

Title and running head: Pharmacy legislation – public protector or professional hindrance?

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Author: Christopher A Langley.

Affiliation: Professor of Pharmacy Law and Practice, School of Life and Health Sciences, Aston University, Birmingham, B4 7ET, UK.

Corresponding author: Prof C. A. Langley, School of Life and Health Sciences, Aston University, Birmingham, B4 7ET, UK; e-mail: c.a.langley@aston.ac.uk.

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PHARMACY LEGISLATION – PUBLIC PROTECTOR OR PROFESSIONAL HINDRANCE?

Pharmacy originates from a background of medication compounding and supply. More recently this role has developed away from an absolute focus on the supply of pharmaceuticals with, for example, the advent of pharmacist prescribing. Nevertheless, for a majority of the profession, medication supply remains a core activity.

Regulation of the pharmacy profession is now the responsibility of the General Pharmaceutical Council, although up until 27 September 2010, this role fell to the Royal Pharmaceutical Society of Great Britain (RPSGB). Before this change, in one of the most high profile legal cases involving a pharmacist in a professional capacity, *R. v Lee*, a pharmacist was prosecuted firstly for gross negligence manslaughter, later revised to offences under the Medicines Act 1968, for a single error relating to medication supply, and was given a suspended custodial sentence. Offences against sections 64 or 85 of the Medicines Act are absolute offences and there is no due diligence defence.

Prosecution of a pharmacist for the supply of incorrect medication may seem a measured course of action to protect the public from the wrongful supply of potent pharmacotherapeutic agents; however, further analysis of *Lee* indicates that this approach may be counterproductive. An appeal of the original conviction in the *Lee* case has resulted in a clarification of the interpretation of section 85(5); however currently, prosecutions under section 64 are still a possibility. Owing to the seriousness of a criminal conviction under section 64, this continuation will potentially stifle the profession's ability to learn from dispensing errors.

Keywords

Dispensing errors, Medication supply, Medicines Act 1968, Pharmacy, Professional regulation, Section 64.

I. INTRODUCTION

The modern profession of pharmacy traces its roots back to the role of the chemist and druggist.¹

The chemist and druggist was the expert in the preparation and supply of medicines, a role which has continued to form the core of pharmacists' activity through to current times. Recent developments within the pharmacy profession have started a move away from an absolute focus on the supply of pharmaceuticals with, for example, the advent of pharmacist prescribing.² Nevertheless, the supply of pharmaceuticals has always been, and for a majority of the profession today remains, the primary role of the pharmacist.

Modern professional healthcare regulation is multifaceted. On the one hand, there is the action a regulator can take in response to an event that has taken place involving a registrant. This event can be directly related to a registrant's healthcare practice, for example the inappropriate or even illegal sales of restricted pharmaceuticals, or be unrelated itself to healthcare activity but could be deemed serious enough to cause doubt to be cast on the ability of the individual to continue with their healthcare practice. Examples in this latter category include drink driving or the abuse (away from the healthcare environment) of controlled substances. On the other hand, there are proactive regulatory decisions whereby the registrant in question may not have actually undertaken or committed any particular act so as to render their conduct or ability to practice in question; however, there may be cause for concern that this may not be the case in the future due to some possible deterioration of a particular situation. Examples where this could be the case include registrants suffering from potentially serious mental illness problems.

The registration of healthcare practitioners and the associated regulation has been brought into focus over recent years partially due to a number of high profile cases. Many of these involved

¹ Royal Pharmaceutical Society. History of pharmacy. See <http://www.rpharms.com/about-pharmacy/history-of-pharmacy.asp> (accessed ~~13-18 June-October~~ 2013).

² Firstly with the introduction of pharmacist supplementary prescribing, followed soon after by the introduction of pharmacist independent prescribing.

members of the medical³ or nursing profession⁴; however, one or two high profile cases have involved pharmacists⁵.

With the recent expansion of the role of the pharmacist into one where they are an increasingly important core member of the multi-disciplinary healthcare team, it is important to examine how the profession has been regulated up to this point and how, in an era where there is an increased focus on the protection of the public from inappropriate action by healthcare professions, these new roles are likely to be regulated in the future.

A. The Role of the Pharmacy Regulator

On the 27th September 2010 the regulation of pharmacy and pharmacists in Great Britain ceased being the responsibility of the Royal Pharmaceutical Society of Great Britain (RPSGB) and passed to a new organisation, the General Pharmaceutical Council (GPhC). Founded in 1841 as the Pharmaceutical Society, the RPSGB had been the representative and regulatory⁶ body for pharmacists for over one hundred years. Although the creation of a regulator which is independent of any representative function brought pharmacy into line with other healthcare professions, this was an important new professional era for both pharmacists and the pharmacy profession.

The Pharmacy Act 1954 established a single committee (known as “The Statutory Committee”) to consider cases of “misconduct” by a pharmacist “such as to render him unfit to be on the register”.⁷

³ For example, see the Bristol Royal Infirmary Enquiry (Learning from Bristol: The Report of the Public Enquiry into Children’s Heart Surgery at the Bristol Royal Infirmary 1984-1995 Cm 5207 (2001)); The Royal Liverpool Children’s Enquiry Report (The Royal Liverpool Children’s Enquiry Report (2001) HC 21-11) and the reports from The Shipman Enquiry (available via The National Archives; see <http://www.nationalarchives.gov.uk/>).

⁴ For example, the nurse Beverly Allitt who was sentenced to thirteen life sentences for murdering four children and attacking nine others at Grantham and Kesteven Hospital in Lincolnshire by injecting them with either potassium chloride or insulin.

⁵ For example, the case of disgraced gynaecologist Rodney Ledward who was also registered with the Royal Pharmaceutical Society of Great Britain (RPSGB) at the time of his removal from the General Medical Council register. Although he did not work in Great Britain following his removal from the medical register, he did register in Ireland and work as a locum pharmacist following the issue by the RPSGB of a “certificate of good standing” to allow his reciprocal registration.

⁶ The Pharmacy Act 1868 set up a register of people qualified to sell, dispense and compound poisons. The Pharmaceutical Society (as it was then known) would examine and register pharmacists, and prosecute them in cases relating to poisons.

⁷ GE Appelbe and J Wingfield. *Dale and AppelbyAppelbe’s Pharmacy Law and Ethics* (9th Edition), 343.

The Statutory Committee received referrals from the RPSGB's Infringements Committee and was described by its then Chairman as having three purposes "*The protection of the public; next comes the honour or dignity of the profession and the third dimension is the best interest of the pharmacist*".⁸ It is clear from this statement that although the Society as a whole undertook a dual role (the regulation of the profession and the representation of members (or fellows⁹); i.e. pharmacists), the Statutory Committee viewed its role very much as a part of the RPSGB's regulatory function by putting public protection and the reputation of the profession before the best interests of the pharmacist (i.e. the member (or fellow)).

The activity of the Statutory Committee (including the action of any residual orders and activities) operated up to 2009 after the establishment of two separate committees, the Health Committee and the Disciplinary Committee under sections 51 and 52 (respectively) of the Pharmacists and Pharmacy Technicians Order 2007 (SI 2007/289). Transitional arrangements were put in place (under section 69 and Schedule 2 of the Pharmacists and Pharmacy Technicians Order 2007) whereby referrals from the Infringements Committee (the predecessor of the newly introduced Investigating Committee) prior to 30th March 2007 were held under the regulations and procedures relating to the Statutory Committee. All new allegations were subsequently referred either to the Disciplinary Committee or Health Committee (or both).

