BUERKI VOTTERO ◆ ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE ◆ AIHP

ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE

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2ND EDITION

Ethical Responsibility

Ethical Responsibility in Pharmacy Practice

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On the cover: The "triad of medical care" has been the basis for the ethical relationship between the pharmacist, the physician, and the patient for centuries. In the background, an early depiction of the triad from Book 7 of the encyclopedia *On the Properties of Things* by Bartholomew the Englishman, published in Westminster about 1495. In the foreground, a photograph of a contemporary triad (courtesy of the Department of Veterans Affairs).

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Introduction to the Second Edition

In the decade since this little textbook was conceived, the American practice of pharmacy has undergone a profound sea change. In the early 1990s, pharmacy educators were still debating whether the entry-level Pharm.D. should be a universal requirement; Congress briefly considered, then quickly dropped, a plan which would have provided the United States with national health insurance, including a prescription benefit; "pharmaceutically assisted death" became a reality in Oregon; OBRA '90 brought legislative grit to the ethical mandate for patient counseling by pharmacists; and the American Pharmaceutical Association established a broad-based committee to develop a code of ethics for all pharmacists. Riding the crest of these waves was the new practice philosophy of pharmaceutical care, so full of professional promise, yet untested in everyday pharmacy practice.

All these changes brought a new interest and urgency to the teaching of professional ethics in our schools and colleges of pharmacy. The AACP's Commission to Implement Change in Pharmaceutical Education included "facility with values and ethical principles" in its statement of general educational outcomes, which were given added importance when adopted as accreditation criteria by the American Council on Pharmaceutical Education; the handful of elective courses that had survived the curricular crunch of the 1990s were dusted off and given new life; our friend and colleague, Amy Haddad, organized a brilliant series of workshops for teachers of pharmacy ethics, including one on the ethics of pharmaceutical care; the American Association of Colleges of Pharmacy supported the creation of an Ethics Special Interest Group (SIG); new textbooks on pharmacy ethics (including this one) appeared on the market; the Code of Ethics for Pharmacists was ratified by members of the American Pharmaceutical Association in 1994 and offered to the profession.

By the end of the decade, the Doctor of Pharmacy degree was the standard entry-level preparation for pharmacy practice; as the baby-boom generation settled into retirement and anecdotage, the demand for prescriptions approached and then exceeded 3 billion orders annually; schools and colleges of pharmacy could not

graduate enough pharmacists to meet the demand, and the institutions themselves reproduced at a rate no one would have predicted ten years earlier; pharmacy technicians graduated from certified programs and were licensed in some states, adding a new fillip to the pharmacy manpower problem; mail-order prescription programs, once dismissed as an annoyance, now set industry standards for speed and reliability in a multibillion-dollar prescription market; direct-to-consumer prescription drug advertising soared and Internet "pharmacies" thrived, giving consumers unprecedented freedom in the choice of their therapy; advanced computer software and robotics promised to free the pharmacist's time to counsel patients, but the OBRA-mandated "offer to counsel" was still too often observed in its breach; the notion of pharmaceutical care has been embraced by the profession, but the practice philosophy still struggles in its implementation, as deep-discount pharmacy chains continue to believe that all the American public wants from its pharmacists is good, cheap prescription drugs delivered up as quickly as possible; and the Code of Ethics for Pharmacists has yet to be universally adopted by the pharmacy profession, as it struggles once again to redefine its societal purpose.

This new edition of *Ethical Responsibility in Pharmacy Practice* includes new sections on controversial topics such as terminal sedation, euthanasia, and assisted suicide; ethical issues associated with controlling prices on prescription medication; and the ethical challenges presented by alternative medications. A commentary has been added to each case study, which pharmacy students should find useful as they develop their own set of professional practice values and methods of resolving the ethical conflicts they will face in their professional practice; an extensive glossary of terms also has been added as a courtesy to the reader. Our educational goal, however, stated in 1994, remains the same: "By introducing students to ethical concepts, giving them directed practice in applying ethical principles, and allowing them to develop skills in problem-solving and critical thinking, the instructor of professional ethics can heighten student sensitivity, increase professional awareness, and, indirectly, improve health care at the critical pharmacist-patient interface."

Introduction to the First Edition

America appears to have been foundering in an ethical crisis for the past several years. As individuals in the highest ranks of government, the clergy, business, and sports became caught in a quagmire of lies, sharp dealing, impropriety, and scandal, Americans began to reexamine the underlying moral tenets in our society and found them wanting. Politicians charged that educators condoned and even fostered a plurality of values in our school systems; educators pointed to the decline in church attendance as the root of the problem; and clergy blamed the government for removing moral teachings from public education on overly zealous Constitutional grounds. At the same time, the American health-care system underwent its most tortuous redefinition in recent history as third parties started to examine quality of care, professional competence, allocation of resources, and to insist upon health maintenance, all within the pervading aura of cost-containment. Finally, an increasingly sophisticated public demanded that its health care be not only more affordable, but virtually flawless in its outcomes. The alternative, it declared, was litigation, and malpractice insurance rates soared.

Throughout this turmoil, American pharmacy emerged remarkably unscathed. Its practitioners basked in the warm glow of public trust and confidence and continued to expand patient services. Pharmacy educators began to stress interpersonal communication skills in their already crowded curricula in an attempt to enhance patient care through improved compliance with prescribed medication. Yet as patient communication increased, the nagging ethical issues of preserving patient confidentiality and autonomy while maintaining openness and truthfulness tested the resourcefulness of pharmacy practitioners and students alike. To be sure, pharmacy ethics has traditionally held a small place in the scheme of pharmaceutical education, if only relegated to a dean intoning the APhA Code of Ethics to his senior pharmacy students on the eve of their graduation. Yet by the mid-1970s, court decisions had seriously eroded the role of codes of ethics in maintaining standards of professional practice beyond that required by law and had brought into question the role that peer review should play in en-

suring a collective self-discipline. Faced with uncertain alternatives and what they perceived to be a crumbling of the nation's moral foundations, pharmacy educators began looked at formal instruction in professional ethics with new interest and commitment. At the same time, leaders in pharmacy practice called for a review of the profession's code of ethics, requesting the APhA to spearhead the development of a new "Code of Ethics for Pharmacists." *Ethical Responsibility in Pharmacy Practice* is the result of this interest and commitment; it would not have been published five years ago.

Instruction in professional ethics in a school or college of pharmacy poses several unusual challenges: To the student inured to scientific facts, reproducible laboratory values, and precise measurements, the study of ethics seems maddeningly arbitrary, a gray morass of competing principles that intrude upon a black-and-white world of unquestioned facts. Moreover, the student must not only master ethical principles, but learn to choose among alternatives and resolve ethical dilemmas at the higher level of abstraction represented by such problem-solving skills. To the instructor who cannot typically claim expertise in moral philosophy at the graduate level and may not be intimately familiar with the ethical dilemmas that plague today's pharmacy practitioners, the teaching of ethics may prove an uncomfortable, even threatening assignment, particularly in the give-and-take arena of small-group discussion. Moreover, the instructor may feel uneasy in taking a personal stand on ethical issues discussed in the classroom setting. Finally, the administrator who feels obliged to include required instruction in ethics in an already overcrowded undergraduate pharmacy curriculum is often caught between the specter of tokenism and the equally unattractive alternative of eliminating or compromising other course work.

The authors have had the luxury of testing out their ideas by teaching professional ethics to small groups of interested pharmacy students in elective proseminars over the past two decades. Upper-division pharmacy students who have had at least a modicum of practical experience in either the hospital or the community setting seem to profit most from weekly two-hour proseminars. While lectures are useful in conveying basic ethical principles, small-group discussions of no more than twenty-five students are necessary to develop the skills of critical thinking and problem-solving upon which intelligent ethical decision-making is based. Moreover, the students learn to become tolerant to a wide range of opinion from their contemporaries, which enhances the learning situation. Although this book has been primarily designed as a text for free-

standing courses in pharmacy ethics, teachers of jurisprudence, dispensing, or clinical practice may wish to use it as a companion text to introduce basic concepts of applied ethical decision-making. Moreover, preceptors in externship and clerkship settings can use the text to complement their individual mentoring of advanced pharmacy students prior to graduation.

