FOREWORD

*David S. Walker**
*Stephen G. Hoag***

The roles and responsibilities of pharmacists have greatly expanded over the past thirty years. From a professional practice model that focused almost exclusively on fast and accurate dispensing of prescription medications, we can now observe practitioners involved in planning specific drug therapy for individual patients and in sharing the professional responsibility for drug therapy outcomes. This changing paradigm of pharmacist responsibility probably began in 1967 when D.C. Brodie advanced the concept of "drug-use control" as the full scope of pharmacy practice.[1] The concept meant that pharmacists should assume responsibility for all aspects of drug use, ranging from procurement and storage to drug utilization.

Since the publication thirty years ago of Brodie's seminal article, virtually thousands of publications have appeared in professional journals describing clinical and patient-oriented services of pharmacists, all representing facets of drug-use control. Perhaps most notable was a landmark publication suggesting that the mission of pharmacy should include responsibility for drug therapy outcomes through meaningful involvement in the care of patients.[2] The concept was termed "pharmaceutical care" and was defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[3] Now widely accepted as the mission of pharmacy practice, the concept of "pharmaceutical care" implies that pharmacists have both the professional capability and the responsibility to provide health care, not just fill prescriptions and dispense medications. Thus, during the last three decades pharmacists have increasingly come to be involved with the medical profession in drug selection and with the patient in drug counseling.

Many reasons justify this new role for pharmacists. Among these is the recognition that problems resulting from drug therapy are significant in frequency, severity, and cost. A recent study estimated that the United States spends nearly $77 billion a year for health care services necessitated by drug-related problems, $40 billion of which is preventable.[4] The frequency of

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* Dwight D. Opperman Distinguished Professor of Law, Drake University School of Law. B.A., Yale University, 1966; LL.B., University of Virginia, 1969.

** Dean, Drake University College of Pharmacy and Health Sciences. B.S., North Dakota State University College of Pharmacy, 1967; M.S., Purdue University School of Pharmacy, 1971; Ph.D., Purdue University School of Pharmacy, 1973.

1. Donald C. Brodie, *Drug-Use Control: Keystone to Pharmaceutical Service*, 1 DRUG INTELLIGENCE & CLINICAL PHARMACY 63, 65 (1967).

2. *See generally* Charles D. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 AM. J. HOSP. PHARMACY 533 (1990).

3. *Id.* at 539.

4. Jeffrey A. Johnson & J. Lyle Bootman, *Drug-Related Morbidity and Mortality: A Cost of Illness Model*, 155 ARCHIVES INTERNAL MED. 1949, 1952 (1995).

adverse drug reactions and the cost in human and financial terms raise important public policy issues.[5] The implication is, of course, that more attention to appropriate drug therapy is needed.

Pharmacists have the knowledge and training to contribute meaningfully to quality health care at manageable costs and can be effective professionals for reducing the incidence and costs of drug-therapy problems. To date, however, many in the profession have not fully met the challenge required by the enlarged mission of pharmacy.[6] Despite the expansion in legitimate professional roles,[7] many pharmacists still practice in a traditional mode, merely dispensing prescription drugs and periodically counseling on the features of the prescribed medication. In such practices, pharmacists have not fully embraced the concept and mission of pharmaceutical care. They remain uninvolved in drug selection, do not participate in design of drug therapy plans, and do not attempt to monitor or intervene in a patient's drug therapy. As a result, widespread differences have developed in the way pharmacy is practiced. Therefore, it is fair to ask whether the pharmacy profession as a whole will be ready to assume a larger role in America's 21st century health care system.[8]

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5. *See generally* Henri R. Manasse, Jr. & Hoag Xiao, *Scope of Medication Use in the United States and Attendant Issues*, 44 DRAKE L. REV. 471 (1996); Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy—Part 1*, 46 AM. J. HOSP. PHARMACY 929 (1989); Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy—Part 2*, 46 AM. J. HOSP. PHARMACY 1141 (1989) [hereinafter *Drug Misadventuring—Part 2*].

6. *See* Susan Headden, *Danger at the Drugstore*, U.S. NEWS & WORLD REP., Aug. 26, 1996, at 46, 47. U.S. News reported, "according to an exclusive new study by *U.S. News* in cooperation with Georgetown University School of Medicine, . . . that many of the nation's pharmacists are falling down on the job. In particular, they are failing to protect consumers against dangerous interactions of prescription drugs, an exploding health-care problem that sends hundreds of thousands of Americans to the hospital every year." *Id.* Results of the study showed, for example, that 30 percent or more of Washington, D.C. pharmacists failed to "challenge doctors who simultaneously prescribed the potentially deadly mix of Seldane, the popular nonsedating antihistamine, and erythromycin, a common antibiotic." *Id.* at 48. *See also* David A. Kessler, *A Challenge for American Pharmacists*, AM. PHARMACY, Jan. 1992, at 33, 34 ("[T]he advancement of the pharmacist's professional aims has not been accompanied by similar strides in practice.").

