THE FDA'S PERSPECTIVE ON THE FUTURE OF PHARMACY

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[The following is the complete text of the address given by Justina A. Molzon at the Drake University Law School and College of Pharmacy Symposium on The Evolving Pharmacy Jurisprudence held on April 9, 1994, in the Pharmacy and Health Services Hall, Des Moines, Iowa.]

Good Afternoon. I bring the warm regards of Dr. David Kessler, who was unable to accept Dean Walker's invitation to speak at this symposium due to prior commitments. He asked that I commend the program committee in putting together an excellent program to examine the contribution that pharmacists can make towards the provision of quality health care and the legal implications of that contribution.

Dr. Kessler's invitation requested that he address the Food and Drug Administration's (FDA) perspective on the expanding role of pharmacists and the contribution they make towards health care reform. I believe that these issues may be considered by focusing on pharmacists' efforts towards increased patient education, monitoring, and adverse event reporting.

We have all read stories about the health care reform debate and the need to find solutions to the medicine-related problems in America today, through such things as cost containment, access to quality care, and prevention of disease. Patient empowerment to make choices about their health care is a pivotal issue. Patients need information to use drugs properly—not only adequate directions for use, but also information on their risks and benefits.

An issue that the Commissioner cares deeply about is patient education and how patient education can make a difference in the nation's health care. In fact in an article in *American Pharmacy* in January of 1992, Dr. Kessler challenged pharmacists to renew their commitment to patient education. In that article, he stated, quoting David Brushwood, the moderator of this morning's session, "pharmacists are the 'gatekeepers at the end of a complex drug distribution system.'"[1] The public holds pharmacists in very high esteem, and it expects

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1. David A. Kessler, *A Challenge for American Pharmacists*, AM. PHARMACY, January 1992, at 36 (quoting David B. Brushwood, *The Pharmacist's Duty to Warn: Toward a Knowledge Based Model of Professional Responsibility*, 40 DRAKE L. REV. 1, 13 (1991).

them to help safeguard and advance public health. A variety of forces, including the OBRA 90 mandate discussed by Ken Baker this morning, are turning patient counseling into the primary role of the pharmacy profession.

As many of you know, at the FDA we have some definite ideas about how to make patient education more effective. I will discuss our approach this afternoon. I will also spend some time discussing the FDA's new Medical Products Reporting Program, MEDWatch. This program is not merely for hospitals and institutions, but is also directed towards community pharmacists.

First is patient education. As Dr. Kessler has pointed out in articles and speeches, the preferred approach for patient education requires all health professionals, including pharmacists, to become more involved, more invested, in the process of patient education. It is clear that patients expect more from their physicians than simply writing prescriptions. It is equally clear that patients expect their pharmacists to do more than fill prescriptions.

When it comes to patient counseling, the question for pharmacists is no longer "Should I counsel?" but "What should I say when I counsel?" If we are to achieve safer and more effective drug use in this country, we must do a better job of communicating with patients. We must bridge the gap that separates patients from their health care providers. There are no short cuts. There are no secrets. The best way to communicate with patients about their medications is to combine personal counseling with written information.

Many professionals and groups have a stake in this process. Pharmacists, nurses, physicians, consumer groups, and the FDA must all increase their efforts. As a physician, Dr. Kessler believes strongly that all health care professionals should become more assertive in providing meaningful information to patients—both oral counseling and written information. And when we speak of written information, we are not thinking about turning pharmacies, or waiting rooms, into reference libraries. We are thinking, rather, about compact personal computers with sophisticated software. We see computers helping to generate not only general information about a drug, but also targeting information to individual patients. In this day and age, with inexpensive personal computers and laser printers, it is inconceivable that a patient should leave the pharmacy without written advice about how to get the maximum benefit out of their medication. Dr. Kessler has made a point of personally getting this message out to pharmacists, nurses, physicians, and other health care providers.