The authors strongly believe that trends in professional values and ethical standards can be understood best within the historical context of American pharmacy practice. For example, while older versions of professional codes of ethics mirror changes in professional practices over time, reflecting changes in educational standards, legal obligations, and professional functions, the newly adopted Code of Ethics for Pharmacists reflects a fundamental shift to an ethos based upon morals and virtues. Accordingly, this text has been designed to reflect the developmental changes in the practice of pharmacy over the past century and to account for the transformation in professional values and ethics engendered by these changes. The ethical issues associated with each topical area considered—pharmacist-patient relationships, professional communications, and drug distribution—have also been developed within their own unique historical contexts.

While the teaching of professional ethics is undoubtedly labor-intensive, it can also be deeply satisfying: By introducing students to ethical concepts, giving them directed practice in applying ethical principles, and allowing them to develop skills in problem-solving and critical thinking, the instructor of professional ethics can heighten student sensitivity, increase professional awareness, and, indirectly, improve health care at the critical pharmacist-patient interface. *Ethical Responsibility in Pharmacy Practice* is our modest contribution to these goals.

CHAPTER 1

PROFESSIONAL VALUES IN PHARMACY PRACTICE

The traditional function of pharmacy practice—compounding and dispensing medications directly to the public in a safe and reliable manner—predates the emergence of the pharmacy profession itself. In every age and in every culture, individuals have taken the rather awesome responsibility for learning about and preparing medicines for others and, in a sense, managing their health care. The practice of pharmacy and, indeed, all healing professions is an intensely personal, peculiarly human activity that has been traditionally guided by such basic human values as compassion, dignity, justice, and truth. In recent times, the importance of these values has been underscored by surgical virtuosity, the prospect of pharmacogenomic drugs, and other dazzling technical innovations that have revolutionized modern medical and pharmaceutical practice.

Although human values are more commonly associated with such humanistic disciplines as philosophy and religion, health professionals are beginning to realize that the success of their medical interventions with their patients depends as much upon interpersonal, value-based relationships as it does upon technical competence. When the full range of personal and societal values associated with pharmacy practice is taken into consideration, even the seemingly benign activity of recommending a nonprescription medication takes on added meaning. Rather than making a quick clinical judgment and recommending a product, pharmacists sensitive to their patients' individual needs may defer a "sale," recommend medical intervention, suggest a change in life style, or just offer comfort and reassurance. To what extent, for example, does the perceived socioeconomic status of the patient determine the extent and nature of the professional services pharmacists provide? To what extent do the pressures for cost-containment influence the pharmacist's drug-product selection process? How does the accep-

tance of the practice philosophy of pharmaceutical care affect the value system of American pharmacists? Indeed, human values seem to be so completely integrated with modern health-care practices, that one might argue that the so-called "ideal" of a highly technical, purely clinical, and "value-free" practice of medicine or pharmacy is neither possible nor even desirable. Thus, any vaunted claim of "value neutrality" in contemporary health-care practices may be no more than a tolerance for a plurality of values or, worse, an excuse to avoid dealing with ethical dilemmas altogether. We must, however, remember the uniqueness of individual personal value systems: our righteous indignation over colleagues who appear to be avoiding moral responsibility very well may be a reaction to the unsettling possibility that they do not hold our values.

Traditional professional values in pharmacy practice

By the end of the nineteenth century, the practice of pharmacy in the United States emerged as a socially necessary function, distinct from medicine, and sanctioned by society. These sanctions took the form of licensure laws and examination procedures that established a benchmark for professional pharmacy practice. Turn-of-the-century pharmacists not only fulfilled their professional function of compounding and dispensing physicians' prescriptions, but also served as self-appointed guardians and advisors, dedicated to protecting their customers from dangerous poisons or fraudulent patent medicines. In some hospitals and other institutions, a handful of pharmacists manufactured irrigating solutions and prepared other drug products in bulk as their primary activity. In neighborhood drugstores, most pharmacists subsidized their professional function by selling other drug-related items and a wide range of so-called "lines"—cosmetics, tobaccos, sodas, sundries, and other unrelated commodities in an essentially mercantile setting. These pharmacists displayed a genuine concern for their patrons, dispensing simple drugs, patent medicines, and homely health-care advice to a trusting, unsophisticated clientele, earning their respect and the sobriquet "Doc." The basic value of pharmacy practice was built upon personal service, which affirmed pharmacists' belief in themselves as health-care professionals.

In burgeoning colleges of pharmacy, avuncular pharmacist-professors emphasized the identification, assaying, and testing of drug products, and the careful weighing, compounding, and dispensing of prescriptions. By the mid-1930s, universally required baccalaureate programs in pharmacy sought to infuse a well-

rounded general education into the traditional professional curriculum, a strategy calculated to result in both professional and public respect. "Your pharmacist is the scientist on the corner," public relations campaigns of the period proudly proclaimed. Licensure boards began to supervise components of practice through internship programs, a remnant of the traditional apprenticeship system of training. In the corner drugstore, good pharmaceutical service was defined in terms of elegantly prepared drug products with neatly-typed labels; hospital pharmacists stocked "drug rooms" from which doctors and nurses could obtain the drugs their patients needed. At about the same time, pharmaceutical manufacturers began to market more effective and sophisticated finished dosage forms that did not require further compounding by individual practitioners. Many pharmacists, however, resisted this technological intrusion and continued to cling to their limited vision of pharmaceutical service, bounded by the traditional compounding and distributive functions. Others even sought to increase this function by promoting so-called U.S.P. and N.F. "propaganda" campaigns through their state pharmaceutical associations. These campaigns encouraged physicians to write prescriptions for formulas in the official compendia that pharmacists could extemporaneously compound instead of merely dispensing the commercially available versions of the same products.[1] Certain groups of pharmacists continue to resist external challenges to their comfortable practice environments. As we will see, mail-order pharmacy operations, prescription insurance programs, and mandated patient counseling spark debates among today's pharmacists as stirring as the struggle to maintain the compounding function of sixty years ago.

By the early 1940s, drug therapy continued to evolve from palliative, symptomatic treatments to specific, effective chemotherapeutic agents. The focus of the pharmacist's professional function in all settings began to shift from the extemporaneous compounding of simple drug products to the increasingly efficient, cost-effective dispensing of dosage forms prepared by large, specialized pharmaceutical manufacturers. In teaching hospitals and other institutions, rededicated to therapeutic effectiveness and better patient services, a growing number of committed pharmacists defined the first practice specialty in pharmacy, one which began to focus upon serving individual patient needs through a system of optimum drug distribution.[2]

In the community setting, the concepts of self-service and mass merchandising redefined first chain and then independent

Edward Parrish (1822-72), author of the 1857 essay "Ethical Analysis," possibly the first serious consideration of American pharmacists' moral responsibilities. (*Kremers Reference Files, F. B. Power Pharmaceutical Library, University of Wisconsin-Madison.*)

In 1848 the Philadelphia College of Pharmacy promulgated the first American code of ethics for pharmacists. The painting "American Pharmacy Builds Its Foundations" by Robert Thom shows the artist's conception of the founding of the College in 1821. (*Illustration courtesy of Parke-Davis, division of Warner Lambert.*)

pharmacy practice, just as they had redefined the grocery and department stores of the 1930s. The steady growth of aggressive drugstore chains, which often considered their prescription departments as just another "line," frustrated many independent pharmacy practitioners. Some simply attempted to compete head-on with the chains in disastrous price-cutting wars; other more professionally minded pharmacists tried to promote their prescription departments while still providing the wide range of merchandise and services that had come to characterize the American drugstore. Despite the sweeping societal changes swirling about them, pharmacists continued to cling to their traditional service value. In their zeal to "serve the public," pharmacists added new "lines," provided free delivery for minor purchases, opened family charge accounts, sold postage stamps, and maintained mind-numbing sixteen-hour work days, seven days a week, providing the high level of service they felt the public expected from their corner drugstore.[3]

In this product-centered practice, professional values were dominated by service and accuracy. Pharmacists provided quick, attentive service and accurately prepared drug products for their patients, most of whom they usually referred to as "patrons" or "customers." Pharmacists prided themselves on the warm, interpersonal relationships they established with their patients, but refrained from taking any active responsibility for their health care, merely recommending either physician intervention or only the most benign over-the-counter remedies. To do otherwise, that is, to engage in so-called "counter-prescribing," would have encroached upon the physician's prerogative to diagnose and prescribe and was therefore considered strictly unethical. These self-imposed limits on professional activity not only restricted the pharmacist's patient-care interventions to superficial encounters, but reinforced the widely accepted product-centered practice standard.