Traditionally, the regulator for pharmacy (the RPSGB) was in effect limited (under the powers granted to it under the Pharmacy Act 1954) more to "reactive" regulation ~~rather~~ than the pro-active regulation which would be required ~~for action~~ to prevent potential issues relating to patient safety arising. Although the RPSGB Inspectorate (which has been continued under the GPhC) was proactive in monitoring potential issues through frequent visits, advice and informal cautions (which were

⁸ *Pharmaceutical Journal*. 14 April 1990, 488.

⁹ Fellows of the Royal Pharmaceutical Society of Great Britain (FRPharmS) were members of not less than twelve years' standing who had made an outstanding original contribution to the advancement of pharmaceutical knowledge or who have attained distinction in the science, practice, profession or history of pharmacy. See GE Appelbe and J Wingfield. *Dale and AppelbyAppelbe's Pharmacy Law and Ethics* (9th Edition), 323.

designed to avoid cases coming before the Statutory Committee), ~~in~~ essence ~~this meant that~~ the regulator only took formal action once an event had taken place. The changes implemented by the Pharmacists and Pharmacy Technicians Order 2007 attempted to address these problems by introducing a “dual-track” approach to the regulatory framework. As outlined above, the RPSGB’s “Statutory Committee” (the disciplinary committee established under the Pharmacy Act 1954) was replaced by two committees; the Disciplinary Committee (which effectively took over the bulk of the workload from the old Statutory Committee) and the Health Committee, both receiving referral from the Investigating Committee (the replacement for the Infringements Committee which referred cases to the Statutory Committee under the 1954 Act). There was also a “fast-track” route directly from the Registrar of the RPSGB to the Disciplinary Committee for urgent cases, including the ability to issue an “interim order”. This heralded a new era for pharmacy regulation as for the first time, explicit reference within the regulatory framework was made to issues relating to registrant’s health in a proactive rather than reactive way. Health referrals would not necessarily be as a direct consequence of the registrant’s own actions¹⁰ and could be considered to be more proactive in nature as an actual incident where the safety of a patient or member of the public has been brought into question may not actually have taken place.

Therefore, the majority of the case history for pharmacy regulation through the professional regulator relates to reactive disciplinary cases where the regulator has taken action to protect the public, with the action triggered by an event either directly related to an individual’s conduct as a healthcare professional or through other action in their personal lives.

However the regulatory landscape is set to change in the future. The disciplinary processes within the Pharmacists and Pharmacy Technicians Order 2007 and as amended under the Pharmacy Order 2010 are set out under the heading of “fitness to practise”. This emphasises a further shift in healthcare regulation from the reactive prevention of additional patient harm to one which encapsulates pro-active prevention as part of its foundation. The Pharmacy Order 2010 merges the

¹⁰ Exceptions could be argued, for example, in the cases of certain substance abuse.

Disciplinary and Health Committees formed under the Pharmacists and Pharmacy Technicians Order 2007, thereby creating three statutory committees; Investigating Committee (in effect a “screening” committee which considered written submissions); Fitness to Practise Committee (the main committee which considered fitness to practise cases from both a health and disciplinary background); and Appeals Committee (the committee which hears appeals against the decision of the Registrar). Appeals of decisions of the Fitness to Practise Committee are heard in the High Court (or the Court of Session if the appellant lives within Scotland).

The powers of the pharmacy regulator are conferred through primary Acts¹¹ and secondary legislation¹². Before the Pharmacists and Pharmacy Technicians Order 2007, the majority of the cases heard by the then regulator (the Royal Pharmaceutical Society of Great Britain - RPSGB) were based on the alleged conduct of the pharmacist.¹³ Therefore, as a majority of the historical cases dealt with by the pharmacy regulator will relate to cases referred by the RPSGB (as the regulator for pharmacy pre-September 2010) to its Statutory Committee (established by the Pharmacy Act 1954 and revised by the Pharmacists and Pharmacy Technicians Order 2007 and Pharmacy Order 2010), many of the cases heard within the legal court system relating to pharmacist regulation are in reference to appeals against the decision of the regulator’s statutory committee(s) (in most cases, the Statutory Committee). However, other cases may be heard within the criminal courts before referral to the professional regulator and this paper will focus on some of the more important court decisions to affect the landscape of pharmacy regulation. This discussion will culminate in a review of one of the most high profile legal cases of recent times involving a pharmacist in a professional capacity, the case of Elizabeth Lee, along with an examination of previous related cases. In *R v Lee*¹⁴, a pharmacist was prosecuted firstly for gross negligence manslaughter, later revised to offences

¹¹ For example, the Pharmacy Act 1954 and the Medicines Act 1968.

¹² For example, the Pharmaceutical Society (Statutory Committee) Order of Council 1978 (SI 1978 No.20).

¹³ Rather than including cases where the fitness to practise of the registrant has been brought into question due to health reasons rather than reasons related solely to the conduct of the registrant.

¹⁴ *R. v Lee (Elizabeth)*. [2010] EWCA Crim 1404.

under the Medicines Act 1968¹⁵, for a single dispensing error. The original allegation of gross negligence manslaughter was made before the dispensing error and the death of the patient were found to be unconnected. Following this finding, and upon pleading guilty to a lesser offence (when compared to gross negligence manslaughter) under the Medicines Act, the pharmacist involved was originally given a suspended custodial sentence.

On the face of it (once the causal link between the dispensing error and the death of the patient was proved not to exist), *Lee* would appear to be a straightforward case involving a simple medication supply error. Ordinarily, cases referred to the regulator involving a single dispensing error would not normally result in a professional conduct hearing because in 1997 the Council of the RPSGB approved “Threshold Criteria” designed to allow minor cases to be dealt with through the use of appropriate advice and guidance (via the Society’s Inspectorate) rather than through referral to the Investigating Committee. This guidance stated that, *inter alia*, single one-off dispensing errors would not form grounds for referral. Previous similar cases to *Lee* had indicated that irrespective of the stance the regulator was likely to adopt, the police were content to pursue criminal charges against a pharmacist for what appeared to members of the profession to be a simple dispensing error; one that any competent pharmacist could (and in all probability would) unintentionally make a number of times throughout the course of their professional career. However what *Lee* showed the profession is that following prosecution, the courts were content to impose a custodial sentence for the offence (albeit a suspended sentence in the case of *Lee*).

It is against the backdrop of a new regulating body for pharmacy and the recent case of *Lee* that we ask how has the profession found itself in this position; a position where a simple (and in most cases minor) unintentional error could lead to serious criminal charges potentially involving a custodial sentence? This paper examines two key legal cases, which occurred prior to *Lee*, to chart the course of pharmacy regulation to this point. Although not the only criminal case involving a pharmacist to

¹⁵ Specifically, sections 64(1) and 85(5)(b) along with 91(1).

be heard within the courts, *Lee* is one of the most important cases relating to how pharmacists perceive they may be dealt with by the regulatory and legal systems in place to protect the public.