Of course, oral counseling combined with written information is not the only way to provide information. There's another method of communicating with patients: direct-to-consumer advertising. The FDA has not encouraged this communications approach. In our view, there is a world of difference between a pharmacist, nurse, or physician counseling a patient about a drug and a pharmaceutical firm "pitching" a product. One is patient education, and the other is promotion. It would be useful if people with a stake in this issue would shift their attention—shift their focus from what happens before a drug is prescribed and pay more attention to what happens after. Instead of promotional efforts—efforts aimed primarily at increasing the number of prescriptions written—it would be useful for companies to work with pharmacists to help patients derive the greatest benefits from their medications. In fact, we are seeing more innovative ways to inform patients about their drugs. My guess is that such efforts,

including unit-of-use packaging and information leaflets, will grow. I should add that this renewed "push to inform" patients about drug products exceeds the personal initiative of one FDA Commissioner.

As we all know, patient counseling and information is here to stay. It is in everyone's best interest. That is why it is important to place this initiative in the context of broader initiatives of the Public Health Service and other organizations. Some of you may be familiar with the ambitious goals of the "Healthy People 2000" program. These are the government's health goals for the year 2000. One of the most important objectives, in our view, calls on the United States to, and I quote, "increase to at least 75 percent the proportion of primary care providers who routinely review with their patients aged 65 and older all prescribed and over-the-counter medicines taken by their patients each time a new medication is prescribed."[2] This ambitious objective focuses on the elderly, because they take proportionally more medications, and because they experience the most severe problems with "mis-medication."

The FDA has already started some projects to help achieve the Healthy People 2000 goal of better educating the public on the medicines they take. Before I tell you about some of them, let me step back for a moment and reflect on this important matter—and tell you why the agency continues to place such a high priority on patient education.

We care because from a public health perspective, we care about educating patients on the proper use of medicines because it helps them to get better. We care because we have learned that if people don't understand what they are taking and how to take it, they won't get the maximum benefit from their medications. For our part, educating patients on the right way to use their prescriptions is part of promoting public health.

Next, we care because we want to prevent harm. We know that no drug is risk free. Taken improperly, they can make people sicker. And adverse reactions can be fatal. By definition, prescription drugs are products with serious toxicity or abuse potential. The serious consequences of drug misuse demands that information about how to take the drug properly be conveyed to the patient, by a pharmacist, every time a prescription is dispensed. We also think patient education is important because we want to do everything we can to optimize drug therapy and prevent unnecessary health costs—like a trip to the emergency room. Incorrect drug use occurs because essential information is not properly communicated—or is incompletely or incorrectly understood, as Dr. Manasse pointed out this morning.

For a pharmacist to discuss with patients each of the 1.6 billion prescriptions dispensed annually is a huge task. It is a task that takes skill, special knowledge, and a pharmacist's time and commitment. But it is a critical task, because without widespread drug counseling, there is no hope of reducing the serious problem of mis-medication, which affects the thirty to fifty-five percent of American patients who fail to comply with their medical regimes.

We know that one of the prime causes of noncompliance is the wide communication gap that has long existed between the health care provider and the

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2. U.S. DEPT. OF HEALTH AND HUMAN SERVICES, HEALTHY PEOPLE 2000, 590 (1992).

patient. The gap is the difference between what patients need to know about their drugs and what they actually learn about them from their physician and pharmacist. This communication gap is also enormously costly. Noncompliance causes a great deal of unnecessary human suffering. Patients who skip dosages or prematurely stop taking drugs frequently pay with their health.

In economic terms, a recent task force estimated the cost of noncompliance to be 100 billion dollars in health care costs and lost productivity. It contributes to premature death, prolonged illnesses, and preventable hospitalizations. With health care costs exceeding thirteen percent of the gross national product, our society cannot afford increased costs with improper use of medicine.

