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SCHROEDER LECTURE

FDA: PROTECTING AND ADVANCING AMERICA'S HEALTH

Mark B. McClellan[†]

I want to thank all of you for having me here today. It is a real pleasure to meet with you and get a sense of the tradition of the Law and Medicine Center here at Case Western Reserve. There have been a lot of contributions made by this program over the last fifty years, but I am here to tell you that we need innovative ideas in law and medicine, and we need them more than ever in health policy. The intersections of law and medicine today are more extensive than ever before, and I want to spend my time and more formal remarks today talking about some of the important challenges that we face and calling for a new approach to handling a number of issues, particularly related to tort law in health policy in this country. I want to start by spending a few minutes reminding you of what has happened to our health care system over the past century.

Medicine has been around a very long time, but modern medicine is a story that began in the twentieth century and really in the last fifty or sixty years. Remember that penicillin was not even invented until 1942, and in the 1940s, some of the leading causes of death were very different from the ones that we are facing today. Life expectancy was substantially shorter, many years less. Since that time, we have moved to a society where people can and should expect to live long, healthy lives well into their seventies, eighties, even beyond. A lot of that progress is the result of innovations in health care.

For over the last fifty years, during the time that the health law center has been in existence here, medical practices have changed fundamentally. There are drugs and medical treatments in use today that are based on a much better understanding of the causes of diseases, and the potential for the future is even greater. Looking forward, there are new sciences based on genomics and proteomics that really have not yet made their way into medical practice. Genetic

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testing is important today, but we are seeing products in early stages of development where genetic tests are paired very particularly with new drugs or a combination device. There is probably more research and development going on, and more investigational treatments in development than ever before, based on these combination of products. And it is important to keep in mind we didn't finish sequencing the human gene until April of this year.

These new sciences, also including nano-technologies, are helping us find new ways of delivering drugs where they are most effective in the body without causing toxicities. One example is combination products, like bioengineered tissues, where the future—and I think the not too distant future—may allow implants of cells that can monitor glucose levels correctly and provide naturally occurring versions of insulin for patients, instead of having insulin injections and blood sticks to check sugar for people with diabetes. These treatments are not that far away.

If you take a step back and ask people who are looking closely at health policy development and medical technology development how they assess the future, they will tell you that for all of the improvements we have seen the last fifty years, the next fifty promise to be even better. More people, especially our seniors, can expect to live a lot longer and better as a result of these continuing kinds of medical innovations.

But we are at a crossroads today. With all this progress, there are also a lot of new concerns, more concerns than ever about increasing medical spending and access to quality care. These were not issues fifty years ago when there were not nearly as many medical treatments available that held the potential for great benefit to the public, but also had significant cost. More than ever, rising costs threaten to price the benefits of modern technology out of the range of many of the patients who most need them. There are other threats to access to high quality care as well. There is no question in my mind that the course we are on now is only going to increase the pressures our health care system is facing. So that's why we need to work together and come up with some creative solutions to get to a better health care system. For the sake of the public health, we need to find better ways to achieve a health system that addresses the growing problems we face—greater costs and less access to care—without sacrificing the potential of medical care today and, especially, the great potential of medical innovation for the future to help us lead better lives, both in the United States and around the world.

Earlier today I had the pleasure of spending time with experts over at the Medical Center, talking about new steps that we are taking at the Food and Drug Administration (“FDA”) to help make health

care more affordable, while still encouraging valuable innovation. A lot of these ideas address the problem of reducing the cost and uncertainty of developing new medical products, which is extremely expensive today and has been getting steadily more so. These are steps that we think can and will improve access to safe and effective treatments, both in the United States and around the world.

We are all in this together, and we all suffer from the same basic kinds of health problems. Addressing these global health challenges is something we are currently undertaking with partners and other regulatory agencies and governments around the world. But with changes in the new technologies that we are trying to help along, we also need improvements in our health insurance programs. Because of the public attention that is focused now more than ever before on the issue of health care affordability, I think we are closer to having action. It took to the point where Americans are extremely angry about the cost of their medicines, particularly prescription drugs, for the attention to really focus on the fact that Americans without health insurance, people who often have some of the most limited ability to pay for these valuable new medical treatments, are paying the highest prices in the world for them.