7. *See* Paul G. Grussing, *A Comparison of Empirical Studies of Pharmacy Practice with Judicial Descriptions*, 44 DRAKE L. REV. 483 (1996).

8. *See The Role of the Pharmacist in Comprehensive Medication Use Management: The Delivery of Pharmaceutical Care.* AN APHA WHITE PAPER (American Pharmaceutical Association), March 1992 [hereinafter APHA WHITE PAPER]. This position paper, issued by the Association's Board of Trustees, asserts that "[t]he mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes." *Id.* at 2. The Board concluded that "the task facing pharmacy in fully assuming responsibility within the nation's health care system for comprehensive medication use management is formidable" and that "[m]any, both within pharmacy and in other health care professions, will be threatened by such a bold assertion of professional prerogatives and goals." *Id.* at 11. However, there is clear need for the pharmacy profession "to rise to the challenge of providing the leadership currently lacking in the medication use process in the United States." *Id.*

Necessarily the role of pharmacists in America's evolving health care system will be shaped by law. The extent to which pharmacy becomes under law the profession envisioned by the mission of pharmaceutical care depends significantly upon the extent to which such an expanded role is recognized by judges, legislators, and regulators. What duties pharmacists owe, to whom such duties are owed, what is the relevant standard of care, and what constitutes breach all define the role of pharmacists and the conduct expected of them.

While widespread differences exist in the way that pharmacy is practiced, widespread differences also exist in the manner in which the pharmacy profession is perceived by the legal system. Legal analysis has not uniformly accepted the changes in mission and practice that leaders in the pharmacy profession created when they expanded the role of the pharmacist into comprehensive medication-use management.

Under the traditional view, pharmacists are responsible for accurately processing prescriptions; and the doctor is responsible for evaluating the patient's condition, selecting the appropriate drug therapy, assessing the risks involved in such therapy, and determining whether and what to advise the patient.[9] It was thought that any such role for pharmacists could improperly and harmfully intrude upon the physician-patient relationship. Pharmacists were thus held to have no duty to warn patients whose prescriptions they were filling,[10] nor was the pharmacist viewed as an integral member of a "team"—providing health care to patients in coordination with the physician. No duty to notify or warn the patient's physician was recognized.[11] Moreover, although liability for bad outcomes could be imposed on the retail pharmacy as a seller, much like other situations in which a seller distributes goods that cause harm to a customer, the notion of the physician as a "learned intermediary" has fixed responsibility on the physician and insulated the pharmacist from responsibility to the patient.

Just as the pharmacy profession has been articulating new roles and an expanded mission for pharmacists, traditional legal analysis has been changing. In varied factual settings courts have found a duty to warn;[12] and

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9. *See* David W. Hepplewhite, *The Traditional Analysis of the Roles and Duties of Pharmacists*, 44 DRAKE L. REV. 519 (1996).

10. *E.g.*, Ramirez v. Richardson-Merrell, Inc., 625 F. Supp. 85 (E.D. Pa. 1986); Ingram v. Hook's Drug, Inc., 476 N.E.2d 881 (Ind. Ct. App. 1985).

11. *See* Eldridge v. Eli Lilly & Co., 485 N.E.2d 551 (1985). According to Henri R. Manasse, Jr., cooperation between and among pharmacists, physicians, and other health care professionals is needed if "an appropriate approach to monitoring and evaluating desired medical outcomes is the goal. . . . Sharing medical findings and diagnoses with the pharmacist will require a substantial rethinking of how medicine and pharmacy are practiced today—each in total isolation and often in perceived adversarial splendor." *Drug Misadventuring—Part 2*, *supra* note 5, at 1150. *See also* David B. Brushwood, *The Pharmacist's Drug Information Responsibility After* McKee v. American Home Products, 48 FOOD & DRUG L.J. 377, 391-93 (1993).

12. *See* cases cited and discussion in Kenneth R. Baker, *The OBRA 90 Mandate and Its Developing Impact on the Pharmacist's Standard of Care*, 44 DRAKE L. REV. 503 (1996), and David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge-Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1 (1991).

in suits against pharmacies, courts are beginning to recognize duties to use professional knowledge in addition to the longstanding duties to perform clerical functions accurately.[13] What duties are owed to the patient, and what is the relevant standard of care? A more discerning inquiry into the pharmacist's knowledge, professional mission, and relevant standard of practice is necessary in order to answer these questions and determine whether there has been a breach of duty.

