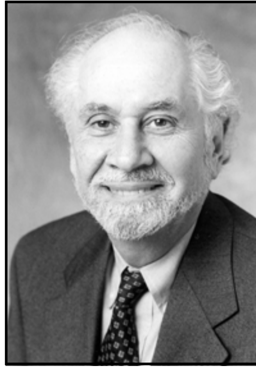

"Only by our involvement with the total medication cycle can we attempt to guarantee safe and effective drug therapy."

Bernard Mehl

(2001)

At the time he received this award, Bernard Mehl was director of pharmacy at Mount Sinai Hospital in New York City and a highly esteemed educator and leader in the field of pharmacoeconomics.

Pharmacy and the Complexity of Health Care

At the time I entered the profession, there were two major areas of practice, community pharmacy, where 90% of pharmacists practiced, and hospital pharmacy, where only a small number could be found. There were other areas where pharmacists practiced, but those areas were very limited in number.

Medicine, nursing, and pharmacy were the major professions that treated the ill, but there was very little integration between them in the process. "Health care" is an expression that may have existed at the time but was not frequently heard and did not have the meaning it has today. There was not a concern in obtaining health care

coverage, and the costs were affordable. Drugs were prescribed and prescriptions were filled at the corner drugstore. Prices for prescriptions were reasonable, and patients did not have any concerns in reference to being able to obtain their medications. Medical care and pharmacy practice were much more simplistic. There was no unit-of-use distribution, no drug information practices, no such person as a clinical pharmacist, and no direct relationship between the hospital patient and the pharmacist, and technology was a mortar and pestle. Today, we as pharmacists and members of society find ourselves a part of the difficulty health care is facing. Let us further explore the problem, our profession's role within it, and how it affects our practices.

In reviewing the recent past and the current state of health care, it is not difficult to see the quandary we are in. It is anticipated that double-digit annual increases in health care costs will occur for the forseeable future. Medicare patients cannot afford the drugs they require because prescription medications are not covered by their plans. Over 40 million Americans are without health care coverage, and many who do have coverage are disappointed with the services provided.[1] Health plans have terminated coverage of many of their members because their cost to the plan was too high. At the same time these events have been occurring, there have been major technological advances in drug development and in other areas of medical care. Health care is no longer a simple service available to the American public.

It is clear that cost is the driving force in the direction health care will take. But at this moment there are no answers to the problem. Governments, state and federal, recognize that Medicare patients cannot afford the cost of their medication but appear to be unable to find the funds to solve the dilemma. At the same time, other payers of health care costs are seeking methods of reducing their expense. This is usually done by shifting costs to employees, attempting to find new approaches, or banding together to try to lower costs by forcing providers to introduce more efficient delivery systems.

When the Medicare program began, drug costs were not a financial issue. Today they are a major problem, with no firm direction coming in sight. The federal government at the time of this writing has not been able to come to an agreement as to what a drug benefit should be or what the anticipated cost would be. The president has suggested an "immediate helping hand" proposal that would provide federal block grants to states.[2] Senate Democrats have proposed a more inclusive program that would provide coverage for low-income beneficiaries on a sliding scale. The Democratic proposal suggests bonuses for community pharmacists in hard-to-serve areas and would require pharmacy performance standards to be met.[3]

What is lacking at this time is the framework for a program acceptable to both parties and an assurance that community and other areas of pharmacy practice will play a pivotal role in the development and functioning of an agreed-to program.

There are approximately 26 states that have active programs to support low-income, elderly patients to purchase medication, either through subsidies or through discounts. It appears that the states are doing more for the elderly patient than the federal government. However, the president has outlined his plan to provide $46 billion over four years to states, allowing the federal government time to give thought

to major changes within the Medicare program.[2]

From the point of view of the profession, our concern should be the future role that the pharmacist would play in reference to increasing the availability of medication and pharmaceutical care to the elderly, as well as all patients, at a reasonable cost. We should not only advocate the availability of drugs but should be developing new thoughts for the future to provide medication in a system with appropriate safeguards for the patient and in tandem with other health professionals. Only by our involvement with the total medication cycle can we attempt to guarantee safe and effective drug therapy.

I seriously doubt that most people would argue the fact that the cost of drugs is, at least in the mind of the general public, the most serious problem in health care today. Currently, overall drug spending is less than 9% of the total national health care cost, and there are predictions of it increasing to 11% by 2008.[4] As for the industry, pharmaceutical manufacturers had sales of prescription drugs of $131.9 billion in the United States in 2000, compared with $111.1 billion in 1999.[5] Medicare's cost for its patients has been estimated to increase by 10.3% per Medicare enrollee, while other benefits are estimated to increase 5.5% annually in the next 10 years.[6] The reasons given for these increases have not changed: the aging population, increased utilization, more expensive drugs, and direct-to-consumer advertising.

