University of East Anglia

The changing landscape of UK pharmacy law in the early 21st century and its effect on the moral agency of pharmacists

Doctor of Philosophy
Norwich Medical School

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December 2019

Contents

Abstract

This thesis draws together a series of publications based on work carried out between 2008 and 2018, which examines various aspects of pharmacy regulation as it is reformed in response to changing perspectives on healthcare.

The regulated activities of pharmacy include supply of medicines, handling of controlled substances, and maintenance of registration with the General Pharmaceutical Council. The legal underpinnings of each of these activities has undergone significant change in the last ten years. Failing to stay abreast of changes to pharmacy law, or to understanding how these changes affect their practice, can leave pharmacists open to criminal prosecution, civil actions, and fitness to practise proceedings.

This regulatory environment can create the potential for moral distress to occur as practitioners are prevented from acting in congruence with their own moral agency.

The submission includes thirteen pieces of work discussed under four headings: the three legally regulated activities mentioned above; and a fourth category dealing with moral considerations raised with respect to conscientious objection and moral distress. Initial analysis of the changing legal landscape identifies possible triggers for moral distress, which are subsequently factored into the development of a tool to measure this phenomenon in community pharmacists.

The earlier publications included in this thesis have had a significant impact on several aspects of pharmacy regulation, while informing the direction of the later work, which seeks to provide an insight into the incidence of moral distress experienced by community pharmacists and provide researchers with a set of tools with which to extend the scope of the literature in this area.

Abbreviations

CD	Controlled drug
CPD	Continuing professional development
ECJ	European Court of Justice
EEA	European Economic Area
EHC	Emergency hormonal contraception
FtP	Fitness to practise
FtPC	Fitness to Practise Committee
GP	General practitioner
GPhC	General Pharmaceutical Council
HMRs	Human Medicines Regulations 2012
LRO	Legislative Reform Order
MDA	Misuse of Drugs Act 1971
MDRs	Misuse of Drugs Regulations 2001
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NPA	National Pharmacy Association
PJ	The Pharmaceutical Journal
RCSI	Royal College of Surgeons in Ireland
REF	Research Excellence Framework
RPS	Royal Pharmaceutical Society
RPSGB	Royal Pharmaceutical Society of Great Britain
SI	Statutory instrument

Acknowledgements

I would like to thank Jennifer Whitty for agreeing to sponsor this submission and for her useful feedback during its preparation. I am grateful to the Department of Clinical and Pharmaceutical Sciences at the University of Hertfordshire, and particularly to Stewart Kirton, for financial assistance.

Publication list

A. **Gallagher, C.T.** and O'Neill, R.C. (2008). Birth of the parallel medicines trade. *The Pharmaceutical Journal:* **280**; 364-367.

B. **Gallagher, C.T.** and O'Neill, R.C. (2008). Recent challenges to parallel trade. *The Pharmaceutical Journal:* **280**; 510-512.

C. **Gallagher, C.T.** and O'Neill, R.C. (2008). Negotiating the parallel imports rules. *The Pharmaceutical Journal:* **280**; 659-661.

D. Hickman, A.C. and **Gallagher, C.T.** (2009). Misuse of drugs legislation and its effect on pharmacists since 2004. *Nottingham Law Journal:* **18(2)**; 1-9.

E. **Gallagher, C.T.**, Hickman, A.C., Hannbeck, L. and Flynn, R.W. (2012). Analysis of enquiries to the National Pharmacy Association following major changes to controlled drug legislation in the UK. *International Journal of Pharmacy Practice:* **20(1)**; 50-56.

F. **Gallagher, C.T.** (2013). Human medicines: the licensing system. *In:* G. E. Applebe & J. Wingfield (Eds.), *Dale and Appelbe's Pharmacy and Medicines Law,* (10th ed.); 39-60. London: Pharmaceutical Press.

G. **Gallagher, C.T.** (2013). Controlled drugs. *In:* G. E. Applebe & J. Wingfield (Eds.), *Dale and Appelbe's Pharmacy and Medicines Law,* (10th ed.); 207-244. London: Pharmaceutical Press.

H. **Gallagher, C.T.**, Holton, A., McDonald, L.J. and Gallagher, P.J. (2013). The fox and the grapes: an Anglo-Irish perspective on conscientious objection to the supply of emergency hormonal contraception without prescription. *Journal of Medical Ethics:* **39(10)**; 638-642.

I. **Gallagher, C.T.**, Greenland, V.A.M. and Hickman, A.C. (2015). Eram, ergo sum? A one-year retrospective study of General Pharmaceutical Council fitness to practise hearings. *International Journal of Pharmacy Practice:* **23(3)**; 205-211.

J. Astbury, J.L., **Gallagher, C.T.** and O'Neill, R.C. (2015). The issue of moral distress in community pharmacy practice: background and research agenda. *International Journal of Pharmacy Practice:* **23(5)**; 361-366.

K. Astbury, J.L., and **Gallagher, C.T.** (2017). Development and evaluation of a moral distress scale for community pharmacists in the UK. *International Journal of Clinical Pharmacy:* **39(1)**; 156-164.

L. **Gallagher, C.T.** Mukhtar, F., Sarfaraz, T. and Chaar, B. (2019). Fit to practise? Processes for dealing with misconduct among pharmacists in Australia, Canada, the UK and US. *Research in Social and Administrative Pharmacy:* **15(10)**; 1195-1203.

M. Astbury, J.L. and **Gallagher, C.T.** (2020). Moral distress among community pharmacists in the United Kingdom: causes and achievable remedies. *Research in Social and Administrative Pharmacy:* **16(3)**; 321-328.

(The papers have been listed in order of publication, as is the norm for submissions of this type. As the narrative structure of the commentary is better served by referencing the publications out of order, this approach has been taken. References to the publications within the text are highlighted in bold type to assist the reader.)

Introduction

This submission describes a selection of publications, each of which contemporaneously addresses a significant change in an aspect of pharmacy law, and critically examines the effect that these changes have on the working practices of pharmacy professionals. The consequences of specific aspects of pharmacy law on the moral agency of pharmacists are then examined in the context of moral distress.

Moral distress was first described as the feeling that arose "when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action".[1](p.6) This definition has undergone numerous refinements by subsequent authors and has broadened in scope to incorporate experiences of moral anguish that arise in response to the inability to enact moral judgements due to a broad range of constraints, including legal requirements, professional regulations, insufficient resources, and personal limitations. It may be thought of as resulting from a barrier an individual's ability to make moral judgments based on some notion of right and wrong, or their "moral agency".

Initially, research focused predominately on the experience of nurses due, in part, to the historical perception of nursing as subordinate to other disciplines within the medical hierarchy, and therefore the most likely to experience distress as a result of the restrictions imposed by others.[2] As the conceptual boundaries of moral distress have developed, so too has the research interest in the experiences of other professional groups. While moral distress was initially delineated within nursing, the concept is relevant across other professional healthcare groups. Each occupation carries its own professional regulations, legal requirements, perception of clinical goals, and relational position with allied disciplines to be balanced against the individual practitioner's moral framework.[3] Moral distress

has been reported by various diverse healthcare disciplines, including psychiatrists, podiatrists, psychologists, and physiotherapists.[4-9]

Whilst it has historically received limited consideration in bioethical discourse, there is an emerging recognition that pharmacy is a value-based profession with a strong ethical grounding.[10] In the past several decades, the pharmacy profession has sought to become more patient-focused, and to embrace an expanded role that shares responsibility for optimal drug-therapy outcomes. Pharmacists play an active and influential role in patient care, and are required to make clinical and ethical decisions regarding safe access to medicines and treatment. As pharmacists expand their roles, there are significantly more opportunities for ethical and moral problems to arise. Additionally, the commercial nature of community pharmacy can also present additional conflicts of interest that pharmacists must continue to address and resolve. These factors may be compounded by the fact that community pharmacists are generally more isolated from support networks than their hospital-based colleagues.