Finally, there are compelling philosophical and ethical reasons why we care about informing patients. People have a right to know. They have a right to full disclosure—to receive adequate information about drugs they are offered. They must give informed consent, something they cannot do if they lack adequate information. These are the main reasons why we are concerned—but there are other related matters that concern us.

Today's pharmaceuticals are not the routine antibiotics of yesterday. We are now approving much more sophisticated and complicated chemical entities which have complex risk/benefit profiles. There are some products on the market that might not be there, such as Accutane, without patient information accompanying the product. Patients must understand the risk and limitations of the products so they can use the drugs properly. By necessity, patient education will become more critical as we approve more drugs like these. By necessity, patients will need to know more, about the risks—as well as the benefits—of the medication. For all these reasons, we expect to see a greater role for pharmacists in improving communications with patients.

Also, consider this—the U.S.'s drug industry is second to none in the world. Every year drug companies spend millions of dollars to do the appropriate kinds of studies to get drugs marketed. Every year the FDA uses enormous resources to make certain that those studies are adequate to determine that the drug is safe and effective and properly labeled. Then untold hours are spent by drug sales representatives informing the physicians of the value of the new products. There is untold commitment to the development and marketing of the drug. But what about the last link in the chain—the patient? Experience tells us *this* is where the problems are—this is where we frequently fail to do an adequate job of communicating—this is where the compliance problems occur. Shouldn't we—pharmacists and other health care providers, FDA, industry, consumer groups, and private organizations—be doing more?

With that said, let me return to some of the projects we are undertaking at the FDA to improve and strengthen patient medication education. The agency is involved in a number of initiatives to increase consumer education about the proper use of medications. Let me tell you about three of them. First, we are undertaking research on how to better communicate with patients about their prescriptions. We want to know what information they obtained at the pharmacy, at the doctor's office, from their friends and relatives, and if patients understand the information. We also want to know how to target the information so that patients will find it useful. We have issued reports over the past four years and plan additional reports in the future.

Second, we have required patient package inserts for about thirty drugs or classes to date. For some of these drugs, we believed specific patient information was essential for the drug to be marketed and used most effectively—like Proscar and Halcion. Third, we continue to work with the National Council for Patient Information and Education (NCPIE) to help them stimulate and coordinate private sector programs to improve patient information and education. I would also like to mention that adverse reactions and drug product problem reporting by health care professionals is also of great concern to the Agency, and I would like to emphasize the importance of pharmacists' participation in this initiative.

In June of 1993, Dr. Kessler announced the launch of MEDWatch, a program designed to promote and facilitate voluntary reporting of serious adverse events and product problems with drugs, including biologics, medical devices, and other medical products regulated by the FDA. Through MEDWatch, the FDA hopes to mobilize the entire health care community behind a more rapid, effective reporting system. Pharmacists' monitoring and reporting of adverse events will contribute to better patient care. They can help us change the culture of medicine. Most importantly, their work will save lives and avert suffering.

The program's four main goals are: (1) to increase awareness of medication- and device-induced disease; (2) to clarify what type of reports the FDA seeks to receive; (3) to make it easier for health professionals to report to the FDA; and (4) to keep health professionals informed about new safety information as it evolves.

In pursuit of our first goal—increasing awareness—the FDA has conducted, with its MEDWatch partners, presentations and exhibits at more than thirty conferences and meetings throughout the country. All professional pharmacy organizations are MEDWatch partners. What we want is for every health professional in the country to know about MEDWatch by the end of this year.

A recent report by the American Medical Association (AMA) stated that it is the ethical responsibility of all physicians to report serious adverse events. Indeed, this is a responsibility of all health professionals—not just doctors, but pharmacists, nurses, dentists, and others. I hope other professional organizations will follow the AMA's lead. The FDA would also like to see incorporation of the concept of drug and device-induced disease into the curricula used to train new health professionals, such as pharmacists.