Shifting professional values in pharmacy practice

In the 1930s, American pharmacy had described its passive relationship with physicians with such trite phrases as "the pharmacist is the handmaiden of the physician." As self-proclaimed "handmaidens," pharmacists viewed their service commitment to the physician as restricted solely to the accurate compounding of unquestioned prescription orders. While pharmacists envisioned themselves as stalwartly protecting the public from harm, ever alert for the occasional physician prescribing error, most felt uncomfortable discussing drug therapy with prescribers, content to

discharge their professional duty at the distributive level only. Pharmacists felt obliged to seek prescribers' permission to clarify dosage directions or even add auxiliary labels; many pharmacists felt secure behind this self-imposed "ethical" barrier.

At about the same time, progressive pharmacy educators sought to introduce not only newer curricular materials based on the emerging pharmaceutical sciences of physical pharmacy and pharmacology, but also hoped to add a so-called "clinical" component to the pharmacist's education, a goal deferred to another generation of practitioner-educators nearly two decades later.[4] The pharmacists prepared by these "new" curricula were now expected to take advantage of commercially available products; moreover, they were also prepared to apply the principles of the new pharmaceutical sciences to their traditional compounding function. Educators felt that these new science-based pharmacists—who now could prepare sterile, isotonic ophthalmic solutions, create ointments and creams with enhanced percutaneous absorptive qualities, and discuss the kinetics of drug degradation with ease and authority—would finally emerge as respected members of the health-care team.[5]

By the 1960s, the growing preoccupation with profits in both hospital and community pharmacy settings had overshadowed and in many cases undermined the traditional service values associated with professional pharmacy practice. In hospitals, specialized pharmacy practitioners managed an increasingly efficient and complex drug distribution system, characterized by unit-dose systems and highly trained pharmacy technicians, and had as their goal providing "the right drug in the right dose to the right patient at the right time." In independent and chain pharmacies alike, many pharmacists retreated behind their prescription counters and concentrated on increasing their productivity and profits, continuing to treat their patients as mere customers. Others, like the visionary Eugene V. White, saw salvation in the "pharmaceutical center" concept, an office practice of pharmacy that promised to separate professional services from the commercialized atmosphere that had stultified pharmacy practice. White abandoned the unrelenting, profit-centered service value that characterized much of pharmacy practice, and adopted a more professional, patient-centered service value, one that utilized patient prescription records and stressed the interpersonal relationship between pharmacists and their patients.[6] While successful in carefully selected locations, the pharmaceutical center concept was far beyond the standard of American pharmacy practice and languished until incorporated into the

clinically oriented practices typified by health maintenance organizations (HMOs) and neighborhood health centers nearly two decades later. Nevertheless, White's emphasis upon a patient-care value in pharmacy practice made a strong and lasting impression on practitioners across the nation, one that helped stimulate a transformation of the value system of the profession itself.

By the mid-1970s, however, evolving pharmacy practice and education began to be redefined in terms of a "clinically oriented" practice value that focussed on pharmacists providing effective drug therapy for their patients through extended interpersonal relationships. New drug regimens increased in complexity, generating such related professional challenges as drug interactions, drug product selection, and therapeutic drug interchanges, suggesting new professional roles and relationships for pharmacists. New, sophisticated dosage forms, such as transdermal patches and intraocular inserts, required not only extended professional knowledge on the part of the pharmacist, but the ability to explain their use to an often-puzzled patient. In hospital settings, pharmacy services expanded to include patient-care activities traditionally provided by nurses, such as intravenous admixture and medication administration programs. These new "clinical pharmacists" began to share the patient-centered value system of American medicine, abandoning subservience for collegiality while seeking—and to a certain extent achieving—professional parity with physicians. For their part, pharmacy educators responded by producing a new generation of scientifically sophisticated, clinically oriented practitioners through specialized "Doctor of Pharmacy" programs. Thus, just as pharmacists shifted the focus of their relationships with patients away from product-centered values, they also shifted the focus of their interprofessional relationships toward a patient-centered value system.

These shifts in professional values among pharmacists signaled the need for a deeper understanding of the human values associated with the patient-centered approach to professional pharmacy practice. Today, despite threatened reductions in patient services due to cost-containment initiatives in the health-care system, we appear to be witnessing a resurgence of the primacy of human values not only in medical and pharmacy practice, but throughout all health-care professions. This patient-sensitive professional attitude is reflected by an increased level of individualized professional service to both patients and physicians, and an increased emphasis upon the noneconomic values associated with drug therapy.

Incorporating human values into pharmacy practice

Up to this point, we have concentrated upon pharmacy's reaction to the many changes that redefined the American health-care system during the past half-century. To what extent has this been a societal-driven phenomenon? Certainly, the American public has held its health-care practitioners to a legally defined standard of practice ever since these standards were promulgated in licensure laws. The information and technological explosions of the last thirty years led some public officials to question whether the minimalistic legal standards of practice were adequate to protect the public health, resulting in such societal interventions as mandatory continued professional education and periodic relicensure procedures designed to presumably safeguard the public from poorly informed or even incompetent health-care practitioners. This concern with professional competence, coupled with the consumerism movement of the 1970s, which demanded full disclosure of product and service information, higher standards of product safety, and fair and equitable health-care costs, all contributed to a publicly driven agenda for health-care professionals that seemed to demand ever-higher standards of professional practice.

Recommitment to the human dignity of the individual. As health-care patterns became more complex and increasingly driven by cost-containment initiatives, some health-care practitioners began distancing themselves from their patients in the interest of efficiency: physicians felt they no longer could afford to make house calls, while nurses sought paraprofessional help for some traditional—if unpleasant—patient-care duties. Patients now found themselves numbered, counted, poked, prodded, and otherwise processed by the efficient, coldly clinical system of modern medical practice. The consumerism movement that had successfully demanded accountability from its health-care practitioners and struck down most of the so-called "ethical" bans on advertising of professional services now turned its attention to patient rights. The American Hospital Association, in response, quickly drafted a a statement on a "Patient's Bill of Rights," conferring upon beleaguered, processed patients the "rights" they already possessed, such as the "right" to be treated in a humane fashion or the "right" to examine their hospital bills. Patients and public officials alike soon saw through this transparent public relations façade, and sought real changes in the way patients were being treated.[7] In recent years, the effort to develop a broadly based

patient's bill of rights has been elevated to the halls of our nation's Congress.

Pharmacists, who had once erected high, elevated prescription counters to screen themselves from direct, "inefficient" patient contact, responded by lowering these physical barriers, altering long-standing psychic constraints to good pharmacy practice. Pharmacists could now discuss complicated drug regimens and potentially embarrassing administration techniques privately with their patients rather than whispering sensitive directions *sotto voce* over a high prescription counter. Other pharmacists, now unfettered by outmoded, paternalistic ethical constraints enjoining them from discussing drug therapy with their patients, constructed patient consultation booths and restructured their entire practice to allow them to focus more intensely upon the pharmacist-patient encounter, creating a patient-centered, rather than a product-centered practice environment. Today, most health-care practitioners have replaced their earlier shrill public relations pronouncements with a sincere rededication to the primacy of human dignity in patient care.