Pharmacists working in the UK operate within a highly regulated occupational sphere and are bound by strict legal frameworks and codes of professional conduct. The extent of legal regulation of pharmacists compared to other healthcare professionals is marked: for example, a single error in the dispensing of medicines may be considered a criminal offence under s.64(1) of the Medicines Act 1968. The law governing pharmacy practice dictates a complex array of professional duties and obligations that pharmacists must adhere to in the course of their work. Pharmacists that contravene the regulatory requirements risk removal from the Register of Pharmacists and loss of their right to practice.

Pharmacy represents the third-largest regulated healthcare profession, with approximately 66,000 pharmacists currently registered to practice within the UK.[11] Although pharmacists roles have developed in recent years to encompass fields including

primary care and public health,[12] the profession has traditionally operated within three areas: community; hospital; and the pharmaceutical industry. The community pharmacy sector incorporates over 11,700 pharmacies and employs approximately 71% of the pharmacy workforce.[13] Over one billion prescriptions are dispensed from community pharmacies each year.[13] Community pharmacists are often the first – and at times only – point of contact for members of the public seeking advice and support with regards to their health and wellbeing. Consequently, pharmacists practicing within this sector play a crucial role in the provision of clinical services, the delivery of public health initiatives, and the reduction of health inequalities.

The regulated activities of pharmacy may be broadly categorised into three areas, namely:

1. Licensing, sale, supply and administration of medicines;
2. Handling of controlled substances that have medical uses; and
3. Obtaining and retaining registration with the General Pharmaceutical Council (GPhC).

These activities are governed by three discrete sets of regulations, each of which has undergone significant change in the past decade. The licensing, sale, etc. of medicines for human use is controlled by the Human Medicines Regulations 2012 (HMRs),[14] and – to a lesser extent – the Medicines Act 1968.[15] Control over access to controlled drugs (CDs) falls under the terms of the Misuse of Drugs Act 1971 and associated regulations, primarily the Misuse of Drugs Regulations 2001.[16, 17] Finally, the regulation of the profession of pharmacy has, since 2010, been the remit of the GPhC, using powers imparted by the Pharmacy Order 2010,[18] and associated rules and guidance.[19-21]

Neglecting to stay abreast of the manifold changes to pharmacy law or failing to understand how these changes affect the various restrictions placed on their practice, can leave pharmacists open to

criminal prosecution, civil actions, and fitness to practise proceedings overseen by the GPhC.

As the legal frameworks and codes of professional conduct guiding pharmacists have been revised, so has the pharmacy profession sought to become more patient-focused and to embrace an expanded role that shares responsibility for optimal patient outcomes. Pharmacy is increasingly recognised as a value-based profession with a strong ethical grounding. A strict regulatory environment creates the potential for moral distress to occur due to the limitations it places on practitioners' ability to act congruence with their own moral judgements.

For example, pharmacists are permitted to supply diamorphine hydrochloride (heroin) to drug addicts provided that certain strict legal criteria are met (**Chapter G**). Making a supply other than under these criteria constitutes a criminal offence that can have potentially career-ending consequences. The treatment of addiction involves teams of healthcare professionals including case-workers, psychiatrists, and community pharmacists, often working in disparate locations. Errors can – and do – occur, putting the pharmacist in the position of making an unlawful supply in the best interest of the patient, or acting lawfully and placing the patient at risk of relapse.

Even the most mundane aspects of medicines law can indirectly lead to situations in which pharmacists must balance the best interests of individual patients with those of the wider public. Parallel trade allows medicines to be procured from European markets at a fraction of the cost of those available from UK wholesalers (**Papers A-C**; **Chapter F**). No major ethical issues are raised by parallel imports in themselves as these products identical to those obtainable through the UK supply chain and provide significant cost savings to the NHS.[1, 2] However, patient autonomy may come into opposition with the commercial pressures inherent in servicing an NHS pharmacy contract (**Fig. 1**). Although the medicines themselves may be

identical, the packaging – which typically involves attaching English-language labels onto the manufacturer's packaging – identifies these products as foreign in origin. Where a patient incorrectly perceives these products as inferior and insists upon the UK variant of their medicine, the pharmacist may find themselves forced to yield to the patient at a cost to their own personal autonomy.

Commentary

Overview

The publications in the following commentary are discussed under four headings, namely: the three legally regulated areas of pharmacy practice outlined above; and a fourth category dealing with moral considerations raised with respect to conscientious objection and moral distress.

I have tried to be mindful of the University's regulations, which outline specific requirements for the award of a PhD by Publication.[22] The publications submitted demonstrate "ability in conducting original investigations" using a range of methodologies employed over the course of the ten-year period during which this work was undertaken.[22](para. 5.1) The body of work includes a significant amount of both doctrinal and empirical legal research, each with their own set of methods and outcomes.

Doctrinal legal research deals with verifying existing knowledge on legal issues, and typically involves studying existing laws, related cases and authoritative materials analytically. In contrast to literature review, content analysis or historical legal research, doctrinal research studies legal propositions based on secondary data of authorities such as statutory materials, court decisions, and guidance documents.

The major purposes of doctrinal legal research include the following:

- to propose new laws, to test them, and add new knowledge to legal scholarship;
- to help maintain continuity, consistency and certainty of law; and
- to advise clients about the application of the law in specific cases,[23]

each of which are in evidence in **Papers A**-**D** and **H.**

The aim of empirical legal research, in contrast, is to investigate the role of regulations at play in society by empirical means. In the case of **Paper E**, quantitative methods are employed to determine how well pharmacists coped with legislative changes directly affecting pharmacy.

Statistical methods employed in the course of this research included Poisson regression (**Paper E**),[24](pp. 740-752) and Pearson's X^2 test (**Paper I**).[25] Additionally, sampling adequacy was verified in **Paper K** using the Kaiser-Meyer-Olkin method, and Bartlett's test and parallel analysis methods were used during the principle component analysis.[26, 27]

In developing a tool to measure moral distress, a three-phase exploratory sequential mixed method design was employed.[28] An initial qualitative phase was followed by quantitative data collection and analysis (**Paper K**), with a final phase integrating the data from the two separate strands (**Paper M**). Initial data collection involved the convening of three semi-structured focus groups. Themes were derived by open coding, grouping and categorising of these data. Thirteen items were generated, which were subjected to content validity and reliability testing before undergoing principle component analysis and construct validity testing.

Papers A-**E**, and **H**-**L**, represent a "significant and coherent contribution to the development of knowledge", as defined by UEA

regulations,[22](para. 5.1) both as discrete works, and through their contribution to the development of an instrument to measure moral distress among community pharmacists (**Papers J**, **L** and **M**) (**Fig. 1**).

