

## REFERENCE DOCUMENT

# Pharmacist Ethics and Professional Autonomy: Imperatives for Keeping Pharmacy Aligned with the Public Interest

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## Introduction

The Working Group (WG) on Pharmacist Ethics and Professional Autonomy was appointed by the International Pharmaceutical Federation's Board of Pharmaceutical Practice Executive Committee (BPP ExCo) in April 2012 (see Appendix A). The rationale for creating the WG was as follows:

FIP leaders have devoted substantial attention in recent years to issues related to pharmacist autonomy, stimulated in part by movements in some countries to liberalise laws that limit community pharmacy ownership to pharmacists. When pharmacists are employed, whether by a pharmacy owner or a health care institution, the tension between the professional imperatives of the practitioner and the financial interests of the owner or institution may compromise the professional service provided to patients. An official FIP document on this topic would serve to broaden understanding within pharmacy and among consumers and public officials about why these issues are important and what steps should be considered to ensure that the public receives optimal value from the profession of pharmacy.

The WG was requested (see Appendix B) "to write a report on the key issues related to ethics, autonomy, and professionalism that face pharmacists in contemporary practice settings around the world."

This report offers a framework for thinking about and assessing issues related to ethics and professional autonomy—issues of vital importance in pharmacy and, indeed, in all the health professions. Separate from this report, the WG has recommended to FIP officials steps that the Federation, its member organisations, and others can take to ensure that pharmacists, regardless of practice setting, have the motivation and the professional autonomy necessary to always serve the best interests of patients.

## FIP Consideration of Pharmacist Ethics and Professional Autonomy

### *Long-Standing Interest in Ethics*

FIP's enduring interest in ethical considerations in pharmacy practice and the pharmaceutical sciences was reaffirmed recently in its Centennial Declaration (October 2012), which includes the following commitment by FIP and its 127 member organisations:

To encourage pharmacists and pharmaceutical scientists to adhere to the highest standards of professional conduct, always giving top priority to serving the best interests of patients and society at large.



For a number of years, the annual FIP Congress has featured plenary sessions on issues of ethics and professionalism associated with pharmacy's expanding scope of practice.

The FIP Statement of Professional Standards: Codes of Ethics for Pharmacists (September 2004) (Appendix C) encourages the appropriate association in every country to develop a code of ethics for pharmacists. The statement lists 14 obligations of pharmacists that should be covered in such codes of ethics. The 2004 Statement replaced a 1997 version of the document. (The WG could not determine if there was an immediate predecessor to the 1997 document, although it did discover that FIP adopted an "International Code of Ethics for Pharmacists" in 1960.)

### ***Potential Erosion of Professional Autonomy***

Beyond this general interest in ethics, an acute concern emerged in recent years among FIP leaders about potential erosion of pharmacist professional autonomy stemming from attempts to liberalise pharmacy ownership laws in European countries. In February 2008, Prof. Kamal K. Midha, President of FIP, asked the Community Pharmacy Section (CPS) to assess this situation. At the time, there was a case before the European Court of Justice that challenged the legality of limiting pharmacy ownership to pharmacists. In June 2008, a working group within CPS submitted to the FIP President its confidential analysis of the implications of the creation of pharmacy chains.

### ***Opinion of European Court of Justice***

Concerning pharmacist ownership, the European Court of Justice issued a very strong opinion in its decision C-171/07 (09 May 2009):

It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence. Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.

The Court pointed out that it is up to Member States to decide whether "operators lacking the status of pharmacist are liable to compromise the independence of employed pharmacists by encouraging them to sell off



medicinal products which it is no longer profitable to keep in stock or whether those operators are liable to make reductions in operating costs which may affect the manner in which medicinal products are supplied at retail level.”

The Court added, Member States can decide that “there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.”

Many European Member States have been influenced by this Court opinion to strongly favour pharmacist ownership.

### ***Symposium on Professional Autonomy***

In September 2009, the FIP Executive Committee and the Community Pharmacy Section convened a leadership symposium for members of the FIP Council on the topic, “Understanding, Preserving, and Protecting Pharmacists’ Professional Autonomy” (see Appendix D). The planners of the symposium described its rationale and purpose as follows:

The traditional model of a pharmacist owning his/her own pharmacy has given way to the chains and multinational operators. Mail-order pharmacy and e-pharmacy (e.g., internet) have changed the availability and accessibility of services. The aim of this leadership conference is to examine how we can assure that these changing conditions will continue to allow pharmacists to provide independent professional judgments and decisions in the best interest of the patient.

A speaker who addressed “Corporatisation of Pharmacy Practice and Pharmacist Autonomy” noted that pharmacists who practice in pharmacies owned by business corporations experience diluted personal responsibility for their practice environment, diffused accountability for the quality of pharmacy services, and diminished attention to professional imperatives (versus business imperatives) in serving patients. Case studies were presented from the United States, Europe, Switzerland, and Japan on seeking balance between “market-driven” and “patient-care-driven” community pharmacist services.

Comments made by members of the Council in open discussion included the following points:

- “Dual loyalty” of pharmacists (to the employer and to the patient) is present in all sectors of pharmacy practice, not just community



pharmacies. The autonomy issue pharmacists face may be as much related to practicing in bureaucratic environments as it is to practicing in retail corporate settings.

- Pharmacy must use both regulation and ethical standards in building a culture of professionalism that is necessary for the preservation of the financial and clinical autonomy of practitioners.
- Pharmacy can be both a good business and an authentic health profession, but this requires conscious efforts to build the professionalism of pharmacists and to ensure that the public understands the profession's social compact.

An FIP official's concluding remarks were encapsulated as follows in FIP's summary of the symposium:

As a profession, pharmacy has a covenant with society, and its practitioners must behave appropriately to preserve the public's trust and to preserve their autonomy. Because of prevailing social, economic, and political forces, there will continue to be immense tension between corporate and professional imperatives in pharmacy. The profession should address this tension forthrightly, actively studying the context in which it functions and outlining a path that will preserve the practitioner autonomy that is necessary for pharmacy to serve the public well.

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### ***Review of Codes of Ethics***

In response to a request from the BPP ExCo, the Social and Administrative Pharmacy Section engaged two of its members in 2011 to examine (1) several pharmacist codes of ethics "for gaps and conflicts" and (2) the FIP statement on Codes of Ethics for Pharmacists for any gaps. The reviewers reported, "Pharmacists are increasingly involved in activities where moral decisions have to be made, where there may be conflict between two or more principles, where different obligations have to be weighed or where a moral duty may conflict with a legal obligation." They recommended that FIP provide "an illustrative set of core principles" that a pharmacist association could use in developing a code of ethics. Further, they suggested expansion of the FIP statement on Codes of Ethics for Pharmacists to (1) address certain topics such as professional autonomy and independence and (2) offer guidance on matters such as "religious and moral beliefs or controversial issues such as euthanasia."

### ***Support of the Efforts of Others***

In conjunction with the 2012 FIP Congress in Amsterdam, the EuroPharm Forum (a joint network of national pharmaceutical associations, the International Pharmaceutical Federation, and the World Health Organization Regional Office for Europe) conducted a session on ensuring professionalism in a commercial marketplace. Also concurrent with the 2012 FIP Congress, the Royal Dutch



Pharmacists Association (KNMP) organised a session for selected participants in the Congress to give the Association feedback on its draft Charter on Pharmacy Ethics and Professionalism. (KNMP conducted a similar session on its final Charter at the 2013 FIP Congress in Dublin.) While these EuroPharm Forum and KNMP sessions were not FIP events, they illustrate that other groups recognise FIP as a convener of pharmacists who share an interest in pharmacy ethics and professionalism, and they suggest that there may be future opportunities for like-minded groups to address pharmacist ethics, professionalism, and autonomy with FIP.

### Survey of FIP Member Organisations

The WG prepared a short survey for the purpose of identifying issues related to pharmacist ethics and autonomy in various countries and to identify any facets of these issues that might otherwise have escaped the WG's attention. Member Organisations of FIP were requested to complete the survey in September 2012; a reminder was sent in December 2012. The results are shown in Appendix E. The 19 responses came predominantly from European countries; also represented were Australia, China, Taiwan, Turkey, and the United States. Five countries each had two respondents. The meagre responses to the survey limited the usefulness of the results.

Nearly all of the respondents said they have a code of ethics for pharmacists in their country, and more than half of them said that their code includes "explicit guidance about professional autonomy." The most frequently cited "barriers to professional autonomy" were "interprofessional constraints (e.g., power imbalance with doctors, hierarchy in the workplace, lack of cultural sensitivity towards older colleagues)" and "financial pressures." Next in frequency were "political constraints on the profession," "pharmacists' lack of self confidence," and "pharmacists' lack of motivation."

Some of the barriers to professional autonomy may be manifestations of the profession's evolution and might not be amenable to intervention, while others (e.g., hierarchy in the workplace, lack of practitioner confidence or motivation) would seem to lend themselves to amelioration. Investigation into ways of dealing with these issues is warranted.

That many codes of ethics include explicit guidance about professional autonomy indicates some level of awareness about the issue and suggests that FIP should consider addressing this topic in future revision of its statement on Codes of Ethics for Pharmacists.





