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Speech before the

American Medical Association

Remarks by

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June 12, 2006

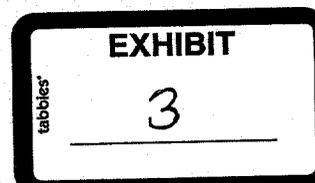
This text contains Dr. Gottlieb's prepared remarks. It should be used with the understanding that some material may have been added or deleted during actual delivery.

Thank you for the invitation to speak here today and to participate in this meeting. I first started attending the AMA's annual meeting here in Chicago when I was a medical student, working as an editor for a student-focused section of JAMA. I have had a profound affection for this organization and especially for its flagship medical journal ever since – and for the special role that all medical journals play in helping to establish medical consensus and promulgating best medical practices. But some of the challenges that the premier medical journals have faced recently when engaging on topics of drug safety and the effective use of new medical products and navigating between the policy and clinical aspects of this issue are of a piece of the broader ones that we all are facing as practicing physicians, when it comes to these same issues. Not just as individual physicians but also as physician led organizations that Americans rely on for clinical leadership and for information to guide their personal decisions.

Clearly there is a renewed focus on issues of drug safety. One of the questions that the public has is whether or not the FDA is doing enough to find out about new safety issues that marketed drugs might have, and whether we are communicating these things quickly enough. Those are fair concerns, and we have been doing a lot at FDA to address them. People are rightly concerned when it takes many years to find out that a marketed drug had a rare but serious side effect. While we are never going to be able to uncover all of the very rare side effects that drugs might have before we approve them, we need to be doing all we can to make sure we uncover them as soon as possible and that we communicate these findings as clearly and as effectively as we can. This takes resources and it takes new ideas and approaches to post-market vigilance, and along with the career staff at FDA, under the leadership of the directors of our medical centers, we have taken a lot of steps recently to meet this challenge.

But there is a second question that I am equally concerned with, and it has to do with how we confront situations where we already know that a drug has a certain side effect at the time of approval, or shortly after. Especially in cases where we know there are some common sense precautions physicians and patients can take to mitigate, or even nearly eliminate the chances of someone suffering these side effects. Yet patients continue to succumb to it anyway, whether it is a cardiac rhythm problem or a liver toxicity problem that is potentiated by a drug-drug interaction or by some pre-diagnosed comorbidity, or something more closely linked to the manner in which a drug is administered.

This challenge cuts directly to issues related to the practice of medicine, and sometimes tugs at where the boundary is between our role at FDA and the role of practicing doctors. I am worried that this boundary



has become increasingly blurry to an outside view, and we at FDA are being increasingly asked by some groups and by political bodies to occasionally step across it, when drug safety issues arise and where our role in influencing how a drug is prescribed can be reasonably assumed to cut down on that risk. I am talking in particular about the increasing number of risk management plans that are becoming part of new drug approvals. These plans attempt to mitigate a certain risk by directly influencing or controlling how a drug is used. Now I think if you look at the places where we have implemented these plans, I think you would agree we have been balanced and careful to respect practice issues. These plans also allow us to often put drugs on the market or keep drugs on the market that otherwise we would not feel comfortable with. But I worry about the future.

My concern is that even though we do not have the legal authority to impose these plans on drug sponsors, they are nonetheless becoming an increasingly prominent condition of certain approvals as we negotiate final labeling over newly approved drugs. It is fair to say, I believe, that these plans are sometimes a less-than-optimal response to more systemic systems problems in the delivery of medical care. But that does not change the final calculus, that there are some real needs that these plans address but also some real challenges we face if these plans continue to become a common feature of drug approvals. In particular, there is a cumulative burden they impose that could encroach on medical practice decisions that doctors make and on patient discretion. This could be especially true when it comes to patients who already have a hard time getting access to specialty care or to the most innovative safe and effective medicines. Patients for example who may receive care in urban settings where busy clinics may not have the time and resources to comply with these plans, or patients who do not have access to specialists who are the favored prescribers under some of these plans, or access to pharmacies able to subsidize all of the requirements. We are especially sensitive to these kinds of concerns when working on the design of these plans.