This is not a sustainable situation. It is a situation that has attracted the attention of policymakers in Washington more than ever before. It is an unfair situation, especially since many of the best drugs available around the world today, and an increasing number of the ones being developed for the future, were discovered and developed right here in the United States.

There is Medicare legislation being considered right now by Congress that will help improve access to drugs. It will help make medications more affordable by giving people insurance assistance and paying for some of their medications. It will also bring prices down by helping seniors, who are often on their own for purchasing drugs at the highest prices, band together to negotiate much lower prices, like large employers, the federal government, and many other governments around the world do for the people that they insure.

These steps are going to help, but they are not enough. I think there is more that we need to do to help bring down medical costs in general and drug costs in particular, and I want to talk about some of the things that might help. To start off with, there has been a lot of attention to the high prices of drugs in the U.S. relative to other countries, and to the fact that development costs in the U.S. are higher. That's primarily true, but that's not all there is to it.

One reason for high prices, some people say, is drug advertising in this country. It is true that as a result of our Constitution and the First Amendment, we have much more advertising—direct to con-

sumer advertising in particular—for medical products in the U.S. that largely does not happen around the world. The U.S. is fairly unique in this regard. And people have thought, aren't the billions of dollars spent on drug advertising an important contributor to the cost of drugs and driving up health care expenses? Now, there has been a large amount of research on this issue, and we reviewed all this at a conference that FDA held last month. I would encourage you to go to our web site, www.fda.gov, to review the findings. There are a number of very interesting academic and policy papers presented on the topic of direct to consumer advertising and, while academics never completely agree on anything, it was fairly clear from the results presented at that conference that the consensus is that DTC advertising generally benefits the public health. For one, it gets more people into treatment for conditions that are undertreated in our population.

If you just think how public views of conditions ranging from depression to cancer have changed: These conditions, which used to be rarely talked about, are now openly discussed, even if (and because) you may be bombarded with advertising. Erectile dysfunction is another condition that people did not talk about before direct to consumer advertising for treatments emerged. There are many more examples of conditions that were undertreated in the U.S. that are more appropriately treated today as a result of advertising.

Advertising clearly needs to adhere to appropriate standards so that doctors and patients get an accurate picture of the key risks and benefits of a treatment. While there is a First Amendment right of free speech that makes it possible for such advertising to occur, I think we at the FDA have clear authority, clear statutory and regulatory authority, to make sure that consumers do not get a misleading picture of the risks and benefits of the treatments being advertised. We are taking additional steps at FDA, and this was one of the reasons for having that conference last month -- to make sure that the information people are getting from direct to consumer advertising is not misleading. This includes developing some new regulatory guidance on how product developers and promoters can comply with our regulations to communicate key risk and benefit information about their products.

These ads are highly visible and, although I think there is room for improvement, it is important to put them in perspective. They account for less than two percent of pharmaceutical spending in this country, and they simply are not big enough to be a key driver of drug costs in the United States. In fact, if you take all marketing costs together, the largest component of marketing costs -- about \$10 billion dollars worth -- are free samples of drugs, which many of you have gotten when you went to your doctor to get treatment for a new condition. These samples help patients find out if a drug works for them

without having to pay for it initially. And it seems like a reasonably good way to help patients learn about whether a drug is right for them cheaply.

People have also argued that drug costs are higher in the United States because there is more spending on so-called “me-too” drugs, drugs that are very similar to products already on the market. I know there is a lot of anger because the drug companies are perceived by some as popularizing drugs that are only slightly different and may offer only marginal benefits over other alternatives. Some of these criticisms are unfair since many of these drugs do provide important benefits to certain patients, such as having fewer side effects, creating a drug you only need to take once a day rather than two to three times a day; or, more importantly, promoting competition by having several drugs in a particular class. When there are several choices available, it has been clearly and empirically demonstrated that prices come down more, as they did, for example, with cholesterol-lowering drugs. But, again, the fact is that “me, too” drugs are not a large part of research and development spending. Throughout the 1990s, for example, only about twenty percent of all the pharmaceutical research and development went into products that were incremental modifications or modifications of existing drugs.