II. LEGAL CASES INVOLVING PHARMACISTS

A significant majority of the cases involving the conduct of pharmacists (including now all cases relating to concerns over the registrant's health) are dealt with by the professional regulator for pharmacy and only reach the legal court system if either (a) the registrant makes an appeal to the High Court (or Court of Session in Scotland) or (b) if the case is referred by the Professional Standards Authority for Health and Social Care (PSA)¹⁶ for review¹⁷. Within this paper, three key legal cases involving pharmacists, the "Peppermint Water" case, the Prestatyn case and finally *Lee*, where the action taken was by the police and courts rather than by the professional regulatory body for pharmacy will be discussed.

A. The "Peppermint Water" Case

A real turning-point in the legal landscape of the modern pharmacy profession surrounds what has become known throughout the pharmacy profession as the "Peppermint Water" case. In this case, a medicinal solution ("Peppermint Water") which needed to be compounded extemporaneously within a community pharmacy was made-up with twenty-times the required amount of chloroform by a pre-registration trainee¹⁸ in 1998. As a result of this formulation error, the patient (a baby) died. Following-on from this event, both the pre-registration trainee and the supervising pharmacist were charged with manslaughter. However, this charge was changed on the day of the trial (which took place nearly two years after the initial event) to an offence under section 64 of the Medicines Act 1968, of supplying a medicinal product not of the nature and quality specified. After both pleaded

¹⁶ Previously known as the Council for Healthcare Regulatory Excellence (CHRE).

¹⁷ The PSA is able to refer cases to court if, after investigation, it believes that the sanctions imposed by the professional regulator are unduly lenient. See: <http://www.professionalstandards.org.uk/> (accessed 13-18 June October 2013).

¹⁸ A pre-registration trainee is an individual who has completed a degree in pharmacy and is working in a professional environment under the direct supervision of a qualified pharmacist for a period of one year. Following the successful completion of the year, the individual is able to register as a pharmacist.

guilty, they received fines of £1000 and £750 (the pharmacist and the pre-registration trainee respectively).¹⁹ Upon conclusion of the legal process, referrals to the RPSGB Statutory Committee were made. This process concluded in a reprimand for the pharmacist and no further action for the pre-registration trainee (thereby allowing the pre-registration trainee to register as a qualified pharmacist upon successful completion of his pre-registration training).²⁰

There are a number of important points that the Peppermint Water case raises. Firstly, this was the first incidence of a member of the profession (albeit through supervision of a trainee²¹) being charged with manslaughter following a dispensing error. In previous cases, if legal proceedings were taken, it was under section 64 of the Medicines Act 1968, the section which was ultimately used in this case. Secondly, in the case of the non-registered staff member (in this case the pre-registration trainee), it is usual that the pharmacist (and possibly also the superintendent pharmacist²²) who is/are prosecuted as any non-registered staff had previously been deemed to be working under their direct supervision.

As the RPSGB had responsibility at the time for enforcing the Medicines Act, cases like this were usually referred to its Infringements Committee (via the Society's Professional Standards Directorate) for a decision as to whether to refer for prosecution or not. Commenting on the process

¹⁹ Boots pharmacist and trainee cleared of baby's manslaughter. *The Pharmaceutical Journal* 2000; 264:390-392.

²⁰ Reprimand for pharmacist in "peppermint water" case. *The Pharmaceutical Journal* 2002; 268:227-228 and No action against pre-registration student involved in "Peppermint Water" tragedy. *The Pharmaceutical Journal* 2001; 267:211-212.

²¹ Pre-registration trainees did not become Members of the Royal Pharmaceutical Society of Great Britain (MRPharmS) until they qualified.

²² As explained by the Pharmaceutical Services Negotiating Committee, "A pharmacy can be registered only by a pharmacist, a partnership consisting entirely of pharmacists, or by a 'body corporate' (usually a limited company). In the case of a body corporate, a superintendent pharmacist must be appointed, to take responsibility for the way in which the company carries out its professional pharmaceutical activities".

<http://psnc.org.uk/contract-it/pharmacy-regulation/opening-a-pharmacy/http://www.psnc.org.uk/pages/opening-a-new-pharmacy.html> (accessed 13-18 June-October 2013).

of this case, and specifically the lack of any action being taken against the company itself (Boots the Chemist), Alan Nathan²³ stated:

Usually cases where dispensing error led to harm to a patient would be referred to the Infringements Committee. It would not only examine evidence for criminal prosecution but would also look at the circumstances surrounding the situation, to see if there had been any apparent negligent or unethical behaviour that might merit referral to the Statutory Committee. I considered that the company had a case to answer as it had been responsible for the trainee being in the branch on the day that the incident occurred, and that the Society's regulations on pre-registration training (Byelaw XX) had not been complied with.²⁴

So what important points did the “Peppermint Water” case highlight? Firstly, there was the issue that for the first time, the police were willing to prosecute a registered pharmacist for manslaughter following death resulting from a single dispensing error. Rather than the case being considered within the regulatory framework of the pharmacy regulator, criminal proceedings were taken by the police. Secondly, individuals working with pharmacy in a non-registered capacity (for example, pharmacy assistants and pre-registration trainees) are not automatically protected from prosecution for a dispensing error even though they are working under the direct supervision of a registered pharmacist. Thirdly, the role of the superintendant pharmacist in serious cases of dispensing error needed clarifying as although it would have been expected that some form of action would have been taken against the superintendant in the “Peppermint Water” case, this did not occur.

B. The Prestatyn Case

After the profession had learned lessons from the “Peppermint Water” case, the next high-profile case involving a pharmacist was what has become known within the profession as the Prestatyn

²³ Alan Nathan was a member of the Royal Pharmaceutical Society of Great Britain's Council for fifteen years between 1986 and 2002. During that time he was a member of the Infringements Committee for all but three years, and was chairman of it for five years.

²⁴ A Nathan. Lessons Learned from the Peppermint Water Case. Available (to members) via the website of the Pharmacists' Defence Association (<http://www.the-pda.org>).

case. In this case, a patient (Alan Clarke) was mistakenly supplied with sertraline²⁵ instead of spironolactone²⁶. The patient was suffering from liver disease and following admission to hospital, subsequently died. The pharmacist (Juliet Hines) and the dispenser (Georgina Mahoney), who originally selected the incorrect drug, were prosecuted, again under section 64 of the Medicines Act. Hines was fined £2,065, with Mahoney being ordered to pay £270.

Although the case against the pharmacist and dispenser were brought under section 64 of the Medicines Act rather than any charge relating more specifically to the death of the patient, it was the decision to hold the dispenser partially responsible, although following the precedent of the “Peppermint Water” case which was subsequently tested when Mahoney challenged this part at the Divisional Court.²⁷ The view of the original Magistrates’ Court was that the dispenser was an important link in the supply chain and although the pharmacist had higher qualifications and a more senior position, this did not absolve the dispenser from responsibility. The basis of the judicial review centred on whether the liability under section 64 of the Medicines Act 1964 should be limited to pharmacists and corporate bodies. The question was whether the presence of a qualified pharmacist within the dispensing supply chain effectively re-starts the supply chain from the point the pharmacist is involved. However the conviction was upheld with the judges stating that there was an obvious public interest in those supplying medication be accountable for any mistakes and that the failings on behalf of the pharmacist did not break the supply chain and render the dispenser not responsible in part for the mistake.

²⁵ An antidepressant drug (a selective serotonin re-uptake inhibitor) used to treat depressive illness, obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder or social anxiety disorder.

²⁶ A diuretic (an aldosterone antagonist) used to treat oedema and ascites in cirrhosis of the liver, malignant ascites, nephrotic syndrome, as an adjunct to treat moderate to severe heart failure and primary hyperaldosteronism.