The good news is I think there are some steps we can take working together to make sure that the laudable medical safety goals that these risk management plans aim to achieve can be accomplished without FDA being directly involved every time. But addressing these healthcare systems problems is going to require a lot more involvement and collaboration of organized medical bodies as well as individual physicians in our work than we have enjoyed in the past.

Now clearly FDA has a big part of the responsibility when it comes to trying to create more opportunities for our agency to collaborate with physicians to achieve our shared public health goals. Part of the fault for any shortcomings in the history of this relationship rests with us, and the fact that we have not always done as much as we can to create opportunities for collaboration with organized medical groups. We are working very hard to change that. In fact, Terry Toigo, FDA's Acting Associate Commissioner for External Relations who is here today, is heading up a team inside FDA that is working to establish an office that will have as its primary goal to enable more regular collaboration and communications around clinical issues with medical organizations like the AMA and the specialty medical groups. But we are also going to need your help, and I would like to spend the balance of my time today talking about these challenges in a little more detail. The steps we are taking at FDA to try and confront them. And then the places where I think we are going to need to work together if we are going to make sure that the boundary between our work and yours remains bright and rigorous, and that it is drawn in a way that maximizes the opportunities for patients to make personal and effective medical decisions. I also want to explain how we believe the new physician label is a significant piece of this effort.

I mentioned at the outset that I believe that the challenges faced by medical journals like JAMA are symbolic of some of these larger issues and of the steps we must take to deal with them. The journals have an essential role to play in promulgating practice standards that help the profession self-regulate itself around best medical practices. Yet the journals have increasingly taken on policy and even political issues. Now social conscience was a prominent feature of the section I worked on when I was a student editor at JAMA, and I know it has always been a defining characteristic of the great medical journals. But more recently the political commentary seems to sometimes be shriller and seems to come at the expense of the journals' essential role in shaping clinical practice, or just at the risk of compromising its impact.

I think all of these challenges cut to a much broader and difficult issue of professional autonomy, and what institutions physicians ought to lean on and what efforts their organizational units ought to take to address the same drug safety concerns that are increasingly being addressed by regulatory agencies like mine, not just the policy questions – and we do appreciate the input at FDA – but also directly influencing the

clinical goals as well. The medical journals should be one such institution. Medical societies serve this role as well. A lot of these drug safety questions are difficult for us to address directly at FDA, because they deal with personal prescribing decisions. The more we promulgate plans that attempt to guide or even control these decisions, the more we encroach on professional autonomy, and the responsibilities doctors have as a profession to address these kinds of practice issues through their own vehicles so that they can continue to personalize care to their patients individual preferences.

The notion that doctors are part of a profession, replete with vehicles for self-regulation and the imposition of appropriate standards of conduct and practice requires that they have institutions in place to develop, promulgate and sometimes enforce those standards. Principle among these is the medical journals, which grew out as organs of the established, independent medical professional societies for the explicit purpose of sharing and popularizing knowledge about best practices. The specific driver for much of my concern, and the growth of arrangements like the risk management plans, has been the real or perceived diminishing of some public confidence in the medical institutions like the journals and the professional groups, as well as the FDA, in the wake of a series of health and medical problems. These problems, I am concerned, have created an opportunity if not a mandate by some to ask the government to significantly change the relationship between the state and medical profession, despite the fact that medical practice decisions and the regulation of medicine was a role always afforded to the states, and despite the fact that Federal agencies like mine lack clear authorities to step in to these medical practice issues. We nonetheless are being pushed and prodded to do just that, and this is not a mandate that we take lightly, or comfortably.

