The Care in Pharmaceutical Care

Henri R. Manasse, Jr.

INTRODUCTION

This paper centers on the *care* in pharmaceutical care. As an applied social scientist in pharmacy and pharmaceutical education, I hope to explore both the theoretical and pragmatic aspects of caring within the framework of social and ethical considerations. In so doing, I hope to develop the implications and necessities for caring within the context of our professional responsibilities and, hence, personal duties to the patient. Finally, I will incorporate some recommendations for those of you who carry the honor and traditions of professional pharmacy practice for contemporary and future pharmacy practice.

THE SOCIAL NEED FOR PHARMACEUTICAL CARE

Much has been said of late about the concept and practical applications of pharmaceutical care. The theoretical groundwork for this discussion has centered on the seminal paper published by Professors Hepler and Strand in the March 1990 issue of the American Journal of Hospital Pharmacy. These authors have stated that:

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that im-

Henri R. Manasse, Jr., Ph.D., is Dean and Professor of Pharmacy Administration at the University of Illinois-Chicago College of Pharmacy, M/C 874, Box 6998, Chicago, IL 60680.

prove a patient's quality of life. These outcomes are 1) cure of a disease, 2) elimination or reduction of a patient's symptomatology, 3) arresting or slowing of a disease process, or 4) preventing a disease or symptomatology.

Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. (1)

These authors also state: "Pharmaceutical care should be integrated with other elements of health care. It is, however, provided for the direct benefit of the patient, and the pharmacist accepts direct responsibility for the quality of that care."

I would like to begin my explorations with the assumption that a substantive need exists in our society for the profession of pharmacy to embrace and apply the concepts of pharmaceutical care. The assumption follows that all practitioners of pharmacy assure that they render this care in every patient encounter, regardless of how simple or complex that engagement may be.

My assumptions that our society needs pharmaceutical care and that all pharmacists should render it are based on four simple givens. Consider them the *foundations* of pharmaceutical care:

- As a profession, we have a societal mandate to develop, procure, and otherwise manage the medicine supply. That fundamentally means that we carry the time-honored responsibility of assuring the effective management, in all that this term means, of the nation's drug supply. Hence, we can anchor a portion of our pharmaceutical care role in what some may term the more traditional aspects of our practice; namely, the distribution of medications.
- 2. We have a further social and, I would submit, an ethical obligation to assure that the intended therapeutic outcomes for a given patient are achieved in a safe, effective, cost-efficient manner. This means that we relate to the care of the patient in such a way that we work with the patient and the prescribing health professional in the achievement of out-

comes that are best for the patient (2). This portion of our pharmaceutical care role has been evolving over the past two decades and must move to a higher level of maturity and consistency in patient expectation.

- 3. Our trust-sacred trust, if you will-with society is to assure that no harm will be brought to the patient as a result of our care. Hence, the profession of pharmacy carries a significant portion of the responsibility to reduce morbidity and mortality associated with drug misadventuring. Drug misadventuring refers to the well-documented events that occur from errors of omission and commission related to drug therapy applications (3). Data show that approximately 10% of emergency room admissions are directly attributable to drug misadventures. A mortality rate of 2 in 1,000 hospital admissions has been documented as being related to medication misadventures. The literature is replete with specific cases where patients have come to dramatic harm and death when drug therapy applications become misadventures.
- 4. We will continue to be challenged by new chemical entities, new technologies of drug administration and drug delivery, more complex biological agents, and an everexpanding level of potency among the agents in the medicine supply. To put this in perspective from an American point of view, the U.S. is approving an average of 23 new chemical entities for marketing each year. Since 1945, over 1,300 new chemical entities have entered the American marketplace. In 1991, a total of 30 new chemical entities and 8 biologicals were approved for marketing and sale in the United States. We are, therefore, called to be avid learners and seekers of new knowledge. We are further obligated, then, to use this knowledge in rendering our care to the patients we serve.

These four givens establish for me the societal need and ethical framework for pharmaceutical care and pharmaceutical care givers. But how is this social relationship established? And how is this relationship honored in the complex way societies function to achieve stability, progress, and happiness for their citizenry?

APPLYING PHARMACY'S SOCIAL COVENANT THROUGH PHARMACEUTICAL CARE

Societies function, in part, through an array of covenants. In democratic nations, the most basic covenants are national constitutions or social declarations. In these constitutions, the rights of the governed and the obligations of the governing are clearly established; declarative statements of human rights assume certain inalienable rights. The American Declaration of Independence, for example, points out that "life, liberty and the pursuit of happiness" are inalienable rights that the governed cannot take away, since these have been endowed to each created being by his or her creator. They are therefore referred to as natural rights.