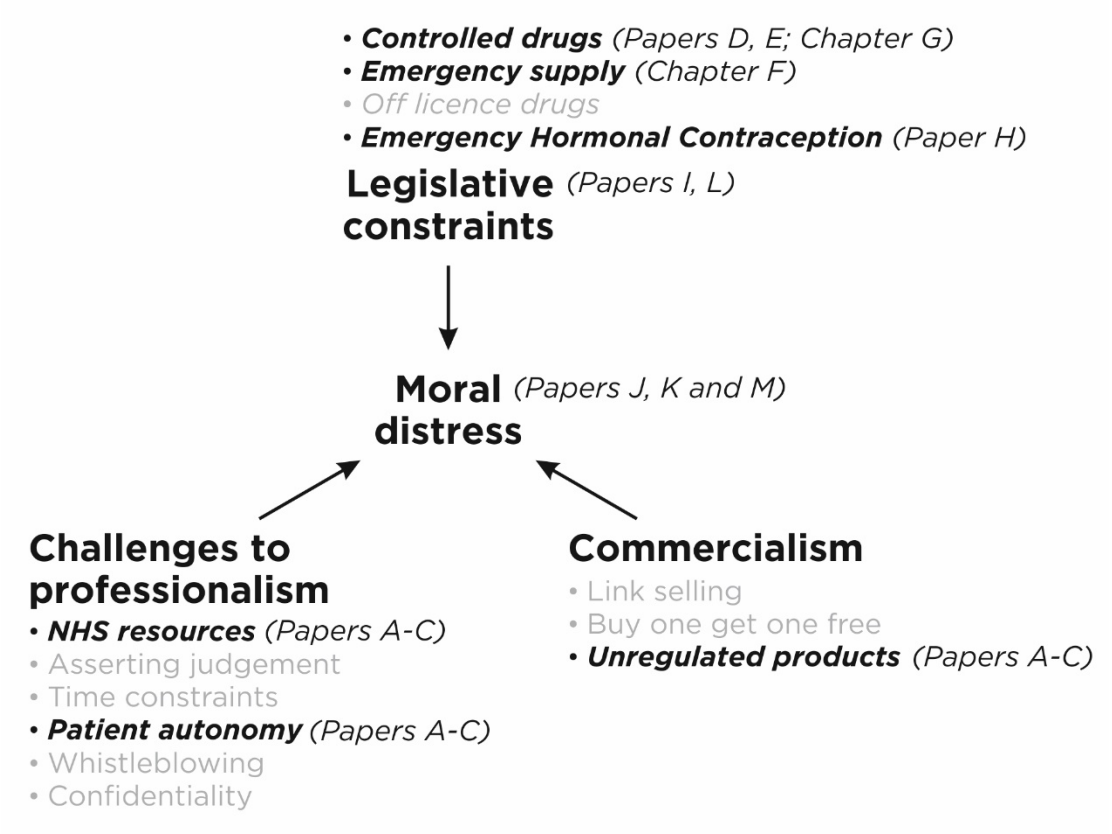

Fig. 1: Flow chart (modified from **Paper K**) outlining how concepts examined in earlier papers were identified as triggers for moral distress, as determined in **Papers J**, **K** and **M**.

Licensing, etc. of medicines

Human Medicines Regulations 2012

EU Council Directives on the licensing of medicines were first entered into UK law by the Medicines Act 1968,[15] which enabled approximately 200 Statutory Instruments (SIs) to be created over the course of the next 44 years. These regulations provided for the various types of licenses required by pharmaceutical manufacturers, as well as for the sale, supply, administration, import, and export of

medicines for use in humans and animals. In August 2012, during the period in which I was preparing **Chapter F** for publication, the HMRs came into force, with the twin aims of bringing the existing legislation into one set of regulations and simplifying the way these provisions were drafted. They set out a comprehensive regime for the authorisation of products; for the distribution of those products; for their labelling and advertising; and for pharmacovigilance.

There are 17 parts of the HMRs as originally enacted, containing 349 regulations, followed by 35 schedules.

Parts 1 and 2 consolidate, with only minor and drafting amendments, the administrative provisions in Part 1 of the Medicines Act 1968

Parts 3 to 9 govern the manufacture and importation of, and wholesale dealing in, medicinal products. After Part 4 establishes that products must not be sold, supplied, or offered for sale or supply in the United Kingdom unless authorised, Parts 5 to 8 provide for the procedures for authorisation by the United Kingdom licensing authority of medicinal products in various categories, namely: allopathic medicines (Part 5); homeopathic medicines (Part 6); traditional herbal medicines (Part 7); and unlicensed medicines required for public health reasons (Part 8). Additionally, these parts of the HMRs consolidate the corresponding parts of the 1968 Act with regulations affecting the licensing process.[29-31]

Part 10 outlines various exemptions from the provisions outlined in Parts 4 to 8, many of which apply to pharmacists and persons conducting a retail pharmacy business.

It is these parts (4-8, 10), accounting for more than one quarter of the 322 pages of the HMRs that are explained and evaluated in **Chapter F**.

Parallel imports

The body of work submitted in support of this application begins with three publications (**Papers A-C**), which together constitute a detailed examination of the legal underpinnings of trade in legitimately produced medicinal products sourced in parallel to the established supply chain.

Unlike the licensing of medicines by the owner of the intellectual property rights, which have been regulated by statute since the enactment of the Medicines Act on 25th October 1968, the bringing to the market of parallel imports has its origins in common law. The historical context of this was the subject of **Paper A**.

The interpretation by the Court of Justice (ECJ) of provisions within the Treaty of Rome which prohibit "quantitative restrictions on imports and all measures having equivalent effect … between Member States",[32](Arts. 30-34) and how these must be balanced against prohibitions justified on "grounds of the protection of health and life of humans",[32](Art. 36) were the starting point for the legalisation of the parallel trade in medicines.[33]

Following this judgement, the European Commission produced a text outlining the basic principles for an abbreviated form of an MA for parallel-traded medicines.[34] Various stakeholders petitioned the ECJ with regard to specific definitions within this text, including "manufacture under license" and "the same group of companies".[35, 36] At the time of writing of this paper, an administrative document issued by the Department of Health was the only guidance available to those wishing to import medicines licensed elsewhere in the European Economic Area (EEA) into the UK. In the absence of any statutory provision for this legitimate activity, **Paper C** examined the pitfalls common to applications for a parallel import license and with supplying parallel imports to UK-based patients. Careful consideration was given to the additional legal challenges – this time

in reference to trademark infringement and market restrictions – that were brought by major pharmaceutical companies seeking to thwart parallel trade by other means.[37, 38] A critical analysis of these challenges was undertaken in **Paper B**.

Provisions in relation to parallel import licences were omitted from Part 5 of the HMRs, and so the information in **Papers A**-**C** remained current after the reform of medicines law in 2012. It was initially unclear how the HMRs would apply to parallel import licences, if at all. Consequently, conditions and requirements essential for patient safety were omitted from the regulations and it was not clear, for example, if there was a power to vary suspend or revoke parallel import licences. In 2014, the Medicines and Healthcare products Regulatory Agency (MHRA) rectified this position so that the conditions and requirements in relation to such licences are now clearly set out in the Regulations.[39] As a result, **Papers A**-**C** now serve mainly as a historical record of the common law regulation of parallel imports.

Controlled drugs

Misuse of Drugs Regulations 2001

Prior to 2004, the legislation relating to controlled drugs had barely changed in 20 years, since the introduction of the Misuse of Drugs Regulations 1985.[40] A large number of significant changes introduced from 2004 to 2007 were precipitated by the actions of Harold Shipman, who was convicted on 31 January 2000 of the murder of 15 of his patients while he was a General Practitioner in Hyde, near Manchester. He was sentenced to life imprisonment. In September 2000, the Secretary of State for Health, Alan Milburn MP, announced that an independent public inquiry would be held under the terms of the Tribunals of Inquiry (Evidence) Act 1921 to establish what changes to current systems of healthcare regulation should be made in order to safeguard patients in the future.

Dame Janet Smith, a High Court judge, was appointed Chairman of The Shipman Inquiry, the work of which began in February 2001. The inquiry's first report, published on 19 July 2002, found that, over a period of more than 20 years, Harold Shipman had secretly obtained very large quantities of diamorphine and subsequently used it to kill many of his patients.[41] Despite the regulatory controls in place, Shipman's diversion of diamorphine went undetected. When it did eventually come to light, it was not because his unlawful acquisition of the drug had been detected, but because he had come under suspicion of murdering Mrs Kathleen Grundy. The report made apparent that the regulatory framework governing the use of controlled drugs had not operated as it should. The purpose of regulation, according to the report, is to ensure accountability for the use of controlled drugs to avoid their diversion to improper use, and to detect such diversion if it occurs.