Shifting trends in disease and drug therapy. The revolution in health-care values did not take place in a therapeutic vacuum. Indeed, such changes could not have occurred two generations ago. By the early 1950s, modern medicine had controlled most acute infectious diseases, and shifted its attention to treating the chronic, debilitating illnesses that infectious diseases had overshadowed by their sheer pervasiveness. Infant mortality receded, patients lived longer, more productive lives, maintained primarily by a host of sophisticated therapeutic agents. In the early 1960s, new psychotropic drugs controlled even acute mental disturbances, promising to empty mental institutions just as improved public health programs and streptomycin had emptied tuberculosis sanatoriums a decade earlier.[8] As a result, patients whose conditions would have warranted hospitalization or institutionalization a generation ago are now being treated by pharmacists on an out-patient basis. Other pharmacists extend the bounds of their practice to include supervising therapies, administering parenteral products in patients' homes, or coordinating hospice care. Moreover, drugs which were once available only by prescription are now available to an increasingly sophisticated public for uncontrolled autotherapy. As a result, pharmacists today deal more frequently with seriously ill or debilitated patients who require not only their full measure of professional expertise, but also an equally full measure of compassion and other human values from their health-care practitioners.

This painting by Robert Thom from the Great Moments in Pharmacy Series depicts the founding of the American Pharmaceutical Association in 1852. The Association established the first national code for pharmacists (see pp. 193-94). (*Illustration courtesy of Parke-Davis, division of Warner Lambert.*)

Charles H. LaWall (1871-1937), Dean of the Philadelphia College of Pharmacy (1918-37) and President of the American Pharmaceutical Association (1918-19), architect of the first modern code of ethics for American pharmacy (1922). (*Kremers Reference Files, F. B. Power Pharmaceutical Library, University of Wisconsin-Madison.*)

Effective drug therapy as an expectation. The past half-century has witnessed a meteoric, almost magical, transformation in drug therapy from palliative, symptomatic remedies to specific, highly potent agents. Once patients began to realize that the drugs prescribed by their physicians could actually eradicate their diseases, often with spectacular speed and efficacy, the miracle of modern medicine became not only a reality, but a common expectation. Just as modern surgical techniques have encouraged patients to elect cosmetic procedures once reserved for correcting serious facial deformities, so, too, have recent pharmacological advances encouraged patients to seek therapeutic treatment for such comparatively minor ailments as acne, hair loss, insomnia, or nervousness. Devotees of this new "pharmacological hedonism" translate ability to expectation; if a drug can produce a beneficial effect, it should be used without reservation, and at the patient's request, a situation further complicated by some pharmaceutical manufacturers' recent forays into direct-to-consumer advertising. Moreover, the aura once surrounding the so-called "miracle drugs" has been extended by the public to include all pharmacological categories; in the world of miracles, there is little margin for therapeutic failure or even compromise. Many patients view even minor side effects as unacceptable, and an ineffective drug regimen raises the specter of a malpractice suit. Such unrealistic public expectations place tremendous pressure on today's practicing physicians and pharmacists who must balance legitimate claims on their services with requests for mundane or even frivolous procedures or medications.

Increasing consumer sophistication. Leaders in organized medicine and pharmacy are keenly aware of the far-reaching impact that increased consumer knowledge and sophistication has had on their patients. While neither profession would willingly return to a standard of practice characterized by hastily scrawled Latinized prescriptions for mysterious medicines, few practitioners feel completely comfortable with patients who maintain their own personal laboratory values and vital signs, and ask for drugs by generic name, as supplied by the *Physicians' Desk Reference.* Fewer still would agree that fully informed patients can or should be full partners in establishing their own unique treatment plan, including their drug therapy.

Informed, medically sophisticated patients naturally seek to use their knowledge, and, in a sense, take control of their disease management and therapy. To an increasing extent, these patients

expect their physicians and pharmacists to include them in many decisions regarding their therapy, rather than meekly submitting to the judgments of these practitioners. In recent years, this shift toward self-determination for one's personal health has been complicated by the wide range of alternative medicines which patients choose to complement their professionally managed therapy. Ideally, the physician, pharmacist, and patient should form a treatment team in which all participate to achieve an agreed-upon treatment goal. This emerging standard of practice, incorporated in the concept of pharmaceutical care, suggests that the pharmacist's responsibility now extends far beyond merely conveying the physician's instructions to the patient in a clear, concise manner. Rather, this standard expects pharmacists not only to help patients interpret their physicians' recommendations, but also to assist physicians in designing therapeutic treatment plans that both recognize enhanced patient knowledge and reflect a new respect for patient autonomy.

Unfortunately, not all patients have a full knowledge of their medical condition. Assuming all patients have such knowledge can lull practitioners into a false sense of security, leading them to take shortcuts in explaining directions for drug regimens, sometimes with tragic results. For example, during a routine follow-up examination, a woman who had been taking a powerful antihypertensive medication was told by her physician that her high blood pressure had been brought under control; unfortunately, he did not tell her that she must continue taking her medicine. Believing that the drug had done its work, the woman stopped taking her blood-pressure medication but did not notify her pharmacist who did not catch the change in her drug therapy; shortly thereafter, she suffered a crippling stroke. Both the physician and the pharmacist had overestimated the level of the woman's medical knowledge; neither had recognized the need to reinforce her understanding of her disease process and the necessity of continuing her drug therapy.

Despite such inherent communication difficulties created by the fragmented nature of our contemporary health-care system, today's pharmacists have a professional responsibility to assess the extent and depth of their patients' knowledge. Such assessments provide a solid base for pharmacists to establish the level of professional counseling their patients may require to successfully manage their drug therapy. Assisting patients to become legitimate partners in designing and managing their personal health-care plan without being perceived as either condescending or paternalistic emerges as one of pharmacy's most daunting professional challenges.

The Pharmacist as a Health-Care Provider

Despite the potential conflicts that can occur between the traditional professional values of pharmacists and the changing societal expectations for medical and pharmacy practitioners outlined above, the pharmacist has recently begun to emerge not only as an active participant in the management of drug therapy, but also as a primary health-care provider. This transformation was slow and tortuous, however, constrained by narrowly conceived—and largely self-imposed—boundaries of practice. These traditional practice boundaries, both professional and legal in nature, are pervasive and continue to persist, hampering the professional development of the pharmacist as a full partner in the contemporary health-care system.

Traditional boundaries of practice

Until comparatively recent times, a pharmacist's practice was bounded quite literally by the prescription counter. Behind the prescription counter, pharmacists compounded or otherwise prepared drugs for distribution in a secluded area, out of public view. At the prescription counter, pharmacists responded politely to requests for information from their patients, generally by simply reiterating the physician's instructions. It was unseemly for patients to know too much about the medicines their physicians prescribed, pharmacists argued. Pharmacists also responded to physicians' queries, but were careful not to stray beyond the rather shallow product information provided in manufacturers' catalogs or the package labeling. To patients and physicians alike, the pharmacist's counseling activities focussed on the drug product, not the therapy the drug was to provide.

Technical competence in compounding and dispensing. Mid-nineteenth-century American pharmacists saw incompetent, poorly educated practitioners as the greatest threat to their recognition as respected members of the health professions.[9] To that end, they organized state boards of pharmacy that served to measure at least the entry-level competence of potential practitioners and exclude the patently incompetent or the charlatan. To a large extent, these measurements relied upon board members' judgments of applicants' technical competence to compound prescription orders in an accurate and elegant manner. In a sense, these measure-

ments came to define the practice of pharmacy itself. Despite higher educational standards and the increasing availability of commercially prepared pharmaceuticals, compounding and dispensing—and, later, dispensing itself—persisted as the *raison d'être* of both pharmacy education and practice well into the 1950s. Pharmacy curricula culminated in a series of courses titled "Dispensing," and state pharmacy practice acts defined the practice of pharmacy in terms of the compounding and dispensing function.[10] Those few pharmacists who sought expanded professional horizons were either ridiculed as impractical dreamers or chastised for trespassing upon the sacred domain of medicine. "Physicians diagnose and prescribe," the conventional wisdom reminded ambitious practitioners, "pharmacists dispense."