Now, finally, there are a lot of people around the world who believe that U.S. drug prices are, in part, higher because our liability system is more costly, and that is what I want to spend a little bit more time on today. These people argue that our liability system encourages lawsuits based on bad outcomes rather than on negligent care and that product developers often incur large payouts in these kinds of suits, many of which may not have clear scientific merit. And it is true I think, and there is good evidence on this, that our liability system does significantly add to costs compared to other nations. That is not the only reason prices are higher here. We here in the U.S. are also supporting the bulk of drug development costs worldwide. That is a broader issue that needs to be addressed. But I want to talk about tort liability and its relationship to the cost of health care in this country because today, more than ever, we need to be looking for ways to improve value in health care, to get better outcomes for patients while spending less money, and that means avoiding any sources of significant costs to our health care system that are not contributing to improving and promoting the health of the public.

I would like to talk more about liability reforms since I hope that many of you who are interested in law and medicine will take up some of the important challenges relating to finding a better way to provide the protection and incentives to prevent poor quality care and negligent care without unnecessarily adding to the cost and access

problems in our health care system. We are going to need your help. From the perspective of the FDA, we are very concerned that our liability system is having some adverse effects on medical care, and is impeding affordable and timely access to innovative medical products. This is especially true in important areas like women's health and pediatric care, where concerns about physician liability, particularly in states that haven't enacted physician liability reforms, have been associated with difficulties in access to obstetrical and pediatric care. As the *New York Times* reported in a front page story just a few months ago, health care experts believe that the unpredictable risk of extreme liability cost is affecting decisions about developing and marketing new drug treatments. These liability risks particularly affect areas like pregnancy care and vaccines where we badly need innovation.

The current liability system is creating problems in access to physicians, and it is increasingly threatening the development of badly needed cures for physicians to use. The legal system is affecting the practice of medicine and the development of medicines in ways that are harmful to patients.

There was another *New York Times* article just today that reviewed how our current legal compensation method—in this case for a large class action settlement—is not doing a very efficient or timely job of compensating patients who are injured as a result of a drug, and this is even after the parties have spent years in court and have reached a settlement. So, there is clearly room for improvement. As we look for ways to make our system of health care more efficient, to get more bang for the buck for what we are spending in health care, we really need to focus on this issue. We need to consider ways to reduce the cost, the delays, and the uncertainty of our liability system.

Now, don't get me wrong. I come from a family of lawyers. I think that tort law and the lawyers who practice it can play an extremely important role in safeguarding the public health. These lawyers need to be there to help patients get redress when they receive negligent care. The problem is that our current liability system is not very well set up to help them do this. There have been comprehensive studies by the Harvard malpractice group and others that have shown that only a small fraction of the cases that result in settlement payments or jury verdicts actually involve low quality care by physicians. Rather, the hallmark of big awards is bad outcomes, not bad care, and only a fraction of the patients who are injured negligently actually end up getting compensation. And when they do, a lot of that money goes to lawyers and to the very high administrative costs of this very inefficient system.

So we need to change the system so it really will help to deter bad care, not just pile on when there are bad outcomes. In a report issued last year, echoed in a followup analysis this year, the Department of Health and Human Services suggested ways that lawyers can help address this problem when it comes to patient care and innovative approaches. These include reasonable limitations on non-economic damages with no limitations on economic losses, such as a mother's ability to provide care at home for her children. It includes so-called early offer programs to try to avoid the extremely high cost and years of delay of compensating injured patients through the judicial system. It includes the idea of science-based health accuracy to assure that credible scientific evidence forms the basis for decisions about negligent care, to help diminish the impact of improperly evaluated science, and to help assure that patients who are truly injured negligently get compensation fairly and in a timely way.

