker, received two different drugs, and he died as the eventual result of the drug-drug interaction. Since the case arose in Michigan, there was reason to believe that the judiciary would hold that no pharmacist owes a patient any duty other than that of technical accuracy. Because of the prior Michigan case law, this case might have been one in which the appellate court would rule in favor of the defense on the "no duty" issue. However, statements made by the defendant pharmacy in their commercial advertising

were of such significance that they altered the factual basis of the plaintiff's claim and produced an unexpected result.

The defendant pharmacy had advertised that its computer system was designed in part to detect harmful drug interactions such as the one that led to Baker's death. Despite providing this assurance in its advertising, the defendant did not prevent the plaintiff's drug interaction. The available technology was not used correctly, because the pharmacy technician overrode the interaction indicated on the computer.

Representations, reliance and duty

In reversing summary judgment granted in favor of the defendant pharmacy by the trial court, the Michigan Court of Appeals held that the pharmacy "voluntarily assumed a duty to utilize the Arbortech Plus computer technology with due care." (544 N.W. 2d 727 (Mich. App. 1996 at page 731) Citing prior case law for the precedent that a defendant can be held liable when it voluntarily assumes a function that it was under no legal obligation to assume, the court thus expanded pharmacist responsibilities in Michigan, beyond technical accuracy to include drug therapy monitoring with the assistance of computer systems.

The ubiquitous nature of computers in contemporary pharmacy practice turns what could have been a narrow exception to a general rule of “no duty” into a new and opposite general rule. Computers are hardly voluntary in pharmacy practice of the twenty-first century. They are as necessary as machine printed instructions for patients, a vast improvement over pen and ink scribbling by a pharmacist or doctor. Escaping liability such as that imposed by *Baker* is hardly possible by opting not to use computers. Technology has enabled pharmacists to provide greater value to patients, and the pharmacist who fails to use available technology has failed in a duty owed to patients.

Pharmacists have the ability to define the relationship they have with patients. The judgement in *Baker* recognized that the “defendant’s advertisements were made to induce customers to utilize its pharmacy.” (544 N.W. 2d 727 (Mich. App. 1996 at page 733) If patients are told to expect nothing more than technical accuracy from pharmacists, then they are likely to expect only that they will receive the correct drug, in the correct strength, with the correct directions for use. “Correctness” would be determined only by the doctor’s prescription; not the patient’s needs. But a pharmacy that advertises, “We accept responsibility for accurately filling your prescription with the drug ordered by your doctor” is not likely to see an increase in business. Patients expect pharmacists to be accurate, and such an advertisement does not distinguish the advertising pharmacy from any other pharmacy.

If patients are told to expect more than technical accuracy from pharmacists, then it is likely that they will elevate their expectations. The *Baker* opinion noted that the “decedent reasonably relied on the allegedly false representation.” (544 N.W. 2d 727 (Mich. App. 1996 at page 732) This finding served as the basis for the court’s ruling that the pharmacy could be liable for fraud or deception. Pharmacist duties expand with patient expectations. Representations by a pharmacist, that are relied on by a patient, create a covenantal relationship between pharmacist and patient. A pharmacist’s promise to perform, in exchange for a patient placing himself or herself in the care of the pharmacist, obliges the pharmacist to keep the promise and meet a duty to the patient.

The concept of duty

To accept responsibility involves a recognition of a duty to respond, or reaction to certain problems. Duty means that there is a certain course of conduct that is due to others (Hepler & Brushwood 1996). The practice of pharmaceutical care obliges the pharmacist to share responsibility for the design, implementation and monitoring of a therapeutic plan which seeks to achieve a set of desired therapeutic objectives. These objectives include a duty to respond to problems with drug therapy. As an essential element of health care, the practice of pharmaceutical care must be carried out in cooperation with patients and other professional members of the health care team. It is clear, however, that pharmaceutical care is provided for the direct benefit of the patient, and the pharmacist must accept direct responsibility for the quality of that care.

Pharmaceutical care is less concerned with the characteristics of the traditional drug use process, and more concerned with monitoring and managing drug therapy. The pharmacist who practices in a pharmaceutical care system focuses less on the initial choice of therapy and more on the continuation of drug therapy. The pharmacist in such a system uses patient-specific evidence to monitor and manage the patient's care. Pharmaceutical care changes episodic drug therapy to coherent, continual care. Responsibility for patient outcomes is spread from the individual physician to the team that includes all primary professional health care providers.

Any professional health care role, including pharmacy, carries with it a special duty to act positively to promote the interests of those who establish a dependent relationship with care providers because of their professional status. The duty to educate patients about medications, or to monitor drug therapy, are examples of pharmacy specific requirements which if violated, lead to an unmet responsibility and therefore a breach of duty. There has been a temptation, particularly by the courts in the United States, to define pharmacist duty by listing an endless series of courses of conduct that must be followed for a responsibility to be met. Some conduct is considered to fall within the existing definition of duty and others not. Incidentally, the pharmacy profession also succumbs to the same temptation, often preferring to dwell on the extremes of duty, liability for prevention of an intentional suicide for example, rather than on the specificity of a single duty.

Duty is not, however, limited to actions specifically required by law. It is submitted that it is more appropriate to define duty in terms of the relationship between two parties. A general duty of care

arises out of a relationship and is circumscribed by the nature of the relationship. Two issues are critical to the determination of the nature of a relationship-based duty: (1) the scope of the risk to the party who is owed a duty, and (2) the character of the interest that may be invaded if the duty goes unmet (Hepler & Brushwood 1996). Such an approach was taken in the exceptional case of *Docken v Ciba-Geigy* (86 Or. App. 277, 739 P. 2d 591 (1987)). The court, in finding that the existence of a legal duty was a question of law rather than a question of fact, defined duty by considering the steps which the pharmacist could reasonably have taken, in light of the apparent risk. The limiting factor on the extent of the duty owed becomes foreseeability of harm.