Recommendations on the following issues were made:

1. prescribing controlled drugs and prescriptions for controlled drugs;
2. arrangements for security and record keeping for controlled drugs in doctors' surgeries;
3. arrangements for security and record keeping for controlled drugs in community pharmacies;
4. computerised record keeping;
5. inspection and monitoring of community pharmacies and surgeries;
6. collection and delivery of controlled drugs in the community;
7. controlled drugs in the community and record keeping; and
8. administration, return, and destruction of controlled drugs in the community.[42](Chapter 14; para. 14.1)

It is noteworthy that six of these eight issues lead to recommendations to tighten the controls on the handling of CDs within pharmacies, though Shipman himself was a general

practitioner (GP), not a pharmacist. At the same time, the UK Government was pursuing a policy of widening the roles of many non-medical health care professionals to include prescribing rights. The years 2004 to 2007, therefore, saw a series of legislative changes affecting community pharmacists in their routine work (**Paper D**). The effect of these changes on the practice of pharmacy was examined by retrospectively analysing enquiries to the National Pharmacy Association (NPA) (**Paper E**).

Following the publication of **Papers A**-**E** , I was invited to contribute two chapters (**F** and **G**) to the 10th edition of Dale and Appelbe's Pharmacy and Medicines Law, which was moving from a co-authored to an edited volume owing to the retirement of the authors. As outlined above, **Chapter G** examined a topic that had undergone significant change since the 9th edition was published four years previously. As I have already described, the law regulating the licensing of medicines (the subject of **Chapter F**) was repealed in 2012. As such, both chapters had to be completely rewritten with reference to the new law in force.

General Pharmaceutical Council

Pharmacy Order 2010

In addition to being subject to legal regulations regarding the handling of medicines and controlled drugs, pharmacists are also directed by guidance and standards published by the General Pharmaceutical Council.

The GPhC is the body responsible the regulation of pharmacists, pharmacy technicians, and pharmacy premises in England, Scotland and Wales. It was created – along with the Royal Pharmaceutical Society (RPS) – from the Royal Pharmaceutical Society of Great Britain (RPSGB) in October 2010, in response to a government White Paper on the regulation of health professionals.[43] At that time, the

RPSGB acted as both the regulator for pharmacy, and also as the representative body responsible for leading the profession. The primary goal of the split was so that representative and regulatory functions of the pharmacy profession could be separated.[43](paras. 1.29-1.36)

The main objective of the GPhC is to protect, promote and maintain the health, safety and well-being of members of the public who use or need the services of registrants. To that end, the Council is empowered by the Pharmacy Order 2010 to ensure that registrants adhere to such standards as it considers necessary for the safe and effective practice of pharmacy.[18](art. 5(1)) These standards initially took the form of a series of guidance documents, which were published in 2010, covering areas including: education and training; pharmacy premises; and continuing professional development (CPD).[44-46] Also included in this collection of guidance documents was the GPhC's *Standards of conduct, ethics and performance*.[47]

These standards largely adopted the wording of the *Code of Ethics for Pharmacists and Pharmacy Technicians* developed by the RPSGB,[48] and were updated in 2012,[49] before being superseded by the current *Standards for Pharmacy Professionals* in May 2017.[50] The GPhC consider these standards a statement of what the public expect from pharmacy professionals, and reflective of what pharmacy professionals expect of themselves and their colleagues. Pharmacy professionals are expected to consider these standards, their legal duties, and any relevant guidance when making decisions related to their practice. Every registered pharmacist is personally accountable for meeting the standards and must be able to justify the decisions they make.

Fitness to practise

The Council has a statutory responsibility to ensure the continuing fitness to practise (FtP) of its registrants under art.4(3)(a) of the

Pharmacy Order 2010.[18] A registrant's FtP may be impaired by reason of, for example, deficient professional performance, a criminal conviction, or failure to maintain standards set by the GPhC.[18](art.51(1)) Under the Fitness to Practise Rules, the GPhC may take action to restrict pharmacists' ability to practise when this is necessary to protect patients and the public.[19] This is achieved through the conduit of the Fitness to Practise Committee (FtPC).

If a pharmacist is referred to the FtPC, there will usually be a public hearing.[51, 52] The hearing is an adversarial process during which witnesses, including the registrant, may be examined and cross-examined. If the committee concludes that the pharmacist's fitness to practise is impaired, it may impose a sanction, up to and including removal of the pharmacist's name from the Register of Pharmacists. Once the committee has made a decision, it makes a formal statement announcing its decision and explaining the reasons for it. These decisions are published online by the GPhC.

Additionally, if, at any point during an investigation, the Registrar of the GPhC is satisfied that it is necessary for the protection of members of the public, or is otherwise in the public interest, he may direct the FtPC to suspend a pharmacist's registration by issuing an interim order.[18](art. 56)(1)) The committee has the authority to impose an order for up to 18 months, subject to a review every 6 months that the order is in force.

Consequences to pharmacists for failing to meet legal requirements or to adhere GPhC standards can be severe. It is, therefore, of interest to know how the GPhC interpret these standards when assessing a registrant's fitness to practise. **Papers I** and **L** are both concerned with the functioning of the GPhC's Fitness to Practise Committee. The former examines whether circumstances described as warranting erasure from the Register of Pharmacists by GPhC guidance do actually lead to that outcome, and whether aggravating and mitigating factors considered by the committee when imposing

sanctions are first considered when determining impairment of fitness to practise. The latter paper critically compares the processes carried out with those of three different jurisdictions based on English common law, namely: Australia, New York (USA), and New Brunswick (Canada).

Moral considerations

Conscientious objection

One piece of GPhC guidance that proved to be particularly contentious was the *Guidance on the provision of pharmacy services affected by religious and moral beliefs*, published in 2010.[53] Although the legal status of emergency hormonal contraception (EHC) is not in question, the law serves only to remove prohibitions on supply; it does not compel any pharmacist to supply the "morning-after pill" against their own religious or moral beliefs. Statute could force pharmacists to provide every service legally requested, if access to treatment was more highly regarded than religious freedom. While usually taking a deontological approach to the formulation of its guidance, the GPhC adopted a pragmatic posture in the face of the potential opposition of clinical and religious viewpoints on EHC. In **Paper H**, the argument is made that the GPhC should either assert that those with strong and sincere objections to performing a basic and routine aspect of their profession should not take up that profession, or that pharmacists not wishing to supply EHC should not be forced to do so, as it compromises their professional autonomy and does not fit with the principle of non-maleficence. Instead they adopted the pragmatic position that "women should be referred to an alternative appropriate source of supply available within the time limits for EHC to be effective".[53] However, the guidance fell short of instructing pharmacists that they must supply the EHC themselves should they be unable to relay the patient to an alternate supplier within that timescale. A major success of this paper was that it started a chain of events leading to the publication of a new

guidance document, *In practice: Guidance on religion, personal values and beliefs*, in June 2017 (see **Impact**, below).[54] This included a hardening of the stance on a pharmacists' right to refuse treatment to clinically appropriate patients by insisting that "they should take steps to make sure the person asking for care is at the centre of their decision-making, so they can access the service they need in a timely manner and without hindrance" and introducing a requirement to "[think] in advance about the areas of their practice which may be affected and making the necessary arrangements, so they do not find themselves in the position where a person's care could be compromised."

