

SCOPE OF MEDICATION USE IN THE UNITED STATES AND ATTENDANT ISSUES

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I. INTRODUCTION

Drugs are powerful agents with dramatic social power, influence, and attribution. They are healers as well as potent symbols of discovery and death. Their healing power is evidenced in the vivid impact that their use has on myriad pathological processes. With the advent of biotechnology,¹ drugs are endowed with new meanings for tinkering with the genetic composition of cells. They are not only symbols of potency, but also of high technology and more recently, of high expenses.²

The international market for pharmaceutical biotechnology products is expected to top \$60 billion in sales by the year 2000.³ The estimated cost of bringing a biopharmaceutical product to market—from discovery to human or animal consumption—is estimated at \$100 million.⁴ The price tag is estimated at \$231 million for a conventional chemical drug product.⁵

The availability, accessibility, and consumption of medications is constantly increasing. More than 450 products have been switched in the past

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1. The term "biotechnology," as used in this article, refers to those discovery and development processes that occur consequent to the manipulation of the genetic composition of human, plant, and animal cellular material.

2. *Biotech Is Coming into Its Own*, CHEMICALWEEK, Jan. 1, 1992, at 29 (predicting U.S. biotechnology sales of \$7.4 billion by 1997).

3. Gene Bylinsky, *Biotech Firms Tackle the Giants*, FORTUNE, Aug. 12, 1991, at 79.

4. *See id.* at 80.

5. *Id.* Conventional drug products are those chemical entities that occur naturally in plant or animal sources or are synthetically developed through chemical synthesis and molecular manipulation. *See id.* at 79-80.

fifteen years from "legend" or "prescription only" status to "market status," which allows those medications to be sold without a prescription.⁶ The latter are referred to as "over the counter" drugs (OTC). Self-medication and OTC drugs have become increasingly popular as the self-care movement has expanded and as individuals act to reduce their personal expenditures for physician visits.⁷ Nearly eighty percent of respondents in a poll of 500 mothers stated that they would give their children nonprescription medications for a fever without consulting a physician.⁸ Approximately sixty percent of the same group would also give their children nonprescription cold medicine.⁹

Drugs have taken on the aura of "silver bullets"—the belief is that devastating diseases can be halted or ameliorated through rational drug therapy. Consider the management of volatile hypertension or maintenance of appropriate blood glucose levels with medications. There are, however, significant risks associated with such drug therapy.¹⁰ Effective and appropriate medical protocol carefully weighs the risks and benefits of drug therapy against known positive and negative consequences. It is impossible, however, to completely negate risks associated with the introduction of chemical agents into the biological system.¹¹ "There is no activity, process, or product that is free from risk. . . . Risks are clearly a part of life. Indeed, it is living that poses risks."¹²

Appropriate medication use is projected to save millions of lives and billions of dollars by the year 2015.¹³ Increases in life expectancy over the past fifty years and associated improvements in the quality of life are powerful testaments to the healing power of drugs. This healing power should not be denied because of a drug's side effects—all drug use involves some degree of side effects. Just as individuals do not give up eating for fear of choking, they should not refuse to take medications for fear of the drug's side effects.

If medications are appropriately selected and used, it necessarily follows that the population's health status would be enhanced. In reality, however, appropriate drug use is not a simple process. The process of medication use involves several basic, yet complex components, such as selection and

6. NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION, OTC FACTS AND FIGURES (1994) [hereinafter NDMA].

7. Hubertus Cranz, *Over-the-Counter Drugs: The Issues*, 5 DRUG SAFETY 120, 120-21 (Supp. 1 1990).

8. *Mothers Use OTC Drugs Ineffectively*, AM. PHARMACY, Jan. 1988, at 7.

9. *Id.*

10. See, e.g., Geoffrey Cowley & Mary Hager, *Some Counter Intelligence*, NEWSWEEK, Mar. 12, 1990, at 82.

11. Henri R. Manasse, Jr., *Medication Use in an Imperfect World: Drug Misadventuring as an Issue of Public Policy*, 46 AM. J. HOSP. PHARMACY 929, 931 (1989).