In truth, pharmacists' education, capabilities, and face-to-face dealings with the patient give them a unique opportunity to prevent bad drug-therapy outcomes. As one well-recognized authority has stated, they are the "gatekeepers at the end of a complex drug distribution system."[14] A number of potential theories exist for recognizing a larger role and expanding legal responsibilities for pharmacists.[15] They could manage the risks of bad outcomes, quite apart from the physician's traditional role of diagnosing conditions, assessing risks, and prescribing treatment.[16]

Congress has recognized this possibility. Perhaps the most significant and far-reaching development in the law affecting the mission and responsibilities of the pharmacy profession is the Omnibus Budget Reconciliation Act of 1990, commonly known as "OBRA 90."[17] As a condition of receiving federal Medicaid matching funds, OBRA 90 mandated that states pass legislation or adopt regulations requiring pharmacists to maintain a record of patient drug therapies, conduct a review of drug therapy before a prescription was filled or delivered, and provide drug counseling. Although these duties were consistent with the direction in which the practice of pharmacy has been developing,[18] they go well beyond the traditional legal analysis of pharmacists' duties and roles. In a majority of states, regulations implementing OBRA 90's mandate were made applicable to *all* prescriptions.[19] The legal environment for pharmacy therefore has changed considerably.

Many questions remain, however. How will judges regard the language of OBRA 90 and the regulations implementing it? Traditional legal analysis will surely change with duties beyond filling prescriptions being recognized.

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13. *E.g.*, Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514 (Ind. 1994); Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129 (Ariz. Ct. App. 1994); Dooley v. Everett, 805 S.W.2d 380 (Tenn. Ct. App. 1990).

14. Brushwood, *supra* note 12, at 3, *quoted with approval* in Kessler, *supra* note 6, at 36. According to Kessler, "Pharmacists, more than any other group, will determine the success or failure of the renewed attempts to raise the level, distribution, and effectiveness of patient information about drugs." *Id.*

15. *See* Hepplewhite, *supra* note 9; David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacist: Should "Can" Imply "Ought"?*, 44 DRAKE L. REV. 439 (1996).

16. *See* Brushwood, *supra* note 11, at 386-87.

17. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (codified in scattered sections of 42 U.S.C.); *see also* Baker, *supra* note 12.

18. *See generally* APhA WHITE PAPER, *supra* note 8; Grussing, *supra* note 7.

19. *See* NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, SURVEY OF PHARMACY LAW 50 (1994).

But how will the regulations be enforced and standards of practice evolve in the pharmacy profession? Will pharmacists embrace them and accept the challenge of the American Pharmaceutical Association "to begin delivering pharmaceutical care today—one patient at a time—until the goal of optimal therapeutic outcomes, under the management of the pharmacist, is achieved for every patient?" [20] Will these be determinative of liability issues in litigation against pharmacists? More broadly, will the thrust of OBRA 90 and the mission and capability of pharmacy transcend the literal terms of the statute and regulations to create duties or standards of care not presently articulated? What will be the defenses or limits to pharmacists' liability for bad drug therapy outcomes? How will the larger role asserted by pharmacists and required by law be received by physicians and other health-care professionals? As pharmacists become a more visible and integral part of our evolving health care system, working in close cooperation with physicians, other health care professionals, pharmaceutical companies and hospitals, will the law move in the direction of enterprise liability, distributing the risk and the cost of its occurrence broadly to include, but not be limited to, pharmacists?[21] Will that, in turn, lead to improved health care and reduced costs?

This issue of the *Drake Law Review* reproduces in substance a symposium at Drake University addressing these issues. It was co-sponsored by the Drake Law School and the Drake University College of Pharmacy and Health Sciences, in conjunction with the American Society for Pharmacy Law. Our intention was to contribute to the ongoing dialogue in the legal, pharmacy, and other health professions framing and addressing questions in our developing health care system. We are indebted to the participants in the conference whose commentary we are pleased and fortunate to publish in this issue of the *Drake Law Review*; and we are grateful to the editorial board and staff of the *Review* for publishing the symposium and their outstanding work in making that possible. We are especially grateful and indebted to Blue Cross and Blue Shield of Iowa, its President and Chief Executive Officer, John D. Forsyth, its former President and Chief Executive Officer, Robert D. Ray, and to OSCO Drug, whose financial support made it possible to hold the symposium and publish the papers of the participants.

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20. APhA WHITE PAPER, *supra* note 8, at 11.

21. *See* Barry R. Furrow, *Enterprise Liability for Bad Outcomes from Drug Therapy: The Doctor, the Hospital, the Pharmacy, and the Drug Firm*, 44 DRAKE L. REV. 377 (1996).