Moral distress

The requirement for pharmacists to act in a manner that is incongruent with their religious or moral beliefs highlighted in **Paper H** prompted a line of research leading to three further publications (**Papers J**, **K** and **M**) investigating the phenomenon of moral distress among community pharmacists in the UK. As described above, moral distress arises from situations in which the individual identifies the morally right action but feels unable to act accordingly due to some other legal or organisational constraint.

Paper J identifies that the work of community pharmacists is subject to strict legal frameworks and codes of professional conduct. This regulatory environment, when taken together with the recognition of pharmacy as a profession with a strong ethical grounding, creates the potential for moral distress to occur as practitioners are prevented from acting in congruence with their own ethical judgements. Studies assessing incidence of moral distress in other healthcare professions are reviewed,[4-9, 55-59] together with a single study assessing the phenomenon in pharmacists working within Sweden's healthcare system.[60, 61]

The lack of a validated tool to quantify moral distress in UK-based community pharmacists is identified. A strategy is developed to address the following: the situations causing moral distress for community pharmacists; the extent to which these pharmacists experience moral distress in their working lives; and what, if anything, can predict the level of moral distress experienced.

The lack of an appropriate tool is remedied in **Paper K**, which describes the three-phase exploratory, sequential mixed-method development of such an instrument.[28, 62] Qualitative methodology was used to explore moral distress from the perspective of practicing community pharmacists and to identify the pharmacy practice situations that they associate with experiences of moral distress. The qualitative findings were used to inform the development of an instrument to capture data regarding the intensity of moral distress and the frequency of its occurrence as experienced by community pharmacists. The survey involved rating individual practice-based scenarios for both frequency and intensity of moral distress using a seven-point Likert Scale. It was subjected to content validity testing before being trialed with a pilot sample. The results of the pilot sample were subsequently used to carry out construct validity and reliability testing. The final questionnaire differed markedly from those described in **Paper J**, which use cumulative scoring, despite the absence of a known and quantifiable relationship between intervals upon which this is premised.

The instrument was distributed as a self-administered online survey, which gave rise to a dataset containing responses from almost 600 full-time community pharmacists (**Paper M**). Major triggers for moral distress in UK-based community pharmacists were identified, and possible underlying causes of moral distress were examined in the light of these.

During the focus group sessions described in **Paper K**, many of the rules and regulations affecting practice identified in the preceding

papers and chapters were identified as sources of moral distress. Scenarios describing several of these were subsequently included in the questionnaire described in **Paper M**, including: dispensing of controlled drugs (**Papers D** and **E**; **Chapter G**); supply of unauthorised medicines in an emergency; prescribing medicines outside their licensed indications (**Chapter F**); supply of EHC (**Paper H**); and the economical provision of drugs (**Papers A**-**C**) (**Fig. 1**).

The knowledge that contravention of the these regulations may constitute a criminal offence, and may additionally establish an impairment of fitness to practise under the GPhC's Fitness to Practise Rules,[19] as highlighted in **Paper K** and described in **Paper I**, can create a barrier to acting morally, which is an essential component for moral distress. Fear of being struck off the Register of Pharmacists following a protracted fitness to practise investigation, as described in **Papers I** and **L**, was cited as the major driver to acting against their own moral judgement

The results of **Paper M** describe for the first time the frequency and severity with which moral distress is experienced by community pharmacists in the UK. Nearly three-quarters of the respondents rated the intensity of distress associated with the inability to dispense CDs as moderate or above. Previous research involving UK pharmacists has highlighted accounts of dilemmas involving this practice scenario.[63, 64] This reflects the data gathered during the qualitative phase of the work (**Paper K**), which indicated that the distress allied to this practice situation was of a particularly high intensity. During focus groups, participants described situations in which they felt confident that the request made by the patient was legitimate, but that the required procedural aspects of dispensing could not be complied with due to absent or incorrectly written prescriptions, which were additionally presented at a time when sourcing a replacement was logistically difficult.

Some triggers identified as significant in focus groups held during the development of the questionnaire (**Paper J**) were not subsequently associated with high moral distress scores in the national sample. During focus groups, pharmacists described a growing sense of powerlessness to ultimately influence the patient's decision on the relative effectiveness of treatments, including parallel imports (**Papers A**-**C**) and non-proprietary medicines (**Chapter F**). During the group discussions, acquiescing to the patient's requests despite believing this to be contrary to their best interests was primarily framed as a means of de-escalating conflict. Ultimately, supplying medicines at the insistence of the customer in instances where this conflicted with their own professional judgement was associated with moral distress of moderate intensity experienced relatively infrequently for many pharmacists. Although the use of parallel imports first discussed in **Paper A** did seed discussions in the development of the moral distress questionnaire, it did was not ultimately cause of severe distress in the overall population.

Some low-scoring items on the questionnaire were examined to determine how their negative effects were minimised, with a view to applying similar approaches to the minimisation of distress in high-scoring scenarios. EHC was found to generate low levels of moral distress in terms of both frequency and intensity. EHC has been highlighted as an area of ethical concern for UK pharmacists:[65, 66] however, the results in **Paper M** indicate that most pharmacists do not experience moral distress in this regard. It was argued in **Paper H** that the GPhC's approach to conscientious objection is philosophically unsatisfactory: however, it does appear to have a positive in terms of its effect on the frequency at which this scenario generates moral distress in practice.

Potential mechanisms for reducing the incidence of moral distress for this professional group are considered in **Paper M**, in which the conclusion was reached that the reduction in the frequency of

occurrence of moral distress is best achieved by the creation of morally habitable workplaces, where possible triggers can be identified and avoided. A meaningful intensity reduction, associated with increased moral competency or moral agency, can be achieved through structured undergraduate ethics education and accessible postgraduate training and resources.

Journal selection

My research in pharmacy ethics and law has always been targeted at practising pharmacists, lawyers engaged in professional regulatory practice and policymakers, in addition to members of the academic community. In order to ensure that the latter group are not the only beneficiaries of this work, I initially targeted publications that could be accessed by all interested parties, not just those with access to academic library catalogues.

The Pharmaceutical Journal (PJ) was the official journal of the RPSGB from its foundation in 1841 until its dissolution in 2010.[67] From July 1870 until September 2010, it was delivered to all UK-registered pharmacists on a weekly basis. As such, it was often the publication of choice for academic researchers wishing to inform practising pharmacists of outcomes with relevance to the day-to-day practice of their profession. High-quality, peer-reviewed research of particular interest to practitioners, including, for example: examining changes in patterns of misuse of over-the-counter medicines;[68] exploring prescribing errors in general practice;[69] or investigating the incidence and nature of drug-related hospital admissions,[70] was often published in the PJ, to reach the largest audience for whom it could provide benefit. Prior to 2010, I regularly published articles intended to inform or influence practising pharmacists – as well as those targeted at pharmacy policymakers – in the PJ.[71-73]

From 2011, I have mostly published research in the area of pharmacy ethics and law in the *International Journal of Pharmacy Practice* (2018

impact factor: 1.310), the *International Journal of Clinical Pharmacy* (2018 impact factor: 1.692), and *Research in Social and Administrative Pharmacy* (2018 impact factor: 2.719). Although not as broadly distributed as the PJ once was, articles published in these journals have been widely reported through national and international news outlets,[11, 74-79] including the PJ,[80, 81] ensuring that they are brought to the attention of those practising pharmacy outside academia.

Paper H was published in the *Journal of Medical Ethics* (2018 impact factor: 2.195; ranked #3 for bioethics).[82]

Contribution to the development of understanding

Impact

Peer-review has been a formal part of scientific communication since the first scientific journals appeared more than 300 years ago. Despite many criticisms about the integrity of peer-review, the majority of the research community still believes it is the best method for assessing the contribution to the development of understanding made by a program of research.[83] As with any submission for a PhD by Publication, this assessment has – by necessity – been made in advance of the thesis being submitted for examination. However, publication is no longer the only manner by which the substance and significance of the research is assessed.