The pharmacist's relationship with a patient has to do primarily with the prevention or minimization of the risks of drug therapy. This includes an accuracy mandate, to assure the correct drug for the patient, with the correct directions for use. It also includes an efficiency mandate, to prevent a patient's unnecessarily using scarce financial resources when an equivalent and less expensive drug is available. More recently, the pharmacist's relationship with the patient has included a quality mandate, requiring that pharmacists evaluate a patient's drug therapy to assure appropriateness of the therapy. Thus, the pharmacist's responsibility is not only to assure accurate and economical drug therapy for patients, it extends also to considering the best interests of the patient.

As was noted above, the character of the interest invaded is also relevant to the issue of duty. Pharmaceutical care is provided for the direct benefit of the patient, and the pharmacist must accept direct responsibility for the quality of that care, even at the expense of the pharmacist's personal immediate interests. As was noted in chapter six, within the pharmacist-patient relationship, patients

not only have an interest in health and well being, but also in autonomy and freedom of choice.

As a provider of pharmaceutical care, a pharmacist does not stand by and permit drug therapy to take its course. The patient, as the recipient and direct beneficiary of pharmaceutical care, is proximate to the pharmacist. A pharmacist has a responsibility to prevent harm to patients from problems with drug use. Furthermore, a pharmacist is an active participant in drug therapy, whose purposeful action in providing pharmaceutical products creates a responsibility to prevent adverse outcomes that might be caused by the provision of pharmaceutical products, or by the failure to provide them. Responsibility is obligatory in pharmacy practice, not discretionary for two reasons. Responsibility is socially imposed, and it arises out of the relationship between a pharmacist and a patient. (Hepler & Brushwood 1996)

Limiting the extent of the duty owed by pharmacists

Legal expectations of pharmacists are expanding, at least in part because drug therapy has begun to cause problems on a scale that has not occurred before. As experts on drug therapy, pharmacists can detect potential problems with a patient's medication use, and can interact with the patient and/or the patient's physician, to resolve the potential problem and protect the patient from harm. The purpose of allowing pharmacists a virtual monopoly over prescription drug distribution is to serve the public interest. Technical accuracy by pharmacists is no longer sufficient to provide adequate protection to the public. Drug therapy monitoring is an additional essential responsibility for pharmacists, because the public expects pharmacists to provide protection from potential problems such as drug-drug

interactions. Pharmacists have represented that this service is available, and they have undertaken to provide the service to the public. More than a mere gratuitous exercise, drug therapy monitoring is a cornerstone of pharmaceutical care, the focus of expanded pharmacy practice. The principles of pharmaceutical care have been incorporated into judicial opinions that have recognized a responsibility for pharmacists to intervene for the patient's benefit when a problem with drug therapy becomes evident.

Just as the knowledge pharmacists have of some potential drug therapy problems can expand pharmacist duties, lack of knowledge can circumscribe pharmacist duties. Many adverse effects of medications are not well documented. The adverse effect may have been associated with a drug, but not causally connected to the drug. Although an adverse effect may have been observed at some time in the past, the significance of the effect can be difficult to understand in the present, and actual harm from drug use is impossible to predict in the future. Pharmacists cannot be held responsible for the failure to use knowledge that is unusable due to its uncertainty.

Drug therapy is necessarily a risky activity, for only by risking harm from drugs can a patient hope to benefit from drugs. The pharmacist's role cannot be risk elimination, because that would mean the end of all drug therapy. Rather, the pharmacist's role requires using available knowledge to minimize the risk of foreseeable adverse consequences to the patient.

When a pharmacist acquires knowledge of a potential problem with drug therapy, the pharmacist's responsibility is to notify the prescriber. Some risks can be minimized by adjustments in a

prescription or by prescribing an alternative medication. Other problems cannot be managed by the prescriber, because there is no alternative method of treatment and the medication is necessary for the patient. Under these circumstances, the pharmacist's responsibility is to educate the patient about potential risks and the steps to be taken in minimizing the risks, as well as describe symptoms that indicate a risk has begun to materialize and warrants contact with the prescriber.

The pharmacist's responsibility for drug therapy monitoring and education of prescribers and patients is limited by the inability of pharmacists to guarantee good outcomes from drug therapy. Pharmacists can be attentive to the need for good therapeutic outcomes, and they can promote good outcomes by caring for patients. In this sense, caring for patients requires that pharmacists think about a patient's drug therapy, apply available knowledge to the solution of potential problems, and intervene to promote good therapeutic outcomes. By accepting responsibility for the outcomes of drug therapy, pharmacists can justify the public trust placed in them as the managers of the country's medications.

Defining the limits of the pharmacy profession's new responsibility for drug therapy monitoring and education of prescribers and patients can and should be achieved by the judiciary. It is submitted, and was noted above, that the pharmacist's new role requires using available knowledge to minimize the risk of foreseeable adverse consequences to the patient. Translating this into a legal standard requires an acceptance that the *pharmacist's duty is to intervene and act for the patient's benefit when the pharmacist knows, or ought to know of a risk to the patient, because of a potential problem with the proposed drug therapy, and when it is reasonably foreseeable that harm will result to the*

patient unless a warning is not given. These two factors – knowledge and foreseeability – will achieve both a legal definition of the pharmacist's expanded responsibility and will place limits on it.

