

# Ethics, Law, and the Emergence of Pharmacists' Responsibility for Patient Care

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I was a freshman pharmacy student at the University of Washington in January 1965. The first issue of *Drug Intelligence* was exactly 2 years away, and I had just completed a course entitled "PHARM 204: Pharmacy Orientation and History" during the previous quarter. My academic success that fall was mixed: I did well in PHARM 204, but nearly flunked Handball and barely got a "C" in MATH 105. I still regard that first quarter as an inauspicious beginning to a love affair with pharmacy that has now exceeded 40 years, but to this day I remember my astonishment at learning in PHARM 204 that for a pharmacist to tell a patient the name of his/her drug without the express permission of the prescribing physician was considered unprofessional in the Code of Ethics of the American Pharmaceutical Association (APhA). The code specified that the "...pharmacist does not discuss the therapeutic effect or composition of the prescription with the patient. When such questions are asked, he suggests that the qualified practitioner is the proper person with whom such matters should be discussed."<sup>1</sup> Or as a practical example, we were told, "If a patient asks what a drug is for, you should ask, 'What did the doctor tell you?' Then, when they tell you, tell them that the doctor is a very bright fellow and that the medication is precisely the right drug for that use." I just couldn't fathom going to school for 5 years to be limited to unthinking and possibly misleading conversations with patients.

It is clear from this one example that the concept of the role of the pharmacist changed during the ensuing 4 decades. Indeed, it is unimaginable that a clinical practice of pharmacy could exist under the strictures of the 1952

An ethical and corresponding legal structure based on physician supremacy over patients and other healthcare professionals has evolved over the past 40 years to recognize patient autonomy and realize that systems and societal structure influence healthcare outcomes as greatly as do provider-patient interactions. Future ethical and legal imperatives for pharmacists will necessitate a profession prepared to deliver primary, secondary, and tertiary care services as part of teams of providers, and less devoted to drug distribution as a professional *raison d'être*.

**KEY WORDS:** legislation, pharmacy ethics, pharmacy law.

Code of Ethics. The current code, adopted by the APhA in 1994, is markedly different. It espouses both an ethic of respect for patient autonomy and pharmacist responsibility for outcomes of care in the context of a covenantal pharmacist-patient relationship.

However, I'm still mindful that pharmacy students of my era were also told that we had a right to refuse to fill any prescription, an ethical principle not mentioned in the 1952 Code of Ethics or in any subsequent revision, and which I believe to be a fallacy that bedevils the profession to this day. An ethic of responsibility would require pharmacists to refuse to fill prescriptions that objectively are harmful to a patient, such as obvious overdoses, therapeutic duplication, or contraindicated drugs. On the other hand, continued assertion of a right to refuse to fill any prescription without needing to state an objective reason is anchored in an earlier, paternalistic ethical view. (I have discussed this more fully in an earlier contribution to *The Annals*.<sup>3</sup>) Also, unfortunately, the recent press coverage of pharmacists' lapses during the dispensing process suggests that many members of our profession retain a limited view of their role. Thus, although the profession has largely cast off its 1930s-era self-perception as "handmaiden of the physician,"<sup>4</sup> it has not yet thoroughly embraced, in its ethical, operational, or legal priorities, a vision of a profession with critical responsibilities for outcomes of patient care that arises from a covenantal relationship with patients.

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How has the profession made this transition, asserting independent responsibility and a commitment to patient care, and gaining in its scope of practice, while retaining among many of its members adherence to an older model related to dispensing and distribution of drugs? The detailed story cannot be covered here. Forty years of leadership within the profession and the pharmacy academy cannot be condensed into a short essay. What I wish to do, though, is highlight what I believe are 2 major societal influences and some key legislative and jurisprudential events that have paved the way for the change or served as signposts along the way.