²⁷ *Mahoney v Prestatyn Magistrates’ Court*. [2009] EWHC 3237 (Admin).

C. The Medicines Act 1968

In both the “Peppermint Water” case and the Prestatyn case, the charges which were eventually brought were done so under section 64 of the Medicines Act 1968. This section states the following within subsection 1:

No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.²⁸

However, it is important to examine the wording of this subsection of the 1968 Act with reference to the activity of pharmacists at the time the Act was written and subsection 5 provides some further clarification:

Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner, the preceding provisions of this section shall have effect as if:

(a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and

(b) in subsection (1) of this section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”.²⁹

Therefore, although subsection 1 refers to purchasers, subsection 5 clarifies that this may also include products supplied under the directions of a medical practitioner (i.e. via a prescription).

However, the supply of medication back in the 1960s and 1970s was vastly different to more recent times. Back when the act was drafted, it would have been more commonplace for the pharmacist to compound a whole array of medicinal products³⁰ in addition to supplying those manufactured elsewhere. Therefore, controls on the quality of the medicinal products being manufactured (either

²⁸ Medicines Act 1968, Section 64(1).

²⁹ Medicines Act 1968, Section 64(5).

³⁰ Termed “extemporaneous dispensing”.

commercially within pharmaceutical companies or extemporaneously by individual pharmacists) was governed by sections of the Medicines Act 1968. Clearly, if a pharmacist (as with a pharmaceutical company) manufactured a medicinal product for a patient which was of a quality deemed to be below that which would be expected, he would be in breach of section 64(1) of the Medicines Act 1968. This is clearly what happened in the “Peppermint Water” case as that was a situation whereby the trainee pharmacist (under the supervision of a qualified pharmacist) compounded a medicinal product which “*is not of the nature or quality demanded by the purchaser*”, insomuch as it contained twenty-times the required amount of chloroform. However, was this same as for the Prestatyn case? Although it could be argued that the medicinal product supplied to the patient (sertraline rather than spironolactone) was “*not of the nature or quality demanded by the purchaser*”, this was because it was completely the wrong medicinal product, rather than being the correct product albeit of a quality that rendered the product either ineffective or dangerous (or both).

So why in the Prestatyn case was the prosecution brought under the Medicines Act at all? In the “Peppermint Water” case, the original charges were ones of manslaughter; however, these were changed to charges under the Medicines Act just before going to court. Two questions arise from the Prestatyn case: (1) did the police decide that a case of manslaughter against each defendant would not succeed and if so, (2) was the case brought under the Medicines Act simply “the next best thing”?

Stephen O Doherty, writing on manslaughter, states that involuntary manslaughter is one of the hardest parts of the criminal law to define.³¹ He goes on to define unlawful act manslaughter, explaining that it requires an unlawful act (i.e. a crime), which is dangerous and leads to the death of an individual. So what is an unlawful act which could lead to a charge of involuntary manslaughter? In the 1937 case of *Andrews v DPP*³², which involved the death of an individual following the dangerous driving of a motor vehicle, it was established that the negligent performance of a lawful

³¹ Stephen O Doherty. Involuntary Manslaughter: Where To Now? *Criminal Law and Justice Weekly* 2004 168 JPN 5.

³² *Andrews v DPP*. [1937] A.C. 576.

act could not constitute unlawful act manslaughter. This would mean that in most situations, unlawful act manslaughter could not arise from a simple dispensing error (as the pharmacist is undertaking a lawful act – the dispensing of medication – and the single dispensing error would relate to a negligent performance of that legal act).

The other arm of manslaughter cases involves gross negligence manslaughter. The test for gross negligence has been laid out in *R. v Adomako*³³ and consists of four elements. Firstly, there must be the existence of a duty of care. Secondly, there needs to be a breach of this duty. Thirdly, the breach of the duty of care needs to have caused the individual's death; and finally, that the "*defendant's conduct departed from the proper standard of care incumbent upon him, involving as it must have done a risk of death... was such that it should be judged criminal*".

Based on this, could a case of manslaughter have succeeded in either the "Peppermint Water" case or the Prestatyn case? In these two cases, it is probably the "Peppermint Water" case which is the odder. The compounding of a medicinal product which contains twenty-times the amount of chloroform required could reasonably easily be argued to be contrary to section 64 of the Medicines Act 1968. Therefore, this is illegal as it is against the criminal law. Following on from this, the use of the incorrectly compounded Peppermint Water directly resulted in the death of the patient. Therefore, why was the case of manslaughter dropped? Furthermore, if it was dropped, which part of the case was deemed not to be correct? As the substituted charges related directly to offences under the Medicines Act 1968 (section 64), one would assume that it was the part relating to the death of the patient. Therefore, the additional question must be why the case was not referred to the regulator (the RPSGB) at that point?

Turning to the Prestatyn case, the process requires a little more examination. In this case, the quality of the product as such was not in question, although the supply of a different medicinal product was still illegal. However, what is interesting is that the eventual charge brought against the pharmacist

³³ *R. v. Adomako*. [1994] 99 Cr. App. R 362.

and dispenser in this case is still under section 64 of the Medicines Act. The supply of sertraline, a prescription only medicine, without the authority of a prescription from an appropriate prescriber (or under the provision of the emergency supply rules) is illegal (as although there was a prescription, it was for another medicinal product; spironolactone). However, this is covered by a different section of the Medicines Act 1968 (section 58) and not the section the charges were brought under (section 64). But what about gross negligence manslaughter as a conviction under that would not require a specifically illegal act to have been performed?

In the *Prestatyn* case, it would have been easy to have demonstrated the presence of duty of care. The pharmacist, and it could be argued the dispenser as well, owed a duty of care to her patients. Next, was there a breach of this duty in the supply of an incorrect medicinal product? Again, it would be reasonably straightforward to argue that the supply of a different medicinal product to the one requested, was a breach of this duty of care. Thirdly, did the breach of this duty of care lead to harm? This is the point where many of these cases start to require a little more questioning as it will differ from case to case as to whether the omission of the required drug and/or the addition to the patient's therapy of a new medication ultimately caused harm and then the patient's death. However, in this particular case, it is plausible to believe that an argument could be made that the supply of sertraline, a drug metabolised in the liver, and the omission of spironolactone to a patient with liver disease could be considered to have caused harm and lead to death, even if that death was inevitable but potentially less imminent. That then brings us to the fourth and final criterion for gross negligence manslaughter; was the pharmacist's and dispenser's action one which departed from the proper standard of care so as to have been one considered criminal. It is here, where the key problem with charges of gross negligence manslaughter relating to simple dispensing errors exists.

In order to examine this fourth criterion within this case, it is important to distinguish it from the "Peppermint Water" case. In that case, the medicinal product was being compounded in the

pharmacy and the problem was an insufficiency of knowledge³⁴, on both the part of the trainee pharmacist and the supervising pharmacist, about the process. It was not something they undertook routinely and as such, they should have been aware whether they were competent or otherwise to undertake the task. The very fact that it was an unusual procedure should have alerted them to the potential dangers involved in not confirming the correct steps. However, this is different from the Prestatyn case as with this case, the action itself was a simple routine task. The pharmaceutical label produced within the pharmacy was correct; it was simply attached to the incorrect packet of medication. The fact that the two drugs involved both start with the letter “s” indicates that in all likelihood, the mistake was a simple picking error, followed by a failure to identify this error at the checking stage. This latter lapse was probably caused by failures linked to the routine nature of pharmaceutical supply. Therefore, could this last series of actions be one which has departed from the proper standards of care and be considered criminal?