Knowledge

Pharmacists possess a variety of different types of knowledge. Firstly, the nature of the pharmacist's technical training, including the current requirement for continuing professional development, means that the pharmacist has extensive knowledge of the pharmacological nature, form and effects of medicinal drug products. The acquisition of this type of knowledge is at the core of the pharmacy curriculum. Secondly, the pharmacist may have specific medical knowledge concerning individual patients. That information may have been imparted by other health care providers, such as a doctor, either through prescription orders, or through other direct contact. The pharmacist may, however, obtain patient-specific medical knowledge which is not in the possession of other health care providers. As has been noted before, pharmacists are highly respected within the community in which they provide their services, and that respect will often result in the imparting of medical information. For example, the patient may tell a pharmacist, rather than a prescribing doctor, that he/she has had a reaction to a specific medication, or is suffering from a particular ailment, or thinks that she is pregnant. In addition, the pharmacist may know that the patient is rarely fully compliant with a prescribed dosage of medication. Further, the pharmacist may be the first source of medical advice for many patients and may, accordingly, impart medical information which the doctor never knows. Finally, the pharmacist may have personal knowledge of individual patients which may

impinge on the proposed medical treatment. For example, the pharmacist may know that the appellant drives, or is employed, or is in financial difficulties or is a carer.

The courts in the United States of America have reacted to the knowledge issue in a limited fashion. In *Leesley v West*, ((1988) 518 N.E. 2d 758), already discussed in detail in chapter four, the court based its finding that pharmacists have no duty to warn of the risks associated with drug products, on the fact that pharmacists lack two different types of knowledge, the medical history and condition of the individual patient, and knowledge that the individual patient has not already received an appropriate warning from the prescribing doctor. In *Ingram v Hook's Drugs Inc.*, ((1985) 476 N.E. 2d 881), again discussed in detail in chapter four, the court in rejecting any extension of existing duties to a duty to warn, stated:

'The decision of weighing the benefits of a medication against potential dangers associated with it requires an individualized medical judgment. This individualized treatment is available in the context of a physician-patient relationship which has the benefits of medical history and extensive medical examinations. It is not present, however, in the context of a pharmacist filling a prescription for a retail customer. The injection of a third party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of the ongoing medical treatment.' ((1985) 476 N.E. 2d 881 at page 887)

In *Stebbins v Concord Wrigley Drugs Inc.*, ((1987) 416 N.W. 2d 381), the court agreed with the earlier reasoning in *Pysz v Henry's Drug Store*, (457 So. 2d 561) and *Jones v Irvin*, (602 F. Supp. 399) in finding that while a pharmacist may have a greater knowledge of drug propensities than a doctor it is the doctor who has the duty to know the drug which is being prescribed and to monitor

the patient. Further requiring a pharmacist to provide a warning would simply compel the pharmacist to second guess every prescription order. In *McKee v American Home Products Corp*, (1989) 782 P.2d 1045 (Wash. 1989)) the court found that:

‘... pharmacists are not doctors and are not licensed to prescribe medication because they lack the physician’s rigorous training in diagnosis and treatment.’ (1989) 782 P.2d 1045 (Wash. 1989) at page 1051)

Two issues emerge from this limited judicial analysis of pharmacist knowledge. The first is the continuing deference to the superior knowledge of the doctor and the primacy of the doctor-patient relationship. As has been noted above, and in the previous chapter, this condescension is misplaced. So too is the second issue which is the limited analysis and virtual dismissal of the factor of pharmacist knowledge. It is submitted that the judges are too focused on what the pharmacists do not know rather than what they do know. So too do they fail to recognise and contextualise the pharmacist’s three different types of knowledge, as defined above.

The pharmacist’s existing knowledge of the pharmacological nature, form and effects of medicinal drug products enables them to clearly identify specific problems with drug therapy, irrespective of any other knowledge of the individual characteristics of the patient. So a pharmacist ought to be under a duty to advise the prescribing health care provider of a clear error on the face of a prescription. For example the drug digoxin, used frequently in the treatment of congestive heart failure, has an extremely high overdose rating. A prescription for digoxin 0.25mg with directions to take one tablet four times per day poses a clear drug therapy problem on its face without any

requirement for further information about the patient. The ignorance of this problem with this drug therapy is clearly dangerous for the patient's health care, and is inconsistent with the pharmacist's claim to expertise in the detection and prevention of adverse outcomes with drug therapy. A legal standard which rewards technical accuracy in prescription processing – so that the dispensing of the prescription in the example noted above would attract no sanction – discounts the ability of the pharmacist to promote good outcomes from drug therapy and fails to impose an appropriate sanction for failure to assume necessary roles.

The decisions cited above are factually correct in concluding that pharmacists do not have the ability to conduct medical examinations on individual patients. It is submitted that pharmacists would not want to have such an opportunity and would not wish to infiltrate the doctor's or other health care provider's areas of expertise. What the pharmacist does want is a recognition that he/she has other skills with respect to the provision of drug therapy and that this includes the possession of both drug information and patient-medical information. Pharmacists do not have to conduct medical examinations to know that patients have asthma, or are being treated for high blood pressure, or have an allergy to aspirin, or may be pregnant, or are taking other medications, or fail routinely to complete courses of medication. Those factors have the potential to create problems with drug therapy for patients with those characteristics and may be unknown to the prescribing doctor. The pharmacist who has knowledge of those characteristics has a parallel ability to use that knowledge to prevent the manifestation of the adverse outcome. A judicial standard which fails to address any aspect of the pharmacist knowledge factor, or dismisses it as less relevant than that of the doctor,

also defaults in recognising the potential of pharmacist knowledge for the prevention of adverse outcomes, the ability of the pharmacist to use that knowledge for the benefit of the patient, and in ratifying that pharmacists have a duty to act accordingly.

Pharmacists also often have personal knowledge of their patients. As noted above, a pharmacist may know that a patient drinks alcohol, or is reporting symptoms of increasing frailty, or drug reaction which he/she has not reported to the doctor. Pharmacists are well placed in the community to observe and identify personal characteristics of patients. Judicial standards should recognise this reality and place patient-specific knowledge alongside drug knowledge and patient-medical knowledge, acknowledge its potential use in preventing adverse drug outcomes and adopt a knowledge based standard in negligence for pharmacists who fail to act in accordance with this mandate.