## Literature Review

Although the WG did not have the resources to conduct a comprehensive review of the world's literature on pharmacist ethics and autonomy, Dr Betty Chaar, co-chair of the WG, led the preparation of a selective review of English-language literature on the topic (see Appendix F). In general, this review showed a vast literature on ethical issues and professional behaviour in pharmacy practice but limited discussion of pharmacist autonomy. However, it must be noted that professions by definition have a high degree of autonomy and self-regulation, and it is self-evident that any threats to these essential features of professions have the potential of eroding practitioners' ability to serve clients unencumbered by conflicts of interest.

## Contemporary Issues in Pharmacist Ethics

The WG identified the following four categories (with specific examples) of ethical issues experienced by pharmacists in all areas of practice:

1. Ethical challenges originating from individual and personal considerations.
  - a. Lack of a sense of professional responsibility.
  - b. Lack of competence.
  - c. Personal values in conflict with professional values, including conflicts that lead to refusal to provide service.
  - d. Stigma (e.g., denying service due to stigma [or inconvenience] towards illicit drug users or persons with disabilities).
  - e. Lack of awareness of principles of ethics in pharmacy.
  - f. Lack of care to apply ethical principles in practice.
  - g. Cultural, religious, or national interests in conflict with professional ethics.
  - h. Personal characteristics and traits (e.g., lack of moral courage).
2. Ethical challenges originating from economic considerations, either by limiting costs or by increasing revenues.
  - a. Managing resources – allocating limited resources.
  - b. Profitability and viability of business (greed vs. reasonable profit).
  - c. Advertising to promote inappropriate consumption.
  - d. Insurance company policies that conflict with patients' best interests.
  - e. Financial incentives offered by industry to sell certain products.
  - f. Workload pressures.
  - g. Products selected for sale in the pharmacy (e.g., tobacco, complementary medicines of unproven efficacy or quality, slimming products that don't work).





- h. Counterfeit drugs.
  - i. Conflict of interest in continuing education presentations.
  - j. Conflict of interest in publishing research findings.
3. Ethical challenges originating from human interactions (employer-employee or between colleagues).
- a. Interprofessional conflict.
  - b. Policy of the owner/employer.
  - c. Conflicts between the employer and the practitioner's commitments to engagement with professional organisations.
  - d. Reporting colleagues ("whistle-blowing").
  - e. Power imbalance and bullying/harassment (and subsequent job insecurity).
  - f. Lack of respect for colleagues.
  - g. Lack of good role modelling and initiative to teach younger practitioners.
  - h. Patient rights (e.g., privacy/confidentiality).
4. Ethical challenges arising from the system or framework of practice.
- a. Barriers imposed by institutional authorities.
  - b. Restrictions/challenges in adopting new technologies.
  - c. Lack of revision (updating) of codes of ethics.
  - d. Varying interpretations of codes of ethics.
  - e. Perceptions that codes of ethics are nonbinding.
  - f. Legislative or regulatory constraints.
  - g. Paradigm shifts; new scientific knowledge (e.g., pharmacogenomics).

## Necessity of Professional Autonomy for Fulfilment of the Pharmacist's Mission

For purposes of this report, the WG defined **professional autonomy** as follows:

The right and privilege granted by a governmental authority to a class of professionals, and to each licensed individual within that profession, to exercise independent, expert judgment within a legally defined scope of practice, to provide services in the best interests of the client.

Professional autonomy helps pharmacists fulfil their societal mission. That mission, as expressed in FIP's Centennial Declaration, is to help patients make responsible use of medicines. The WG identified the following three general types of benefits (with specific examples) derived from professional autonomy for pharmacists:



1. Pharmacist professional autonomy benefits society at large by facilitating:
  - a. Service motivated by the best interests of patients.
  - b. Attention to patients' expectations.
  - c. Collaboration and synchronisation (as a professional with unique competencies) with other health care professionals, with the aim of achieving optimal outcomes for the patient.
  - d. Willingness of pharmacists to do whatever they can to help society.
  - e. Application of competence in pharmaceutical care.
  - f. Consumer access to, and willingness to pay for, trusted services from pharmacists.
  - g. Preservation of drug-product quality and safety.
  - h. Improvement of health care systems.
  - i. A buffer between pharmaceutical marketing and the public.
  
2. Pharmacist professional autonomy strengthens the profession of pharmacy by facilitating:
  - a. Preservation of the reputation of the profession and its commitment to serving the best interests of patients.
  - b. Enhancement of public trust in the profession.
  - c. Practitioner commitment to advance and change.
  - d. Improvement of pharmacy practice.
  - e. Avoidance of the perception that pharmacists have a conflict of interest when they recommend a product.
  - f. Preservation of pharmacists' professional privileges.
  - g. Assurance that a pharmacist is always present during the hours a pharmacy is open.
  
3. Pharmacist professional autonomy benefits individual practitioners by facilitating:
  - a. Exercise of independent professional judgment.
  - b. Maintenance of contemporary knowledge, skills, and abilities (continuous professional development).
  - c. Enhancement of professional confidence.
  - d. Self-assessment and self-discipline.
  - e. Enhancement of job security by recognizing that employed pharmacists are responsible for their own professional-practice decisions, insulated from the proprietor's or institution's interests.



## **Additional WG Observations and Findings**

The following additional observations and findings are based on the WG's analysis of the key issues in pharmacy ethics and professional autonomy and its review of the related literature.

### ***Threats to Professional Autonomy in Health Care***

Because of international trends in health care delivery and financing, practitioners in most (perhaps all) health professions are experiencing threats to professional autonomy. The issue is not unique to pharmacy, and the WG has no reason to believe that it is concentrated in particular areas of the globe or in countries at particular levels of development. Erosion of professional autonomy makes it more difficult for health professionals, including pharmacists, to consistently give undivided attention to serving the best interests of patients. As commercial or profit-seeking interests influence patient-care decisions, without intervening impartial professional judgment, the risk of patient harm or wasteful expenditures escalates. The risks associated with erosion of health-professional autonomy are poorly understood by consumers, policy makers, health insurance executives, hospital and health care administrators, and many health-care practitioners.

### ***Moral Courage***

Immense strength of character (moral courage) is often required for health professionals, including pharmacists, to resist employer or insurance mandates that are economically motivated and contrary to the best interests of patients. The moral courage of individual health professionals, including pharmacists, can be buttressed through support from mentors, peers, and professional associations.

### ***Universal Issue in Pharmacy***

Pharmacists in all practice settings (including community pharmacy, hospital pharmacy, academia, public health pharmacy, managed care pharmacy, clinical laboratory pharmacy, and industrial pharmacy) are confronted with ethical challenges, and those challenges are likely to increase in the future. There is not a consistent approach among countries in seeking compliance with pharmacist codes of ethics; methods range from rigorous enforcement through a country's legal system to haphazard application of peer pressure. The level of pharmacists' professional autonomy, which varies greatly around the world, is influenced by many factors, including a country's history, social structures, social systems (e.g., economic, legal, political, and cultural systems), method of health care delivery and financing, and system of pharmacy education.



### ***Pharmacy's Professional Transition***

Issues of ethical behaviour and autonomy are especially important to pharmacy practice because the profession is in transition, moving from largely a supply function to a patient-care function. This transition will be impeded if practitioners do not have sufficient autonomy to act in support of patients' best interests. If pharmacy practice were to limit itself strictly to a supply function, various forces—economic, technologic, social, and political—would likely coalesce over time to replace the pharmacist with other less expensive means of safely supplying medicines to patients. On the other hand, if pharmacists move toward assuming responsibility for helping patients and health professionals make the best use of medicines, they will be providing a higher value service than a mere supply function—a vital and complex service that is generally lacking in health care today. As pharmacist associations attempt to stimulate pharmacy's professional transition, they should help their members understand and address the ethical and moral dimensions of this transition. In countries in which the education of pharmacists has prepared them to enlarge their role in fostering responsible use of medicines, pharmacy practitioners have a moral obligation to put that education to its fullest use. In countries in which laws require pharmacists to own community pharmacies, the case for preserving those laws will be stronger if pharmacists are engaged in professional activities beyond the supply function and have demonstrated that they are a vital force in improving outcomes from the use of medicines.

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### ***Opportunities for FIP***

Given FIP's long-standing interest in issues related to pharmacist ethics and professional autonomy, it now has an opportunity to use the report of the WG to raise awareness among pharmacists, pharmacy organisations, and other relevant parties around the world about the importance of these issues. FIP also has an opportunity to consider, based on this report, what additional concrete actions it could take to advance two objectives: (1) motivating pharmacists to comply with high professional standards, and (2) encouraging governments, health care payers, and employers of pharmacists to grant pharmacists sufficient professional autonomy to help ensure that patients and society as a whole benefit from their expertise in the responsible use of medicines.

### ***Oath / Promise of a Pharmacist***

The WG believes that an important way to establish and reinforce the commitment of pharmacists to ethical behaviour is to ask pharmacy students and new pharmacy graduates to promise, in public, before their mentors and peers, to follow a high standard of professional conduct. Mentors can reinforce this promise during experiential education and internships. Also, established practitioners can be invited to repeat this promise at professional conferences



(including those of FIP). Schools of pharmacy and pharmacist organisations in a number of countries have adopted language for an “Oath / Promise of a Pharmacist” for this purpose.