For one thing, this conflicts with the notion that medicine should enjoy a degree of self-governance when it comes to enforcing standards. This notion is a key to a definition of professional autonomy. Perhaps Paul Starr captured this concept most effectively when he referred to medicine as a "sovereign" profession. The contract between professions and society is relatively simple, Starr said. Professions are granted a monopoly over the use of a body of knowledge on the understanding that they will guarantee competence, provide altruistic service, and conduct their affairs with morality and integrity. We would all agree that doctors aspire to do just that and the self regulation, on which professional independence in medicine depend, is something I know no doctor takes for granted. But traditionally the province of state authorities, the regulation of medical professionals is already becoming a national concern. This is, in part, the result of sympathetic critics who increasingly reflect a wider public perception that doctors seem reluctant to assure their own competence and protect patients from poor practice. These critics argue that the medical establishment is failing to make self regulation demonstrably effective and responsive. Now I do not agree with these observations but we cannot deny that these beliefs exist. To address these challenges, we need to work together. If you agree with the premise that government is increasingly influencing ordinary clinical decisions previously left to doctors and patients, and I hear regularly from doctors who do, then I believe FDA has been both a part of the problem and can be part of the solution.

The ability for medical organizations to self regulate their clinical standards is only as robust as the information they have on which to base those standards, and the partnerships they have to help embrace and promulgate them. It is on these latter two opportunities, where I believe FDA can play an important, collaborative role, and I believe some of the steps we have already taken can provide valuable tools to help us meet these challenges. This is especially true when it comes to risk communication and the way that we inform the public and physicians of what we are learning about new medical products. Whether it is improving our dialogue and our collaboration with physician groups, more carefully crafting the messages we deliver to consumers, or improving the predictability and consistency of our labeling and our other reporting vehicles, we are working hard to improve and expand the tools and practices through which we communicate bottom-line medical information.

It is clear to all of us, that the social sciences of disseminating risk information, and of measuring how consumers respond to and use this information, are sciences that are being rapidly developed and expanded. If you look inside many corporations today, you will find people expert in risk communications whose primary job it is to craft information tools that can be more effectively used by consumers. This was not always the case. Such experts did not always exist.

At FDA, the task of measuring consumer perception and peoples' reaction to information, and using this scientific information to more finely tune the way we speak, is also becoming a more important part of our work. This is true not only in how we communicate safety information about drugs, but in many parts of our work. It is true, for example, in how we measure consumer response to drug advertising to ensure that

there is fair balance. It is true in how we craft a public health advisory warning of a problem with a medical device. It is true in how we measure how people respond to the health information included on food labels – so that we can provide appropriate guidance that makes sure we take opportunities to promote information that motivates people to adopt healthy diets.

As the amount and complexity of information that we provide continues to mount -- a result not only of our desire to speak more openly but also the increasingly complexity of medicine and science itself -- we know that we also need to continue to improve how we approach the social sciences of risk communication and the social sciences of measuring consumer perceptions to information. To these ends, we have recently taken a number of steps to improve our approach to risk communication and other social sciences. I want to take a moment to mention just a few of them.

We recently had a two-day workshop on risk communication, to gather information and research on how we can incorporate some of these new tools and approaches into our work. We appointed a new Associate Director for Safety Policy and Communication in our drug center and we are currently developing a comprehensive plan to modernize our approach to the social sciences across FDA. I hope this latter effort will eventually be similar in scope to the successful approach we took under our critical path initiative to modernize the scientific tools of drug development. Another big part of this effort is the new physician label format which was discussed by Bob Temple. The changes, which were made -- with a lot of input from medical organizations such as the AMA as well as individual clinicians -- are aimed at improving patient safety by making it easier for healthcare professionals to locate, read, and use prescribing information, thereby increasing the extent to which healthcare professionals rely on it.

FDA made these changes because, in recent years, there has been an increase in the length, detail, and complexity of the prescribing information, making it more difficult to find the right information at the right time. In the new format, which will be phased in gradually, some prescribing information will be located in newly created or different sections or subsections. Also, some individual sections in the old format have been combined in the new format and some new information that was not mandatory under the old requirements is now required. Under the new rules, for example, there will be introductory information called "Highlights of Prescribing Information." This new section will be added to the beginning of the prescribing information. The Highlights will provide a concise summary of information most important to prescribers and will refer them to the appropriate section or sections in the Full Prescribing Information where additional, more detailed information is located. They will typically be half a page in length and will include, among other things, a list of all substantive changes made to the following sections of the FPI within the past year, the Boxed Warning if one exists, as well as the Indication and Usage, Dosage and Administration, Contraindications, and Warnings and Precautions. The corresponding new or revised text in the FPI will also be identified by a vertical line in the left margin. This will help clinicians quickly identify new information that has been added to the prescribing information. The date of FDA approval of the original drug will also be prominently listed to allow for easy identification of new products.