Limited counseling and triage function. Given the rigidly defined boundaries of professional practice described above, American pharmacists in the 1920s limited their "counseling" activities to recommending patent medicines and providing homely first-aid advice for life's aches and pains, minor injuries, and other annoyances. In the arena of prescription medication, traditional practice boundaries and contemporary codes of ethics strictly enjoined pharmacists from divulging any more information than provided by the physician's prescribed instructions.[11]

As modern and effective chemotherapeutic agents emerged in the 1940s, the therapeutic gulf between over-the-counter and prescribed medications grew wider and more distinct. Nevertheless, either silence or perfunctory, largely noninformative advice persisted as a standard of counseling practice among pharmacists throughout the 1960s.[12] When confronted by patients with direct requests for assistance with an alarming rash or another potentially serious ailment, most pharmacists satisfied themselves that they were performing an important and professional "triage function" by deciding which of their patients required medical attention by a physician and which could be satisfied by recommending an over-the-counter drug or another simple treatment plan.

Legal boundaries of practice

For nearly 150 years, American pharmacy practice has been bounded and, in a sense, shaped by legislation. First through state laws restricting the sale of poisons, then through federal laws controlling the distribution of narcotics, pharmacists became accus-

tomed to adhering to a wide range of regulations and legislation controlling their professional practice. Later, as therapeutic agents became more powerful and potentially more dangerous, some pharmacists actively sought the protection of both state and federal law and the resulting comfort afforded by a practice whose boundaries were defined by laws, rules, and regulations rather than by individual professional decisions. By the 1950s, this welter of federal and state legislation had removed all but a few vestigial traces of the professional discretion an earlier generation of pharmacists had enjoyed.

Boundaries established by pharmacy practice acts. The early state pharmacy practice acts defined which drugs could be sold directly to the public, by whom, and under what conditions. These state acts primarily focussed upon the drug product itself and the manner in which it could be dispensed rather than any professional or consultative service the pharmacist could provide. In lieu of any federal legislation distinguishing between drug products that required a physician's supervision and those that could be safely used by the public for self-treatment, these early state pharmacy practice acts set aside the most potentially dangerous drugs in the pharmacist's armamentarium—poisons, narcotics, barbiturates, and hormones—for the physician's prescription, foreshadowing the rigorous prescription-only federal legislation of the 1950s.

Nevertheless, while strictly prohibited from diagnosing disease, prescribing drugs, or otherwise engaging in the practice of medicine, some pharmacists routinely engaged in recommending to their patients some of the more potent medicines available to them at that time. This practice of so-called "counter-prescribing" was savagely denounced by the medical profession, and stands in sharp contrast to the clearly defined standard of practice employed when these same drugs were dispensed on a physician's prescription: as we have suggested, pharmacists maintained a respectful silence when these drugs were prescribed, a silence sharply defined and undergirded by a professional code of ethics, but often offered free advice about their over-the-counter cousins.

Boundaries established by state and federal agencies. While turn-of-the-century state pharmacy practice acts provided adequate controls over pharmacists and their distributive practices, these acts did not address the perplexing problems of drug adulteration and misbranding which had plagued generations of pharmacists. The Food and Drugs Act of 1906 brought both domestic

manufacturers of legitimate, so-called "ethical" pharmaceuticals[13] and patent medicines and nostrums under the umbrella of federal legislation for the first time. The Act not only effectively eliminated adulterated drugs, but also controlled misbranding by establishing stringent labeling requirements. Pharmaceutical manufacturers were required to identify the names and amounts of the active ingredients in their products and label them with honest therapeutic claims.[14] Some manufacturers proudly met the new federal mandate, changing their formulas or dropping label claims that could not be sustained in court;[15] others evaded the law by simply transferring false or misleading label claims to their advertising.

By the late 1930s, as therapeutic agents became more powerful—and potentially more dangerous—the federal government looked to pharmaceutical manufacturers to establish stricter guidelines to better distinguish between drugs that needed some medical supervision and those that could be used safely for self-treatment by the general public, a function primarily controlled by state pharmacy laws. It soon became clear, however, that America's pharmaceutical manufacturers held a wide spectrum of values when it came to distinguishing between drugs for which prescriptions were recommended and their over-the-counter cousins: Some of these manufacturers, seeking a broader market for their drug products, developed complicated—if strictly legal—labeling for products that had traditionally been distributed under medical supervision; other manufacturers, wary of the legal liability associated with injuries caused by unsupervised drug use or interested in exploiting the more exclusive prescription-only cachet for their drug products, developed overly restrictive labeling for products that had traditionally been sold at the corner drugstore.

Prompted by the tragedy of the Elixir of Sulfanilamide poisonings and the ensuing public furor,[16] the federal Food, Drug and Cosmetic Act of 1938 required pharmaceutical manufacturers of new drug products to document that their products could be safely used before marketing them. The Act not only addressed purity and safety, but subtly affected labeling requirements as well. Manufacturers were required to develop "adequate directions for use," later defined as directions a lay person could understand well enough to use a drug product safely. Drugs labeled "Caution: to be used only by or on the prescription of a physician, dentist, or veterinarian," however, were exempted from bearing such directions, a provision that had the unintended effect of encouraging many pharmaceutical manufacturers to designate all their products for

prescription use only. Some manufacturers labeled a drug product with "adequate directions for use"; others labeled the same drug product with the "Caution:" statement; some did both.

The resulting confusion posed both a legal quagmire and a potential professional dilemma to practicing pharmacists: drugs not covered by state board regulations, such as sulfonamides and penicillin, could be legally distributed by the pharmacist without a prescription. The "Caution:" statement was a warning statement to the patient; it did not prohibit the sale of a certain class of drug products. Pharmacists either filled prescriptions for these products or solicitously inquired if their patients were under a doctor's care before dispensing the products. Less scrupulous pharmacists who sold products without such assurances were subject to federal prosecution, not because they had dispensed a "Caution:" drug without a prescription, but because they had caused the drug to be "misbranded," that is, dispensed without "adequate directions for use."[17] The resulting confusion and specter of increased legal liability frustrated and worried even the most conscientious pharmacist.

In 1948, Congress passed the Miller Amendment to the 1938 Act, extending the definition of interstate commerce of drug products to include all levels of distribution from manufacturer to consumer, including the pharmacists' final repackaging and labeling activities. By 1950, the situation had become critical: Pharmacists prosecuted under the new law sought assistance from their professional associations; organized pharmacy, in turn, sought a legal clarification of the matter. The Durham-Humphrey Amendment of 1951 supplied the long-needed definition of the kinds of drugs that must be labeled for prescription use only.[18] Moreover, the Amendment prohibited prescription refills without the expressed authorization of the prescriber, eliminating the time-honored professional prerogative of the pharmacist to monitor and control their patients' drug therapy, thereby substituting federal law for a traditional ethic of the profession. Hailed at its passage as a sensible solution to a vexing professional problem, the Durham-Humphrey Amendment is now often criticized for not only eliminating traditional professional functions, but also for seriously hampering the pharmacist's professional development as a full partner with the physician in today's emerging health-care environment.[19]

The Amendment had profound ethical and legal ramifications for American pharmacy practice. In the arena of ethics, the Amendment replaced the pharmacist's traditional duty to warn patients of the potential dangers which might be associated with con-

tinuing their prescription drug therapy with a simple legal rule: prescriptions could be refilled only by a physician's authorization. Moreover, by providing a legal—rather than a professional—basis for deciding whether or not to refill patients' prescriptions, the Amendment had the unintended effect of subtly shifting the nature of pharmacists' legal liability, as reflected by the spate of malpractice claims during the past decade.[20]