## Conclusion

Throughout its history, the profession of pharmacy has served humanity well around the globe. Although pharmacy has great potential for extending its record of service, it faces many obstacles in attempting to do so, not the least of which are challenges related to professional ethics and autonomy. Pharmacy cannot achieve its full potential, and patients will not benefit from that potential, unless pharmacists are committed to the highest standards of professional conduct and have sufficient autonomy to serve patients’ best interests. In explicating the most important dimensions of this issue, this report reinforces FIP’s long-standing support of ethical principles, and it suggests the need for FIP to also strongly advocate for a sufficient measure of pharmacist autonomy in all sectors of the profession.



## Appendix A – Members and Process of the FIP Working Group on Pharmacist Ethics and Professional Autonomy

### Co-chairs:

- Betty B. Chaar (Australia)
- William A. Zellmer (United States)

### Members:

- Nkwenti Davidson Achu (Cameroon)
- Daisuke Kobayashi (Japan)
- Arijana Meštrović (Croatia)
- Sirpa Peura (Finland)
- Farshad H. Shirazi (Iran)
- Luc Besançon (FIP)

The WG was appointed in April 2012 and met in July 2012 at FIP headquarters in The Hague and in October 2012 at the FIP Congress in Amsterdam. Other work was conducted via electronic communications.

The WG submitted an interim report in October 2012 to the Board of Pharmaceutical Practice Executive Committee (BPP ExCo) and a draft final report in March 2013. Based on comments received in April 2013 from the BPP and the BPP ExCo, the WG revised its report and submitted it in May 2013. At a meeting with the Board of Pharmaceutical Practice on 2 September 2013, the co-chairs of the WG were requested to have the WG consider comments on the report raised by members of the FIP Council at its meeting on 31 August 2013.

The final version of the report, dated 25 September 2013, takes into account comments from the Council.



## Appendix B – Terms of Reference: Working Group on Pharmacist Ethics and Professional Autonomy

### *Introduction*

FIP leaders have devoted substantial attention in recent years to issues related to pharmacist autonomy, stimulated in part by movements in some countries to liberalise laws that limit community pharmacy ownership to pharmacists. When pharmacists are employed, whether by a pharmacy owner or a health care institution, the tension between the professional imperatives of the practitioner and the financial interests of the owner or institution may compromise the professional service provided to patients. An official FIP document on this topic would serve to broaden understanding within pharmacy and among consumers and public officials about why these issues are important and what steps should be considered to ensure that the public receives optimal value from the profession of pharmacy.

### *Objective*

The objective of this working group is to write a report on the key issues related to ethics, autonomy, and professionalism that face pharmacists in contemporary practice settings around the world.

The report should be drafted with the intent that it will be officially adopted and disseminated by FIP.

The primary facets of the report should be as follows:

1. Discussion of the general relationship between pharmacist professional autonomy (in all sectors of practice) and the responsible use of medicines.
2. Discussion of the importance of practitioner autonomy in fulfilling the profession's societal mandate, highlighting the relationship between pharmacist autonomy and public trust.
3. Discussion of the challenges related to ethics, autonomy, and professionalism that confront practicing pharmacists, including why this issue is important to the public.
  - a. Specific issues in community pharmacy practice (e.g., effect of pharmacy ownership on pharmacist behaviour).
  - b. Specific issues in hospital pharmacy practice (e.g., effect of institutional bureaucracy and financial imperatives on pharmacist behaviour).
  - c. Specific issues in other areas of pharmacy practice, including industrial pharmacy, long-term-care pharmacy practice and population-based pharmacy practice (i.e., pharmacy benefit management companies).





4. Guidance to the following groups on how to ensure that the decisions, behaviours, and overall performance of practicing pharmacists are motivated primarily by pharmacists' desire to serve the best interests of patients:
  - a. Pharmacists
  - b. Employers of pharmacists
  - c. Pharmacist professional associations
  - d. Governmental bodies
  - e. Health care organisations

### ***Desired Outcomes***

The FIP Board of Pharmaceutical Practice Executive Committee (BPPEC) requests that the report specifically addresses the following topics and make related recommendations as appropriate:

1. How ethics, autonomy, and professionalism worldwide are:
  - a. Discussed in pharmacy codes of ethics and
  - b. Integrated into legal frameworks relating to the practice of pharmacy.
2. Whether governments are influencing or overriding self-regulation in the implementation of codes of ethics and in other means of controlling the profession of pharmacy.
3. Importance of practitioner autonomy in fulfilling the profession's societal mandate.
4. Whether the pharmacist's legal scope of practice allows for practitioner intervention based on clinical judgment, as a facet of professional autonomy.
5. Whether there is sufficient education and training of pharmacists in ethics and professionalism.
6. Whether there are conflicts or dualities of interest in pharmacist practice.
7. Whether financial factors affect pharmacist behaviour.

### ***Working Group Process and Time Schedule***

The working group should base its report on the professional literature, previous work within FIP (e.g., the 2009 FIP leadership symposium on "Understanding, Preserving, and Protecting Pharmacists' Professional Autonomy"), observations about contemporary pharmacy practice, and consultation with appropriate experts and authorities.

To achieve desired outcomes, the BPPEC suggests the following process be used:

1. That the working group survey FIP member organisations for their views on pharmacist ethics, autonomy, and professionalism in their countries, and



2. That the working group conduct a comprehensive review of literature relevant to its assignment, then
3. Amalgamate results of survey and literature review in a draft report to FIP.

The working group is requested to submit a draft of its report in time for review by the BPPEC at the FIP Centennial Congress in October 2012 by and to manage (in consultation with appropriate FIP leaders and staff) the overall process so as to conclude its work by March 2013.

### ***Composition***

Among the interests or areas of expertise that should be considered for appointment to the working group are the following:

- Community pharmacy practice
- Hospital pharmacy practice
- Long-term-care pharmacy practice
- Population-based pharmacy practice
- Pharmacy academia
- Pharmacy practice regulation
- Professional ethics
- Patient advocacy



## Appendix C—FIP Statement of Professional Standards: Codes of Ethics for Pharmacists (2004)

A profession is identified by the willingness of individual practitioners to comply with ethical and professional standards, which exceed minimum legal requirements.

The pharmacist continues to be the health professional who is the expert on medicines.

Pharmacists are also given the responsibility to help people to maintain good health, to avoid ill health and, where medication is appropriate, to promote the rational use of medicines and to assist patients to acquire, and gain maximum therapeutic benefit from, their medicines. The role of the pharmacist is continuing to develop.

Recognising these circumstances, this statement of professional standards relating to codes of ethics for pharmacists is intended to reaffirm and state publicly, the obligations that form the basis of the roles and responsibilities of pharmacists. These obligations, based on moral principles and values, are provided to enable national associations of pharmacists, through their individual codes of ethics, to guide pharmacists in their relationships with patients, other health professionals and society generally.

### Against this background, and for this purpose, the FIP recommends that

1. In every country, the appropriate association of pharmacists should produce a Code of Ethics for pharmacists setting out their professional obligations and take steps to ensure that pharmacists comply with the provisions of that Code.
2. The obligations of pharmacists set out in these codes should include
  - to act with fairness and equity in the allocation of any health resources made available to them.
  - to ensure that their priorities are the safety, well being and best interests of those to whom they provide professional services and that they act at all times with integrity in their dealings with them.
  - to collaborate with other health professionals to ensure that the best possible quality of healthcare is provided both to individuals and the community at large.
  - to respect the rights of individual patients to participate in decisions about their treatment with medicinal products and to encourage them to do so.<sup>1</sup>
  - to recognise and respect the cultural differences, beliefs and values of patients, particularly as they may affect a patient's attitude to suggested treatment.



- to respect and protect the confidentiality of information acquired in the course of providing professional services and ensure that information about an individual is not disclosed to others except with the informed consent of that individual or in specified exceptional circumstances.<sup>2</sup>
- to act in accordance with professional standards and scientific principles.
- to act with honesty and integrity in their relationships with other health professionals, including pharmacist colleagues, and not engage in any behaviour or activity likely to bring the profession into disrepute or undermine public confidence in the profession.
- to ensure that they keep their knowledge and professional skills up-to-date through continuing professional development.<sup>3</sup>
- to comply with legislation and accepted codes and standards of practice in the provision of all professional services and pharmaceutical products and ensure the integrity of the supply chain for medicines by purchasing only from reputable sources.<sup>4,5</sup>
- to ensure that members of support staff to whom tasks are delegated have the competencies necessary for the efficient and effective undertaking of these tasks.
- to ensure that all information provided to patients, other members of the public and other health professionals is accurate and objective, and is given in a manner designed to ensure that it is understood.
- to treat all those who seek their services with courtesy and respect.
- to ensure the continuity of provision of professional services in the event of conflict with personal moral beliefs or closure of a pharmacy. In the event of labour disputes, to make every effort to ensure that people continue to have access to pharmaceutical services.

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This Statement replaces that adopted by the Council of FIP in 1997.