Additionally, much of the information contained in the body of the FPI will be reorganized and reordered to make it easier to find and use. Frequently used sections, such as the Indications and Usage, and Dosage and Administration sections, have been moved to the front of the prescribing information. By creating a Patient Counseling Information section, information that healthcare professionals can use when counseling patients has been made more prominent. If the drug also has FDA-approved patient information, it will be reprinted in or accompany the prescribing information. Sections containing risk information are also now all located together. For example, risk information that had been listed separately in either the Warnings section or in the Precautions section is combined into a new Warnings and Precautions section. In addition, new sections have been created that address specific safety issues, for example Drug Interactions and Use in Specific Populations. Certain graphical features including minimum font type size and standardized bolding are now also required, so that the prescribing information is easier to read.

The new label format is not just an end in itself but an important piece of a broader initiative to make reliable prescribing information more easily available through electronic formats. For example, for the first time, all of the information in the physician label will now have unique electronic identifiers associated with it so it can be more easily archived, searched and retrieved. In addition, starting last November, healthcare professionals, patients, and other consumers have been able to access high-quality, up-to-date information on medications via the Internet free of charge through the Daily Med system, which receives, distributes and displays medication information that has been developed by Federal agencies.

This is a monumental change in the way medical information is made available that would not be possible without the leadership and hard work of the professional staff at FDA's Drug Center and especially my colleagues Dr. Janet Woodcock and Dr. Steven Galson. We also recently required drug makers to start submitting label changes electronically in a standard format that, after verification by the FDA, will make updating labels with new information seamless, and automatic. Imagine a world where the most relevant information in the product labels, for example new updates or the most common side effects or the prescribing information, can be easily pulled off the web or better yet, pushed to you on your PDA. You can be instantly updated each time new safety warnings are added or new information about a common drug's benefits. Doctors could receive special alerts only for the drugs they are most likely to prescribe.

Now I do not believe our challenges stops with just providing good information. I also believe we need to leverage our relationships with medical groups like yours to collaborate on the development of new tools and programs that help this information get integrated into practice efforts, whether its jointly sponsored CME focused on drug safety issues or opportunities to opine in your journals or present at your regular medical gatherings. These voluntary collaborations make a lot of sense, and in some cases they may be a lot more effective than schemes that simply try to limit certain prescribing behavior and create a lot of red tape and paperwork. They also help preserve the most important medical decision of all, the one that a patient makes in consultation with her doctor.

We need to make sure we remain guided by a framework where all of our roles are clearly defined, the boundaries of our work respected, and the public health aims we pursue done in close collaboration. FDA will continue to work aggressively and rigorously to develop the best information possible about a drug and its side effects, and promulgate reliable and up-to-date labeling advice on how to prescribe new products in a way that maximizes their benefits and minimizes their risks. Doctors will continue to be relied upon to make evidence-based decisions guided by their continuing knowledge of evolving information and most importantly the personal preferences of their well-informed patients.

Our being here today I hope is another step on the way to working more closely with you. The work that Terry and her team are doing in constituting a true health professionals office inside FDA, that can provide a coordinating role to this activity, is another step. The work we have done recently to design drug safety update pages to be included in the medical journals is one more. And there are other ideas we are working through, many in partnership with medical groups.

So I hope this marks a beginning in a closer relationship that has one bottom line in mind: How can we work together to make sure that doctors and patients have the opportunity to maximize the value of new medical products, in a way that preserves the ability for people to make individualized choices free from restrictive burdens but also in a way that encourages best practices. We look forward to pursuing these goals, and to working with many of you on them.

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