Boundaries established by case law. During the decades following World War II, the American public became accustomed to the therapeutic miracles it received in prescription bottles. Antiinfectives, tranquilizers, and, later, oral contraceptives were cursorily provided by harried pharmacists increasingly preoccupied with managing a rapidly increasing prescription volume, rising overhead costs, and ruinous price-cutting battles. These new drugs were not only more potent, but possessed a much narrower range of therapeutic safety; there was little, if any, room for error. Pharmacists soon learned they could no longer solely rely upon their memories or notes scribbled upon the back of prescription orders to alert them to the new professional challenge of drug-drug interactions. Pharmacists employed crude handwritten patient prescription profiles to detect drug interactions, an innovation heralded as an opportunity for an expanded professional function, a function that soon became ingrained as a new standard of practice. This new standard soon became viewed as a legal standard of practice as well: Pharmacists were now expected to detect and warn their patients of potential drug interactions and to intervene with the physician to avoid therapeutic misadventures; pharmacists who did not employ these new drug monitoring systems faced the very real risk of being considered professionally irresponsible or, worse, being convicted of malpractice for disregarding their new legal duty to warn. This new legal responsibility, combined with the public's concern for professional accountability, and fanned by the consumerism movement of the 1960s, increased the professional liability of the practicing pharmacist to a level undreamed of a decade earlier. In an increasing litigious society, patients sued their pharmacist if they felt they had been injured, treated unfairly, or just slighted. Pharmacy malpractice insurance premiums soared, and pharmacists became acutely aware of their expanded legal liability. This shift in the nature of professional liability, therefore, has altered the very nature of contemporary courtroom cases affecting pharmacists by emphasizing the importance of pharmacists' duty to warn rather than their failure to follow federal and state drug law. This

specter of increased professional liability has thus profoundly affected pharmacists' view of the importance of performing their professional functions.

Expanding boundaries of practice

By the early 1950s, Americans had stopped worrying about the threatened postwar recession; the United States economy was booming: families moved to the rapidly expanding suburbs to enjoy a lifestyle formerly reserved for the affluent; American pharmacy enjoyed unprecedented growth, particularly in the rapidly developing drugstore chain sector, a growth accompanied by fierce competition. America's pharmaceutical manufacturers embarked upon expanded programs of research and development, filling the drug market with new and more effective trademarked prescription specialties, heavily advertised in medical journals and promoted by an aggressive sales force. Between 1948 and 1960, for example, a period of relatively slow population growth, the number of prescriptions dispensed increased by 70 per cent, yet accounted for nearly a four-fold increase in prescription dollar volume.[21] What Americans wanted most, community pharmacists decided, were large, modern, self-service stores, quick service, and low prices; hospital pharmacists responded by developing drug delivery systems characterized by accuracy, efficiency, and economy.

Expanding societal expectations. The consumerism movement of the early 1970s focussed the American public's attention upon professional accountability, both in terms of competency to practice, which resulted in legislation mandating continued professional education, and in terms of enhanced standards of practice, which were debated extensively by the pharmaceutical community throughout the decade and finally set down on paper in 1979.[22] Patients challenged physicians and pharmacists alike with their demands to become active, knowledgeable partners in the design of their drug therapy. The *Physicians' Desk Reference*, once restricted to professional distribution, became a best-seller at America's bookstores. Activists petitioned legislators to strike down laws and state board regulations prohibiting prescription drug advertising and generic drug substitution, while the profession itself responded with such remedies as prescription price posting, patient prescription profiles, and patient counseling in the community setting, and instituted drug utilization review and drug formularies in the hos-

pital setting.[23] These public and professional initiatives focussed upon patient care, first as a concept, then as a right. Practitioners began to realize that they could not provide individualized patient care without caring for patients as individuals.

At the same time, public health activists, including some of the more visionary members of the health professions, expanded the concept of health beyond the mere absence of disease, envisioning a new high plain of personal health, which they termed "high-level wellness." Concerned and determined pharmacists increased their health promotions, adding blood-pressure monitoring devices to their pharmacies, providing diabetes screening programs, or offering cholesterol-level determinations to their patrons.

Evolving professional functions. By the 1960s, compounding had become a scientifically based, highly technical, and sophisticated function, but one rarely performed in practice, a mere remnant of a proud professional past. Dispensing itself was recognized and institutionalized as the legitimate and sole professional function of the pharmacist. Isolated from all other aspects of patient care, the pharmacist's professional function typically ended once the prescription was brought to the prescription counter or delivered to the hospital ward. Dissatisfied by the lack of challenge and prestige associated with the dispensing function, some pharmacists sought to expand their diminishing professional role by engaging in other product-related professional activities: Some sought expanded professional prestige by promoting themselves as advisors to the physician, comparing and contrasting commercially available drug products; others found solace in advising the public on the use of nonprescription medication or durable medical equipment; still others established patient prescription record systems as an efficient way to locate prescriptions and prepare tax records.

In the 1970s, pharmacists continued to develop other product-related professional services appropriate to their science-based education: To some educators and practitioners, the rapidly expanding availability of generic drug products and the subsequent repeal of the so-called "antisubstitution laws" signaled the need for an expanded advisory role to physicians in the area of drug product selection, particularly in institutional settings, where pharmacists now participated in the deliberations of pharmacy and therapeutics committees. Some pharmacists studied charts allowing them to compare and contrast nonprescription drug products; others urged Congress to establish a third class of drugs which could be sold only by a pharmacist;[24] still others modified patient prescription

record systems to serve as the basis for detecting drug interactions or potential abuse problems. The development of computerized patient prescription record systems, with sophisticated drug interaction modules, however, transformed the pharmacist's informational function from the mere collecting, retrieving, and transmitting of data to the actual interpretation of clinically significant interactions, a role for which many pharmacists were ill-prepared. Similarly, it soon became clear that pharmacists could not be expected to interpret or even have access to the welter of chemical, pharmaceutical—and later biological—equivalency data necessary to effectively help the physician select drug products. At the same time, a new breed of clinical pharmacists argued persuasively that professional redemption lay in a radical shift from a product-oriented to a patient-oriented practice, a practice that emphasized expanded patient counseling and, in a sense, a return to patient-care functions reminiscent of an earlier generation of pharmacy practitioners.

The concept of pharmaceutical care. In a seminal paper titled "Opportunities and Responsibilities in Pharmaceutical Care," C. Douglas Hepler and Linda M. Strand proposed a new philosophy of pharmacy practice far beyond the rather limited expectations of most pharmacy practitioners, even those dedicated to the patient-oriented practices embraced by the term "clinical pharmacy." Speaking at a 1989 conference focussing on evolving pharmacy practice for the twenty-first century, Hepler and Strand reviewed the alarming extent of drug-related morbidity and mortality in the American health-care system. They concluded that this problem could only be addressed by a fundamental change in the pharmacist's professional function, a concept they referred to as "pharmaceutical care."

Defining pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life," Hepler and Strand argued that the costly social problem of "drug misadventuring" could be reduced or even eliminated by pharmacists' intervention. Rather than restricting the pharmacist's professional role to merely supplying and monitoring drug therapy, Hepler and Strand built upon concepts of clinical pharmacy to create "a process in which a pharmacist cooperates with a patient and other health professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient." Central to their shared vision is the establishment of a "mutually beneficial

exchange in which the patient grants authority to the provider, and the provider gives competence and commitment to the patient."[25]

Leaders in the generally conservative world of pharmaceutical education embraced the philosophy of pharmaceutical care with an ardor rarely seen in academic circles. The American Association of Colleges of Pharmacy's Commission to Implement Change in Pharmaceutical Education hailed the new philosophy as "truly a revolutionary concept in the practice of pharmacy" not only because its practitioners assume responsibility for the outcomes of drug therapy in patients, but because "it espouses CARING, an emotional commitment to the welfare of patients as individuals who require and deserve pharmacists' compassion, concern and trust." While some skeptics dismissed the Commission's enthusiasm as yet another attempt to justify the expansion of the clinical component of the pharmacy curriculum, they could not ignore the Commission's recommendations that the Association "adopt pharmaceutical care as the philosophy of pharmacy practice on which practitioner education must be based" and that member colleges and faculty "immediately commit themselves to curricular changes which . . . engenders competencies and outcomes essential to pharmaceutical care," both of which were adopted by the Association's House of Delegates in 1992.[26] That same year, the Association voted to support the inclusion of these outcomes and competencies in the revised accreditation standards of the American Council on Pharmaceutical Education, the body which accredits all entry-level pharmaceutical education programs.[27]

Concluding Remarks

The practice philosophy of pharmaceutical care has acquired an enviable currency in the world of pharmaceutical education and the world of pharmacy practice as well. When fully implemented, the philosophy will achieve the redefinition of professional pharmacy practice functions that its proponents envision. To be sure, the profession faces daunting challenges to its traditional functional autonomy: state and federal governments, insurance companies, and other third parties exert unrelenting pressures for cost control and enhanced professional service in the delivery of prescription and nonprescription medication to the public. The profession has responded to these pressures by increasingly relying on paraprofessional help, robotics, and computer-assisted patient in-

formation systems to manage its interpersonal patient-care functions. Just as pharmacy has learned it can no longer focus exclusively upon the mere safe distribution of drugs or even upon expanded clinical functions in order to justify its societal function, it may also learn it cannot solely rely upon the enhanced, personalized clinical services encompassed by the concept of pharmaceutical care for its *raison d'être*.