Similarly, tort law can potentially be a very important force for improving the development and use of safe and effective medicines, which is one of our top health priorities at FDA. In cases where manufacturers have a clear adverse effect on the quality of health care, where they provide fraudulent information to us or where they deliberately withhold important information about safety problems associated with their products, they should be held accountable, and a tort system is a great way to do that. The dedicated members of our legal profession have always provided and continue to provide protection from those who prey on consumers intentionally and who intentionally try to pass off harmful products. The threat of litigation can be an extremely important disincentive to many predatory behaviors that could take advantage of vulnerable patients, and we need that in a system like ours, where medicine is getting more complicated and there are opportunities for people to take advantage of patients.

But once again, the problem is that our current liability system does not reward the lawyers that focus their efforts on the real public health threats that we are not already addressing through other regulatory means. Instead, the most experienced and aggressive and well-financed plaintiffs' law firms know the biggest payouts can go to those who exploit the FDA's decisions in support of our mission to promote the safe and effective use of medications.

More and more often, mass tort firms are specializing in taking a new product warning or withdrawal decision that we make and using it to pile litigation on the company. The lawyers are doing what we want patients and doctors to do. They are reading the warnings that we put on products, and they are taking action when we add a warning or withdraw a product from the market based on our analysis of new information. Using the information that they get from us, these law-

yers file a few suits for very sick patients in states and counties that are considered quite favorable to plaintiffs, while they build up big inventories of less seriously ill patients or even people who used the drug but are not even sick. One woman who talked to a reporter in Jackson, Mississippi summed it up this way: When she read that the drug Propulsid might cause harm, she stopped taking it, and she signed up for a lawsuit. "Actually, I didn't get hurt by the drug," she told the newspaper, but because she had taken the drug, she said she thought she would join the class action suit "and I might get a couple thousand dollars."

Well, today can we really afford a couple extra thousand dollars every time a patient uses a drug, even if it does not harm them? Yet, there is a whole industry that is developing around this approach. A trial lawyers group known as "Mass Torts Made Perfect," which specializes in securities, drug, and environmental litigation, has the slogan "the knowledge to conquer," referring to their litigation strategies. Their web site, www.masstortsmadep perfect.com, has a sampling of some of their seminar titles, including "Accutane: New Material, Systemic Injury" and "Phenylpropanolamine: Freight Train of Poison," and they have plenty of good advice, too. One of the well-known plaintiff attorneys with this group helpfully suggested at one of their earlier meetings that trial attorneys could reward the people who flush out the most clients by sending them steaks or turkeys at Christmas. Instead of pursuing wrongdoing, this group is using our legal system to pile litigation on to companies based on the FDA's legitimate warnings about the risks of medical products.

This is a problem because every single medical product that we approve carries risks as well as benefits. High quality medical care, in fact, is all about managing risks, including the balancing of risk of treatments with the often more serious risks of illness. Medical care almost never involves eliminating risks, and the point of our warnings and the other science-based information on a medical product label is to help manage the risks effectively. Medical product labels exist to help doctors and patients get the up-to-date scientific information they need about risks and benefits so they can maximize benefits and avoid risks. We should do all we can to learn more about products that are on the market, even, as with menopausal hormone therapies, products that have been on the market for decades. We need to actively encourage the development of new information, which is critical to assessing risks. We need to encourage all steps that generate information and use it effectively. It may lead to new indications for use, new warnings for physicians or patients, or, if new information is unfavorable enough, it may lead to product withdrawals.

When the FDA takes an action to add a black box warning or to remove a drug from the market, that should not be an automatic alert to the trial lawyers to pile litigation on. We learn more all the time about drugs and we want companies to help us in that effort, not to be afraid to work to develop better information on potential safety concerns for fear that that information will trigger lawsuits. What we need is lawyers directing their efforts to deter the negligent behavior that companies sometimes engage in, such as deliberately misleading us by withholding known information on adverse events. But instead of pursuing legitimate targets of bad behavior, lawyers are often pursuing targets of opportunity. Today, developers of new medical products that are designed to treat serious illnesses increasingly need to set aside billions of dollars or redirect their research activities from potentially valuable directions in anticipation of the potentially unlimited risk of mass tort lawsuits. The growing practice of pulling together these lawsuits based on actions by the FDA is altering the development of medical products in ways that reduce health care quality and access.