The knowledge factor should be used by the judiciary to define and to limit the pharmacist's expanded duty with respect to drug therapy monitoring. In summary, the judiciary should recognise that a pharmacist has a responsibility to act for the benefit of the patient, (the responsibility already assumed by the profession in the pharmaceutical care model) when he or she knows or ought to know of a potential problem with drug therapy. As such, knowledge includes actual knowledge – the incorrect dosage of digoxin noted above, for example and constructive knowledge, that is what a pharmacist ought to know or could have known.

The knowledge factor also provides a limit on the pharmacist's responsibility. A pharmacist can have

no responsibility outside of his/her actual or constructive knowledge. There are certain risks or potential problems with drug therapy of which a pharmacist can never have knowledge. For the most part, modern drug therapy works well. However, problems do arise with drug therapy. Licensing and approval does not necessarily mean that a drug is problem free. Even proper diagnosis of a patient's condition, followed by the appropriate selection of a patient's medication, will not ensure a successful outcome from drug therapy. Toxicities and therapeutic failures can occur from either the chemistry of the drug, the chemistry of the patient, or both. These latter failures can never be anticipated by any health care provider and there can be no knowledge of them. Under the proposed theory, there can be no liability or rather no responsibility without knowledge.

A knowledge based approach to pharmacist responsibility for drug therapy monitoring has a basis in the existing U.S. jurisprudence. The Supreme Court of New York in *Hand v Krakowski*, ((1982) 89 A.D. 2d 650, 453 N.Y.S. 2d 121), already discussed in chapter four, and in finding that a pharmacist does, in certain circumstances, owe a duty to warn, found the key issue to be the knowledge of the defendant pharmacists:

'Here, the decedent's pharmaceutical records identified her as an "alcoholic". Yet, [the defendants] during the ten month period preceding decedent's death, issued to her 728 units of psychotropic drugs knowing that such opiates are contraindicated with the use of alcohol ... Such conduct, in our view, could be found to constitute a breach of a druggist's duty of ordinary care in that it knowingly ignores the dangers and consequences of ingestion by an alcoholic of prescription drugs commonly recognised to be contraindicated.

... Here, [the defendants] knew that the decedent was alcoholic and knew, or should have known, that the prescribed drugs were contraindicated and, therefore, extremely dangerous to the well-being of its customer. Clearly under these circumstances, the

dispensing druggist may have had a duty to warn decedent of the grave danger involved and to inquire of the prescribing doctors if such drugs should not be discontinued.' ((1982) 89 A.D. 2d 650, 453 N.Y.S. 2d 121 at page 122)

The significance of *Hand* is that it recognises both that there are circumstances when a warning is required and circumstances when it is not. The key factor separating these circumstances is the knowledge of the pharmacist.

In *Riff v Morgan Pharmacy* ((1986) 508 A 2d 1247), again discussed in detail in chapter four, the court confirmed the nature of the duty which is owed by a pharmacist:

'A pharmacist is a professional. In the performance of his professional duties he will be held to the standard of care, skill, intelligence which ordinarily characterises the profession. Public policy requires that pharmacists who prepare and dispense drugs and medicines for use in the human body must be held responsible for the failure to exercise the degree of care and vigilance commensurate with the harm which would be likely to result from relaxing it.' ((1986) 508 A 2d 1247 at page 1251)

Applying those principles to the facts before him, the judge found that there was sufficient credible evidence presented to establish that the defendant pharmacy breached its duty to exercise due care and diligence in the performance of its professional duties. It had done so by failing to warn the patient or notify the prescribing doctor of the **obvious** inadequacies appearing on the face of the prescription which created a **substantial risk** of **serious harm** to the plaintiff. But for this negligence the error and subsequent injuries would not have occurred.

It is generally agreed that the decision in *Riff*, while framing the duty in terms of warning patient

and/or doctor of an **obvious** inadequacy on the face of the prescription creating a risk of substantial harm to the patient, is significant in establishing a standard that requires more than correct prescription filling, and in recognising that patients are seeking information which enhances drug therapy and which the pharmacist can provide without interfering with the doctor-patient relationship. The decision in *Riff* clearly requires that a pharmacist apply knowledge about drugs to the facts of a situation and acts for the patient's benefit by providing a warning, when a drug has been prescribed in a way that presents a substantial risk of serious harm.

In *Ferguson v Williams* ((1988) 374 S.E. 2d 438) the court had held:

'While a pharmacist has only a duty to act with due, ordinary care and diligence, this duty, like all others, expands and contracts with the circumstances. Here, it is alleged that the defendant ... undertook to dispense not only drugs, but advice also. While a pharmacist has no duty to advise absent knowledge of the circumstances ... once a pharmacist is alerted to the specific facts and he or she undertakes to advise a customer, the pharmacist then has a duty to advise correctly'((1988) 374 S.E. 2d 438 at page 440)

As was discussed in chapter four, it is now accepted (Brushwood 1991 and McCormick 1992) that the decision in *Ferguson* is sensible in that it requires that pharmacists give warnings regarding drug-specific information, given the pharmacist's extensive training in pharmacology and pharmacokinetics, resulting in the acquisition of detailed knowledge of a drug's properties and propensities. As a result, pharmacists are more likely to be more knowledgeable than doctors with respect to drug products. Further the patient, by seeking advice from the pharmacist, is demonstrating that he or she is not placing a primary reliance on the doctor. Rather the patient is seeking the advice

of a professional, perceived to be an authoritative source of information. The decision reinforces the view that public policy is being served by requiring a pharmacist to warn patients:

‘The judicial trend which is seen in *Ferguson* does not suggest that pharmacists must warn all customers of the potential side effects of their medications. Rather, it suggests that the duties of a pharmacist are not limited to counting pills. If a customer seeks the learned guidance of a pharmacist, *Ferguson* requires the pharmacist to inform the customer in a manner commensurate with his pharmaceutical training and expertise.’
(McCormick 1992:231)

There are strong arguments for developing a jurisprudence with respect to the knowledge factor along the lines of the decisions in *Hand*, *Riff*, and *Dooley v Everett*. Such a jurisprudence recognises rather than rejects the existence of the pharmacist’s knowledge, permits the utilisation of such knowledge for the patient’s direct benefit, elevates the pharmacist’s responsibility with respect to drug therapy monitoring to legal standard, and goes part of the way to defining and limiting the extent of the duty owed.