The first influence is the birth of the bioethics discipline, which arguably has its roots in the Nürnberg trials following World War II. However, the 1960s and 1970s must be recognized as the time of the true genesis of our current understanding of bioethics in the US. Beecher's<sup>5,6</sup> exploration of ethical lapses in medical treatment and research, and the development of the artificial kidney machine at the University of Washington—and the “God Committee” in Seattle to determine how to allocate the limited number of machines to the large number of needy patients<sup>7</sup>—led to heightened awareness of ethical issues, many of them related to human trials of novel drug therapy or to the adverse effects of medical progress. The revelations of the infamous Tuskegee Study in 1973<sup>8</sup> helped spur the 1974 passage of the National Research Act (Pub. L. 93-348) and the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced the Belmont Report<sup>9</sup> in 1979. The Belmont Report encompassed several tenets of emerging principles for medical ethics including respect for persons, beneficence, and justice. It also discussed a concept regarding therapeutic decision-making that first appeared in federal law in the 1962 Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (Pub. L. 87-781): formal assessment of risk and benefits. It was also the first federal law to require informed consent for research using human subjects.

The second important factor leading to changes in the role of pharmacists, in my opinion, was the women's health movement. My earliest recollection of this emerging social force was the publication in 1971 of *Our Bodies, Ourselves* by what became the Boston Women's Health Book Collective. As recently summarized by Keefe et al.,<sup>10</sup> the women's health movement, along with other social activists, “...wrested control of ‘authoritative knowledge’ that had once been the sole domain of ‘experts’ with advanced medical training. They used this knowledge to empower ‘average’ people with medical information, [and] promote self help...”. I have always believed that this movement, largely grass-roots and locally organized, set the stage, through its action in numerous cities and states, for many changes in state laws affecting medical and pharmacy practice.

Some of the most important changes seem to me to include the repeal of ant substitution laws and the passage of drug price posting regulations in the early 1970s. These were followed by legislation or regulation requiring the disclosure of the drug name on the prescription label, the maintenance of patient profiles, and mandatory patient counseling. The self-help movement assault on physician domination of health care seems clearly to have presaged the expansion of scope of practice for nurse practitioners, physician assistants, optometrists, naturopaths, and pharmacists, among others. Certainly in my own career, the seminal passage of a new pharmacy practice act in Washington in 1979 has been critical to the emergence of a new perspective on the role of pharmacists in my home state, and Washington's example has been followed elsewhere. The legislation added 3 major areas to the scope of the practice of pharmacy: administration of drugs, monitoring of drug therapy (including ordering of drug therapy-related laboratory tests), and “the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs.”<sup>11</sup> It was a key recognition of pharmacy leadership in Washington that this expanded scope was best implemented by being imbedded in the statutory definition of practice, and thus was applicable to all licensed pharmacists, not requiring special certification or training beyond that specified for pharmacists generally.

Armed with an emerging consensus that health care should respect patient autonomy and that therapies should be evaluated carefully in terms of benefits versus risks, and with emerging challenges in health care being described in terms of cost, access, and quality, pharmacists found themselves well positioned (if not necessarily well prepared) to contribute to the solutions for these challenges. The history subsequently cataloged in *The Annals* and other facets of the pharmaceutical literature is largely one of steady progress. (Although it seemed at the time to progress haltingly, when seen through the retrospective of one pharmacist's career, an amazing amount of change has occurred.) However, as innovative practitioners pushed ahead the frontiers of practice, the realization that the pharmacy academy was not adapting rapidly enough to the needs of the emerging profession led to a key event: the release in 1975 of *Pharmacists for the Future*, or the Millis Commission Report.<sup>12</sup> It has always been my sense that this report was more the recognition that a paradigm shift had occurred than a precipitating factor of the change. Nevertheless, the Millis Commission marked the beginning of more than 30 years of critical involvement by the pharmacy academy, represented by the American Association of Colleges of Pharmacy, in affecting the direction that the profession would take.

The last 40 years have also been marked by significant federal court decisions and a slowly changing perception of the role of pharmacists in state courts. One of the pivotal Supreme Court decisions directly involving pharmacy was its 1976 decision striking a Virginia State Board of Pharmacy ban on drug price advertising.<sup>13</sup> On First Amendment grounds, the court declared that the state did not have a compelling interest in preventing patients from learning of prices for prescription drugs and comparing pharmacies on the basis of price for similar services. Many pharmacists regard this opinion as a low point in judicial respect for our profession, owing to Justice Burger's comment therein that "it is clear that in this regard [the dispensing of brand name drugs] [the pharmacist] no more renders a true professional service than does a clerk who sells law books." From my perspective, however, this case placed upon state agencies the duty to regulate in the public interest, not solely in the interests of a profession, and while it undoubtedly added to the competitive nature of the retail pharmacy marketplace, it also made it easier for pharmacists to challenge restrictions on their practice that were stifling innovations in providing patient care. To this day, the strongest argument for expansion of the role of the pharmacist lies in our ability to improve the welfare of patients.