12. Ralph L. Keeney, *Decisions About Life-Threatening Risks*, 331 NEW ENG. J. MED. 193, 193 (1994).

13. *Drugs Will Save Millions of Lives and Billions of Dollars by 2015*, DRUG TOPICS, April 8, 1991, at 14.

prescribing, preparation and dispensing, administration, evaluation, and adjustment.¹⁴

The drug use process also involves a number of organizations and people in addition to the patients themselves. The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), through its medication use indicator task forces, developed a schematic of these relationships as a basis for determining priorities for resolving medication use issues in organized health care settings.¹⁵

In both the drug use process and the medication use system, physicians and pharmacists serve in critical judgmental and evaluative roles. Physicians' input focuses primarily on diagnosis and linking the diagnosis to effective treatment options. Pharmacists, on the other hand, join physicians in assessing appropriate therapeutic options—once a decision for a specific therapeutic plan is made, pharmacists enter into a partnership with prescribers to monitor and manage the patient. Unintended and undesired results may occur if any one of the key functions, as developed by the JCAHO, go awry. The following table lists important processes in the medication delivery system.

Key Function: The Appropriate, Safe, Effective, and Efficient Use of Medications¹⁶

Major Components	Processes
Prescribing	<ol style="list-style-type: none"> 1. Assessing the need for and selecting the correct drug 2. Individualizing the therapeutic regimen 3. Designating the desired therapeutic response
Dispensing	<ol style="list-style-type: none"> 4. Reviewing the order 5. Processing the order 6. Compounding/preparing the drug 7. Dispensing of the drug in a timely manner
Administering	<ol style="list-style-type: none"> 8. Administering the right medication to the right patient 9. Administering the medication when indicated 10. Informing the patient about the

14. See generally MICKEY C. SMITH & DAVID A. KNAPP, *PHARMACY, DRUGS AND MEDICAL CARE* 150-59 (5th ed. 1992) (categorizing the functions of pharmacists into four categories: 1) professional functions; 2) technical functions; 3) administrative, supervisory, and managerial functions; and 4) entrepreneurial functions).

15. Deborah M. Nadzam, *Development of Medication-Use Indicators by the Joint Commission on Accreditation of Healthcare Organizations*, 48 AM. J. HOSP. PHARMACY 1925, 1925-29 (1991).

16. See Rhonda Leach Schaff et al., *Development of the Joint Commission's Indicators for Monitoring the Medication Use System*, 26 HOSP. PHARMACY 326, 328 (1991).

Monitoring	11. Including the patient in administration
	12. Monitoring and documenting the patient's response
Systems/ Management Control	13. Identifying and reporting adverse drug reactions
	14. Re-evaluating the drug selection, drug regimen, frequency and duration
	15. Collaborating and communicating amongst caregivers
	16. Reviewing and managing the patient's complete therapeutic drug regimen

II. SCOPE OF PRESCRIPTION AND NONPRESCRIPTION DRUG USAGE IN THE UNITED STATES

Pharmaceuticals, whether legend or OTC, have gained pre-eminent status in America as a medical treatment resource. Most medical problems, whether severe or minor ailments, may be first treatable with medications. Medical science is substantially closer to reaching the pinnacle of the "pill for every ill" ideal.¹⁷ The realization of this ideal is evidenced in data related to sales, usage, intensity, and expenditures, and by observing the pharmaceutical promotion scenery.¹⁸

Drugs accounted for approximately eight percent of total personal health care expenditures in the United States for 1993.¹⁹ Of the estimated \$903 billion spent in the United States on health care in 1993, almost \$13 billion was spent on nonprescription medicines.²⁰ Hospitals spent \$10 billion on drugs in 1993.²¹ "Retail pharmacies, HMOs and other providers of outpatient drugs spent about \$40 billion."²² Medicaid program expenditures for medications alone add up to an estimated \$8.2 billion.²³