As desirable as these sophisticated distributive and enhanced clinical services may be, they cannot substitute for the value-based professional decisions that are the hallmark of a profession. Such values as compassion, faithfulness, and fairness define the very essence of pharmaceutical care; as this concept matures, practitioners will identify other associated virtues and values. By not reflecting upon the human values associated with pharmacy as a practice, pharmacists may weaken the fundamental moral underpinnings of pharmacy as a profession. Pharmaceutical care in its fullest sense involves professional care decisions beyond enhanced therapeutic outcomes. Practitioners who embrace the tenets of pharmaceutical care would do well to consider the moral and ethical implications implicit within this new philosophy of practice. It is these implications and the moral and ethical basis for the professional practice of pharmacy that we will be examining in the ensuing chapters.

Study Questions

1.1 Express, in your own words, the moral basis for the profession of pharmacy.

1.2 Explain and defend the personal value(s) that you consider the most important to the ethical practice of pharmacy.

1.3 Outline the implications for expanded ethical responsibilities for pharmacy practitioners as they embrace the tenets of pharmaceutical care.

1.4 What is the most compelling moral aspect of making a commitment to the welfare of patients based upon compassion, concern, and trust?

References

1. U.S.P. and N.F. "propaganda" was one of the activities undertaken by the American Pharmaceutical Association's new local branches in 1906, when these compendia became the federally recognized standards for American drug products. By the late 1930s, pharmacists' interest in physicians writing individualized prescriptions for their patients—rather than prescribing standardized commercial products—prompted the Association to organize a series of conferences on the topic. See C. S. N. Hallberg, "The American Pharmaceutical Association—The Post-Graduate Course for the Retail Pharmacist," *Bulletin of the American Pharmaceutical Association 1*:10 (October, 1906), p. 314; "Meeting of the State Committees on U.S.P. and N.F. Promotion," *Journal of the American Pharmaceutical Association 27*:11 (November, 1938), pp. 1161-62; and "Conference of State Committees on U.S.P.-N.F. Promotion," *ibid. 28*:11 (November, 1939), pp. 943-44.
2. Pharmacy historian Glenn Sonnedecker notes that minimum standards for hospital pharmacists, adopted by the American College of Surgeons in 1936, and the emergence of the American Society of Hospital Pharmacists in 1942 as an independent organization signaled new stature and goals for the specialty. "What could scarcely be foreseen was the transformation that would occur within a quarter century to bring the hospital pharmacist out of his basement 'drug room' and into an unprecedented professional enthusiasm and stature in the history of American pharmacy." Glenn Sonnedecker, *Kremers and Urdang's History of Pharmacy*, 4th ed., rev. (Philadelphia: J. B. Lippincott Company, 1976), p. 320.
3. Sonnedecker notes that "grossly commercialized" conditions of practice, where prescription service was "exploited through flamboyant advertising" became widespread during the 1950s, "bringing pressure especially on urban pharmacists who tried to maintain full professional services and the standards that have given pharmacy its standing as one of the health professions." *Ibid.*, p. 297.
4. In the early 1940s, for example, L. Wait Rising developed an experimental course in which students did "a great variety of laboratory work under actual conditions of practice with close supervision by both professional pharmacist and instructor." L. Wait Rising, "Theory and Practice Can Be Combined," *American Journal of Pharmaceutical Education 9*:4 (October, 1945), p. 558. Heber W. Youngken, Jr., later reported that the innovation created "a state of confusion . . . whereby similar programs in pharmaceutical education were . . . discouraged." H[eber] W. Youngken, Jr., "The Washington Experiment—Clinical Pharmacy," *American Journal of Pharmaceutical Education 17*:1 (January, 1953), p. 67.
5. In 1974, for example, University of California School of Pharmacy Dean Jere E. Goyan remarked that these "new" curricula produced "a generation of pharmacists who knew the chemical structures of phenobarbital and procaine, including several pathways to their synthesis, and other arcane knowledge for which, to put it politely, they found little use." Jere E. Goyan, "Pharmacy Practice—Structure and Function,"

American Journal of Pharmaceutical Education 38:5 (December, 1974), p. 693.

6. "The primary element must be the personal, professional relationship between the pharmacist and his patient based on the sincere interest of the pharmacist in the health and welfare of his patient and his family," White stated in 1965. "I have found if you convince the patient his health and welfare is your objective and your intention is not a selfish mercenary one he will literally beat a path to your pharmacy door." Eugene V. White, "Behind the Scenes of the Pharmaceutical Center," *Journal of the American Pharmaceutical Association NS5*:10 (October, 1965), p. 532.
7. See, for example, "Statement on a Patient's Bill of Rights," in André L. Lee and Godfrey Jacobs, "Workshop Airs Patients' Rights," *Hospitals 47*:4 (February 16, 1973), p. 41. The statement was affirmed by the Board of Trustees of the American Hospital Association on November 17, 1972. Ethicist Willard Gaylin characterizes the Statement as "not only pretentious but deceptive" and charges that this document "perpetuates the very paternalism that precipitated the abuses" it seeks to correct. "It is the thief lecturing his victim on self-protection," Gaylin thunders. "It is not for the hospital community to outline the rights it will offer, but rather for the patient consumer to delineate and then demand those rights to which he feels entitled." Willard Gaylin, "The Patient's Bill of Rights," *Saturday Review of the Sciences 1*:2 February 24, 1973), p. 22. A revision of the Bill of Rights was approved by the American Hospital Association's Board of Trustees on October 21, 1992 (see Appendix B).
8. For the interplay between modern public health and antibiotic drug therapy in their treatment of tuberculosis, see James Bordley, III and A. McGehee Harvey, *Two Centuries of American Medicine, 1776-1976* (Philadelphia: W. B. Saunders Company, 1976), pp. 206-13 and 456-60.
9. Thus, in 1854 William Procter, Jr., and Edward Parrish complained bitterly about the nation's "incompetent drug clerks," most of whom were neither trained through a legally indentured apprenticeship nor held to an honor-bound obligation. "These clerks in turn become principals, and have the direction of others—alas! for the progeny that some of them bring forth, as ignorance multiplied by ignorance will produce neither knowledge nor skill." W[illiam] Procter, Jr., E[dward] Parrish, D[avid] Stewart, and J[ohn] Meakim, "Address to the Pharmaceutists of the United States," *Proceedings of the American Pharmaceutical Association 3* (1854), p. 14.
10. As late as 1960, for example, the AACP-NABP Joint Committee to Redefine the Term "Pharmacy" also redefined the "practice of pharmacy" in terms of the "important distributive function of the pharmacist" which "includes prescription drugs as well as those sold directly to the consumer," and hoped that the new definition would be incorporated into state pharmacy practice acts. See Linwood F. Tice, "Report of the AACP-NABP Joint Committee to Redefine the Term 'Pharmacy'," *American Journal of Pharmaceutical Education 25*:1 (Winter, 1961), p. 102.
11. The pharmacist "should never discuss the therapeutic effect of a Physician's prescription with a patron nor disclose details of composition which the Physician has withheld, suggesting to the patient that such details can be properly discussed with the prescriber only," the 1922 APhA Code intoned. See "Code of Ethics of the American Pharmaceutical Association," *Journal of the American Pharmaceutical Association*

11:9 (September, 1922), p. 729.