The state court record regarding pharmacists' professional responsibilities continues to develop, and its history cannot be adequately recounted here. It seems clear to me, however, that the state courts have largely followed, rather than led, the profession's assumption of responsibility for outcomes of patient care. While there are many cases that could be cited to illustrate this trend, I would draw readers' attention to the 2005 decision in Florida in the case of *Powers v. Thobani*.<sup>14</sup> The 4th District Court of Appeals of Florida relates the 1965 decision in *McLeod v. W.S. Merrill Co.*<sup>15</sup> to an emerging conception of pharmacists' duties and states that "we are unwilling to hold that under no set of alleged or discoverable facts could [the plaintiff] sustain negligence claims" against pharmacists who otherwise accurately filled multiple authorized prescriptions for apparently excessive doses of oxycodone, carisoprodol, and other drugs.

On the medical ethics side, the courts have dealt with several major issues—none of which were considered prominent in 1960—that have shaped the current practice of medicine and pharmacy: consent to treatment, foregoing life support, advanced directives, the rights of children, reproductive rights, medical confidentiality, and aid in dying. Some of these issues now seem settled matters, but appropriate decisions at the beginning and end of life clearly remain disputed issues in the US. Pharmacists once seemed to have a limited role in these medically dramatic decisions, but our increasing clinical involvement with our patients has now placed us squarely into these controversies.

Where does the profession go from here? It was once thought that our health system tackled quality first, provid-

ing what many assert to be the "best medical care in the world," and then faced issues of cost and access in recent decades. The emerging concern, of course, is that the US now spends more on medical technology and services per capita than the rest of the world, but our societal outcomes of care lag behind our industrialized peers. It seems to me that a focus on quality of care by individual practitioners has helped create the ability to bring almost miraculous technology to individual patients, but it has ignored system-level imperatives. From an ethical perspective, the bioethics movement has emphasized the provider–client level of interaction, placing responsibility on individual practitioners to assure that patients' autonomy is respected. In his commentary on Albert Jonsen's book, *The Birth of Bioethics*,<sup>16</sup> Baker<sup>17</sup> concludes that, "The genius of bioethics, as with classical liberalism, lies in its recognition of the value of dialogue and compromise.... Bioethics succeeded by giving voice to the patient over the physician. What remains to be seen is whether it will sustain the patient against the corporation." I believe there will be a greater emphasis in the future on the ethics of teams and systems. Glaser<sup>18</sup> advocates that there are "three realms of ethics": individual, organizational, and societal, and argues that we cannot succeed in the first realm unless we solve the problems in the others. The findings of the Institute of Medicine in its Quality Chasm series of publications clearly suggest that on the operational level as well, problems with patient care at the provider–patient level cannot be resolved unless institutional-level and societal barriers to quality are removed.

Quality redefined in terms of system-level outcomes is emerging as our next frontier. Pharmacists will succeed in the legal and ethical domains to the extent that they are prepared to deliver patient care as part of a team. I am made optimistic by the conclusions of the Pharmacy Manpower Project, which projects a significant shortfall of pharmacists in 2020 based on the needs for pharmacists to serve as providers of primary, secondary, and tertiary patient-care services, while assuming a significant reduction in the need for pharmacists involved in order fulfillment.<sup>19</sup> The key imperative resulting from these conclusions is that pharmacists must be prepared—and must prepare themselves—for clinical practice within healthcare systems and teams, and must be less devoted to drug distribution as a professional *raison d'être*. Fortunately, the eventual retirement of pharmacists such as me, who were inculcated with ethical and legal imperatives dating to a much older paradigm, should make way for the transition to a profession composed of our younger successors whose training and enculturation will fit them well for new realities. However, since I believe the profession is largely becoming what I thought it could be when I was taking PHARM 204, I think I'll stick around just a while longer.

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