#### References:

<sup>1</sup> FIP Statement of Professional Standards on the Role of the Pharmacist in Encouraging Adherence to Long-Term Treatments (Sydney 2003)

<sup>2</sup> FIP Statement of Policy on Confidentiality of Information gained in the course of Pharmacy Practice (2004, New Orleans)

<sup>3</sup> FIP Statement of Professional Standards on Continuing Professional Development (2002, Nice)



<sup>4</sup> The Tokyo Declaration (1993) Standards for quality of pharmacy services (FIP Guidelines for Good Pharmacy Practice, September 1993) and revised version FIP/WHO GPP (1997, Vancouver)

<sup>5</sup> FIP Statement of Policy on Counterfeit Medicines (2003, Sydney)

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## Appendix D—Summary of FIP Symposium on Professional Autonomy “Understanding, Preserving, and Protecting Pharmacists’ Professional Autonomy”

Summary of a Leadership Symposium Attended by Members of the Council of the International Pharmaceutical Federation

Istanbul, Turkey  
8 September 2009

### ***Objective of the Symposium***

The planners of this symposium—the FIP Executive Committee and the Community Pharmacy Section—described its rationale and purpose as follows:

The environments where pharmacists practice today are diverse and changing rapidly. Dispensing services have been augmented with cognitive services. The traditional model of a pharmacist owning his/her own pharmacy has given way to the chains and multinational operators. Mail-order pharmacy and e-pharmacy (e.g. internet) has changed the availability and accessibility of services. The aim of this leadership conference is to examine how we can assure that these changing conditions will continue to allow pharmacists to provide independent professional judgments and decisions in the best interest of the patient. The other aim is to discuss what kind of social contract we retain with the patient and what kind of regulation is needed in order to provide the best possible pharmaceutical care.

### ***Opening of the Symposium***

The session was opened by Kamal Midha, President of FIP, and Martine Chauvé, President of the FIP Community Pharmacy Section. Dr. Midha noted that pharmacy practice around the world is changing in ways that put patients (rather than drug products) at the centre of the pharmacist’s focus. This shift is posing new ethical challenges for pharmacists, and their organisations must help them deal with these issues. Ms. Chauvé said that laws in some countries that limit pharmacy ownership to pharmacists are being challenged by legislatures and the courts, which is threatening the ability of pharmacists to maintain control over their professional practices.

### ***Corporatisation of Pharmacy Practice and Pharmacist Autonomy***

William A. Zellmer began his keynote address by asserting that most pharmacists today do not have control over their practice environment, which prevents patients from receiving the full benefit of the pharmacist’s expertise and diminishes the stature of the profession of pharmacy.



Central to this topic is the issue of why society needs pharmacists. If the pharmacist's mission is only to provide the medicine, then society may support other safe, efficient, and low-cost ways for that function to be performed. However, if the pharmacist's mission is to help people make the best use of medicines, then the profession has a role that is of high value to society, probably more satisfying to pharmacists, and perhaps more protective of autonomy in corporate practice environments.

Corporations naturally attempt to standardise services or products, reduce complex activities to a series of simple functions that can be automated or performed by low-paid workers, and maximise productivity and profitability. The corporate model of pharmacy practice dilutes personal responsibility of the pharmacist, gives top priority to business issues rather than individual patient concerns, presumes that medicines can be treated as commodities and that patient reaction to medicines is standardised, and diffuses accountability for the quality of services.

The educator Parker Palmer has written that many people today work for businesses, institutions, and organisations to which they subordinate their personal sense of what is right; in Palmer's words, these individuals lead "divided lives." Palmer has argued that professional persons must be taught how not to subsume their knowledge and ethics to the needs of the corporation or institution that employs them. He has appealed to universities to prepare a "new professional," which he defines as "a person who is not only competent in his or her discipline but [also] has the skill and will to deal with the institutional pathologies that threaten the profession's highest standards." Palmer's ideas have direct application in pharmacy.

Two broad categories of steps must be taken to ensure appropriate alignment between the talents of pharmacists and the needs of patients who take medicines: (1) reforming the structure of pharmacy practice (including, for example, relationships with physicians, role of technicians, and payment for services) and (2) increasing the pharmacist's professional self concept and autonomy. Structural reforms have received much attention in pharmacy whereas the need to reform pharmacists' self concept (i.e., their inner lives) has been generally ignored.

Pharmacist associations and schools of pharmacy should focus on bolstering the inner lives of pharmacists by helping students and practitioners understand that they have power over their places of practice, by teaching them how to cultivate communities of discernment and support among their peers, and by teaching them how to be true to what they know is right in helping patients make the best use of medicines.





Zellmer stated, “Reduced to its essence, the challenge facing pharmacy is to find a way for pharmacists to live undivided, authentic lives—for pharmacists to open their eyes, their minds, and their hearts to the people who need help in making the best use of their medicines. Pharmacists cannot fulfil such a mission unless they have ethical autonomy and the courage to act on it.” He challenged FIP leaders to focus not only on structural reforms in pharmacy but also on what they can do to encourage and support pharmacists in making a deep commitment to practice their profession in ways that are consistent with what they know must be done to help patients optimise the benefits and reduce the risks of their use of medicines.

### ***Market-Driven Pharmacist Services***

Monika Sidler, representing the Federation of Swiss Patient Organisations, discussed patient expectations of pharmacists, which centre on the provision of information and advice about prescription and nonprescription medicines. Pharmacists should help patients understand complex, technical information, striking an appropriate balance between “certainty” and “uncertainty” in translating knowledge to a patient’s specific situation.

When pharmacists pay careful attention to quality assurance in conformance with professional guidelines, patients are more confident in their medicines, are more likely to comply with treatment, and will have a better sense of the value of their medicines. Electronic records, including e-prescribing and electronic health-insurance communications, contribute to the patient’s perception of quality in health care. Among the challenges that patients perceive related to pharmacist services are counterfeit medicines, medicines advertising, self-medication, and assessment of the relationship between the benefits and costs of medicines.

### ***Patient-Care-Driven Pharmacist Services***

Andrew Gilbert of Australia prepared remarks (which were delivered by his colleague Ross McKinnon) on community pharmacy practice in his country, which he characterised as “market driven” and as following the “cash and wrap” approach of retail discounters. Unfortunately, pharmacy is the only health profession that does not demand demonstrated competence in the patient-care process as a requirement of licensure. The experience of Australia, which has a strong law requiring pharmacist ownership of pharmacies, demonstrates that regulation alone will not ensure that the profession fulfils its social responsibility; this will be realised only through the profession’s value system and the ethics and competency of individual pharmacists.

Pharmacists must find the courage not to tolerate situations in which they are prevented from exercising their professional autonomy and where work



practices compromise patient safety and professional ethics. In Australia, pharmacy's social contract is specified by the government in that citizens have the right to pharmacist consultation about the appropriateness of a medicine and about its safe use. However, pharmacists are not held accountable for consultation and most of them opt for a "non-professional, high throughput discount market-driven model of supply." Government officials apparently favour a mixed retail/professional model for pharmacy, but a pure retail model predominates at the moment. Current conditions will prevail unless pharmacists change their focus from the drug product to patient consultation as the economic driver of their practice.

Although pharmacists in Australia are eligible for a \$200 fee for a "Home Medicines Review," very few have been accredited to provide this service and fewer than 5% of high-risk patients are offered the service because pharmacists are preoccupied with supply functions in a market-driven model of practice.

The essential step on a path from the current situation is for pharmacists to agree upon an aspirational goal and a model for delivery of patient-focused pharmaceutical care. It would then be possible to establish a competency-based training program and build mentoring systems for young and early-career pharmacists. Pharmacists should be required to demonstrate competence in the delivery of patient-focused pharmaceutical care as a prerequisite to licensure. The FIP vision for patient-focused pharmaceutical care will be realised only if individual pharmacists embrace the principles of the vision.

### ***Case Studies on Seeking Balance between Market-Driven and Patient-Care-Driven Approaches to Pharmacist Practice***

**United States.** Thomas E. Menighan discussed the tension between business and clinical imperatives in community pharmacy practice. Pharmacists are moving toward attaining authority to make patient care decisions, accountability for compliance with standards, and assumption of responsibility for the outcomes of medicine use. Examples of innovative pharmacist services that have attracted substantial support and that are being compensated include medication therapy management, vaccine administration, and collaborative drug therapy management. Common perceptions of pharmacists as "cost controllers" or "formulary enforcers" stand in the way of their recognition as patient care providers. In the context of health reform, there is substantial interest in the "medical home" model for delivering health care services, which may offer new opportunities for pharmacists to serve the medicine-use-related needs of ambulatory patients as part of multidisciplinary health care teams. There is an urgent need for pharmacists to innovate in their services, establish practice standards, and spend more time directly with patients, coaching them in appropriate use of medicines.