The constitutions of democratic nations go further to delineate the responsibilities that both the governed and the governing assume as they enter into a relationship of mutual support. A covenantal bond is thus constructed. The governing will appropriately obey and maintain the laws of the land, while the governed will follow the rules of law to assure mutual tranquility. This democratic ideal will last only as long as the covenant between the governing and the governed is honored.

We see a similar example of a covenantal relationship in the world's dominant religions. The common thread of a covenant between the individual and some supreme, omnipotent authority is demonstrated in theological foundations. Man is given certain promises for just rewards in exchange for his commitment to follow the precepts of the faith, dogma, and doctrines.

Society has similarly constructed covenants with certain occupations we have come to know as professions. Through its legal system and the accepted norms of social expression, society has given the privilege to certain of its members to perform those functions which members of the society are ill-equipped to handle on their own. This relationship is noteworthy.

In this relationship, the recipients of the services of a professional give up a certain degree of their autonomy in decision making and judgment in exchange for the knowledge, skills, and practices of the professional. The client or patient will also allow the engagement of the professional in certain behaviors that under any

other circumstance and with any other outsider would not be allowed. Consider, for example, the willingness of the accountant's client to fully divulge financial information in exchange for the accountant's confidentiality and ultimate financial guidance. Consider as well the fact that we all willingly undress when we meet the physician and subject ourselves to poking and prodding, sometimes in places where we would not let others tread. In this social exchange, we expect confidentiality, poise, appropriateness, and respect for our dignity.

This exchange underscores the importance of the covenantal relationship that exists between the patient and the care giver. The patient gives himself up to the care giver to be cared for. In this transaction, the expectation on the part of the patient is that he or she will be properly cared for. In the medical encounter, this means that an appropriate diagnosis will be constructed from which a treatment plan may be developed.

Professionals, then, serve as agents of the society. They serve on behalf of the society by doing for it what it cannot do for itself. Professionals, through a demonstration of their skills and knowledge (e.g., licensure, registration, certification), are then allowed to enter the world of special privilege. This is the sacred trust that society transfers to its professionals. But society then places the expectation on professionals to render their knowledge, skills, and care on its behalf. This is no small responsibility. Moreover, there are high prices to be paid if the sacred trust is violated. We have seen some of these price tags among those of our colleagues who have lost their privilege to care for others.

Pharmacy's covenant with the patient is the very essence of the profession's being. In some of my writings, I have referred to this essence as being pharmacy's soul (4). If we remove all of the trappings of what we do and how we function, our responsibilities are focused on the social covenant we have with the patient or patients for whom we care. In fact, if we did not have this covenantal relationship with society's members, then the social basis of our profession would likely disintegrate rather quickly.

As societies evolve, so do their relationships with and definitions of the role functions of their professions. In and of themselves, occupations and, hence, professions evolve and change. The profession of pharmacy is not, nor should it be, immune from such evolution. If we are to care for the members of society, then we must be responsive to the changes that occur in our knowledge systems and their respective applications.

In the contemporary and future evolution of patient needs with respect to medication use, our profession has come to reexamine, deliberate, and redefine its covenantal relationships with the members it serves. Much of this discussion is centered on adopting the principles of pharmaceutical care and developing schemes for their implementation. The American Pharmaceutical Association is about to release a Task Force Report that puts forward specific recommendations for redefining and reprofessionalizing pharmacy in the context of the principles embedded in the concept of pharmaceutical care.

THE IMPLICATIONS OF CARE AND COVENANT (FOR THE PROFESSION OF PHARMACY

As pharmacy practitioners who respect our covenantal relationship with society, we have chosen to serve others. Consequently, our oath to "help your fellow creatures in pain" lays claim to a repayment of a societal debt. That debt is grounded in the special privilege we have as professionals to serve and protect within an aura of trust, confidence, and reliance given to us by our patients.

Any human being or collection of humans has limited fiscal and psychological resources. We must, therefore, husband these resources with care and distribute them with careful attention to needs. The profession will have to assure that its talents are applied where they will have an impact on the life of a patient or on the decision of a colleague. Such actions take energy. And as we learned in the principles of thermodynamics, energy is not an unlimited resource. We must, then, carefully use our professional and personal energies to apply the knowledge of our chosen profession to patient caring.