Approximately 1.623 billion prescriptions were dispensed in pharmacies in 1993.²⁴ "Total retail sales topped the \$2 trillion mark last year, up

17. See Cowley & Hager, *supra* note 10, at 82.

18. See generally Martha Glaser, *Annual Rx Review: A New High*, DRUG TOPICS, Mar. 21, 1994, at 30.

19. James Heenan, *Prescription Drug Benefits in a Managed Care Plan: Balancing Quality and Costs*, 7 MED. INTERFACE, Jan. 1994, at 84, 85.

20. NDMA, *supra* note 6.

21. Lisa Scott, *Healthcare Update*, MODERN HEALTHCARE, June 20, 1994, at 18.

22. *Id.*

23. David G. Schulke, *A Congressional Perspective on Inappropriate Drug Therapy and Drug Utilization Review*, 50 CLINICAL PHARMACOLOGY THERAPY 606, 606 (1991).

24. Glaser, *supra* note 18, at 30.

6.3%.²⁵ It is estimated that the sales of nonprescription drug products will be \$40 billion by the end of the 1990s.²⁶

Each hospitalized patient receives approximately ten to fifteen drug administrations per twenty-four hour period.²⁷ When the magnitude of 1,163,460 beds (assuming a sixty-seven percent occupancy rate) in America's 6467 hospitals is considered, the drug administration data is staggering.²⁸ Add to these figures the approximately 1.6 million long-term care and nursing home beds,²⁹ and the total number of daily drug administrations exceeds 30.1 million.

Drug promotion is both aggressive and pervasive. Sales pitches, advertising trinkets, and slick ads fill professional journals. In the absence of a stricter policy by the U.S. Food and Drug Administration (FDA) against such advertising, several leading pharmaceutical manufacturers are appealing to the consumer to increase prescription demand. Such consumer-targeted advertising is now routinely seen in newspapers, weekly news magazines, and particularly, traditionally women's magazines. These advertisements are aimed at inducing doctor visits for the purpose of obtaining prescriptions for the advertised drugs.

III. NEW DRUG DEVELOPMENT IN THE UNITED STATES

The U.S. pharmaceutical manufacturing industry continues to be research and discovery intensive. The history of new molecular entity approvals demonstrates the industry's progressiveness. Between 1940 and 1974, 956 new molecular entities (NMEs) were approved by the FDA, representing an average of 27 NME approvals per year.³⁰ Between 1975 and 1993, 415 NMEs were approved by the FDA, representing an average of 21.84 NME approvals per year.³¹ Approval rate for the period was approximately 1.8 NMEs per month or one approval every two weeks. In 1994, pharmaceutical researchers expected seven existing drugs to be listed for new indications³² and nine existing drugs to be approved for use in new

25. *Latelines*, DRUG TOPICS, Mar. 21, 1994, at 6.

26. Cowley & Hager, *supra* note 10, at 82.

27. Manasse, *supra* note 11, at 930; NEIL M. DAVIS & MICHAEL R. COHEN, MEDICATION ERRORS: CAUSES AND PREVENTION 1 (1981).

28. AMERICAN HOSP. ASS'N, AMERICAN HOSPITAL ASSOCIATION HOSPITAL STATISTICS 20 (1994) (citing data compiled from the 1993 Annual Survey of Hospitals).

29. MARION MERRELL Dow, A MANAGED CARE DIGEST: LONG TERM CARE EDITION 4 (1994).

30. Paul de Haen, Inc., *Compilation of New Drugs: 1940 thru 1975*, PHARMACY TIMES, Mar. 1976, at 40, 42 (1976).

31. See OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R & D: COSTS, RISKS AND REWARDS 160 (1993); Kenneth I. Kaitin et al., *The New Drug Approvals of 1990, 1991, and 1992: Trends in Drug Development*, 34 J. CLINICAL PHARMACOLOGY 120, 121 (1994); 1992 New Drug Approvals, PHARMACY TODAY, Feb. 1, 1993, at 4, 4; Daniel A. Hussar, *New Drugs of 1993*, AM. PHARMACY, Mar. 1994, at 24, 24.