**European Union.** John Chave said that optimal pharmacy practice requires both (1) pharmacist behaviour focused on patient safety and appropriate health outcomes and (2) patient and payer willingness and expectation to receive a professional service based on knowledge and skill. Community pharmacists and the European Commission are debating the following questions: are pharmacists' professional standards alone sufficient to resist commercial pressures that could cause a decline in pharmacist services, and are government regulations (e.g., restrictions on pharmacy ownership, limits on pharmacy locations, and restrictions on the sale of nonprescription medicines) in the public interest or do they only serve to protect pharmacists' income and reduce innovation? Community pharmacists believe that the following factors may contribute to the decline of pharmacy: the European Commission's support of the "efficient markets" paradigm, the "consumer choice" paradigm, excessive use of retailing to support pharmacy activities, and belief in the "self-reliance" of informed patients. The limits of consumer sovereignty are demonstrated by under-appreciated pharmaceutical risk, active resistance to counselling, self-determined concept of adherence, acceptance of increased risk for lower cost, preference for brand names over generics, requests for advertised medicines, and preference for traditional remedies over evidenced-based therapies. Current income levels of pharmacists, which are under downward pressure, have positive societal value in terms of ensuring service in less economically attractive areas, ensuring parity with comparable health professions, and ensuring that good students are attracted to the profession. Some regulation of the profession is necessary, but it must not be allowed to stifle innovation.

**Switzerland.** Dominique Jordan reviewed efforts in his country to rationalise the payment system for pharmacy services within the framework of national and private health insurance. The Swiss pharmacy market includes 485 independent community pharmacies, 11 virtual chains with 812 pharmacies, and 9 corporate chains with 427 pharmacies as well as multiple retail outlets that sell nonprescription medicines, dispensing physicians, and mail order pharmacies. Through law and contracts with insurers, pharmacies are remunerated separately for (1) pharmacists' professional services (e.g., prescription verification, patient history) and (2) the costs of operations and capital. Payment is linked to a well-articulated point system for the full range of pharmacist services (e.g., 4 points for a "medication check" in the dispensing process; 45 points for a "polymedication check" for patients with at least four medicines). Future plans for pharmacist services include definition of a gatekeeping role in collaboration with physicians, a role in primary health care, and a role in integrated care with local health practitioners and telemedicine links to more distant practitioners.



**Japan.** Nobuo Yamamoto discussed efforts in Japan to establish standards for community pharmacy services in the context of national policy to shift medicine dispensing from physicians to pharmacists and in light of a new law to remove the restriction on the sale of nonprescription medicines to pharmacies. Japan now has three categories of nonprescription medicines classified according to safety; only pharmacists may sell Schedule 1 items; products in Schedules 2 or 3 may also be sold by “registered sellers” who are credentialed at the prefecture level (pharmacists are licensed at the national level). Efforts are underway to encourage pharmacists to expand and professionalise their role in advising consumers on nonprescription medicines. Pharmacists are encouraged to maintain medicine records on all their clients, to practice according to the principles of pharmaceutical care, and to comply with Good Pharmacy Practice standards.

### ***Open Discussion***

The following points were raised by members of the Council in open discussion following the formal presentations:

- “Dual loyalty” of pharmacists (to the employer and to the patient) is present in all sectors of pharmacy practice, not just community pharmacies. The autonomy issue pharmacists face may be as much related to practicing in bureaucratic environments as it is to practicing in retail corporate settings.
- Regrettably, pharmacy does not have as much political strength or power as the profession of medicine; pharmacy’s ability to retain the autonomy of its practitioners is less than that for medicine.
- A key factor that determines the level of practice is what is in the pharmacist’s mind (his or her self-concept as a health professional).
- Pharmacy must use both regulation and ethical standards in building a culture of professionalism that is necessary for the preservation of the financial and clinical autonomy of practitioners.
- Pharmacy can be both a good business and an authentic health profession, but this requires conscious efforts to build the professionalism of pharmacists and to ensure that the public understands the profession’s social compact.

### ***Summary and Conclusions***

Henri R. Manasse, Jr., commented on the key points of the symposium and offered suggestions about next steps on the vital issue of pharmacist autonomy. It is time for truth-telling in pharmacy with respect to (1) the limited professional role of most pharmacists, (2) the conflict in mission between corporations (which are accountable to stockholders) and the profession of pharmacy (which is accountable to society), (3) pharmacist-owned pharmacies



that do not put the needs of patients first. As a profession, pharmacy has a covenant with society, and its practitioners must behave appropriately to preserve the public's trust and to preserve their autonomy. Because of prevailing social, economic, and political forces, there will continue to be immense tension between corporate and professional imperatives in pharmacy. The profession should address this tension forthrightly, actively studying the context in which it functions and outlining a path that will preserve the practitioner autonomy that is necessary for pharmacy to serve the public well.

Manasse offered the following suggestions:

- Community pharmacies and other pharmacies that serve ambulatory patients should be redesigned to permit private conversations between the pharmacist and the patient and to convey the image of a health care setting rather than that of a retail setting.
- Schools of pharmacy should emphasise the profession's social covenant and work harder on developing the professional self concept of their graduates.
- Pharmacist associations should foster deep discussions of the relationship between practitioner behaviour and the image of the profession, and they should adopt a progressive vision for the future of pharmacy practice and work assertively to help their members achieve that vision.
- Pharmacists should use patient records to focus on the overall quality of care and outcomes of treatment; these records should not be just a list of medicines.
- The pharmacist (not the pharmacy assistant or technician) must always be the one who communicates face to face with the patient or caregiver.
- Pharmacists should communicate to patients and to prescribers the results of their efforts to help patients make the best use of medicines.
- New models of pharmacist accountability for the outcomes of medicine use should be developed.
- Pharmacists should strive to be in union with physicians and nurses as an interdisciplinary team serving patients; constructive engagement should be sought with patient organisations.
- Existing pharmacy laws and regulations should be reviewed and enhanced with the goal of fostering an appropriate level of pharmacist autonomy and accountability.
- New models of pharmacist payment for clinical services should be developed.
- Successful practitioner efforts to transform pharmacy practice from a supply function to a clinical function should be celebrated and publicised within the profession.



Manasse commended the Community Pharmacy Section of FIP for collaborating in the creation of this stimulating symposium, and he thanked the speakers for their thought-provoking remarks.

This summary of the Leadership Symposium was prepared by William A. Zellmer under the guidance and direction of Henri R. Manasse, Jr.

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## Appendix E - Results of Ethics/Autonomy Survey of FIP Member Organisations (September-December 2012)

Statement	Strongly Disagree	Disagree	Agree	Strongly Agree
Pharmacists in my country understand completely their ethical obligations.	0	6	12	1
In my country the profession devotes a lot of time to promoting ethical behaviour.	1	6	8	3
In my country pharmacists receive good education on profess. ethics.	1	5	12	1
My country's code of ethics for pharmacists includes explicit guidance about professional autonomy.*	1	2	12	3
My country's code of ethics for pharmacists is up-to-date and reflects contemporary needs.	1	6	10	1
My country's code of ethics is legally binding (i.e., the pharmacist can be held responsible and disciplined for breaking any of its principles).	1	3	12	2
Consumers in my country expect the pharmacist to give independent advice without bias (conflict of interest).	0	2	10	5
Administration of a pharmacist oath at graduation is important.**	0	1	12	6
<i>What issues would you like to add to your code of ethics?</i>				
It must be up to date and it has to be obligatory.				
I would add compulsory attendance to the code of ethics programs by professional bodies for colleagues in order to inform them about updated issues on this matter.				
Good pharmacy practice guidelines must include medicine safety issues.				
Most important issues remain those that reflect the fact that the interest of the patient always comes first and is more important than any other factor that might influence the professional choices and behaviour of pharmacists.				
<i>Please indicate your level of agreement with the following statements: The following factors are important barriers to pharmacists' professional autonomy in my country:</i>				



Barrier	Strongly Disagree	Disagree	Agree	Strongly Agree
Political constraints on the profession	0	3	11	4
Interprofessional constraints (e.g., power imbalance with doctors, hierarchy in the workplace, cultural sensitivity towards older colleagues)	0	2	9	8
Financial pressures	0	2	5	12
Pharmacists' job security	2	6	8	3
Pharmacist lack of self confidence	0	5	10	4
Pharmacist lack of ethical literacy (i.e., knowledge and understanding of ethical principles in pharmacy)	1	10	3	5
Lack of health literacy of the consumer (i.e., ignorance of effect and side effects of medicines; misunderstanding due to advertising, etc.)	1	5	10	3
Legal restrictions	2	9	6	2
Pharmacists' lack of competence, perceived or real (i.e., feeling lack sufficient contemporary knowledge and skills)	3	5	8	3
Pharmacists' lack of motivation	1	4	10	4
<i>Other obstructions or challenges to professional autonomy in the practice of pharmacy in your country.</i>				
Unregulated (extreme liberalisation) of the pharmaceutical sector.				
The ownership of pharmacies by medical insurers or medical funders has led to an unfair advantage. Then, banking sector has also not extended financial assistance to individuals who want to open own pharmacies. This has led to false declaration by pharmacists, when the pharmacy is funded by non-pharmacists. Pharmacists may then exhibit unethical behaviour to satisfy their 'masters.'				

\*18 of 19 respondents said their country has a code of ethics for pharmacists.

\*\*11 of 19 respondents said new pharmacy graduates in their country take an oath that commits them to pursue their profession with high ethical standards.



## Appendix F—Literature Review on Pharmacist Ethics and Professional Autonomy

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*and William A. Zellmer, BS Pharm, MPH, Pharmacy Foresight Consulting, Bethesda, Maryland, USA.*

### Overview

The following is a review of a selection of the English-language literature relating to the undertakings of the Working Group on Pharmacist Ethics and Professional Autonomy, International Pharmaceutical Federation (FIP), conducted in February 2013. Considering the many languages in which ethics in pharmacy has been written about, it was not possible to comprehensively review all international literature; however, we believe the scope of the literature in the English language sufficiently reflects the perspectives of the majority of pharmacists around the world, particularly in relation to professional autonomy.