This paradigm shift in pharmacy derives its implications from the myriad external and internal influences that determine the course of our profession and its practice patterns. Here I will limit my exploration of these implications to three major areas. These include, but are obviously not limited to:

- The public policy foundations that have and continue to be developed in support of applying pharmaceutical care
- The need for changing the practice patterns and functions of pharmacists
- The effects that applying pharmaceutical care will have on the Standards of Practice in Pharmacy and the accountability of the profession.

THE PUBLIC POLICY FOUNDATIONS THAT SUPPORT PHARMACEUTICAL CARE

Over the course of the past decade, we have witnessed an interesting drift in public policy with respect to the professional responsibilities of pharmacists. In particular, there has been a steady, albeit slow, evolution of public expectation for care to be rendered by pharmacists. This evolutionary progression of public policy reflects policymakers' ever-increasing concern about the appropriate utilization and cost management of pharmaceuticals.

Perhaps the most evident public policies regarding pharmaceutical care are those laws and regulations that govern the use of medications in nursing homes and skilled care facilities. Where public funds are used to reimburse pharmaceutical services, there are very specific mandates governing the assessment of therapeutic outcomes. These mandates are anchored in rules and regulations promulgated by the Health Care Financing Administration (HCFA) within the authority given to this agency through the Social Security Act. Indeed, patients cared for in these facilities are the beneficiaries of consultant pharmacists' services. Such largely cognitive services rendered by pharmacists are reimbursed by the federal government.

A second foundational anchor of public policy for the application of pharmaceutical care is found in the provisions of the 1990 Omnibus Budget Reconciliation Act, fondly referred to as OBRA 1990. This federal legislation has mandated very specific pharmaceutical care functions for Medicaid patients utilizing medications as part of therapeutic intervention. The mandated counseling functions, the requirements for retrospective and prospective drug utilization review, and the establishment of drug utilization review organizations jointly composed of pharmacists and physicians are ample evidence of societal will.

The OBRA 1990 provisions are rooted in the ill-fated legal mandates of the Medicare Catastrophic Care Act of 1988. While this latter legislation was repealed by Congress, the notions of pharmaceutical care envisioned in that legislation have already found their way into the provisions of OBRA 1990. I would submit that other provisions of the Medicare Catastrophic Care Act will find their way into future pieces of health care and budget legislation in the federal arena.

Two reports issued by the Inspector General of the U.S. Department of Health and Human Services are also noteworthy as public policy foundations for pharmaceutical care. One report specifically points to the "worthiness" of a more clinically oriented focus in the community pharmacy, while simultaneously recognizing the serious barriers to such a focus in these settings. The Inspector General specifically challenges the profession to remove these barriers and thus render a more patient-specific care service in the community pharmacy.

In another report, the Inspector General examines boards of pharmacy and the practice acts of the states within the context of improving patient care and applying competent care practices. Boards of pharmacy are challenged in this report to reexamine their practices with specific attention to their practices for handling pharmacists who are incompetent to provide appropriate care for patients. The Inspector General further recommends a careful review of pharmacy practice acts and thus a determination as to whether these facilitate or impede improved patient care by pharmacists.

Another important public policy evolution is evidenced in the drift of opinion surrounding the doctrine of the pharmacist's duty to warn. As Professor David Brushwood has chronicled in his recent publication in the *Drake Law Review*, the state courts have variedly interpreted state practice acts with respect to the pharma-

cist's duty to warn patients of potential side effects associated with medication use (5). On the one hand, we witness narrow opinions that offer no such duty to warn and thus define the pharmacist's role strictly as one of handing the patient a properly filled prescription. On the other hand, we witness rather broad opinions, such as those offered in Pennsylvania and Tennessee, that specifically mandate that the pharmacist be his brother's keeper. These opinions affirm a duty to protect the patient through prospective warning. I would submit that the courts will move more and more toward affirming the pharmacist's duty to warn.

These, then, are critical public policy foundations that undergird the societal mandate for pharmaceutical care and its appropriate application. Consequently, pharmacists have a social and ethical obligation to respond to such public policy mandates. Moreover, pharmacy as a profession should consider itself empowered by these mandates.