Foreseeability

So far, it has been advocated that pharmacists should have a responsibility to act for the benefit of an individual patient where he/she knows or ought to know of a potential problem with drug therapy. The knowledge factor both defines and limit the extent of the duty which is owed. While knowledge is an important factor in determining the extent of the duty owed, it is not the only one. The potential problem with drug therapy or adverse outcome must be foreseeable.

Foreseeability is the second factor which will also both define and place limits on the extent of the new duty owed.

As a general rule, foreseeability is seen as an essential element in the determination of the existence of a duty, or of any extension of that duty. In *Caparo Industries Plc v Dickman*, ([1990] 2 AC 605) Lord Bridge accepted that in determining the existence and scope of the duty of care which one person may owe to another, it is now difficult to find any single general principle to provide a practical test which could be applied to every situation to determine whether a duty is owed. What could be determined, however, was a number of different criteria which must be satisfied before any court would be willing to impose a duty of care. The first of these criteria (and arguably the most important), had to be foreseeability of harm.

It is clear that a defendant cannot be liable if the particular harm which the plaintiff suffers is not foreseeable. To put things more positively, an individual will only have to take action to prevent harm where that individual recognises the potential for harm. If the risk is wholly unforeseeable then no liability attaches. Even where the risk is foreseeable, liability may still be avoided. A further limiting factor is placed on the foreseeability issue by the courts' insistence that the risk has to be *reasonably* foreseeable. In turn, it is arguable that the foreseeability issue acts a strong limiting factor on the knowledge issue. Even where the defendant has knowledge of particular facts, there will be no duty to act in the absence of a reasonably formed belief that harm will ensue unless appropriate action is taken. Reasonable foreseeability includes an assessment,

according to the standard of an objective reasonable defendant, of the magnitude or materiality of the risk.

In the context subject to analysis in this thesis, the foreseeability issue operates as follows. A pharmacist, with appropriate knowledge of particular facts, that is given what he/she knows about a particular drug therapy and/or a particular patient, will be under a duty to warn where he/she has also formed a reasonable belief that a possible problem with the drug therapy is likely to evolve into an actual problem unless a warning is given. Problems with drug therapy can be reasonably foreseeable to a pharmacist both with and without actual or constructive knowledge of the patient's individual characteristics. In the example cited above, it is reasonably foreseeable that the prescription for digoxin amounts to a problem with drug therapy and that harm will result if no action is taken, without the pharmacist knowing anything more about the individual patient.

Other types of harm will only be reasonably foreseeable in the presence of actual knowledge of the patient's individual characteristics. Some patients, (including this author), are allergic to aspirin and are therefore susceptible to particular drug-drug interactions, not experienced by those without the allergy. Absence of knowledge of the patient's particular characteristics is a factor to be taken into account in the assessment of reasonable foreseeability of harm.

As with the knowledge issue, the foreseeability issue has a strong basis in the jurisprudence of the United States' courts. That jurisprudence shows the effectiveness of the foreseeability issue in both

defining and limiting an expanded duty for pharmacists in drug therapy monitoring In *Kirk v Michael Reese Hospital and Medical Center* (117 Ill. 2d 507, 513 N.E. 2d 387 (1987), the plaintiff had alleged that the defendant hospital had failed to warn a patient that medications administered and prescribed in the hospital before the patient's discharge might cause drowsiness and might impair the patient's ability to drive. The patient was a passenger in a car driven by the patient in these circumstances, and which subsequently crashed causing the passenger significant personal injuries. The Supreme Court of Illinois concluded that the existence of the duty to warn as claimed by the plaintiff, was dependent on a number of factors, foremost amongst which, was the question of foreseeability of harm:

'This court has held that "the existence of a legal duty is not to be bottomed on the factor of foreseeability alone" but on whether the harm reasonably was foreseeable ... This standard of reasonable foreseeability governs the foreseeability of injury from the defendant's conduct to the plaintiff ... Although the reasonable foreseeability of injury is a key concern in determining whether a duty exists, it is not the only consideration. The question of duty in a negligence action should take into account the likelihood of injury, the magnitude of the burden of guarding against it and the consequences of placing that burden upon the defendant.' (117 Ill. 2d 507, 513 N.E. 2d 387 (1987) at page 396)

In *Pittman v The Upjohn Company*, ((1994) 890 S.W. 2d 425), already discussed in detail in chapter four, an action was brought on behalf of the plaintiff who had sustained permanent brain damage after taking medication prescribed for a relative, in the mistaken belief that it was a different drug. The action was taken against the drug's manufacturer, the prescribing doctor and the pharmacy where the prescription had been filled. It was alleged that each of the defendants had a duty to warn of the dangerous properties of the prescribed drug and the potential deadly consequences of its being

consumed by someone other than the person for whom it was prescribed. The judgment of the Tennessee Court of Appeals examined the liability of each of these defendants in turn.

The pharmacy had two main arguments in its defence. It agreed with the doctor's argument that it owed no duty to a non-patient who improperly used a drug dispensed by it and also that it had fulfilled the only duty owed to its patient by filling the prescription according to the doctor's order. The court's response to these arguments was that if the only duty owed by the pharmacy were to fill the prescription correctly then there would be no duty owed to a non-patient because, obviously, the pharmacy would have no higher duty to a non-patient than to a patient. However the court stated that a pharmacist is a professional who has a duty to his or her patients to exercise the standard of care required by the pharmacy profession in the same or similar communities in which the pharmacist practices. The court noted that the increased complexity of pharmacotherapeutics and accompanying adverse drug reactions and drug interactions have resulted in an expanded role for pharmacists as drug therapy counsellors. The court also observed a trend towards patient-oriented clinical pharmacy practice.