### Background

The changing environment in which pharmacy practice operates around the world today is challenging in many ways, calling for pharmacists to reflect on their professional ethics, in particular in relation to professional autonomy. Pharmacy practice has seen the commodification of healthcare and a global shift towards corporatisation, where pharmacy chains have steadily replaced the traditional independent ownership model. In this environment pharmacists appear to experience diminished autonomy, as they subsume their knowledge and ethics to the needs of the corporation that employs them. Perceptions of pharmacists as “dispensers” and “shopkeepers” and the lack of recognition of pharmacists’ professional status have also resulted in young pharmacists across the globe feeling a loss of professional identity and disillusion in the profession.

In the face of these challenges, pharmacists must re-evaluate how their role in the healthcare team can fulfill their social mandate and benefit the patient’s best interests. This review aims to provide a brief overview of the literature pertaining to aspects concerning professional ethics in pharmacy, with a focus on professional autonomy, conflicts of interest in healthcare and contemporary challenges facing the profession of pharmacy today.

### *Ethics in the Professional Life—Some Evolving History*

Ethics in healthcare as we know it today generally has its roots in history from the time of Hippocrates(1). The paradigm of this ethical foundation of



healthcare is the Hippocratic Oath, which, according to some scholars, emerged not from the general milieu of the Greek philosophers in medicine but even further back in history, to the philosophical-religious cult of the Pythagoreans (1-3). The Oath served a number of purposes, including the binding together of healthcare professionals into a cohesive and effective social force, with a clearly articulated focus on principles of patient care, privacy and to “do no harm.” In relation to medical ethics, the Oath has had the most significant influence and has remained over the millennia central to healthcare ethics to the present day.(4)

Profound issues and perspectives about healthcare have come to the forefront in modern history and into the 21st century. In particular, post World War II, the emergence of human rights has been a driving social and political agenda in healthcare. Movements such as consumerism, feminism and human rights movements, have also immensely influenced ethics in healthcare.(5) In addition to these influences, healthcare professionals operate today in an environment of intense technical, pharmaceutical and medical progress, giving rise to many ethical challenges in professional practice, as reflected in the main body of this FIP Working Group report.

Ethics in the specific context of professional behaviour has therefore emerged over the last few decades as an increasingly important aspect of practice and research in healthcare professions around the world. To date, however, research in pharmacy ethics, both empirical and theoretical, is relatively scarce. (6-8) There is far more literature available in the philosophy of healthcare professions, such as medicine and nursing, than in pharmacy.(7, 9) However, there are many shared values with pharmacy in the context of patient care and application of principles of bioethics.

Nevertheless, each profession is distinguished by its specific roles and duties, necessitating some degree of specificity in ethical principles applicable to practitioners of each health care profession. Not all principles of professional ethics applicable to medical practitioners are relevant to other healthcare providers. Hence there is bound to be a specific scope of ethics particular to pharmacy.(10)

Ethics as it applies to the practice of pharmacy has, with only a few exceptions, mainly been articulated in codes or pronouncements from professional bodies, opinions in editorials, textbooks or debates. A few have engaged in philosophical analysis of the core values in the profession.(7, 11-14, 96)

An endeavour to examine the philosophical foundations of pharmacy ethics (predominantly in the community setting) has been made in the USA over the past few decades, particularly in the works of Robert Veatch, a renowned



ethicist in healthcare, Robert Buerki, Louis Vottero, Amy Haddad, Charles Hepler (co-founder of the conceptualisation of pharmaceutical care), and Joseph Fink amongst many others.(15-21)

Over twenty years ago, at a conference convened in the USA (1985) entitled “The Challenge of Ethics in Pharmacy Practice,” the importance of codes and the role of society in pharmacy ethics were examined. Principles such as beneficence (“to do good”), respect for patient autonomy, veracity, promise keeping, non-maleficence (“to do no harm”), and justice (both social justice and distributive justice) were identified as pertinent to the practice of pharmacy. Moreover, it was observed that with the advent of contemporary patient-focused healthcare, a shift in ethical orientation in pharmacy practice had taken place, rendering traditional paternalism no longer acceptable.(16)

That conference was a significant forum for the discussion of ethics in contemporary pharmacy practice, in which many ethicists presented their interpretations and perspectives, both philosophical and practical. Robert Veatch analysed the origins of some relatively newer concepts and principles in terms of fundamental theories of utilitarianism and deontology and the relevance of these principles to pharmacy.(15) Veatch highlighted, in addition to autonomy and justice, the relevance in pharmacy of veracity and promise-keeping, derived from the principle of respect for the individual.

Veatch (22) also launched a case-based series in the late 1980s that analysed 32 examples of ethical dilemmas in hospital pharmacy.(23, 24) The issues tackled in this exceptional series reflected a vast scope of ethical challenges in the practice of hospital pharmacy. Examples of issues covered were: maintaining patient confidentiality, questioning motives for prescribing, pharmacists’ refusal to supply a medicine (for a number of different reasons), conflicts of interest, charging for drugs, a request to mislabel a prescription, patients’ right to refuse medication, drugs in short supply, and unethical research.

Similarly, the Pharmaceutical Society of Australia recently launched a series of case-based articles in which young pharmacists were invited to submit anonymous letters describing ethical challenges in practice, which were analysed by Chaar.(25-30) These articles addressed ethical challenges young pharmacists face such as perceptions of lack of autonomy, insecurity and lack of confidence, the role of the preceptor/owner in modeling professionalism, and other aspects of practice. The framework used to analyse these cases was the Code of Ethics for Pharmacists.(31) The Society, in response to the plethora of cases submitted and feedback about the continuing series, established the Ethics Advisory Committee, announced at its Annual General Meeting in October 2012.



Some empirical research has also been conducted on moral reasoning capabilities of pharmacists in the USA, Canada, the UK and Australia. (6, 32-35) The outcomes of some of these studies have pointed to the higher propensity for ethical challenges in the community setting. They also highlighted the importance of the student experience and the need to initiate teaching pharmacy ethics early in the curriculum and in continued lifelong learning.

These analytical perceptions enriched the tapestry of ethical reflection in pharmacy, and adequately set the scene for further discussion of some of the ethical challenges (some yet to be resolved), which pharmacists face on a day-to-day basis.(10) Up until recent times, no concern was expressed relating to commodification of healthcare and the ever growing concern about dualities or conflicts of interest in pharmacy. A new era of role conflict and ethical challenges is emerging.

### ***Pharmacy as a Profession***

Professionalism in pharmacy has long been a contentious issue creating an ongoing debate among healthcare professions about the status of pharmacy. A profession itself as defined in Greenwood's "Attribute Theory" is an occupation with attributes such as: a formalised education process, a unique body of knowledge, community-oriented values, a code of ethics, formal recognition and ultimately the complete autonomy of the profession. Pharmacy meets all these attribution criteria, there is no doubt, but there have been challenges over time. Doubts have been raised concerning certain assumptions about pharmacy's professionalism, such as community-orientation vis-à-vis business viability and aspects of autonomy in evolving business models.(36)

Consequently, since the historical shift from compounder of medicines to supplier of mass-produced pharmaceuticals, community pharmacy practice, as far back as the 1960s was characterised as an "incomplete or marginal profession," comprised of elements considered to be both professional and non-professional. There was (and still is) a perceived conflict of interest between the sales of commodities and serving patients' best interests.(36, 37)

Recognition of the increasing role conflict, in the community pharmacy setting in particular, has prompted pharmacists over the last few decades to review their role in healthcare. Another factor prompting this review has been that documented inappropriate use of medicines (which could be ameliorated by pharmacists) is imposing an immense burden on health expenditures and patient safety.

By 1986, pharmacy was described as a "profession in transition" where significant changes, partly in response to its perceived loss of function, social power and status, created a movement toward a patient-oriented role for



pharmacists in general, and the emergence of a new “clinical pharmacist” role for pharmacists. (38, 39)

One notable representation of this change is manifested in constant reviews of codes of professional ethics around the world. Professional codes of ethics over the centuries have served as publicly proclaimed benchmarks for standards of professional conduct, above and beyond minimal legal and social expectations. These codes have also served to exert a positive, cohesive force upon individual members of a profession, and as products of professional associations, they reflect the consensus of a wide range of practitioners’ opinions regarding contemporary norms of the profession.(17)

To facilitate change, leaders seeking to redefine their profession attempt to express and strengthen the community orientation of their group, taking pains to construct or reconstruct their codes of ethics. (40) Thus, as the profession of pharmacy became more patient focused, codes of ethics in pharmacy in many countries reflected the change from traditional values to patient-centred care.

The profession of pharmacy proceeded to prove its value in many examples of good quality healthcare services developed and implemented in pharmacies around the world. A few literature reviews conducted by Chisholm-Burns et al. (2010) (41, 42) and Patwardhan et al. (2012) (43) highlighted the many ways in which pharmacists can make a noticeable contribution to the care of patients with chronic diseases. Examples include improving adherence to medications and preventing potentially harmful risks and prescription errors, thereby greatly improving patient outcomes and safety, as well as increasing cost-effective quality use of medicines.