THE NEED FOR CHANGING PRACTICE PATTERNS AND FUNCTIONS OF PHARMACISTS

In a speech I made this past March to the Annual Meeting of the American Pharmaceutical Association, I noted that "the opportunity to care . . . is very different from the reality of caring '' (6). I would submit that in many of pharmacy's workplaces in America the opportunity to care far exceeds the reality of care shown by pharmacy practitioners. Nonetheless, let me expand on this idea a bit by quoting sociologist Harvey Smith:

Every profession operates in terms of a basic set of fictions about itself. These provide the profession with a comforting self-image, some stereotype to help meet and adapt to the varied and often drastic contingencies of everyday operation. The Air Force pilot gazing up into the blue, Pasteur, Osler, Florence Nightingale-these are symbols of professional fictions. These fictions help to define immediate functions; they help the professional person to relate to others in terms of some mutuality of expectancy; they are often primary foci of recruitment. Therefore, they perform a useful and necessary function. As with all fictions operating in human behavior, however, unless there is occasional testing of reality, the individual, or the profession, is in danger. If the profession has come sincerely to believe in a set of fictions too grossly at variance with reality, the final contemplation of that reality may indeed be a shock. (7)

I find that analysis sobering. It is particularly sobering when we speak of the availability of pharmacies in virtually every community and area of developed nations. It is even more sobering when we examine how most pharmacists spend their time.

The reciprocal relationship of care and covenant need much more substantial expression in the daily practice of all pharmacists. Caring is a simple act: it simply means that we have a relationship with another human being that is aimed toward securing mutual benefits with long-lasting meaning for both parties. The essence of pharmaceutical care is the relationship between patient and pharmacist that assures the appropriate drug therapy outcomes will be forthcoming and that we intervene on behalf of the patient when difficulties arise in therapies. This means that we must delegate the repetitive production functions of the practice to automation and pharmacy technicians. Our efforts as pharmacists must be on the firing line of therapeutic decision making and outcomes assurance. Our time and talent must be linked to adding value to the care of the patient.

Now I know that this may sound like heresy to some. Others will find such a direction liberating and satisfying. The reality is that the distributive tasks that for the past 50 years have characterized much of pharmacy's role can, in effect, be handled well by other means such as robotics systems and paraprofessionals. For those of you who are pessimistic about the abilities of robots and automation applications to perform the prescription-filling function, I would advise you to visit a mail-order prescription service factory. These organizations can process upwards of 15,000 prescription orders daily!

University-educated people are not needed to do the daily "grinding" of the prescription-filling work task. While such individuals

must still be responsible for its management, their participation in the distribution component of pharmacy's work responsibilities must be minimized so that their talents can be turned toward pharmaceutical care. This will be a challenge to all pharmacists over the next decade as the workplace and its practice patterns become restructured.

This challenge will likely be accelerated by the continuous upward progression of pharmacists' salaries. Furthermore, acceleration of this trend will be fueled by the continuing shortage of pharmacists. The changing values and interests of new matriculants in pharmacy will also add to increasing dissatisfaction with the prescription-filling task. The combination of these elements sets an interesting stage for the restructuring of pharmacy practice—in some cases, whether we like it or not.

In one future scenario, all chronic medications will be provided to patients through the mail and/or parcel delivery services, and acute medications will be available to patients through automated prescription-filling machines (much like the automated tellers that our banks use). In such a scenario, the need for pharmacists in the drug distribution chain is seriously decreased. Whether such a scenario is good public policy or good patient care is up to our society to decide; however, this scenario is not unrealistic, given a careful analysis of the events of the day.

EFFECTS ON THE STANDARDS OF PRACTICE IN PHARMACY AND ACCOUNTABILITY OF THE PROFESSION

As I have heretofore related, we have witnessed an interesting drift of judicial opinion on the matter of the pharmacist's duty to warn and an evolution of public policy relating to pharmaceutical care for the patient. We can expect that as the norms of practice change and encompass the theme of assuring appropriate patient outcomes, legal mandates will quickly follow. However, we should not wait until the courts decide what is right for us; rather, we should empower ourselves to do what we know is right for the patient.

If, for example, we know that assessing the blood level of theophylline in an asthmatic child is an appropriate method of assuring intended therapeutic outcomes, then why do we not apply this science to our practice? A similar question can be applied to anticoagulants, aminoglycoside antibiotics, seizure control agents, and cardiac drugs. Why, after 20 years of scientific and technological advancements in pharmacokinetics and biopharmacy, do we not routinely apply these developments to patient care?

As our profession begins to transfer its science and technological largesse to the direct care of the patient, we must also engage ourselves in better documentation of our interventions on behalf of the patient (8). A pharmaceutical record in this instance should be more than a simple itemization of the drugs, dosage forms, and dosages dispensed. The pharmaceutical record that I have in mind would begin from a knowledge of the diagnosis, relevant laboratory and physical findings, and other information that puts the patient in a physiological, pathological, and behavioral context.