32. Indications are "special symptom[s] or the like that point[] out a suitable remedy or treatment or show[] the presence of a disease." RANDOM HOUSE DICTIONARY 972 (2d ed. 1987). The use of drugs for new indications must be approved by the FDA through safety and efficacy

drug delivery systems, the mechanism by which a drug is "delivered" into the body, such as tablets, ointments, sprays, or intravenous solutions.³³ Additionally, 220 drugs for specific diseases—such as cardiovascular disease, central nervous system disease, and infectious disease, were under investigation in 1994.³⁴ A wide array of new drugs are in clinical trials and many of these will likely become available within the next few years.³⁵

IV. DRUG MISADVENTURING: PROBLEMS IN THE IMPERFECT WORLD

While drug therapy has evolved into a "high-tech" framework, the prescribing, utilization, and management of drug therapy needs to move into a corresponding "high-touch" stage. This means all health care professionals working with patients who are using medications should monitor and evaluate patients continuously during drug therapy. Numerous instances have shown that failing to be in such a high-touch mode will more than likely result in adverse drug effects.³⁶ The term "adverse drug reaction" is used to indicate the negative effect of a drug administered in an allowable, advisable dosage.³⁷ The term "drug misadventuring" is a more inclusive term to denote anything that goes wrong with drug therapy.³⁸

A drug misadventure may be defined as:

an iatrogenic³⁹ hazard or incident

- (1) That is an inherent risk when drug therapy is indicated.
- (2) That is created through either omission or commission by the administration of a drug or drugs during which a patient is harmed, with effects ranging from mild discomfort to fatality.
- (3) Whose outcome may or may not be independent of pre-existing pathology or disease process.
- (4) That may be attributable to error (human or system, or both), immunological response, or idiosyncratic response.
- (5) That is always unexpected and thus unacceptable to patient and prescriber.⁴⁰

determinations. After approval has been achieved, the product labeling may be expanded to include the new indication. Approved drugs may be prescribed, however, for "off-label" indications before the indication has been approved by the FDA.

33. Dianne B. Williams, *New Drugs for 1994*, 9 THE CONSULTANT PHARMACIST 395, 399, 400 (1994).

34. *Id.* at 400, 402-04.

35. *Id.* at 399.

36. See, e.g., Manasse, *supra* note 11.

37. *Id.* at 933.

38. *Id.* at 935.

39. Iatrogenic means a disease or incident "induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures." MERRIAM-WEBSTER'S COLLEGiate DICTIONARY 573 (10th ed. 1993).

40. Manasse, *supra* note 11, at 935.

Drug misadventuring is indeed a reality in America's health care system. Drug misadventuring can result in increased hospital admissions, emergency room admissions, morbidity, mortality, and prolonged length of stay.⁴¹ According to recent reviews, drug-induced illnesses account for approximately five percent of all hospital admissions.⁴² In one emergency department studied, for example, the physicians did not routinely screen for potential drug interactions, even when a medication history was available.⁴³ Drug-related illnesses and hospital admissions have also been examined in specific medical departments.⁴⁴

For some specific populations, data similar to aggregate hospital admission results has been recorded. The American Academy of Pediatrics conducted a study in two large pediatric hospitals which disclosed the extent of pharmacological error on pediatric patients to be between 4.5 and 4.9 per 1000 medication orders.⁴⁵ Approximately 40-45% of elderly patients do not take prescribed medications properly.⁴⁶ These incidents, most of which result in substantial negative medical, social, and financial outcomes, indicate a serious public health problem.

Studies have also shown that medication noncompliance results not only in wasted money,⁴⁷ but does not produce the anticipated treatment goal.⁴⁸ According to a Gallup survey, drug-induced impairment costs the U.S. health industry 14 million lost work days each year.⁴⁹ This particular problem is gaining increased national attention as research reports, court decisions, and press releases have devoted attention to the national dilemma.⁵⁰

41. *Id.* at 936-42.