The problem with the classification of a simple dispensing error as a criminal departure from the proper standard of care is the fact that every dispensing pharmacist could (and in all likelihood, will) easily make the same mistake several times within their professional career. The Prestatyn case did not go as far as doing this and so this particular question was not answered here. As described above, charges were brought under section 64 of the Medicines Act 1968 and fines imposed. However had a charge of gross negligence manslaughter been made, let alone proven, it would have sent waves of concern through the pharmaceutical profession.

D. The Lee Case - Background

In 2007 a pharmacist (Elizabeth Lee), who had been registered since 31st July 2000, was working as a locum in a Tesco Stores pharmacy. As a locum pharmacist, she was not, therefore, an employee of the company. A patient, S³⁵, a 72-year old female was suffering from wheezing, inflammation and an

³⁴ Both from the perspective of the individuals’ personal compounding knowledge and the available supporting information within the pharmacy.

³⁵ Later know to be Mrs Carmel Sheller.

infection in one lung. As a result, her general practitioner had prescribed amoxicillin³⁶ (an antibiotic) and prednisolone³⁷ (a corticosteroid). The amoxicillin was correctly dispensed by the pharmacy but although the correct label for the prednisolone had been generated by the pharmacy computer labelling system, it had been incorrectly adhered to a packet containing propranolol (a beta-blocker). It was not established which staff member generated the labels for the prescription, or which staff members dispensed both the correct and incorrect items; however, Lee's initials were on the pharmacy label indicating that she, as the supervising pharmacist, had checked the medication and the label before it was passed to the patient. The patient took the medication as labelled on 30th August 2007 (a Thursday) and collapsed later that day with a blood pressure measurement of 65/62; however, after treatment, this increased quickly to 137/70. Unfortunately, on 2nd September 2007 (the following Sunday) the patient died. The pharmacy where the error took place was situated within a Tesco supermarket in Windsor. The pharmacy was open between 09:00 and 19:00 and would typically dispense around 300 items a day.

E. The Legal Process

Lee was initially charged with gross negligence manslaughter; however, when the causal link between the dispensing error and the patient's death could not be established, the following charges were brought. Firstly, a charge under section 85(5)(b) along with section 91(1) of the Medicines Act and secondly, a charge under section 64(1)³⁸ relating to the quality of the medicinal product (as with the "Peppermint Water" and Prestatyn cases). Although the section 64 charge could be considered to be following previous similar cases, the additional charge under section 85(5)(b) along with section 91(1) of the Medicines Act were new and very worrying as the outcome of a successful prosecution under section 85(5)(b) along with section 91(1) could result in a custodial sentence. Section 85(5)(b) of the Medicines Act states:

³⁶ 21 amoxicillin 500 mg capsules at a dose of one, three times a day.

³⁷ 40 prednisolone 5 mg tablets at a dose of 40 mg (i.e. eight tablets) daily.

³⁸ In conjunction with section 67(1) of the Medicines Act.

*Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.*³⁹

Furthermore, section 91(1) reads:

*Subject to sections 121 and 122 of this Act, any person who contravenes the provisions of section 85(5), section 86(3) or section 90(2) of this Act shall be guilty of an offence and liable (a) on summary conviction, to a fine not exceeding £400; (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.*⁴⁰

At the original trial at the Old Bailey on 2nd April 2008, the defence made a number of arguments on points of law, one of which included the question as to whether a pharmacist supplying medication (as in this case) satisfies the purposes of section 85(5)(b). The judge within the court (the Recorder of London, HHJ Beaumont QC) indicated that the jury could find the defendant supplied the medication for the purposes of section 85(5)(b) and upon clarification of this point, Lee pleaded guilty to count 1 of the indictment (the charge under section 85(5)(b) along with section 91(1) of the Medicines Act) in an attempt to lighten any potential sentence imposed. Based on the outcomes of similar previous cases (the “Peppermint Water” case and the Prestatyn case where the sentences imposed had been fines of around £1,000), it was expected that the outcome of pleading guilty would be a fine. However, upon pleading guilty to an offence under section 85(5), the Recorder of London sentenced Lee to three months imprisonment suspended for eighteen months with a requirement of supervision for twelve months. In addition, the judge made it clear that the sentence imposed had given full credit to the guilty plea, indicating that had Lee pleaded not guilty and been found guilty by a jury, the sentence imposed would have been much greater. Nevertheless, although the

³⁹ Medicines Act 1968, section 85(5)(b).

⁴⁰ Medicines Act 1968, section 91(1).

defendant pleaded guilty, the judge did allow leave for appeal stating that the issue concerning the scope and application of section 85(5) was sufficiently arguable.

F. The Appeal

At the appeal⁴¹, the appellant accepted that the medicinal product supplied was labelled in such a way as to mislead as to the nature or quality of the product. It was also accepted that offences under sections 85(5)(b) and 91(1) together created an offence of strict liability⁴². Therefore, the appeal centred around *“whether the defendant was capable of being a person who ‘in the course of a business carried on by her’, sold or supplied or had in her possession for the purposes of sale or supply medicinal products in a package that was likely to mislead as to the nature or quality of the product in the package”*. Therefore, it was argued that as the defendant was a locum pharmacist, she could not be held accountable under section 85(5)(b) as it is Tesco Stores and not she who is carrying on the business.

In discussing the applicability of Section 85(5)(b) to the defendant the judges examined other parts of the Medicines Act. One of the key sections discussed was section 52(1), which states:

Subject to any exemption conferred by or under this Part of this Act, on and after such day as the Ministers may by order appoint for the purposes of this section (in this Part of this Act referred to as “the appointed day”) no person shall, in the course of a business carried on by him, sell by retail, offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product which is not a medicinal product on a general sale list, unless (a) that person is, in respect of that business, a person lawfully conducting a retail pharmacy business; (b) the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy; and (c) that person, or, if the transaction is

⁴¹ *Op. Cit.*, fn 14.

⁴² A strict liability offence would mean that there does not need to be any culpability, i.e. there is no need for the proof of any *mens rea*.

*carried out on his behalf by another person, then that other person, is, or acts under the supervision of, a pharmacist.*⁴³

It was noted that in discussion of the lawful sale or supply of medicines not on the general sales list⁴⁴, section 52(1)(c) specifically distinguishes between individuals who are lawfully carrying out a retail pharmacy business and those who are acting on their behalf. Therefore based on the wording of this section of the Act, and some other similar sections, the judges came to the conclusion that the correct interpretation of section 85(5) is that it is the person (either an individual or a body corporate) who is carrying on the business, not the employed (or locum) pharmacist, who is liable for any offences under these sections. Furthermore, the judges summarised that it is sections 64(1) and 67 of the Medicines Act which are directly applicable to the person who actually supplied the incorrect medication, i.e. the appellant in this case. Therefore, the convictions relating to sections 85(5)(b) and 91 were quashed and the offence under section 64(1) substituted; for which Lee pleaded guilty. The penalty for the offence committed under section 64(1) was then set at £300.