As for the pharmacy's duty to the patient, the court concluded:

'The record shows that the duty owed [the patient] was greater than merely filling the physician's prescription correctly. As indicated by the evidence in the record, Micronase posed a danger to [the patient] even if taken according to the physician's order. The pharmacy customer was not aware of that danger because she had not been advised by either the physician, who prescribed the unavoidably unsafe drug or the pharmacy which dispensed the drug. A significant factor affecting the pharmacy's duty was the knowledge that no warning had been given by the physician. Under these

circumstances, it was reasonably foreseeable that [the patient] was at risk of injury. Consequently the pharmacy, as well as the physician, owed her the duty to warn.' ((1994) 890 S.W. 2d 425 at 435)

Thus, the court rejected the pharmacy's argument that its only duty was correctly to process the prescription, supporting the submitted view of this thesis that judicial recognition of an expanded duty with respect to drug therapy monitoring is essential.

However, having established that the pharmacy had a duty to warn the patient, the court had to consider whether this duty extended to the plaintiff who was not a patient. The court adopted the same rationale towards the pharmacy that it had toward the doctor because the dangers posed by glyburide were equally foreseeable by the doctor and the pharmacist. Consequently the duty to the patient did not extend to the non-patient because of the lack of foreseeability of the harm that occurred.

'The issue being tested on this motion for summary judgement is the likelihood that an adult guest of [the doctor's] patient would take the drug accidentally. If a reasonable person could foresee the probability of this occurrence, the law imposes a duty of reasonable care, care commensurate with the risk. Such reasonable care must be given meaning in relation to all relevant circumstances; the degree of foreseeability needed to establish a duty of care decreases in proportion to the magnitude of the foreseeable harm.' ((1994) 890 S.W. 2d 425 at 435)

The foreseeability factor operated effectively in *Pittman* to achieve a fair outcome. The court, while recognising an expanded duty for pharmacists with respect to drug therapy monitoring, used

the foreseeability factor to limit that duty and to rule that while pharmacists are expected to monitor drug therapy, they cannot be expected to be responsible for every adverse outcome of drug therapy. A further illustration of this point is to be found in the case of *Laws v Johnson* (799 S.W. 2d 249 Tenn. App. 1990), the plaintiff had argued that the defendant pharmacist's failure to provide a manufacturer's package insert with his dispensed medication constituted a failure to warn. Further this failure to warn resulted in him continuing to take the medication, the side effects of which caused him to have a series of heart attacks. One of the two grounds for the rejection of this claim by the Court of Appeals of Tennessee was the conclusion that the heart attacks were not a reasonably foreseeable risk to any of the plaintiff's health care providers. Indeed, the plaintiff's doctor had also advised the plaintiff to continue taking the medication, even after the plaintiff had obtained the relevant package insert, because the risk of heart attack was so small.

Other cases have shown that the courts have recognised that certain types of problem with drug therapy are reasonably foreseeable and require action on the part of the pharmacist in the form of warnings or counselling. In *Ferguson v Williams*, ((1988) 374 S.E. 2d 438), already referred to above and in chapter four, the court after accepting that the knowledge factor was sufficient to create a duty of care on the part of the pharmacist, also recognised that the harm resultant on the failure to provide the warning – the death of the plaintiff's husband due to a known drug-drug interaction – was reasonably foreseeable. Similarly, in *Frye v Medicare-Glaser Corp.* (579 N.E. 2d 1255, Ill. App. 1991), the Appellate Court of Illinois, after accepting that a pharmacist who

voluntarily offers to counsel a patient on drug therapy owes a duty to the patient to ensure that the warning is accurate, found that the harm resultant on the careless warning - the death of the plaintiff's husband after the ingestion of the prescribed medication with alcohol - was reasonably foreseeable.

As with the knowledge factor, there are strong arguments for developing a jurisprudence with respect to the foreseeability factor along the lines of the decisions in *Laws*, *Pittman*, *Ferguson* and *Frye*. Such a jurisprudence places the pharmacist's knowledge in context, and recognises that there are limits on the type of adverse outcome which the pharmacist can be expected to prevent.

Introducing certainty - the enactment in the United Kingdom of OBRA-90 equivalent legislation?

It is arguable that the examination of the past, current and developing case-law, undertaken in chapter four, demonstrates that the judiciary is uncertain, changeable and, to a certain extent, unpredictable in its approach to definition, interpretation and analysis of pharmacist responsibility. Particular and distinct attitudes have been taken in discrete periods of time and in separate jurisdictions. Further, it could be contended that the analysis undertaken in chapter six, while concluding that the pre-conditions are present for a re-examination of professional relationships, responsibilities, and duties to take place in the United Kingdom, gave no definitive evidence of a current development in that direction, and relies on speculation that the ongoing general trend in the transfer of new forms of liability between the United States of America and the United

Kingdom, will be maintained in this specialist area. Equally, it could be submitted that the extensive analysis of a potential jurisprudence based on the factors of knowledge and foreseeability is simply that - potential and possible - and too redolent of assumption and theory.

In short, the conservative and cautious pharmacist will counter that there is too much uncertainty in permitting the judiciary to develop, by definition and interpretation, the limits of professional responsibility. The immediate response to such concern and wariness is contained in the conclusion to chapter six and to this chapter. It is a necessary and welcome implication of a move towards expanded responsibility that it brings with it the potential for expanded liability should the responsibility be exercised in a careless fashion. It is necessary because the traditional legal standard which insisted that pharmacists are only liable for mechanistic errors is legally inappropriate to the expanded role. It is welcome because the imposition of legal liability to perform a role gives greater authority to a claim to have that role. It is important that judicial standards recognise and welcome the pharmacist's new role and place pharmacist responsibility in a modern context.