Clearly, pharmacists can be considered valuable contributors to provision of good quality healthcare. There is a plethora of literature representing the services introduced in pharmacy practice around the world, and there is no doubt that the profession has advanced immensely in the last few decades.(44) However, it has not been a smooth transition. Problems have arisen (including objections from the medical profession), which have been addressed somewhat with evidence and change-management strategies.(39,40) Other concerns have emerged in response to the overtaking of the profession’s traditional model of community pharmacy ownership by global corporate bodies.

As a result, while modern codes of ethics in pharmacy emphasise that the dignity and welfare of patients must be paramount, it has also been recognised that this commitment to the dignity and welfare of patients can be compromised when pharmacists allow business objectives to influence and control their conduct.(45)





### ***Lack of Recognition of the “Professional” Status of Pharmacists***

Agomo (2012) presented the challenges preventing pharmacy from being recognised by some as a “true” profession, and the inability of pharmacists to utilise their professional knowledge and skills.(46) He states that the argument that pharmacy is not a “true” profession is due to a number of reasons such as:

1. Pharmacy does not have control over the social object of its practice: medicine.
2. Pharmacy seems to be guided by commercial interests.
3. Pharmacy has not been able to define its professional functions and roles properly.

There appears to be a lack of recognition of the “professional” status of pharmacists and the ambit of their professional skills and knowledge by the public and patients, other healthcare professionals, as well as policy makers and legislators. In a global trend, the majority of pharmacists have been forced into either employee status or into locum positions, minimising their impact on the professional development of pharmacy. Community pharmacists in the US and UK have been described by other healthcare professionals as “shopkeepers” and “dispensers.”(46) In India the potential contributions of community pharmacist towards the provisions of pharmaceutical services have only recently been recognised, but not well respected.(47) Globally, despite pharmacists regularly being rated by the public as among the most trusted healthcare professionals in polls around the world, policy makers and legislators seem to have little appreciation for the professional scope of a pharmacist’s knowledge and skills.(48)

The challenges to professional status have also resulted in the disillusionment of young pharmacists and a loss of professional identity. Pharmacy students are told that when they get out into practice, physicians will solicit their expertise in determining drug therapies, that patients will begin to expect medication management services and that someday, pharmacists will be allowed prescribing authority. However, in reality, student pharmacist expectations of what they will experience in practice are often not met, resulting in disillusion and discouragement.(48)

### ***Challenges to Pharmacist Professionalism and Autonomy***

Professionalism is a way of life for the most effective and successful healthcare professionals, and it is that message that pharmacy students, residents and new practitioners must adopt.(49) There is a vast array of literature about professionalism, defined in the Oxford dictionary as: “the competence or skill expected of a professional”; but it is important to relate this in the context of this review, to the profession of pharmacy specifically. Professionalism encompasses many behaviours that are commonly expressed in codes of ethics



and guidelines, emphasizing integrity, care and prioritizing of patient safety and principles of ethics in healthcare.

Zlatic, in his in-depth analysis of professionalism in pharmacy, touches on a number of intriguing points.<sup>(93)</sup> He notes “that professionalism, once taken for granted in professional education must now be ‘taught’ and assessed, signals a sea change,” suggesting this should be taken as stimulus to examine what constitutes professionalism in pharmacy. After describing the evolutionary history of professionalism unfolding from traditional definitions, to the influences of modern day social media and technology (YouTube and Facebook included), the author launches into exploring the “human nature of professionalism.” He encourages the embracing of transformational forces, and highlights the need for wise leadership to create supportive structures, institutions and environments necessary for practitioners to maintain the fiducial (i.e., based on confidence and trust) obligations that underlie the social contract between pharmacists and society. By the end of his chapter, drawing on several authors’ opinions and writings, Zlatic concludes that professionalism is about human relationship. He states:

With wisdom and insight the professions can continue to distinguish themselves from occupations by grounding their practice in fiducial relationships. It is this human relationship that allows the professions to exist in the first place. And as the profession of pharmacy continues to evolve, it is this human relationship that should guide practice for the clinical pharmacist in the clinic, classroom and laboratory. <sup>(93)</sup>

From another perspective, within the profession, as noted in the Leadership Symposium of the FIP (2009) (see Appendix D), it is generally understood that “a pharmacist’s mission is not only to provide medicine, but also to help people make the best use of medicines, a professional role of high value to society and more satisfying to pharmacists.”<sup>(50)</sup>

Thus, from a more practical perspective, pharmacists as the most accessible of all healthcare workers have increasingly redefined their role in the healthcare team to include services such as medication reviews and chronic care counselling to better serve their communities. <sup>(38, 43)</sup> The expansion of their role, in line with the pharmacist’s mission to help people make the best use of medicines, is critical to the recognition of pharmacist professional status, improving job satisfaction for pharmacists and protecting professional autonomy in today’s practice environment.<sup>(51)</sup> This requires high levels of professionalism, accountability (defined as: responsibility to someone or for some activity) and autonomy in practice.<sup>(52)</sup>



The major challenge to this concept, however, is that the traditional model of a community pharmacist owning his/her own pharmacy has given way to the chains and multinational operators.(53) The majority of pharmacists around the globe today are employed professionals in one way or another – either by corporate bodies or by other individual pharmacists; and generally speaking there are more pharmacists than there are positions. As such they are subject to divided loyalties between their professional duties and their desire for job security. (54)

According to Agomo (2012), maintaining professional status in this environment is not simply guaranteed through advancing education, special skills and licensing.(46) There needs to be a wider scope of resolutions in addition to counseling and other services. Some suggestions proposed were:

- Continuing education, volunteering and professional activities which are also important to developing professionalism in pharmacy practice.
- Students must learn and adopt the values, attitudes and practice behaviours of a professional through experiential learning (work experience).
- In the USA and Canada many schools hold “white-coat ceremonies” at the time students commence their professional studies. In some countries, newly graduated or licensed pharmacists take an oath or pledge of professionalism.
- The ideals of professionalism may be developed by enhancing the image of the profession through the provision of innovative services and supporting pharmacists to develop an ideology that asserts greater commitment to quality rather than the economic efficiency of work and economic gain.

Students and residents are trained to be professionals, in both community and hospital settings, lifting their expectations of pharmacy practice to lofty ideals of professionalism in contemporary practice.(52, 55-58) Young pharmacists experience disillusionment when they are unable to use the professional skills they acquire during their training.(46, 97) Students reflect on how their sense of professional autonomy is diminished when they view other practitioners engaging in unethical behaviour and when their employers use financial targets to compel them to sell stock.

Role modeling, setting an example to young pharmacists, is an under-investigated issue but may be addressed by pharmacy organisations and continuing education. Students in a study by Schafheutle et al. in 2012 identified role models as particularly influential in learning professionalism in pharmacy. (59) The students also stated that learning professionalism needed



to be grounded and longitudinal throughout the curriculum, e.g., that explicit statements in yearbooks and codes of conduct would be valuable.

Another crucial aspect of professionalism is the importance of integrity and care for patient safety in practice. Incidents of medication-related patient harm caused by lack of pharmacist attention erode public confidence in the profession. For example, a recent editorial in the US deplored the lack of professionally and ethically motivated oversight by pharmacists in a case of large-scale compounding, which resulted in contaminated injections that caused a number of deaths and immense suffering and expense. The author stated:

The public will not take seriously pharmacists' claims of professional autonomy and professional status until pharmacists consistently demonstrate their overarching commitment to the safety and well-being of patients.(60)

In a society where patients, doctors and other healthcare professionals question the integrity of pharmacists and the value of pharmacists' involvement in the healthcare team, pharmacists must distinguish themselves in responsible, ethical practice, making patient-care and safety their core business and make their worth known.(48, 96)

In some countries the challenges are of a different nature. A review of the literature by Basak et al. in 2009 highlighted multidimensional challenges for community pharmacists and pharmacy practice in India.(47) Lack of appropriate training and engagement of pharmacists in healthcare was demonstrated in a study where a survey revealed that 95% of respondents were not aware of the existence of tuberculosis control program in India. Another survey revealed that 99% of patients and doctors do not trust the community pharmacist on health and prescription related issues, leading to poor social status and inability to take up counseling. The pharmacist's primary role in India is reportedly reduced to dispensing, with few community pharmacies undertaking compounding. Dispensing consists of instantaneous supply/sale of medicines with or without prescription, and is mostly performed by non-pharmacists, without counseling. Further, many drugs in India are dispensed illegally without prescription by drug sellers with little or no knowledge of laws governing sale of medicines. Basak concludes that major reform is required in order for the profession, professional organisations, legislators, universities and the public to recognise the role of pharmacists in patient care.(47) These observations are by no means unique to India. In most countries around the world, pharmacists would agree, the profession of pharmacy is in a similar state of affairs.