We are all quite aware of the AIDS drug dilemma and the comparative cost of drugs to patients in the United States and in poorer nations that, even with reduced prices, do not have the funds to provide medications to their citizens with HIV. In addition, we do not have to go very far to observe the cost differential of drugs in the United States and the cost of the same drugs in Canada and Mexico, to begin to wonder why are we paying such high prices compared with other countries. How do we justify these differences? This is not an easy question to answer. We are the wealthiest nation in the world, and an argument could be made that we can afford the cost. But let us not forget that 40 million Americans still do not have medical coverage, and some of our other patients must make decisions as to buying medication or food. How do we justify this?

There is general agreement that new drugs have had a major effect on the cost of health care by reducing surgery and patient hospital stays. There is no denying that our older population continues to increase and that the baby boomers will soon be the elders of our society. It is also no secret that the elderly, who are the major purchasers of drugs, are living longer and obviously have the greatest need. As we introduce new drugs for medical conditions for which there was no therapy in the past, the cost of drug therapy will continue to rise.

The pharmaceutical industry states that the high cost of pharmaceuticals is necessary for continued research to uncover new, effective therapy. When we review the number of mergers within the industry, we learn that one of the needs for mergers is the need to have additional funds to support new research. This statement can be supported by the fact that the majority of spending for research and development is mainly centered in recently merged companies. But it does not answer the question of why there is such a large price differential for drugs between the United States and

other countries. Aside from the poorer nations of the world, how do we defend this cost differential?

The pharmaceutical industry is said to be the most profitable industry in the United States, but it defends itself by noting that it is also at high risk for the drugs that do not make the grade for acceptance onto the market. In addition, industry is currently spending over $22 billion per year on research and development.[7] No question a huge sum; however, how much is spent on direct-to-patient advertising?

If we look at the positive side of the high cost for drugs, we see many new exciting entities being approved and made available to the public. This dual situation is another of the complexities that we find in our health care system today. There is no easy answer to the dilemma. What we do know is that we want and need new agents for the elderly and the uncontrolled diseases that exist. How we accomplish this task is the problem we now face.

Traditionally the pharmacist served patients from the corner drugstore. It was a place where "Doc" would talk to his patients, know their families, and give advice on drug therapy and was available to discuss patient ailments. This has changed; the corner drugstore is a thing of the past in many areas of our country. It has been replaced by large drugstore chains whose pharmacists usually do not have the time to talk to customers. The one-on-one relationship does not exist as in the past.

High-tech innovations are being introduced within which there is no oral communication between physician and pharmacist and pharmacist and patient. One could argue that this is no different from practice in mail-order pharmaceutical services. But there does appear to be a difference, as demonstrated by one of the first online pharmacies, PlanetRx. com, leaving the retail health arena for the very reason noted, lack of interaction between patient and the local pharmacist.[8]

To further complicate pharmacy and other medical practices, the Health Insurance Portability and Accountability Act is being seriously questioned. Among the concerns is the need for prior consent that could prohibit pharmacists from using required medical information before obtaining signed consent from the patient. The outcome of the interpretation of the law could have a major effect on pharmacy practice, as well as other areas of health care. Although one's privacy should be protected, it should not override the need for information that could affect pharmaceutical care, as well as the services of other medical entities. The Department of Health and Human Services (DHHS) has stated that physicians and hospitals will have access to needed medical information to properly treat patients. We must be sure that DHHS includes this availability to all providers who require the information necessary to properly care for patients. The current final rule states that consent must be obtained before providing treatment, receiving payment, or performing health care functions. The pharmacist has been classified as a health care provider and thus is subject to the law. Fortunately, the secretary of DHHS has stated that the department will be clarifying the guidelines to avoid medication problems.[9] The more complex our society becomes and concerned with many of the factors we now take for granted, such as medical information, the more aware we must become to avoid complexity from interfering with patient care.

The introduction of managed care has changed the manner in which health care services are provided. This change has come about by integrating the components of health care and changing the existing relationship among providers, patients, and organizations. In addition, there have been major changes in the relationship of physicians, pharmacists, and other health professionals with the patients they serve. Patients have become more autonomous in their dealings with health professionals and more sensitive to the cost of treatment.

Serving more than 40% of the population, managed care may be the most powerful force in health care apart from the federal government, and the pharmacist's activities within managed care services have changed traditional pharmacy roles.[10] Managed care organizations have recognized the ability of the pharmacist to contribute to the overall treatment of the patient, as well as the need to control the escalating cost of drug therapy. It now appears that there is recognition of the relationship between the increased cost of medication therapy and the decrease in hospitalization of patients; this change has been noted by the managed care groups. With the acceptance of this belief, we can anticipate further changes to meet patients' needs and in so doing increase the responsibility of the pharmacist. This increase in responsibility will occur in both professional practice and fiscal activities. We can also anticipate a closer relationship between physician and pharmacist, and this integration of services will continue increasing the treatment involvement of the profession in providing health care. The concept of the physician diagnosing and the pharmacist prescribing may truly become a reality of the future.

The Institute of Medicine report *To Err Is Human: Building a Safer Health System* brought to the attention of the public what we already knew: Medication errors occur.[11] It is usually a system problem that causes errors; they occur in excessive numbers, and they can be prevented. However, if we do not prevent the current loss of life and harm to patients by medication errors, someone else will. As I am sure you know, the profession has become much more active than in the past to introduce new programs to prevent errors. Although our profession has brought this problem to the public in the past, it is unfortunate we did not receive the credit due. However, the important point is that the spotlight is shining on a problem that can be corrected or at least minimized.