42. Thomas R. Einarson, *Drug-Related Hospital Admissions*, 27 ANNALS PHARMACOTHERAPY 832, 838 (1993).

43. Mark H. Beers et al., *Potential Adverse Drug Interactions in the Emergency Room*, 112 ANNALS INTERNAL MED. 61, 63 (1990).

44. See, e.g., Jesper Hallas et al., *Drug-Related Illness as a Cause of Admission to a Department of Respiratory Medicine*, 59 RESPIRATION 30 (1992); Jesper Hallas et al., *Drug Related Admissions to a Cardiology Department: Frequency and Avoidability*, 228 J. INTERNAL MED. 379 (1990).

45. Hugo L. Folli et al., *Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals*, 79 PEDIATRICS 718, 719 (1987).

46. Daniel Morrow et al., *Adherence and Medication Instructions*, 36 J. AM. GERIATRICS SOC'Y 1147, 1147 (1988).

47. See, e.g., Jan Erickson, *The Cost of Medication Noncompliance*, J. AM. ASS'N PREFERRED PROVIDER ORGANIZATIONS, Apr.-May 1993, at 33, 33-34, 38, 40; Ji. M. Koo & Edward D. Renner, *Cost of Inappropriate Use of Ciprofloxacin in Ambulatory Care*, 9 J. PHARMACY TECH. 246, 246-48 (1993); Sean D. Sullivan et al., *Noncompliance with Medication Regimens and Subsequent Hospitalizations: A Literature Analysis and Cost of Hospitalization Estimate*, 2 J. RES. PHARMACEUTICAL ECON. 19, 19-33 (1990).

48. See Jesper Hallas et al., *Drug Related Admissions to Medical Wards: A Population Based Survey*, 33 BRIT. J. CLINICAL PHARMACOLOGY 61, 64 (1992); DAVID L. SACKETT ET AL., *Helping Patients Follow the Treatments You Prescribe*, in CLINICAL EPIDEMIOLOGY: A BASIC SCIENCE FOR CLINICAL MEDICINE 249, 249-81 (2d ed. 1991).

49. Eric Vaughan, *Allergy, Cold Sufferers Must Cope with Effects of OTC Medications*, OCCUPATIONAL HEALTH & SAFETY, Apr. 1991, at 28, 28.

50. See, e.g., Elizabeth L. Allan & Kenneth N. Barker, *Fundamentals of Medication Error Research*, 47 AM. J. HOSP. PHARMACY 555 (1990); Miles C. Allison et al.,

Medication errors are also a serious problem in our contemporary health care system. Michael Cohen has catalogued medication errors and noted twenty-five varieties of these errors, ranging from misinterpretation of abbreviations to failure to verify orders.⁵¹ Cohen estimates approximately twelve percent of medication orders in hospitals will have errors associated with them,⁵² which implies 120 potential problems per 1000 medication orders. A recent study found "[p]hysicians prescribe potentially inappropriate medications for nearly a quarter of all older people in the community, placing them at risk of drug adverse effects such as cognitive impairment and sedation."⁵³

It has been shown in recent years that adverse drug reactions continue to be grossly under-reported to the FDA. Between three percent and eleven percent of hospital admissions are attributable to adverse drug reactions.⁵⁴ According to one study, however, less than one percent of suspected serious drug reactions are reported to the FDA.⁵⁵ Therefore, there is a need to develop a more accurate and definitive reporting system and better characterized epidemiology of drug misadventuring. Such data would not only serve to correctly catalogue incidences and the prevalence of adverse drug reactions, but would bring much needed policy attention to the problem of under-reporting and help establish a more definitive epidemiology of drug misadventuring.