No one doubts that we can most effectively shape the culture of medicine by intervening early, while future practitioners' habits are still being formed. We must build awareness of drug and device-induced disease into the education of all health professionals, from the very beginning of their training. We must drive home these concepts—not just in clinical pharmacology courses—but throughout the entire course of training. Only by doing so can we hope to guarantee that if something goes seriously wrong with a patient, every practitioner will instinctively consider the possibility of an adverse reaction and report appropriate suspicions. The FDA, professional associations, and other MEDWatch partners will work with deans of health professional schools to find ways to improve curricula in this important area.

Our second major goal when we launched MEDWatch was to communicate clearly that the FDA wants reports of serious adverse events. The FDA does not want reports on every adverse event and encourages reporters to

be selective in their reporting. By concentrating on reports with serious outcomes, health care professionals can help the FDA focus on events with potentially significant public health impacts. What do we mean by serious? We mean events that involve death, a life-threatening condition, hospitalization, disability, a congenital anomaly, or intervention necessary to prevent permanent damage.

The third goal of the MEDWatch program was to make it easier for health professionals to report to the FDA. With this in mind, we consolidated the different forms that were previously used to report adverse events, and created a single postage-paid form that could be sent via mail, fax, or computer modem. This form has been widely distributed by the FDA, our partners, and other interested organizations. The form may be obtained by dialing 1-800-FDA-1088 or from the *FDA Medical Bulletin* and Physician's Desk Reference (PDR). The astute individual practitioner is the critical link in the postmarketing surveillance of medical products. We must never forget that one astute reporter can indeed make a difference. Only through the keen eyes of the individual practitioner, such as a pharmacist, can the FDA hope to see the big picture. Only with the help of a nationwide network of practitioners can we conduct the epidemiological surveillance of drug and device-induced disease. No adverse reaction reporting system can work unless it is a two-way street. In addition to receiving information from the professional community, the FDA must keep professionals informed about new safety discoveries. This is the fourth goal of MEDWatch.

We view feedback to practitioners as the FDA's most important contribution to the MEDWatch partnership. It enables health professionals to incorporate new safety information into their daily practice. It reminds them of the need to report medication- and device-induced disease. It shows them that their reports have an impact. The FDA is committed to improving our feedback system over the next year. We are now in the process of examining new options for timely feedback mechanisms. Systems that will keep health professionals aware of all safety issues and labeling changes—not just those reported in the news media or "Dear Doctor" letters. Already, we have developed several vehicles to keep practitioners on the cutting edge of safe medicine. These include a quarterly insert in the *FDA Medical Bulletin*, which is distributed widely to the nation's health professionals, and a quarterly *MEDWatch Update*, which tells our partners about reports we've heard and actions we've taken. We are considering additional communication vehicles, and we welcome your suggestions.

Finally, I am pleased to report that on January 27, a proposed new rule to protect reporters' confidentiality was published in the *Federal Register*.[3] We know that concerns about confidentiality have inhibited adverse event reporting, particularly reports of medications errors. Currently, about twenty-five percent of reports to MEDWatch request that identities not be released to the manufacturer. Let me be clear: the FDA has always had the power to protect confidentiality. We have always held patient identity in the strictest confidence. And we have always successfully intervened in court cases of which we are aware to protect the identity of reporters. Our proposed rule would extend the

3. Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3944 (1994) (codified at 21 C.F.R. pt. 20).

power to protect confidentiality to manufacturers who receive adverse event reports. It would pre-empt the establishment or continuation of any state or local rule that requires or permits disclosure of reporters and patients. With this new rule, I hope all health professionals will be more willing to share their identities with manufacturers so that manufacturers will have access to the same data that the FDA does. On this note of well-grounded optimism, I would like to conclude my remarks.

We believe we are making great strides in the area of patient education and adverse event reporting. But we all know that much more needs to be done. We have learned that education requires a long-term commitment, not a quick-fix program. We are learning from others and we are learning from our own initiatives. Please let us know what you are doing and what needs to be done. We look forward to your continued cooperation and support.

Thank you for your time and enjoy the rest of the meeting.