G. The Views of the Coroner

In discussing the case of *Lee*, it is worth highlighting the views of the Coroner for Berkshire (Peter J Bedford). In addition to confirming that the dispensing error was not the cause of the patient's death, the Coroner made a number of recommendations, which he was entitled to do under the Coroners (Amendments) Rules 2008⁴⁵. He raised a number of concerns surrounding the dispensing process and in particular, what he described as *"the apparent lack of an existing system that allows clear identification of dispensed medication from the packaging"*. In addition, he reinforced the concept that the dispensing and subsequent supply of medication should ideally involve two

⁴³ Medicines Act, section 52(1).

⁴⁴ The general sales list is the list of medicines which may be sold to an individual without the need for a prescription or the supervision of a pharmacist. Medicinal products in the other two categories are referred to as Prescription Only Medicines (POMs) and Pharmacy (P) medicines.

⁴⁵ Coroners (Amendments) Rules 2008, section 43.

separate, qualified pharmacy staff members (for example, a pharmacist and a qualified pharmacy technician or dispenser).⁴⁶

H. The Role of the Pharmacy Regulator in the Lee Case

At the end of 2007, while the legal process outlined above was still ongoing, Lee came to the point where she would have needed to renew her registration with the RPSGB. At this point she declared that she was under investigation by the police and chose to transfer to the non-practising register.⁴⁷ At the end of 2008, Lee applied to come off the pharmacy register altogether; however, this request was refused and the RPSGB instigated its own investigation into her conduct. As part of the rules for regulating registrants made under section 60 of the Health Act 1990, the registration system was designed so as to prevent registrants simply resigning from the register to prevent any regulatory action being taken against them. The decision to keep Lee on the register to allow the RPSGB to undertake its own regulatory investigation was appealed against by Lee stating that it was not in the public interest for the regulator to undertake its own action as, *inter alia*, Lee has no intention to ever practise as a pharmacist again and that the punishment she had received so far from the courts was far in excess of any action the regulator could take. On the 8th May 2009 the RPSGB confirmed that it would be taking no further action and allowed Lee to retire from the register.

III. DISCUSSION

So in the future, shaped by a background rooted in the “Peppermint Water” case, the Prestatyn case and *Lee*, what will happen to pharmacists who make simple dispensing errors? For a majority of them, the error will either be identified before the erroneous product leaves the pharmacy (i.e. at some point during the checking process) or it will be detected by the patient and returned to the pharmacy for replacement (and no further action is taken). Nevertheless, there will be some which

⁴⁶ Personal communication from the Pharmacists Defence Association, 4 November 2011.

⁴⁷ At the time, the then pharmacy regulator (the RPSGB) had two registers for pharmacists. One practising register and one non-practising register whereby pharmacists could remain as members of the RPSGB (and receive all the benefits of membership) but were not undertaking work as a practising pharmacist.

go further; what is likely happen in these situations? There are three potential official routes available following-on from a simple dispensing error.

Firstly, the patient concerned could complain to the pharmacy where the error took place (in a majority of cases, this would be the company which owned the pharmacy premises where the error was made) and register a complaint. This would then be handled within the company as a civil claim and usually some form of financial compensation (including, if relevant, an amount to cover the claimant's legal fees) would be offered. Secondly, the patient could report the matter to the professional regulator (the General Pharmaceutical Council in the case of pharmacy) who could investigate as a professional matter. Either one of these options could be chosen or indeed, the patient concerned could choose to do both. There are a reasonable number of these claims made to companies every day; however, the key factor is that the patients concerned did not suffer any major harm as a result of the error. The key driver for the claim is either financial compensation and/or ensuring that the pharmacist who has made the error is reported to their regulatory body.

Thirdly, although there are a reasonable number of low-level errors, from time to time a dispensing error will result in significant harm to a patient and it is at this point that the police are likely to get involved. Should the patient die, then the police are likely to instigate an investigation to look at the potential charge of gross negligence manslaughter. This was the situation initially with both the "Peppermint Water" case and *Lee*. However, if this is not the ultimate course of action by the police⁴⁸ then often section 64(1) prosecutions follow. As outlined above, the future possibility of prosecutions under section 85(5) of the Medicines Act 1968 are no longer an option as the courts have clarified that section 85(5) only applies to retail pharmacy businesses (i.e. the pharmacy companies) and not an employee pharmacist. Nevertheless, in spite of the apparent inappropriate use of section 64(1), criminal charges under this section of the Act remain a real possibility and so this keeps simple dispensing errors as potential criminal acts.

⁴⁸ As, for example, in both the "Peppermint Water" case and in *Lee* the charges of gross negligence manslaughter were dropped and substituted for charges under the Medicines Act (under section 64(1) and (initially) 85(5) respectively).

A. Section 64 of the Medicines Act

Unfortunately for the pharmacy profession, Lee pleaded guilty to the substituted charge under section 64(1) of the Medicines Act (so as to avoid having to defend the substituted charge in a further court case) and, understandably, has no intention of appealing against this conviction (as she has no desire to pursue any further action which would result in a further court appearance). Nevertheless, this still leaves the profession with the question as to what would have happened had Lee appealed against the substituted charge under section 64. Section 64(1) of the Medicines Act 1968 states: *“No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser”*. But what does this actually mean? Can it be argued that supplying the wrong medicinal product results in a quality which is not of the required nature? This part of the Act was intended to prevent the adulteration of medicines by suppliers to maximise profits. For example, by including less than the stated amount of a potent ingredient, the supplier could incur a reduced production cost thereby increasing profit. The correct ingredient would still be present in the formulation, just in a reduced concentration. By examining this type of scenario, it can be seen that section 64 of the Medicines Act would be used to prosecute individuals who undertook this type of activity. Indeed, it could be argued that in the “Peppermint Water” case, the product did contain the correct ingredient just not in the correct concentration (in this case too much through error rather than too little through design). Therefore, a prosecution under section 64(1) could be seen as appropriate; or at least more appropriate than its use within both the Prestatyn case and *Lee*. This is because in both the Prestatyn case and in *Lee* it was the wrong product which was supplied rather than the right drug at the wrong concentration. However, in both cases it was clear that the prosecuting authorities wanted to ensure that a charge was brought and in some ways, section 64(1) of the Medicines Act was the best that there was.

B. Dispensing Errors

In order to debate further whether it is appropriate for any section of the Medicines Act to be used to prosecute simple dispensing errors (i.e. the supply of the incorrect medication which is not either deliberate or one which causes significant harm to, or the death of, a patient), it is important to understand why dispensing errors occur and what can be done to minimise their occurrence.

Dispensing errors form one part of the larger arena of medication errors. Medication errors can occur in the prescribing, dispensing or administration of medicines⁴⁹ and it has been shown that the majority of the errors will occur as a result of poor prescribing⁵⁰. Although some of the problems which existed in the medication supply process have been reduced significantly in recent times by the use of technology (for example, the selection of the wrong product for supply based on an error caused by the illegibility of the prescriber's handwriting), many still exist. The National Patient Safety Agency Report from 2004 (from the UK) and the US Institute of Medicine Report from 2000 both indicate that the majority of medication errors were not caused by the reckless behaviour of healthcare professionals and therefore have causes which are much more complex in origin.⁵¹ Work examining the errors made by prescribers during the prescribing phase of medication supply has indicated that a majority of mistakes were made because of slips in attention or because prescribers did not apply relevant rules.⁵² This would seem to correlate with a number of the contributory factors leading to at least some of the dispensing errors outlined within this paper.