In June, 1993, the FDA, the American Medical Association, and seventy health organizations, announced a new system, MedWatch, which encourages a broad array of health care professionals to regard reporting as a fundamental professional and public health responsibility.⁵⁶ During a six month period in 1993, about four thousand adverse events were reported through the MedWatch system, approximately fifty-five percent of which were catalogued as serious by FDA standards.⁵⁷ Among these reports, fifty-five percent were received from pharmacists and sixteen percent from physicians.⁵⁸

Gastrointestinal Damage Associated with the Use of Nonsteroidal Antiinflammatory Drugs, 327 NEW ENG. J. MED. 749 (1992); Mark H. Beers et al., *Inappropriate Medication Prescribing in Skilled-Nursing Facilities*, 117 ANNALS INTERNAL MED. 684 (1992); Mark H. Beers et al., *The Accuracy of Medication Histories in the Hospital Medical Records of Elderly Persons*, 38 J. AM. GERIATRIC SOC'Y 1183 (1990); *Drug Death Dose Errors Admitted*, PHARMACEUTICAL J., Sept. 28, 1991, at 421.

51. See generally DAVIS & COHEN, *supra* note 27 (discussing types of medication errors based on published medication error studies).

52. *Id.* at 1.

53. Sharon M. Willcox et al., *Inappropriate Drug Prescribing for the Community-Dwelling Elderly*, 272 JAMA 292, 292 (1994).

54. Keith Beard, *Adverse Reactions as a Cause of Hospital Admissions in the Aged*, 2 DRUG AGING 356, 358-61 (1992).

55. H. Denman Scott et al., *Rhode Island Physicians' Recognition and Reporting of Adverse Drug Reactions*, 70 R.I. MED. J. 311, 313 (1987).

56. Laurie Jones, *Getting Physicians to Watch for Side Effects*, AM. MED. NEWS, Feb. 14, 1994, at 3.

57. *Id.*

58. *Id.* at 9.

In addition to these efforts, mandatory reporting of medication errors resulting in death was called for by Congressmen William Coyne (D. Pa.) and Pete Stark (D. Cal.) under the rubric of the Safe Medications Act of 1993.⁵⁹ The bill proposes the creation of a national medication error data bank to analyze trends relating to medication-related deaths.⁶⁰ The bill required pharmacies, hospitals, long-term care facilities, physicians' offices, and other health-care facilities to report any error in prescribing, dispensing, or administering drugs resulting in a patient's death.⁶¹ While the 1993 legislation was not passed by Congress, a similar bill was introduced during a 1995 legislative session and may surface again in a future congressional session.⁶²

Through these efforts, it will be feasible to determine where misadventuring problems exist and how best to prevent them. Of course, increased responsibilities for reporting involve increased costs for both medical and administrative staff. There comes a point, however, when saving lives is worth spending money. "Hence, [the] critical question is how we should use economic resources most effectively to reduce risk."⁶³

V. EXPECTATIONS FOR THE FUTURE

The ultimate goal for health care professionals involved in the drug use process and its appropriate administration is to optimize the outcomes of rational drug therapy, thereby minimizing and eliminating drug misadventuring. For the achievement of this goal, there must be maximum interplay between physicians and pharmacists as they perform their respective decisive roles in applying a rational drug therapy process. The line demarcating physician and pharmacist responsibility therefore becomes blurred.

Appropriate choice of a drug and its dosage form, coupled with safe and effective dosing, are the premises of rational drug therapy. Avoidance of drug-drug, drug-food, and drug-disease interactions and unnecessary poly-drug use are also critical variables in assuring the safety and efficacy of drug therapy. Patient factors, such as compliance and concomitant use of self-prescribed therapies, nonprescription drug use for example, are also important variables in the therapy process. Vulnerable populations such as the elderly and children need special attention to assure "safety-net" protection from drug misadventures. Failure to initially fill or later to refill prescriptions "has resulted in an estimated annual cost of \$8.6 billion for increased hospital admissions and physicians visits—nearly one percent of the country's total health care expenditures."⁶⁴

59. H.R. 3632, 103d Cong., 1st Sess. (1993); see also Carol Uken, *Congressmen Eye Mandatory Rx Reporting*, DRUG TOPICS, Mar. 21, 1994, at 15 (discussing the proposed legislation).