One of the ironies of the current state of health care and drug therapy is the formation of the Leapfrog Group.[12] The group is a coalition of large companies that have targeted medical errors as a means to rid health care of its inefficiencies and thus increase patient safety and decrease cost. There will also be initiatives to combat the rising cost of drug therapy by encouraging the use of generic drugs and countering direct-to-consumer advertising. Although we may not agree with the motivation that gave rise to the group, we can be in agreement with the intent to reduce the inefficiencies we currently find within many areas of health care. The fact is that other groups have different agendas than we have for accomplishing a given task; if the outcome is safer medication utilization, we should cooperate and welcome their assistance in meeting the goal of reducing drug costs and medication errors.

In recent years we have made major advances in the field of medicine and perhaps

even more in the area of drug therapy. These advances have demonstrated the need for change within the practice of pharmacy. Automation has been introduced into hospital practice in recent years, and we now see and can expect more efficient technology becoming available. The need to follow through on the entire drug treatment cycle with or without new technology has been known to be a necessity to deliver the right drug to the right patient without errors occurring. In order to accomplish this task, there is the need for the profession to accept the challenge to be responsible for the entire medication cycle. This requires pharmacists to practice at the patient's bedside.

Among the difficulties we face in accomplishing this task is that other areas of health care have recognized the value of the pharmacist much more quickly than the hospital field, the original target area. Our schools of pharmacy are preparing people who are well trained and capable of practicing in all areas of health care. There are now significant numbers of practitioners who have left hospitals to practice in HMOs, managed care, and the pharmaceutical industry. This has caused a shortage of trained staff to assume responsibilities within the hospital setting, thus preventing further direct patient care activities alongside other practitioners who have come to understand, accept, and encourage such involvement of pharmacists in care.

We must also come to closure on the role of the technician in our practices. This issue is now long-standing and varies significantly from state to state and hospital to hospital. Most important, levels of technician training and knowledge also vary. As we automate our practices, the need for highly trained pharmacists will decrease in the area of medication preparation and allow for an increase in the scope of direct patient care. However, this cannot occur to the level that is required without the necessary practice standards being accepted and approved by the appropriate state governmental bodies. This is another area we must concentrate on to further the pharmacist's involvement in direct patient care.

At the 2000 ASHP Annual Meeting, Linda Kohn of the Institute of Medicine challenged us to do more: "Pharmacists cannot create a safe environment for patients by staying within the pharmacy's walls. The profession must continue to demonstrate how systems can be improved to reduce errors today and if possible to eliminate them tomorrow."

Once again, we have been challenged to increase the role of the pharmacist while in the process of providing care to the members of our society who are in need of health care services. In the past these challenges have come from the profession itself. We are now experiencing the results of our past success of increasing our involvement in the process, and it is up to us to move our profession along the path of providing better health care to our communities.

I realize that I have covered a wide area of practice and concern, but the reality is there are many factors that are affecting our ability to properly serve patients in the complex world of health care. This points out the need for the profession to be involved within all areas of treatment to properly provide pharmaceutical care. Our agenda and our contribution to treatment must be recognized as an important role in the health system within which we practice.

We have a great deal to offer; however, it is my opinion that our major concern must be the fact that we are losing many of our best and brightest practitioners from direct patient care to other areas of the profession. This is a loss we cannot accept and must find the means to prevent from continuing. If we do not take appropriate action, we will not be able to provide the care patients expect. As a profession, we have come a long way, and, although there is still a long road ahead of us, I am sure we will be successful.

I have used the term "complexity" many times in this article, and yet, if we look into the future, we see complexity beyond what we have ever thought possible. The new field of gene-based diagnostics and therapy may allow a patient to be scanned for thousands of diseases. The intent is to determine the relationship of genes to human diseases and hopefully to introduce new guidelines to avoid unwanted medication events and increasing drug effectiveness.

The field of pharmacoeconomics is well established, but we are still exploring methods for its use in direct care on an individual patient basis. In both of these areas of research and clinical utilization, we can expect significant improvement in patient treatment, as well as decreasing patient drug costs, by providing the appropriate agents. We can also expect new fields of therapy to become available that will further increase our ability to treat patients in a more effective and safer manner. Although there may be even more complexities in the future, I am hopeful that there will be better treatments available, at a cost that will be affordable, for all patients in our society.

In conclusion, I want to thank my partner, Florence, who has spent a lifetime with me, reads the morning medical news to me, is my advisor and inspiration. I want to thank Stephanie, Spence, Lilly, and Gary and, my new little kids, Jessie, Carson, Elijah for the happiness they bring us. To my friends and colleagues, to Seymour Katz and Bruce Kay whom I will miss, I owe you all thanks for your support and I share this honor with you. Lastly to ASHP, the organization that has always been my guiding light.

(For the complete list of references cited, please see page 1511 of the *American Journal of Health-System Pharmacy,* Aug. 15, 2001.)

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