12. The 1952 APhA Code continued to enjoin the pharmacist to "not discuss the therapeutic effects or composition of a prescription with a patient. When such questions are asked, he suggests that the qualified practitioner is the proper person with whom such matters should be discussed." This restrictive prohibition was deleted from the 1969 version of the Code. See "Code of Ethics of the American Pharmaceutical Association," *Journal of the American Pharmaceutical Association 13*:10 (October, 1952), p. 722; and "APhA Code of Ethics," *ibid. NS9*:11 (November, 1969), p. 552.
13. The term "ethical specialty" was coined in 1876 by Detroit drug manufacturer Frederick Stearns to distinguish his line of "simple preparations in popular-sized packages, bearing full directions for use and . . . a plain statement of the names and quantities of their ingredients." See "Frederick Stearns, Pharmacist: An Appreciation," *The New Idea 27*:1 (First Quarter, 1905), p. 3. The term "ethical" was later used to distinguish manufactured drug products promoted to the medical profession from those promoted directly to the public.
14. For a brief, insightful historical development of the 1906 Act, see Wallace F. Janssen, "Pharmacy and the Food and Drug Law: A Significant Relationship," *American Pharmacy NS21*:4 (April, 1981), pp. 212-21. An earlier piece of federal legislation, the Import Drugs Act of 1848, provided for laboratory inspections at ports of entry and for detention, destruction, or re-exporting of shipments not meeting pharmacopeial standards, but suffered from lack of enforcement. *Ibid.*, p. 214.
15. Thus, Lloyd Brothers, the Cincinnati-based manufacturer of single-ingredient "Specific Medicines," remarked in their 1921 catalogue that "the fact that when the National law passed, every Specific Medicine was found to conform to its severest requirement, was a great satisfaction to physicians and a matter of pride to us. Every Specific Medicine in every jobbing house in America is correctly labeled in the form the Government approves, and is true to name and quality." Lloyd Brothers, *Dose Book of Fine Medicinal Specialties* (Lloyd Brothers: Cincinnati, Ohio, 1921), pp. 66-67.
16. For example, Mrs. Maise Nidiffer, who had lost her six-year-old daughter to the Elixir, wrote a heart-rendering letter to President Franklin D. Roosevelt. "It is my plea that you will take steps to prevent such sales of drugs that will take little lives and leave such suffering behind," Mrs. Nidiffer begged, adding, "Surely we can have laws governing doctors also who will give such a medicine, not knowing to what extent its danger." H[enry] A. Wallace, "Report of the Secretary of Agriculture on Deaths Due to Elixir Sulfanilamide-Massengill," *Elixir Sulfanilamide: Letter from the Secretary of Agriculture Transmitting in Response to Senate Resolution No. 194, a Report on Elixir Sulfanilamide-Massengill*, Senate Document No. 124, 75th Congress, 2d Session (Washington, D.C.: Government Printing Office, 1937), p. 8.
17. Janssen, "Pharmacy and the Food and Drug Law," (n. 14) p. 218. "This legally complex approach was cumbersome, confusing and contradictory," Janssen contends. "Moreover, it was difficult for FDA . . . to enforce the new distinction between prescription and OTC drugs . . . [since] the law contained no definition of a prescription drug, and FDA had not presumed to provide one."

18. For a contemporary analysis of the Durham-Humphrey controversy, see Robert P. Fischelis, "The Pharmacist's Right and Duty to Exercise Professional Judgment," *Journal of the American Pharmaceutical Association* (Practical Pharmacy Edition) *11*:4 (April, 1950), pp. 218-25.
19. For the most part, American pharmacists have aggressively sought legislative protection, while at the same time bitterly decrying governmental intervention in their professional practice. Charles D. Hepler notes that the Durham-Humphrey amendment "prevented pharmacists from recommending many useful drugs and limited the scope of their judgment and problem-solving." Charles D. Hepler, "The Third Wave in Pharmaceutical Education: The Clinical Movement," *American Journal of Pharmaceutical Education 51*:4 (Winter, 1987), pp. 371-72.
20. See, for example, Jesse C. Vivian, "Pharmacy Malpractice: Crisis or Crucible?" *American Pharmacy NS34*:4 (April, 1994), pp. 25-30; and Walter L. Fitzgerald, Jr., "Legal Control of Pharmacy Services," in *OBRA '90: A Practical Guide to Effecting Pharmaceutical Care*, edited by Bruce R. Canaday (Washington, D.C.: American Pharmaceutical Association, 1994), pp. 47-55.
21. "Rx Sales Outstrip U.S. Income Growth," *Drug Topics 93*:9 (April 25, 1949), p. 1; and "Average Doctor Wrote 167 Fewer Rxs in 1960 Than In 1959, A.D. Study Shows," *American Druggist 144*:3 (August 7, 1961), p. 7; Pharmacy historian Glenn Sonnedecker attributes this growth to "therapeutically active substances being dispensed more often individually (rather than combined in a single prescription); to more effective medicaments becoming available, leading to their freer use and sometimes overuse; to a more affluent society in the period; growth of 'third-party payment'; and other factors." See Sonnedecker, *Kremers and Urdang's History of Pharmacy* (n. 2), p. 313; also see Pharmaceutical Manufacturers Association, *Prescription Drug Industry Fact Book* (Washington, D.C.: Pharmaceutical Manufacturers Association, [1973]), p. 31.
22. The new "Standards of Practice" for the profession of pharmacy were completed in 1979 after "six grueling years of work and an investment by the American Pharmaceutical Association and the American Association of Colleges of Pharmacy of more than $250,000." The Standards included sections on the general management and administration of the pharmacy, activities related to processing prescriptions, patient-care functions, and the education of health-care professionals and patients. See Samuel H. Kalman and John F. Schlegel, "Standards of Practice for the Profession of Pharmacy," *American Pharmacy NS19*:3 (March, 1979), pp. 133-45. Also see "National Study Shows What Pharmacists Actually Do," *ibid.*, pp. 146-47.
23. In the early 1970s, for example, the National Association of Retired Persons was active at the state level seeking repeal of antisubstitution laws, while Ralph Nader's consumer group Public Interest won a court battle allowing advertising of prescription prices. See Mickey C. Smith and David A. Knapp, *Pharmacy, Drugs and Medical Care*, 3rd ed. (Baltimore: Williams & Wilkins), p. 148.
24. As early as 1960, the American Pharmaceutical Association's Committee on Legislation drew the Association's attention to "an intermediate category of drugs which either were formerly under the prescription legend or which contain one or more drugs which by themselves are prescription legend drugs. All these drugs must have their distribution su-

pervised by registered pharmacists." See "Legal Blotter: Drug Classification Questions," *Journal of the American Pharmaceutical Association NS5*:1 (January, 1965), pp. 30-31. While never implemented, the concept became a *cause célèbre* for the Association throughout the 1960s. See, for example, Richard P. Penna, "Control of Over-the-Counter Medication," *ibid. NS5*:11 (November, 1965), pp. 584-86; Harold L. Marquis, "Problems Involved in Drug Reclassification," *ibid. NS7*:4 (April, 1967), pp. 170-73; and a characteristically forceful defense by Executive Director William S. Apple, "Pharmacy's New Rx Evolution," *ibid. NS7*:9 (September, 1967), pp. 474- 77, 484.

25. Charles D. Hepler and Linda M. Strand, "Opportunities and Responsibilities in Pharmaceutical Care," *American Journal of Pharmaceutical Education 53*:[5] (Winter Supplement, 1989), p. 15S.
26. Commission to Implement Change in Pharmaceutical Education, "Background Paper II: Entry Level, Curricular Outcomes, Curricular Content and Educational Process," *AACP News* Special Report (March, 1991), pp. 1 and 9.
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