From these parameters, the pharmaceutical record I envision would be the foundation for constructing the therapeutic plan. It would go further than the present system to record the progress of the patient as monitored within protocols that are relevant to the therapy applied. If, in the course of the monitoring, outcomes are not being achieved or danger signs set in, then communication with the prescribing colleague must ensue to change the course of therapy. The latter interventionist activity must likewise be recorded.

My focus on new thinking about a pharmaceutical record is presented here because I firmly believe that such activity will more clearly express the accountability of pharmacy for patient care. From our present record systems, all we can generally say about our contributions to patient care is that the patient received, or the nursing station received, such and such a medication. That is typically where our records stop. We are, therefore, hard-pressed to define our work efforts and knowledge applications much beyond drug distribution.

If we take an accountability approach to bringing value-added care to the patient, then we should likewise be willing to document our efforts and stand behind what we have done for the patient. That is not an unreasonable direction for our profession. It is par-

ticularly applicable to a trust relationship with the patient and our prescriber colleagues. Moreover, it distinctly displays our willingness to put our skills and knowledge on the line in the relationship among drug therapy, the patient, and the prescriber.

CONCLUSIONS

We have covered a lot of ground which I trust you have found stimulating for further thought, deliberation, discussion, and argument. The ideas I have put forward require reflective and introspective thinking. I hope that you will engage in thoughtful analysis and dialogue over what I have put forward.

I have attempted to express my thoughts on the *perestroika* that I believe is necessary in pharmacy if the profession is to continue to be viable well into the next century. While I would hope that our changes would be more ordered and systematic than the political *perestroika* we have witnessed over the last weeks and months in the former Soviet Union and Eastern Europe, we might experience a similarly tumultuous restructuring of our profession.

As the prices and complexity of pharmaceutical agents increase, so too will our necessity to adapt to shifting paradigms of practice functions become a reality. We therefore need a professional solidarity to embrace change in a constructive, positive, and meaningful fashion. To quote Relman, "[pharmacy] is a profoundly human discipline that is intimately concerned with the psyche and the soul" (9).

The various notions and ideas that I have put forward here are being discussed around the globe. At the recently concluded World Pharmacy Congress 1991, held in Washington, DC early in September, I heard fragments of the very ideas I have shared here. From papers on the status of robotics and automation in prescription filling to presentations on the use of smart cards for better documenting patient care intervention, pharmacists the world over are creating new models of practice that are relevant to patient needs. I find that exciting. And I also find it a bit scary. None of us knows where change will ultimately take us. Worse yet, we are not always in control of the changes that affect us. But adaptation

to dramatic change is likely another dimension that separates us humans from our animal friends.

All of us in this profession of pharmacy must reach into our collective souls to define the future of our contributions to patient care. Whether educator or industrial manager, hospital pharmacist or community pharmacist, young or old, each of us in his or her own environment and his or her own way must contemplate a changing order in his or her personal and professional life.

That will be the challenge. In accepting this challenge, we must draw on our collective wisdom to create a right course. As you think about that challenge, keep in mind a thought taken from Robert Fulghum's book All I Really Need to Know I Learned in Kindergarren: "When you go out into the world, watch out for traffic, hold hands and stick together" (10). Hold hands and stick together will you? And advance the care of each and every patient in the State of Tennessee and all those other parts of our nation in which you will be practicing.

REFERENCES

- Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.
 - 2. Penna RP. Forces shaping pharmacy's future. J Mich Pharm 1991;29: 120-3.
- Manasse HR, Jr. Medication use in an imperfect world: drug misadventuring as an issue of public policy. Am J Hosp Pharm 1989;46:924-44; 1141-52.
 - 4. Manasse HR, Jr. Where is pharmacy's soul? Unpublished.
- Brushwood DB. The pharmacist's duty to warn: toward a knowledgebased model of professional responsibility. Drake Law Rev 1991;40:1-60.
- Manasse HR, Jr. The role of the pharmacist in comprehensive drug therapy management. Unpublished.
- Smith HL. Contingencies of professional differentiation. In: Nosow S, Form WH, eds. Man, work and society. New York: Basic Books, Inc., 1962: 219-24.
- 8. Angaran DM. Quality assurance to quality improvement: measuring and monitoring pharmaceutical care. Am J Hosp Pharm 1991;48:1901-7.
- Relman AS. The health care industry: where is it taking us? N Engl J Med 1991;325:854-9.
- 10. Fulghum R. All I really need to know I learned in kindergarten. New York: Villard Books, 1989.