The Research Excellence Framework (REF) is the UK's system for assessing the quality of research in UK higher education institutions. In 2014, for the first time, it took the impact of research into account in its evaluation of quality.[84](para. 10a) Impact, in this context, is defined as "an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia." In addition to their acceptance in peer-reviewed journals, several of the papers

submitted here have a wider impact in the regulation of pharmacy in the UK.

Conscientious objection

Since its formation, the GPhC has supported the right of individual pharmacists to "conscientiously object" to the provision of EHC to clinically suitable patients on religious or ethical grounds. Following the meeting of the governing council of GPhC on 12 April 2012, Chief Executive and Registrar Duncan Rudkin said that the council would not be changing Standard 3.4 of the *Standards of Conduct, Ethics and Performance*, which allows pharmacists to refuse to supply EHC provided certain criteria are met. Mr Rudkin stated, "We're not aware of any particular conflict and the council doesn't see any case for changing [the standards] at the moment".[85]

Paper H, published in the *Journal of Medical Ethics* on 31 January 2013 called for the GPhC to either enhance, or do away with, "conscience clauses" in respect to the supply of EHC. It received extensive press coverage on both print and on-line media, including *The Scotsman*, *The Yorkshire Post*, *The Northern Echo* and *The Daily Telegraph* (**Fig. 2**).[11, 74-76, 78, 79, 86]

The GPhC's initial response to the article was, again, to emphasise that the current standards on the provision of pharmacy services affected by religious and moral beliefs were adequate.[80] In an interview published in *The Pharmaceutical Journal*, Mr Rudkin stated that the existing standards "remind pharmacists that they must not discriminate against patients on the grounds of religion, belief, lifestyle or for any other reason."

The Daily Telegraph

News Bulletin

Morning-after pill curbs 'a muddle'

The right of pharmacists to opt out of providing the morning-after pill without a prescription risks unwanted pregnancies, according to researchers.

It also undermines the principle of universal health care in the NHS, according to a paper published in the *Journal of Medical Ethics*.

Pharmacists can decline services with which they disagree on moral or religious grounds. A significant number, mainly Christians and Muslims, have refused women the morning-after pill because they believe it is a form of abortion. But Dr Cathal Gallagher, of the department of pharmacy at Hertfordshire University, and colleagues say these "conscience clauses" should either be banned or enhanced because they are creating a muddle.

YORKSHIRE POST

Experts call for pill clause clarification

CURRENT "conscience clauses" which allow pharmacists to opt-out of giving women the morning-after pill are not satisfactory, experts said.

These clauses should either be banned or enhanced so that pharmacists and patients know exactly where they stand, according to researchers from the University of Hertfordshire and the Royal College of Surgeons in Ireland writing in the *Journal of Medical Ethics*.

The Northern Echo

Call for action on pill rules

"CONSCIENCE clauses" that allow pharmacists to opt-out of giving women the morning after pill are not satisfactory, experts said.

These clauses should be banned or enhanced so that pharmacists and patients know exactly where they stand, researchers at the University of Hertfordshire and the Royal College of Surgeons, in Ireland, said.

In the UK, pharmacists have been able to give women the morning after pill without prescription since 2001.

THE SCOTSMAN

Morning after pill opt-outs 'not satisfactory'

ELLA PICKOVER

CURRENT "conscience clauses" which allow pharmacists to opt-out of giving women the morning-after pill are not satisfactory, experts said.

These clauses should either be banned or enhanced so that pharmacists and patients know exactly where they stand, researchers said.

In the UK, pharmacists have been able to give women the morning-after pill without prescription since 2001. But conscience clauses allow pharmacists to opt out of giving emergency hormonal contraception (EHC) on religious or moral grounds, providing they refer patients to other providers willing to prescribe the product.

Writing in the *Journal of Medical Ethics*, the authors said the status quo was "not satisfactory" to either conscientious objectors or to those who must regulate them.

They said that pharmacists who objected to supplying the pill "have allowed themselves to be convinced that referral to another willing supplier is ethically different from supply" and that regulators have created a "pass the buck system".

The authors, from the University of Hertfordshire and the Royal College of Surgeons in Ireland, wrote: "Either the General Pharmaceutical Council and Pharmaceutical Society of Ireland must compel all pharmacists to dispense emergency contraception to all patients meeting the clinical criteria who request it regardless of their own moral or religious objections, or the pharmacist must refuse both to supply EHC and to refer the patient to an alternative supplier and confront the possible consequence of a complaint against them for poor professional performance or professional misconduct.

"The alternative is to remain locked in the current cycles of mutual cognitive dissonance."

Fig. 2: Collage of press clippings from 31 January 2013 citing research published in the *Journal of Medical Ethics* (**Paper H**). (© Newspaper Licensing Agency.)

As interest increased and further articles were published,[81, 87, 88] the GPhC released a further statement to the press.[89] On 8 February 2013, the GPhC "pledged to review pharmacists' right to refuse to supply emergency contraception". Mr Rudkin stated that "the GPhC will launch a patient consultation, set to begin at the start of 2014, in an attempt to gauge opinion on whether pharmacists should be allowed to refer patients to other providers if they have a moral or religious objection to dispensing emergency contraception themselves". It was a "huge piece of work" and there were strong views on both sides, Mr Rudkin warned. On 24 June 2013, The GPhC announced that "conscience clause will face an official review after

fresh criticism … of powers that allow pharmacists to refuse services on religious grounds".[90]

In its corporate plan for 2014-15, the GPhC published a timescale in which this work will be carried out as part of the review of its standards of conduct, ethics and performance.[91] The resulting public consultation closed on 7 March 2017.[92] The guidance document, *In practice: Guidance on religion, personal values and beliefs,* published on 22 June 2017, included provision that pharmacists must "recognise their own values and beliefs but [must] not impose them on other people."[54] The conscience clause, whereby a pharmacist choosing not to supply Emergency Hormonal Contraception could refer women to an alternative appropriate source of supply available within the time limits for EHC to be effective,[93] was replaced with a requirement to make the necessary arrangements in advance, so they do not find themselves in the position where a person's care could be compromised.[54]

Fitness to practise

On 3 November 2014, **Paper I**, examining the fitness to practise procedures of the GPhC, was published in the *International Journal of Pharmacy Practice*.[51] Again, I was contacted by the press to provide some quotation to give context to their coverage. When asked if the GPhC would be acting on the findings, Mr Rudkin stated that "the GPhC [would] reflect on the researchers' findings".[94] On 20 November, the GPhC published a discussion document outlining proposed changes to the guidance that the Fitness to Practise Committee use in reaching decisions. This was followed on 17 February 2015 by the launch of a public consultation, closing on 31 March, which proposed changes to the guidance that fitness to practise committees use in reaching decisions.[95] The document, *Good decision making: fitness to practise hearings and sanctions*

guidance, came into effect on 20 July 2015,[96] replacing the previous indicative sanctions guidance.[97]

Limitations

Given that this body of work spans over ten years of practice in a rapidly changing occupational sphere, it is to be expected that some of the earlier research is now of historical, rather than contemporary, interest. Although extremely relevant at the time of their publication in 2008, **Papers A-C** examine a set of common law processes that largely ceased to apply following the amendment of the HMRs in 2014. Whilst the HMRs and Pharmacy Order should continue to apply (subject to minor amendments) for many years to come, it is likely that the Misuse of Drugs Regulations will be significantly updated in the short-to-medium term.