Another complex issue in relation to professional autonomy is the right of the healthcare professional to decline treatment due to conscientious objection; i.e., in the case of pharmacy, the active moral objection to the purpose and use of certain pharmaceuticals. Although this controversial issue is beyond the scope of this review, a statement by the renowned ethicist Nancy Berlinger (2008, The Hastings Center) captures the general consensus that when moral objection is accepted, “Health care providers with moral objections to providing specific services have an obligation to minimise disruption in deliver of care and burdens on other providers.” (95)

### ***Conflicts of Interest in Pharmacy—Duality of Interest***

The duality of interest vested in the business of pharmacy (i.e., the sale of medicinal and other products alongside serving patients’ best interests) is a prominent, controversial issue. Charging for cognitive services in pharmacy, specifically those beyond the mere transmittal of basic information, has yet to be embraced let alone widespread, in most countries. Hence, whilst the pharmacist remains the most accessible healthcare provider, and can be consulted free of charge by any passerby, there remains the thorny issue of viability of the business in balance with patient-centred care.

The pharmacist as a professional generally enjoys high levels of social/community trust. To maintain viability of the business of pharmacy, the community pharmacy owner must employ marketing strategies, to sustain continuity of career and livelihood. Some pharmacists/corporations exacerbate the perception by adopting aggressively competitive marketing ploys, thereby heightening sensitivity to the integrity and trustworthiness of pharmacists’ advice.

The fine line between a “duality of interest,” considered legitimate and realistic, is often crossed to become a clear conflict of interest – which is regarded with mistrust and disdain.(61, 62) We discuss this issue in further depth later in this review. Whether the competitive model of community pharmacy, favoured by many Western country governments, is a suitably ethical framework for the profession, is a contentious issue. Some highly regulated Northern European models of pharmacy practice could exemplify good balance between business concerns and caring for the health and well being of patients/clients. (10)

Importantly, this problem is not limited to public perception of the role of pharmacy. Business matters affecting professional ethics of the individual employed pharmacist is also of growing concern. Employed pharmacists in every sector of the profession, including the pharmaceutical industry, have expressed increasing unease about their ever-diminishing professional autonomy.(11, 13, 36, 49, 54, 63) Most pharmacists today do not have control over their practice environment, as the corporate model of pharmacy practice



dilutes personal responsibility of the pharmacist, commodifies medicines, and gives top priority to business issues over patient concerns.(45, 46) Employed pharmacists constitute the majority of pharmacists in any country and this real concern does not bode well for the future of the profession.(48, 50)

### ***Pharmacists' Relationships with the Pharmaceutical Industry***

Banks (2005) explored a slightly different pathway of ethical discourse: the relationship between the pharmacist and the pharmaceutical industry from the perspective of conflicts of interest relating to marketing incentives (e.g., gifts, bonuses, etc).(64) He was of the opinion that a more thorough understanding of conflicts of interest (COIs) and how to avoid them will help pharmacists meet their obligation to provide the best patient care.(64) His article explores the divided loyalties of pharmacists through their relationships with pharmaceutical manufacturers that give rise to conflicts of interest and challenge their professionalism and ethical stance. Banks discussed the prevalence of behaviour leading to COIs, the negative effects of pharmacist COIs on patient care, and actions pharmacists can take to avoid COIs.

Similar to the case of physicians,(65, 66) pharmacists may become involved in ethically questionable relationships with drug manufacturers that conflict with their professional duty to act in the best interests of patients. According to Banks, gifts, sham consulting and sham research are increasingly directed at pharmacists as their therapeutic influence expands in the US. He maintains that pharmacists must exercise their autonomy and advocate for patients rather than serve the interests of the drug industry.

Banks also stated that pharmacists' ethical standards stipulate fidelity to patients, and serving the needs of society with an altruistic goal, as opposed to a materialistic one. Claiming that pharmacy codes of ethics do not make clear distinctions about potential COIs, he suggested that pharmacists ought to exert control over their relationships with pharmaceutical manufacturers and work to neutralise information asymmetry, retrieving drug information from authoritative sources and challenging manufacturers to document their promotional claims. Pharmacists, schools, and professional organisations can do more to expand knowledge and forge a new consensus regarding COIs in pharmacy. Pharmacists are also well positioned to advocate for patients rather than serve the interests of the drug industry.(64) This issue has been well documented in other literature, and in some countries there are guidelines in place for avoidance of ethical challenges in this context and other similar scenarios. (66, 67)

### ***Pharmacists Working within the Pharmaceutical Industry***

Pharmacists working in the pharmaceutical industry may sometimes be challenged with ethical issues relating to their role in commodification of



medicines and promotion of pharmaceutical products. For example, pharmacists employed by the pharmaceutical industry may be involved in or witness to, the design and/or dissemination of direct-to-consumer-advertising (DTCA) of prescription or over-the-counter medicines. It has been widely recognised that DTCA in all its forms, whether for prescription or nonprescription medicines, is a major concern to pharmacists, physicians and those concerned about public health in general. This issue has also been a major concern of FIP and WHO. (68-77) Pharmacists involved in promoting medicines in such a manner may not be compliant with the profession's social mandate, that being primarily patient safety and serving their best interests. The literature appears to be devoid of study or discussion of the ethical considerations associated with pharmacist employment by the pharmaceutical industry. It would be helpful to know, for example, how such pharmacists balance the ethical imperatives of a health care professional and the business imperatives of their employers.

### ***A Major Challenge: Corporatisation of Pharmacies and Diminishing Autonomy***

For the purposes of this report, the FIP Working Group has defined professional autonomy as:

The right and privilege granted by a governmental authority to a class of professionals, and to each licensed individual within that profession, to exercise independent, expert judgment within a legally defined scope of practice, to provide services in the best interests of the client.

The ownership of community pharmacies globally is being controlled by a small number of corporate entities. Market-driven, discount pharmacy chains are on the rise as continued pricing pressures, key drug patents expirations, and government-funding reforms squeeze margins and take the focus away from patient care. (92)

Evidence shows that increased corporatisation of pharmacies creates a "duality of interest," diminishes pharmacist professional autonomy and threatens patient safety. Hussar (2012), in an article entitled "Our Professional Autonomy and the Health of our Patients are at Risk!" eloquently presented his concerns about professional autonomy in pharmacy (78). He identifies the risks inherent in neglecting the issue of professional autonomy in practice, calling for a number of recommendations to be adopted by pharmacy organisations. Two of these recommendations, relevant to the aim of this review are:

1. The entire profession of pharmacy must demonstrate a strong commitment to increase the number of independent pharmacies and to support and advance progressive models of practice in these pharmacies.





2. Independent pharmacists and the organisations in which they are participants must communicate more effectively and collaborate in addressing challenges and working toward professional goals.

Perepelkin et al. found that pharmacy managers (i.e., those in charge of the pharmacy) working in a corporate pharmacy environment in Canada are less orientated to their business role when compared to those working in an independent or franchise pharmacy environment.(54) In addition, while respondents in the same study rated their authority similarly, autonomy, decision-making capabilities and control were found to be most limited among corporate respondents and, to a lesser extent, among franchise managers.

Basak et al. in 2009 (47) revealed that the majority of ownership in India is by non-pharmacists and the significant rise in the proportion of chain store pharmacies in the last decade has seen pharmacists' primary role reduced to instantaneous dispensing, without counseling.

Bush et al. (2009) found that corporatisation of the United Kingdom community pharmacy sector may threaten to constrain attempts at re-professionalisation through role extension and a drive for greater pharmacy involvement in public health. (53)

### ***Commodification (Commercialisation) of Healthcare and Divided Loyalties***

The price, cost, quality, availability and distribution of health care are increasingly left to the works of the competitive marketplace, limiting the accessibility of healthcare to consumers and producing detrimental effects on the ethics and practices of the healthcare industry. (79, 80) In a pharmacy context, increased competition and financial concerns have produced ethical dilemmas as pharmacists in all settings (individual or corporate) find their loyalties divided between conflicting financial and professional duties.(25, 36, 81) However, a number of researchers agree with Wingfield et al., who found that although business and commercial values led to ethical issues (such as controlling profit and customer pressure), company and organisational policies were also key elements weighing in on the shift in values and commercialisation of the profession.(7)

United States and Canadian studies by Latif et al. suggested that the hospital pharmacy environment was more conducive to clinical reasoning in that it was devoid of individual financial conflicts of interest. It was found that pharmacists who remained in practice longer received lower moral reasoning scores and students also scored lower in moral reasoning scores after exposure to community pharmacy (33-35, 82-90). Hibbert et al. noted the influence of self-





interest, commercial/organisational values, and legal concerns in the decision making of pharmacists in the UK.(81) Cooper et al. raised ethical concerns among UK pharmacists relating to charging for monitored dosage systems, branded medicine substitution, pressure to link-sell medicines, concern for customer poverty and selling confectionary.(63)

Pellegrino maintains that healthcare is not a commodity (i.e., a commercial product) and should not be treated as such. This point is also reinforced by Starr in an earlier publication. (91) A pharmacist, as part of the healthcare team, must recognise the primacy of the patient's best interest in their decisions, exercise restraint on self-interest, and treat healthcare as a common good rather than a commodity in a profit-driven marketplace. (80, 91)

### **Conclusion**

This literature review has highlighted several historical and contemporary issues and concerns relating to professional ethics and autonomy in the profession of pharmacy around the world. Findings and recommendations in this body of literature may assist FIP in leading the profession to implement professional and cultural change to enable it to face the challenges of contemporary practice.

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