Those members of the pharmacy profession who have consistently argued for an expansion of professional role will welcome the analysis of the judicial response, both actual and potential, to the re-interpretation of professional responsibility, and will see this as a positive development. They will also respond to the opportunity to influence future judicial thinking by emphasising a willingness to assume full responsibility for knowledge based drug therapy monitoring but also by

arguing that a limit has to be placed on that responsibility and that the pharmacist's role cannot be risk elimination.

Those who are apprehensive about permitting the re-definition of professional responsibility to be left in the unrestrained hands of the judiciary might advocate the enactment, in the United Kingdom, of OBRA-90 equivalent legislation. As was noted in chapter five, OBRA-90 places a legislative gloss on a series of developments within and without the pharmacy profession. The legislation has had the effect of strengthening pharmacy's grip on its entitlement to professional recognition. The legislation sought both to improve and limit health care spending and recognise professional roles, enhance pharmacy practice standards, and improve the outcome of drug therapy for patients, by bettering patient compliance with drug regimes. As was noted in the introduction to this chapter, it was the pharmacy profession which sought to convince the U.S. government sub-committees that the increased use of drug reviews and counselling, the pharmacy profession's driving aspiration, would lead to fewer hospitalisations, as previously non-compliant patients could be persuaded of the benefits of drug therapy as an alternative to more expensive medical interventions such as surgery. The legislative scheme provided direct economic and health care benefits.

Enshrining the new role in legislation has provided the impetus for the profession to take further steps forward. The further analysis in chapter five showed that the profession has largely

welcomed the latest development, agreeing that it provides a specific endorsement for pharmacy's future. The key to its success lies in the clarity of the definitions of professional role and function, the placing a limit on the necessary sanctions for abrogating such roles, and in providing the pharmacy profession with a comprehensible, regulatory structure within which to move forward.

Pharmacy in the United Kingdom has always been keen to classify and characterise its professional roles in a regulatory format (Mullan 2000). The profession appears to welcome the definition and interpretation of functions and duties through legislative enactment. Further, other professions, including health care professions, have advocated the adoption of a regulatory structure for professional roles and functions. As a step towards further certainty and confidence in a necessary legal recognition of new roles and responsibilities, the profession might actively endorse the passing of new legislation in the United Kingdom, which parallels the structure of OBRA-90. As the analysis in chapter five also showed, there is still much to be achieved with OBRA-90, and many of its aspects, including the important issue of sanctions, remain to be interpreted by the courts. It is clear, however, that the majority of the pharmacy profession in the United States of America remains convinced that that the legislation builds on and continues the process of new role recognition, and strengthens the view that the determination of pharmacy standards by the profession itself is appropriate.

Conclusion

If the pharmacy profession requires a *moral* justification for the assumption of expanded responsibility, it is to be found in the facts of *Cafarelle v Brockton Oaks CVS, Inc.* (Mass. Sup. Ct.No. 94-0414A, April 1996), already discussed in detail in chapter four. Jennifer Cafarelle began treatment for asthma when she was three and one half years old. The doctor who began her initial treatment, and other doctors with whom he was associated, treated her until her death. Jennifer had moderate asthma with occasional severe exacerbations which required aggressive therapy with corticosteroids, environmental control, and allergy injections. She was admitted several times to the hospital suffering from status asthmaticus, which is a severe and prolonged asthma attack. She also had frequent visits to her doctor for acute asthma. In the year before her death, Jennifer's doctors treated her approximately once per month. During that time, she was prescribed a Proventil Inhaler to be used on an 'as needed' basis. She was also taking Theodur tablets, Intal/Alupent (administered through an electrical nebuliser), Alupent tablets, and Azmacort.

Proventil and Azmacort are beta-agonists and are used to treat the symptoms of asthma by opening up the lung passages; they do not affect the inflammation in the lungs. Refill frequency is particularly important with beta-agonist inhalers, because increased frequency of inhaler use may presage an asthmatic crisis. From knowledge that an inhaler is being used too frequently, it is possible to also learn that the patient's asthma is worsening and/or that the patient's inhaler technique has degraded so that the patient is not receiving the full dose from the inhaler. These problems (and others) can be managed effectively if discovered through drug therapy monitoring.

The Proventil inhaler contained two hundred metered doses. At eight puffs per day, the inhaler should have lasted about one month. Her doctor gave evidence that when he first issued the inhaler, he instructed Jennifer on the proper breathing technique and he advised her not to use the inhaler more than two puffs up to four times per day maximum. He also stated that he discussed with Jennifer and her mother the consequences of exceeding the recommended maximum dosage and that he told them that overuse of the inhaler could result in possible accelerated heart rate or cardiac arrhythmia and the masking of worsening symptoms of asthma. In the seven month period before Jennifer's death, Jennifer's doctors had issued her with a number of prescriptions for Proventil inhalers, all of which were filled at the defendant pharmacy.

During the relevant period, the defendant pharmacy had an in-store computer used by the pharmacists when filling and refilling prescriptions. This computer system allowed the pharmacist to access a patient's prescription profile showing the patient's entire prescription history at that pharmacy. When a prescription was initially filled, the pharmacist would type into the computer the number of days that the prescription should last based on the quantity and dosage prescribed by the physician. If a customer requested a refill too soon, the computer alerted the pharmacist with a warning prompt. The purpose of the warning prompt was for insurance payment purposes and also to alert the pharmacist that the customer may be overusing the medication. The pharmacist would have to manually override the warning prompt if he/she made the decision to dispense the prescription in spite of the warning.