It must be noted at this point that not all possible triggers identified from the earlier paper were reported to ultimately give rise to moral distress to the same extent, if at all. Although several issues reported in the literature, such as CDs dispensing and time constraints did generate significant distress, others including EHC did not.

The use of a frequency scale within the moral distress questionnaire was not meaningful for those pharmacists working on a part-time basis and a large volume of participants were subsequently parsed from the sample. This element of the design ideally requires modification before any further use. However, the results indicate that the current instrument is both valid and reliable.

Future work

In **Paper M**, it is acknowledged that a reduction in moral distress scores may not be indicative of growing moral competence or morally congruent practice but may instead reflect a reduction in moral sensitivity and ethical engagement. Further research is required to further explore the relationships between moral distress

and other aspects of ethical decision-making, particularly moral sensitivity and moral reasoning. A greater understanding of the relationship between moral distress and moral decision-making would inform potential educational interventions to reduce moral distress.

There is significant scope to create and evaluate educational initiatives to reduce moral distress within this occupational sphere. It is vital that interventions are developed to support individuals while targeting the external mediators of moral distress, including the moral habitability of the community pharmacy environment. Further research is required to develop and evaluate interventions that aim to enable practitioners to reflect on their experiences of moral distress and take positive action in response to them. Exploring reflective practice may be pivotal in the development of interventions aiming to reduce the incidence of moral distress by fostering the development of moral competency and the enactment of moral agency.

Summary

The degree of PhD by publication is required to meet the same standards for award of a traditional PhD.[22](para. 7.4) The requirement for a PhD to make a "significant contribution to understanding" is traditionally assessed through peer-review. The body of work submitted in pursuit of this award includes no fewer than eleven peer-reviewed publications. The analysis of each of the three areas of pharmacy law that have undergone major change in the early 21st century have given rise to at least two discrete publications each, while also contributing to research examining the phenomenon of moral distress in pharmacists, which itself led to a further three publications. A range of techniques including doctrinal and empirical legal research; and a range of quantitative and qualitative methodologies were employed at each stage of this coherent body of work.

In addition, this work has had significant impact outside academic circles. Within the context of interdisciplinary legal research, the desired outcome is to facilitate a future change, either in the law itself, in the manner of its administration, or in its effects on those who work within the area it seeks to regulate. Elements of this research have influenced the direction of the regulation of the pharmacy profession with respect to both withholding treatments on moral or religious grounds and fitness to practise.

Collaboration

The body of work supporting this submission was carried out between May 2008 and January 2019 in my capacity as a member of academic staff with the School of Pharmacy at the University of Hertfordshire. With the exception of **Chapters F** and **G**, all of the publications were co-authored. In each case, I was the principal investigator and corresponding author. Written confirmation by at least one co-author per published work is provided in **Appendix II**, in accordance with university regulations.[22](para. 5.2(2))

Jayne Astbury (**Papers J**, **K** and **M**), Victoria Greenland (**Paper I**), Adrienne Hickman (**Papers D**, **E** and **I**), Lisa McDonald (**Paper H**), Fatima Mukhtar (**Paper K**), and Toorpakiy Sarfaraz (**Paper L**) were all students working under my supervision.

Alice Holton (**Paper H**) was a student working under the supervision of Prof. Paul Gallagher (**Paper H**) at the Royal College of Surgeons in Ireland (RCSI). Paul provided a historical context for the use of EHC in the Republic of Ireland, and to detail its current legal status in that jurisdiction.

Richard O'Neill (**Papers A**, **B**, **C** and **J**) was Associate Head (and, latterly, Head) of the School of Pharmacy from 2005 until his retirement in 2015. At the start of my academic career, he was assigned as my mentor as part of the university's probationary

process for new staff. Richard's revised these papers, excising redundant text and providing advice on the structure of what remained. Additionally, Richard ensured that I was provided with protected time to dedicate to research and writing and allowed me to trade in the value of his name within the academic pharmacy community when applying for grant funding in support of my work.

As Head of Pharmacy Services at the NPA, Leyla Hannbeck (**Paper E**) provided access to call logs from their *Information Services* department for analysis.

Robert Flynn (**Paper E**) was a lecturer in pharmacy practice at the University of Hertfordshire from October 2010 to September 2011. Together, we processed the data that would form the basis of **Paper E**.

Betty Chaar (**Paper K**) is an associate professor in pharmacy law and practice at the University of Sydney. Betty provided confirmation that the narrative relating to the each state or territory's enactment of Australia's "National Law" was accurate,[98] and provided insight as to the nature and extent of guidance received by pharmacy tribunal members.

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Publications

Due to copyright restrictions, the full text of the publications submitted in support of this thesis cannot be made publicly available on the UEA Digital Repository. The following list of the publications includes hyperlinks (where available) to locations where each may be accessed with the copyright holder's permission:

A. **Gallagher, C.T.** and O'Neill, R.C. (2008). Birth of the parallel medicines trade. *The Pharmaceutical Journal:* **280**; 364-367. URL: https://www.pharmaceutical-journal.com/libres/pdf/articles/pj_20080329_parallel.pdf

B. **Gallagher, C.T.** and O'Neill, R.C. (2008). Recent challenges to parallel trade. *The Pharmaceutical Journal:* **280**; 510-512. URL: https://www.pharmaceutical-journal.com/libres/pdf/articles/pj_20080426_parallel.pdf

C. **Gallagher, C.T.** and O'Neill, R.C. (2008). Negotiating the parallel imports rules. *The Pharmaceutical Journal:* **280**; 659-661. URL: https://www.pharmaceutical-journal.com/libres/pdf/articles/pj_20080531_parallel.pdf

D. Hickman, A.C. and **Gallagher, C.T.** (2009). Misuse of drugs legislation and its effect on pharmacists since 2004. *Nottingham Law Journal:* **18(2)**; 1-9. URL: https://www4.ntu.ac.uk/nls/document_uploads/112695.pdf

E. **Gallagher, C.T.**, Hickman, A.C., Hannbeck, L. and Flynn, R.W. (2012). Analysis of enquiries to the National Pharmacy Association following major changes to controlled drug legislation in the UK. *International Journal of Pharmacy Practice:* **20(1)**; 50-56. DOI: 10.1111/j.2042-7174.2011.00162.x

F. **Gallagher, C.T.** (2013). Human medicines: the licensing system. *In:* G. E. Applebe & J. Wingfield (Eds.), *Dale and Appelbe's Pharmacy and Medicines Law,* (10th ed.); 39-60. London: Pharmaceutical Press.

G. **Gallagher, C.T.** (2013). Controlled drugs. *In:* G. E. Applebe & J. Wingfield (Eds.), *Dale and Appelbe's Pharmacy and Medicines Law,* (10th ed.); 207-244. London: Pharmaceutical Press.