If the majority of medication errors are in essence mistakes caused by slips or lapses, rather than deliberate acts in their own right, in order to take steps to reduce or eliminate them, we need to be able to study situations where errors have occurred. However, part of the problem in being able to study medication errors is that by highlighting the fact that an error has occurred, the healthcare

⁴⁹ DJP Williams. Medication Errors. *J R Coll Physicians Edinb* 2007; 37:343-346.

⁵⁰ N Barber, M Rawlins and B Dean Franklin. Reducing prescribing error: competence, control, and culture. *Qual Saf Health Care* 2003; 12:29-32.

⁵¹ *Op. Cit.*, fn 49.

⁵² B Dean, M Schachter, C Vincent and N Barber. Causes of prescribing errors in hospital inpatient: a prospective study. *The Lancet* 2002; 359:1373-1378.

professional(s) involved in the error are risking civil and/or professional action and in some cases, even the risk of criminal charges being brought. Therefore, many will remain unreported, or at least minimally reported; however, to reduce the incidence of medication error it is exactly these incidents which need to be reported and studied.

Williams discusses the issue of learning from errors by highlighting that although individuals may be reluctant to report errors, in order to create a culture of safety, errors need to be reported so that systems can be implemented to prevent them from happening again.⁵³ He goes on to outline the following approaches to reduce dispensing errors:⁵⁴

Ensuring a safe dispensing procedure.

Separating drugs with a similar name or appearance.

Keeping interruptions in the dispensing procedure to a minimum and maintaining the workload of the pharmacist at a safe and manageable level.

Awareness of high risk drugs such as potassium chloride and cytotoxic agents.

Introducing safe systematic procedures for dispensing medicines in the pharmacy.

Although initially these approaches may seem simplistic, upon further examination, it is clear that a failure within one or more of these areas led to the errors outlined above. For example, one of the causative factors for the “Peppermint Water” case was the fact that it was a high risk procedure as it involved the compounding of the medicinal product in the pharmacy. In *Lee*, one of the causative factors was related to the workload and dispensing processes within the pharmacy (the limited availability of rest time, for example).

⁵³ *Op. Cit.*, fn 49.

⁵⁴ *Op. Cit.*, fn 49.

The impact of interruptions and distractions within pharmacy has been studied and found to be linked.⁵⁵ A study from 1992 based in an ambulatory care pharmacy at a general medical-surgical hospital in the United States found that in a twenty-three day period, 164 errors were identified from a total of 5072 prescriptions (an overall error rate of 3.23%). Of the errors detected, wrong label information was the most common (80% of all the detected errors). Over the study period, a total of 2022 interruptions⁵⁶ and 2457 distractions⁵⁷ were noted and interestingly, the error rate for sets of prescriptions where there was one or more interruption or distraction rose to 6.65% and 6.55% respectively. The authors concluded by stating that within an ambulatory care pharmacy, an increase in the error rate over a half-hour period, especially errors involving incorrect labelling, were associated with interruptions and distractions. Although this study was conducted a while back (1992), it is clear that the location of the community-based dispensing process, within busy high-street pharmacies, means that pharmacy staff will be subject to interruptions and distractions throughout the day. Therefore, it is not surprising that errors do occur. Furthermore, with the development of the role of the community pharmacy into one which now provides a whole range of additional pharmaceutical services⁵⁸ it is likely that interruptions and distractions will only increase.

So in order to be able to reduce the incidence of medication supply errors caused specifically by the dispensing part of the process, it is important for individuals to report these errors. However, with the risk of potential criminal proceedings being started for offences under section 64 of the Medicines Act, it is clear that the decriminalisation of dispensing errors would, in the long-term,

⁵⁵ EA Flynn, KN Barker, JT Gibson, RE Pearson, BA Berger and LA Smith. Impact of interruptions and distractions on dispensing errors in an ambulatory care pharmacy. *American Journal of Health-System Pharmacists* 1999; 56(13):1319-1325.

⁵⁶ In this study, an interruption was defined as “the cessation of productive activity before the current prescription-filling task was completed for any externally imposed, observable or audible reason”. An interruption was not counted when workers stopped productive activity of their own volition.

⁵⁷ In this study, a distraction was defined as “a stimulus from a source external to the pharmacist that was not followed by cessation of activity but by the pharmacist continuing productive efforts while responding in a manner that was observable”.

⁵⁸ For example, smoking cessation and weight management services, Medicines Use Reviews and New Medicines Services, along with the “Ask Your Pharmacist” campaign (see <http://www.npa.co.uk/>, accessed 18 June-October 2013), to name just a few.

assist in reducing their occurrence rather than sending the signal that it is less of a problem if these occurrences happen.

C. The Decriminalisation of Dispensing Errors

If, as described above, Lee's conviction under section 64(1) of the Medicines Act had been successfully appealed then this would have meant that future dispensing errors could no longer be pursued as a section 64 offence. As all previous similar cases involved charges under section 64, this would potentially have had the effect of decriminalising dispensing errors. However, ~~there are other sections of the Medicines Act which could potentially be used to prosecute a pharmacist who makes a simple dispensing error (i.e. one which doesn't result in the death of the patient or the patient suffering any significant harm) and so even an appeal against a section 64(1) conviction for a simple dispensing error may not have had the effect that that many members of the profession and professional representative organisations such as the Pharmacists' Defence Association (PDA) have been campaigning for.~~

The key question which needs answering before any decriminalisation of simple dispensing errors could take place is whether the decriminalisation ~~of dispensing errors~~ would poses a risk to patients and the public. Dispensing errors which were potentially avoidable and result in the death of the patient can still be pursued as offences of gross negligence manslaughter. As outlined in above, no prosecution based on a simple dispensing error has gone this far yet and so successful prosecutions leading to convictions of gross negligence manslaughter are still a real possibility. Any proposals to decriminalise dispensing errors would not change this. However, whether a simple dispensing error results in the death of the patient or has no real adverse effect is in most cases, simply down to fortune. Whether the patient suffers harm or ultimately death is often down to which wrong product was selected, who it was mistakenly given to and how much the patient took before realising there was an error. In most cases, the answer to all of these points is simply a matter of luck. As outlined in the previous section, in almost all cases where the wrong medication is given to a

patient, the pharmacist (and assisting staff) does not intend to harm the patient. Therefore, the outcome of the error and the effect on the pharmacist (and assisting staff) is largely down to chance, and civil actions for compensation and effective regulation via the pharmacy regulator would seem to be appropriate available courses of action. The pharmacy regulator (The GPhC and previously, the RPSGB) has been effective in its regulation of registrants and that the courts have stated that the degree to which an individual has transgressed the acceptable professional standards is a matter for the professional regulator to decide. Furthermore, the removal of the risk of criminal charges being brought following a simple dispensing error would also remove one of the key barriers experienced by pharmacists in reporting errors and enabling others to learn from the error made to prevent any reoccurrence.