More and more we are hearing from patient groups who have concerns about the development or availability of needed treatments and also worry that litigation has become an impediment to high quality care. These groups believe, as I do, that companies should be held accountable and that patients who are injured negligently should be compensated in a timely way. But all of them worry that our current system is failing, especially at a time of rising health care costs, because of the increasing cost and difficulty of developing new treatments and the declining productivity in research programs. We need a better system, one that encourages innovations in health care along with good behavior by product developers.

In addition to reducing access to medical care, the litigation system contributes to some other, potentially even more serious, barriers to high quality care. For example, one proven approach to reducing errors and complications is patient safety and quality improvement programs implemented by doctors and health care organizations working together to collect and share information on quality problems and medical errors. With better information systems, health professionals may be able to determine ways to avoid these complications in the first place. They need to talk about the problems, they need to measure, they need to write down the information, and they need to take action accordingly. It can work.

As the Institute of Medicine and many other non-partisan medical institutions have pointed out, this kind of honest information sharing within and among health care organizations is essential for implementing quality systems in health care by creating an environment

that helps doctors get it right in an increasingly complex and hurried system. This process can generate substantial improvements in our health care system and avoid the thousands of deaths and billions of dollars in added health care costs resulting from medical errors and preventable adverse events.

Unfortunately, these efforts are blocked by fears of litigation. If health professionals write down information about errors and near misses and how they can be avoided, these good faith efforts to improve quality and safety become targets for lawsuits. This creates an environment in which risk management means minimizing the risk of lawsuits by avoiding the honesty and candor that are vital to reduce patient risk in a complex industry like health care.

I think we need to create an environment in which everyone is rewarded for being concerned first and foremost about risk management for patients, not risk management for lawsuits. That is why I am very pleased that the House of Representatives has passed legislation by a wide bipartisan margin that will improve health care quality by providing appropriate confidentiality protections for patient safety activities that generate new information to help people avoid errors. This will help health care organizations identify and act on ways to improve safety and quality. It will also help the FDA get more timely information on important risks involving the products we regulate. It is a big step forward in the quality of care. And I hope the Senate will act on this soon. It still is not settled. In fact, I was disappointed to learn recently that certain consumer groups with a large lawyer presence like Consumer's Union actually opposed this bipartisan legislation because they are worried that some of the information generated might not be usable in lawsuits. If we do not have these protections, the information is not going to be there in the first place. This legislation is not taking away any rights or any basis for bringing lawsuits against physicians. It is intended to prevent the kinds of medical errors and problems that would generate the legitimate lawsuits in the first place and make us all better off.

Here again, this is a case where I think there is a better way forward to encourage quality and safety to protect patients through steps to improve our litigation system. Once again, at the FDA, we see some similar problems involving the medical products we regulate. We work diligently to keep product labels up to date, complete, accurate and understandable. Medical researchers and companies are important contributors in this effort. We have taken a number of steps recently to bring clarity to the risk information we provide in product labels, and we are going to take a lot more in the near future. Our regulations increasingly make it clear that contradictions in warnings should only be included on product labels when they are scientifically

appropriate. We have also issued guidances making clear that similar judiciousness, similar emphasis on plain language and communicating effectively with accurate science-based decisions, should guide decisions with respect to the inclusion of adverse event information in labeling. We do not want a laundry list; we want science-based, understandable labels that can more effectively support high quality patient care. As I have said, the objective of these efforts is to make the package inserts, the labeling information that the FDA provides, more useful to doctors and patients by reducing the unnecessary, unsubstantiated, or otherwise misleading information about the risks of a drug.

The fact that we have to devote additional efforts to this problem is an indication that there are growing obstacles to science-based effective labeling.

Not enough doctors read the drug labels from the package inserts that we provide. We know this information is not being presented now in its most useful format, and that is why we are working right now, as I said, on an improved format. Many have suggested that what we need to do is have a nice summary section upfront that captures key product information, including the most important benefits and risks and have navigable links so this information can be used in electronic data management systems to get to more detailed information that is relevant to particular kinds of patients, particular indications, or particular issues related to a given drug if a doctor wants to learn more or if a patient wants to learn more. We have developed, therefore, a proposed rule that is intended to do just that, but we received in comments a lot of criticism noting that if we only include certain information that we deem important in the summary section, the companies may be sued for withholding appropriate information on risks. This is impacting how we are trying to make medical information on product labels more understandable and useful to improve patient care.