H. **Gallagher, C.T.**, Holton, A., McDonald, L.J. and Gallagher, P.J. (2013). The fox and the grapes: an Anglo-Irish perspective on conscientious objection to the supply of emergency hormonal contraception without prescription. *Journal of Medical Ethics:* **39(10)**; 638-642.
DOI: 10.1136/medethics-2012-100975

I. **Gallagher, C.T.**, Greenland, V.A.M. and Hickman, A.C. (2015). Eram, ergo sum? A one-year retrospective study of General Pharmaceutical Council fitness to practise hearings. *International Journal of Pharmacy Practice:* **23(3)**; 205-211.
DOI: 10.1111/ijpp.12151

J. Astbury, J.L., **Gallagher, C.T.** and O'Neill, R.C. (2015). The issue of moral distress in community pharmacy practice: background and research agenda. *International Journal of Pharmacy Practice:* **23(5)**; 361-366.
DOI: 10.1111/ijpp.12174

K. Astbury, J.L., and **Gallagher, C.T.** (2017). Development and evaluation of a moral distress scale for community pharmacists in the UK. *International Journal of Clinical Pharmacy:* **39(1)**; 156-164. DOI: 10.1007/s11096-016-0413-3

L. **Gallagher, C.T.** Mukhtar, F., Sarfaraz, T. and Chaar, B. (2019). Fit to practise? Processes for dealing with misconduct among pharmacists in Australia, Canada, the UK and US. *Research in Social and Administrative Pharmacy:* **15(10)**; 1195-1203. DOI: 10.1016/j.sapharm.2018.10.025

M. Astbury, J.L. and **Gallagher, C.T.** (2020). Moral distress among community pharmacists in the United Kingdom: causes and achievable remedies. *Research in Social and Administrative Pharmacy:* **16(3)**; *321-328.* DOI: 10.1016/j.sapharm.2019.05.019

Co-author statements

University of Hertfordshire UH
Department of Clinical and Pharmaceutical Sciences
College Lane
Hatfield
AL10 9AB

27 September 2019

Dear Sir or Madam,

It is my pleasure to write this letter of support for Cathal Gallagher's doctoral submission, entitled: *The changing landscape of UK pharmacy law in the early 21st century apropos the moral agency of pharmacists*.

Specifically, I have been asked to comment on the candidate's own original contribution to preparing the following four papers:

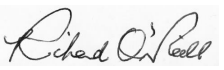
> **Gallagher, C.T.** and O'Neill, R.C. (2008). Birth of the parallel medicines trade. *The Pharmaceutical Journal:* **280**; 364-367.
>
> **Gallagher, C.T.** and O'Neill, R.C. (2008). Recent challenges to parallel trade. *The Pharmaceutical Journal:* **280**; 510-512.
>
> **Gallagher, C.T.** and O'Neill, R.C. (2008). Negotiating the parallel imports rules. *The Pharmaceutical Journal:* **280**; 659-661.
>
> Astbury, J.L., **Gallagher, C.T.** and O'Neill, R.C. (2015). The issue of moral distress in community pharmacy practice: background and research agenda. *International Journal of Pharmacy Practice:* **23(5)**; 361-366.

The intellectual input for the first three papers – which outlined and assessed the legal underpinnings of parallel imports as they stood at the time – was almost entirely Cathal's. My contribution was limited to an advisory role: mainly helping Cathal to refine what was a rather large and unwieldy text into three concise and publishable papers.

My role was in the final paper was also very limited. The design of the investigation, submission of the grant, and analysis of outcomes were all led by Cathal, who was assisted in data collection and preparation for publication by his student, Jayne Astbury.

Please do not hesitate to contact me if you require any further information.

Yours faithfully,



Richard O'Neill (Former Head of School of Pharmacy)

MANCHESTER 1824
The University of Manchester

Division of Pharmacy & Optometry
University of Manchester
1st Floor, Stopford Building
Oxford Road
Manchester, M13 9PT

Dear Sir or Madam.

I have been asked by Cathal Gallagher to write a letter of support for doctoral submission, "*The changing landscape of UK pharmacy law in the early 21st century apropos the moral agency of pharmacists*", which I am happy to do.

The papers on which we were co-authors were:

Astbury, J.L., Gallagher, C.T. and O'Neill, R.C. (2015). The issue of moral distress in community pharmacy practice: background and research agenda. *International Journal of Pharmacy Practice*: 23(5); 361-366.

Astbury, J.L., and Gallagher, C.T. (2017). Development and evaluation of a moral distress scale for community pharmacists in the UK. *International Journal of Clinical Pharmacy:* 39(1); 156-164.

Astbury, J.L. and Gallagher, C.T. (2019). Moral distress among community pharmacists: causes and achievable remedies. *Research in Social and Administrative Pharmacy*, (ePub ahead of print).

Cathal was the principal investigator on this research project into moral distress among community pharmacists, which was funded by grants obtained by him from Pharmacy Research UK and the University of Hertfordshire. I worked as a student and research assistant under his supervision.

Cathal was always very supportive of my career during my time at the University of Hertfordshire, and insisted that I be listed as first author on all papers we published together.

If there is anything else I can do in furtherance of his application, please do not hesitate to contact me.

Yours faithfully,

Jayne Astbury
Research Associate
Centre for Pharmacy Workforce Studies
University of Manchester

31 Welwyn Hall Gardens
Welwyn
Herts
AL6 9LF

15 December 2019

To whom it may concern,

This is to confirm that Cathal Gallagher was the lead author on the following papers:

1. Hickman, A.C. and Gallagher, C.T. (2009). Misuse of drugs legislation and its effect on pharmacists since 2004. Nottingham Law Journal: 18(2); 1-9

2. Gallagher, C.Y.,Hickman, A.C., Hannbeck , L. and Flynn, R.W. (2012). Analysis of enquiries to the National Pharmacy Association following major changes to controlled drug legislation in the UK. International Journal of Pharmacy Practice: 20(1); 50-56.

3. Gallagher, C.T., Greenland, V.A.M. and Hickman, A.C. (2015). Eram, ergo sum? A one-year retrospective study of General Pharmaceutical Council fitness to practise hearings. International Journal of Pharmacy Practice: 23(3); 205-211.

During the preparation of the first two papers, I was an undergraduate student at the University of Hertfordshire working under the supervision of Dr Gallagher. The final paper was published after I had graduated as a preliminary study in support of an application for PhD funding. As the named applicant, my input was limited to preparation of the completed study for publication.

Yours faithfully

Adrienne Claire Horrocks (formerly Hickman)
MRPharmS
GPhC No: 2077073

Department of Pharmacy
18 Science Drive 4
Singapore 117543

30 September 2019

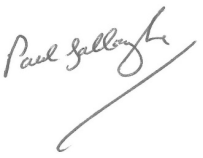
To whom it may concern.

This is to confirm that Cathal Gallagher was lead author on the following paper:

> Gallagher, C.T., Holton, A., McDonald, L.J. and Gallagher, P.J. (2013). *The fox and the grapes: an Anglo-Irish perspective on conscientious objection to the supply of emergency hormonal contraception without prescription*. Journal of Medical Ethics: **39(10)**; 638-642.

I can confirm that Dr Gallagher was involved in all aspects of the research and publication. This paper was a collaboration between the University of Hertfordshire and the Royal College of Surgeons in Ireland, where I was Head of the School of Pharmacy. Alice Holton and Lisa McDonald were undergraduate pharmacy students acting under the direct supervision of myself and Cathal, respectively.

If I can provide any additional information do not hesitate to contact me. Thank you for your consideration of this request.



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24th November 2019

Dear Sir or Madam.

It is my pleasure to write this letter outlining my input into the paper co-authored by Cathal Gallagher and me, in support of his doctoral submission.

> Gallagher, C.T. Mukhtar, F., Sarfaraz, T. and Chaar, B. (2019). *Fit to practise? Processes for dealing with misconduct among pharmacists in Australia, Canada, the UK and US.* Research in Social and Administrative Pharmacy: **15(10)**; 1195-1203.

The design of the investigation, conduct of the research, analysis of the outcomes, and preparation of the work for publication was carried out by Cathal, who was assisted by two undergraduate students (also named on the paper) as part of their *Research Methods* module.

Cathal and I have been attempting to obtain funding for a large-scale project comparing the regulation of healthcare practitioners in the UK and Australia. This paper was the first step in our collaboration. As an expert in Australian pharmacy law, I verified that the information relating to State, Territorial and Commonwealth law were accurate (which they were).

Please do not hesitate to contact me if you require any further information.

Yours faithfully.

Betty B. Chaar, BPharm MHL PhD

Associate Professor

ABN: 15 211 513 464