As discussed previously, Lee successfully appealed her conviction under section 85(5) of the Medicines Act and accepted the substituted charge under section 64(1). Not to have accepted it, or appealing further against the substituted charge would have resulted in further court appearances. Understandably for Lee, this was a step too far and so she accepted the fine imposed for the substituted charge under section 64(1). However, this was probably the best chance that there had been to clarify this section of the Act in the courts. Previous cases (the “Peppermint Water” case and the Prestatyn case) had all involved employee pharmacists and so the individuals involved were likely to have been encouraged by the employing companies to plead guilty to section 64 charges. As has now been clarified, charges under section 85(5) can only be brought against a pharmacy organisation rather than an individual pharmacist (or other member of pharmacy support staff) and so (albeit that the “Peppermint Water” case and the Prestatyn case took place before *Lee* and the clarification of section 85(5) of the Medicines Act), it was better for the employing pharmacy organisations for their employees to be prosecuted under section 64(1) than to risk any potential action to be taken against the company. However, *Lee* involved a locum pharmacist and so the link between the pharmacy company and the pharmacist, which was present in the other cases, didn’t exist. Representatives from the PDA, who were involved in the appeal of the prosecution under

section 85(5) believe that had they gone back to the Court of Appeal and challenged the substituted charge, they would have been successful.⁵⁹

Furthermore, there is an indication from the appeal hearing that if it hadn't been for unfortunate timing, the appeal judges may have made a judgement on the applicability of section 64(1) prosecutions. At the appeal hearing for the section 85(5) conviction, the defence made reference to soon to be published CPS guidance to prosecutors with regard to dispensing errors.⁶⁰ The guidance refers to both section 64(1) and section 85(5). The decision making process outlined in the guidance states the following:

When applying the public interest factors in the Code, prosecutors should consider the following points:

- 1. The culpability of those involved in the dispensing error; for example, was it simply an error or is there evidence of recklessness or intent?*
- 2. The seriousness of the dispensing error; for example, were the drugs particularly dangerous or poisonous in themselves, requiring very careful handling and additional checks to be in place, or was the dosage dispensed substantially greater than that prescribed or substantially beyond the usual treatment range?*
- 3. The consequences of the dispensing error; for example, did it lead to death or moderate or severe harm, or did it have the potential to do so (without, for example, the intervention of another person)?*
- 4. The actions of the pharmacist, pharmacy technician or any other person following the incident; did he or she report the incident and co-operate with the investigation or was there a failure to record or report the error, or evidence that it was concealed?*

⁵⁹ Substantial progress made as a result of the Elizabeth Lee appeal. Insight, the magazine of the Pharmacists' Defence Association (Community Edition), Summer 2010, 8-9.

⁶⁰ The Crown Prosecution Service. Medicines Act 1968. See http://www.cps.gov.uk/legal/l_to_o/medicines_act_1968 (accessed 13-18 June-October 2013).

5. *Is there evidence that the pharmacist, pharmacy technician or any other person has made other dispensing errors?*
6. *Has regulatory or remedial action been taken in respect of the pharmacist, pharmacy technician or any other person, or is it likely to be taken?*

Had the judges accepted that the code was about to be implemented, it was quite likely that the offence under section 64(1) would not have been substituted. However, the Crown Prosecution Service lawyers stated that the publication of the guidance was not imminent as the various parties working on the guidance had reached an impasse.⁶¹ In fact, the guidance was actually published on the 21st June 2010, which was only 26 days after the hearing in the Court of Appeal.⁶²

Since *Lee*, the PDA has been campaigning further for changes to the Medicines Act to be made to decriminalise dispensing errors. In 2011, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a consultation on changes to the 1968 Medicines Act and other medicines legislation and on 14 August 2012, the Human Medicines Regulations⁶³ came into force, under the Health and Social Care Act 2012. The purpose of the new Regulations was to consolidate the provisions of the Medicines Act 1968, over two hundred statutory instruments and a number of EU directives into one piece of secondary legislation. The Regulations have resulted in sections of the Medicines Act 1968 being repealed, however the Act remains partially because it provides the necessary powers for some other important secondary legislation. Nevertheless, this process has not repealed or altered either section 64 or section 85 of the Medicines Act 1968, which remain in force. Although there was considerable debate about this topic during consultations on the new Regulations, the MHRA decided that they did not have sufficient powers under current legislation to make major changes.

⁶¹ *Op. Cit.*, fn 59.

⁶² The long awaited CPS Guidance. *Insight*, the magazine of the Pharmacists' Defence Association (Community Edition), Summer 2010, 10-11.

⁶³ Human Medicines Regulations 2012.

IV. CONCLUSIONS

By the very nature of the work undertaken by pharmacists, the profession of pharmacy is one which carries with it the risk of causing unintentional harm to patients. Pharmaceutical products are by their very design, powerful and potent items and if administered incorrectly, have the potential to harm or kill patients. Therefore, pharmacists and pharmacy support staff are taught how to manage these risks and how to conduct themselves in a professional manner both whilst working as a healthcare professional and in their personal life.

The role of pharmacy regulation falls to the General Pharmaceutical Council (GPhC) and prior to that, the Royal Pharmaceutical Society of Great Britain (RPSGB). A review of cases has indicated that there are some cases whereby pharmacists and support staff have been prosecuted under the Medicines Act 1968 for dispensing errors which could have been dealt with much better by the pharmacy regulator. Examining the chain of cases heard in court over time, it would initially appear that although the potential seriousness of the conduct within the cases has decreased, the penalties being imposed by the legal system had increased. The “Peppermint Water” case involved the direct death of the patient through a failure of the dispensing system, but only resulted in fines under section 64(1). However *Lee*, a simple dispensing error which at most caused some harm to the patient (but, crucially, not the death of the patient), resulted initially in a (suspended) custodial sentence under section 85(5). The appeal of the conviction under section 85(5) resulted in a substituted charge under section 64(1). Therefore, as this substituted charge wasn’t appealed, convictions under section 64(1) are still a real possibility.

Following-on from *Lee*, the Crown Prosecution Service issued guidance to prosecutors on the prosecutions following dispensing errors. Therefore, this should go some way to ensuring that a standardised approach is followed by prosecutors. With an estimated three dispensing errors per pharmacy per week⁶⁴, there is a real chance that a case like *Lee* could happen again fairly soon.

⁶⁴ *Op. Cit.*, fn 62.

However, it is now not possible for charges to be made against individuals under section 85(5) and so although section 64(1) charges could still currently be brought, the risk to the pharmacist (or pharmacy support staff member) is reduced.

The introduction of the Human Medicines Regulations 2012 has not had an effect on either section 64 or section 85 of the Medicines Act 1968, as both sections still remain in force. Although there was considerable debate about this topic during consultations on the new regulations, the MHRA decided that they did not have sufficient powers under current legislation to make major changes.

Ideally, simple dispensing errors which are not being pursued by prosecutors as offences such as gross negligence manslaughter, should be referred to the profession's regulator for action. The decriminalisation of dispensing errors would result in this situation and remove the potentially arbitrary prosecutions brought under section 64(1). In addition, the removal of the threat of criminal charges following a simple dispensing error will facilitate the reporting of dispensing errors and enable the profession to learn from any errors which do occur. This knowledge can then be used to assist in preventing any future occurrence of that particular error.

Looking to the future, the balance of medicines legislation and statutory independent professional regulation and consistency with other health professionals is being examined as part of the UK Chief Pharmaceutical Officers' "Rebalancing Review".⁶⁵ However, the absence of any alteration to sections 64 and 85 in the recent review of the Medicines Act 1968 means that the decriminalisation of dispensing errors, and the associated benefits in assisting in reducing future dispensing errors, still remains a way off.

⁶⁵ See: <https://www.gov.uk/government/news/statement-on-medicines-and-pharmacy-regulation-from-the-uk-chief-pharmaceutical-officers-published#C4> (accessed 13-18 June-October 2013).