According to an expert witness retained by the plaintiff, pharmacists at the defendant pharmacy dispensed the inhalers approximately three times more frequently than is standard practice or recommended use of the medications. A pharmacist, giving evidence on behalf of the defendant pharmacy, agreed that a pharmacist had a duty to alert the doctor when the pharmacy computer warned that the customer might be overusing the prescribed medication and that the pharmacist had a duty to warn the patient that she might be overusing the medication. He also stated that he called Jennifer's doctor's office to express concern about the overuse of the Proventil inhalers, and that he had expressed similar to her parents. No documentation was produced to substantiate the claims of warnings to the doctor, and Jennifer's parents contended that they were never informed by the pharmacy of the dangers associated with overusing the medication.

In relation to specific evidence concerning the entering of a new prescription for the inhaler into the pharmacy computer as a fifteen day supply, as opposed to the previous twenty five day supply, with no parallel alteration in the amount supplied, the pharmacist gave evidence that he informed her doctor's office that this change was needed to provide the medication at a faster rate and to ensure that the insurance company would pay for the medication. He also stated that he had received approval of this change from a staff member at the doctor's office. The prescriptions, allegedly authorising these changes, did not, however, indicate a reduction in the amount of medicine Jennifer received or a change in the rate which the inhaler was supposed to be used.

So a thirteen year old girl dies from respiratory failure associated with a severe asthma condition

which she had since infancy, because, in part, her pharmacy carelessly filled prescriptions by supplying medication to her, at a rate faster than that prescribed. Further, the pharmacy refused to fill the prescriptions before the normal time and failed to warn the girl, her parents, or her doctor, that she was overusing the prescribed medication and that such overuse was potentially dangerous.

The reaction of some within the pharmacy profession to the facts of the *Cafarelle* case has been to argue that the facts are extreme, that there was clear carelessness on the part of the pharmacist, and that no reasonable and prudent pharmacist, faced with the same set of facts, would have acted in the same way. The facts are not extreme. Jennifer Cafarelle had a problem with drug therapy, was experiencing poor outcomes with her drug therapy, and had a reasonable expectation that her health care providers would act to prevent or minimise those outcomes arising. Jennifer Cafarelle's health care providers included her pharmacist with whom she had a direct and proximate relationship.

As was noted above, the pharmacist's relationship with a patient has to do primarily with the prevention or minimization of the risks of drug therapy. As experts on drug therapy, pharmacists can detect potential problems with a patient's medication use, and can interact with the patient and/or the patient's doctor, to resolve the potential problem and protect the patient from harm. Those with problems in drug therapy, be they Jennifer Cafarelle with her asthma or those allergic to aspirin, have a right to have that drug therapy monitored by their pharmacist.

If pharmacists require a *professional* justification for assuming an additional responsibility for drug

therapy monitoring, it lies in the conclusion reached in chapters one, two and three. The pharmacy profession, world-wide, is at risk of alienation from the mainstream of health care provision. The practice of pharmacy has changed dramatically and the twenty-first century professional roles and functions of pharmacists are wholly different to those experienced in the nineteenth and twentieth. Yet, as the analysis in chapters five and six has shown, the profession has been thrown a life-line to prevent its withdrawal from healthcare and its restoration to primacy. Factors such as the increasing complexity of drug therapy, the demands of the public for increased participation in health care, the health care policy-makers' mandate to reduce health care expenditure, and the re-alignment of the position of the main participants in the drug distribution system, have forced the pharmacy profession back into the health care team. The social bias, the policy shift and the legislative trend, evidenced by the enactment of OBRA-90 in the United States of America, is towards pharmacy rather than away. Health care is stating that it needs pharmacy to adopt a drug monitoring role just at the time when pharmacy needs a new health care role.

What the pharmacy profession makes of these developments is for the pharmacy profession to decide. It is clear, however, that the factors leading to a re-evaluation of the roles and functions of pharmacists also mandate a legal re-examination of professional responsibility. Several justifications are offered for this conclusion. As was noted at the conclusion of chapter three, the role of pharmacists (and indeed other health care providers) in a health care system is necessarily shaped by law. The extent to which pharmacy assumes under law the mission of pharmaceutical care depends

significantly upon the extent to which such an expanded role is recognised by judges, and legislators. What duties pharmacists owe, to whom such duties are owed, what is the relevant standard of care, and what constitutes breach all define the role of pharmacists and the conduct expected of them. Judicial recognition of a particular duty is very persuasive of a professional claim to it. To this extent, pharmacy needs a *legal* justification for its expanded role.

As was noted in chapter six, society is evidencing an increase in medical negligence claims, and a significant expansion in the number of such claims which allege failures in drug therapy. There is also evidence of parallel eagerness within the legal profession to satisfy the requirements of the casualties of drug complications. Existing legal analysis suggests that the other participants within the drug distribution system who might be the subject defendants of such actions have negotiated their way out of liability. The re-distribution of responsibility for drug dispersal towards the pharmacist increases the potential for increased liability should responsibility not be exercised appropriately.

The pharmacy profession is in a position to influence the extent of further judicial definition and expansion of duty. As has been noted above there is a sound basis for the development of a jurisprudence which seeks both to define and limit expanded pharmacist responsibility with respect to drug therapy monitoring. The factors of knowledge and foreseeability, concepts already embedded in judicial reasoning on the definition of duty, can be used effectively by the judiciary to promote the parallel notions that pharmacists can and should intervene for the patient's benefit when

a problem with drug therapy becomes evident, and also that there are limits to what pharmacists can do. The pharmacy profession should welcome the current legal trends towards expanded responsibility. Those tendencies accord with the profession's own desire for an extended role, place that role in context and define and limit the extent of the new duty. The corollary is that the rejection of a duty to warn would allow the profession of pharmacy to abrogate its duty to use a reasonable level of knowledge, training and experience for the benefit of its patients.

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