60. H.R. 3632, 103d Cong., 1st Sess. § 3 (1993).

61. *Id.* § 2.

62. 141 CONG. REC. E1321 (daily ed. June 22, 1995) (statement of Rep. Coyne).

63. Keeney, *supra* note 12, at 195.

64. COALITION FOR CONSUMER ACCESS TO PHARMACEUTICAL CARE, AN INVITATION TO ACTION: A REPORT FROM THE COALITION FOR CONSUMER ACCESS TO PHARMACEUTICAL CARE 4 (1994).

"About seventy percent of adverse effects are predictable and preventable through logical application of existing information."⁶⁵ Patient education focusing on appropriate medication has proven effective in terms of reducing the number of adverse drug reactions and assuring appropriate drug therapy outcomes.⁶⁶

Evaluative research shows that appropriate intervention by pharmacists can improve outcomes and reduce pharmaceutical costs.⁶⁷ This is largely accomplished by preventing, detecting, and resolving drug-related problems that can lead to drug-related morbidity and mortality.⁶⁸ Risk management relating to proper drug use is a significant part of a pharmacist's responsibilities. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90)⁶⁹ established a statutory basis for counseling and drug utilization review.⁷⁰ OBRA 90 enables all pharmacists to become increasingly involved in caring for their patients through counseling and providing health information.⁷¹ Meanwhile, it sets a higher standard for the pharmacy profession. No longer is it sufficient to choose the correct medication and properly label and package the drug. It is incumbent upon pharmacists to extend protection of the patient using medications begun by the physician who chooses the drug therapy.

As the health care system in the United States reorganizes around the themes of care integration and risk sharing for patient care, the management of risks associated with drug misadventuring will become critical in system planning. When risks associated with medication use are recognized for what they mean in quality of care and financial terms, risk reduction will necessarily need to include better patient management through the partnership of physician and pharmacist. No longer will it suffice to say that pharmacist collaboration with physicians in applying the drug use process interferes with the physician-patient relationship. Nor will it suffice to say pharmacists failing to exert due diligence to avoid drug misadventures are only following the orders of prescribers.

A rational public policy would focus on the "brother's keeper" doctrine articulated by a Pennsylvania court in *Riff v. Morgan Pharmacy*.⁷² The doctrine states that all health professionals who play a role in the drug use process have an affirmative responsibility to protect the patient.⁷³ Moreover, rational public policy would recognize that scientific contributions enhance

65. *Id.*

66. See generally Ruth Ann C. Opdycke et al., *A Systematic Approach to Educating Elderly Patients About Their Medications*, 19 PATIENT EDUC. & COUNSELING 43 (1992).

67. Charles D. Hepler & Linda M. Strand, *Opportunities and Responsibilities in Pharmaceutical Care*, 47 AM. J. HOSP. PHARMACY 533, 537-38 (1990).

68. *Id.* at 538.

69. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388-143 (codified in scattered sections of 42 U.S.C.).

70. 42 U.S.C. § 1396r-8(g)(2)(A)(i)-(ii).

71. *Id.*

72. *Riff v. Morgan Pharmacy*, 508 A.2d 1247 (Pa. Super. Ct. 1986), *appeal denied*, 524 A.2d 494 (Pa. 1987).

73. *Id.* at 1253.

patient care when each health care professional brings his or her expertise to a rational decision and management process.

In the case of pharmacists, curricula and clinical experience requirements for licensure are extensive. The concentrated focus on the study of drugs and their effects is substantially stronger in pharmacy education than in the education of physicians. Consequently, the joint efforts of diagnostic and treatment skills between physicians and pharmacists is an effective mechanism by which care is enhanced and risk is reduced. The goal, after all, is to benefit the patient.