We need to do more here today. Regulations on labeling formats alone are not enough to make labels as useful as possible. What's needed is a culture of patient safety when it comes to medical products and an environment that focuses on reducing risks and improving benefits for patients in product development and product use. As long as the product developers and researchers and others that we work with to develop the product labels are facing an environment in which any adverse outcome can result in major lawsuits, we end up producing labels that are probably more useful for lawyers than they are for doctors and patients.

Here again, creative legal entrepreneurship has become an impediment to sound medical judgment. Sometimes a plaintiff will file a product liability lawsuit that complains that the FDA made a mistake

in judging when particular risk information should be added to a product's label. We try to make sure that any and all appropriate information, any and all science-based information, is included on the product label. That is our mission. That is why the FDA has the statutory authority to monitor product labels and to update them along with the science and why we have developed a comprehensive scientific review process and an on-going evaluation process. But the legal environment in which we are operating makes that increasingly challenging. When the FDA considers and rejects some labeling language regarding the risk of a particular adverse event, we base that decision on a rigorous science-based, often peer-reviewed, system that carefully evaluates the evidence and the proposed warning. Yet, state courts today are sometimes allowing lawsuits against manufacturers who, at FDA's instruction, did not add certain warning language to a product label, where we told them specifically not to add it. These manufacturers are still getting sued. And so, because risk management often means reducing liability risk, not reducing patient risk, there is pressure to make labels read more like liability avoidance tools than efficient documents for conveying up-to-date, science-based risk and benefit information so that doctors can help patients.

To protect and improve the health of the public, we need product labels written with the patient in mind, not a jury. By getting information to patients and doctors, it is possible to achieve systematic improvements in medical outcomes through creating this environment that encourages and promotes getting accurate information out to doctors and patients and other health professionals that need it.

To accomplish this goal, we have participated in some product liability lawsuits in which the plaintiffs ask courts to find that a product developer's statements on the product label were inadequate, even though they met the comprehensive and specific standards of FDA's science-based system of drug regulation. We have done this before, but we have had to intervene more often in recent years. In one case, the plaintiff sought to require a suicide warning in the labeling of an antidepressant when FDA had specifically considered and rejected this warning three times because it was scientifically unsupportable and because in our scientific judgment—the judgment of our independent experts—the drawing of unwarranted attention to an unproven but serious risk could lead to undertreatment of depression.

I intend to continue to make sure that at the FDA we are using all available evidence to guide our decisions on product labels. We are doing more than ever to improve our product information, but I worry that the increasing involvement of different juries in different states with standards different from ours could impact the consistency and scientific accuracy of our labels. When the liability system threatened

the development of life-saving medical products in the past, we found some creative solutions.

One such creative solution was the response to the childhood vaccines crisis in the 1980s. Under the weight of some very costly litigation involving rare but serious adverse events that had occurred in children who had taken childhood vaccines, which is basically all children in this country, prices for vaccines had increased tenfold, and the number of manufacturers had dropped from twenty to only four, and only two manufacturers remained in the United States. So Congress took most childhood vaccine litigation out of the tort system, and the solution—the Vaccine Compensation Fund -- was set up to provide timely compensation to patients that are injured without finding fault with these known side effects associated with some of the vaccine. This Vaccine Compensation Fund has worked very well for a while.

And today vaccines are safer than ever, despite or because of these fundamental liability reforms. The gaps in this program are now leading to new litigation that again threatens the stability of the vaccine market. The stakes for resolving these challenges to availability and affordability of new medical products could not be higher. As I mentioned before, we are at a point where the new technology developed over the last two decades is starting to yield some breakthrough treatments. In recent months, for example, we have approved some new, more targeted, molecular-based treatments for cancer. These breakthroughs may be the leading edge of what could well be the “biomedical century” in the coming years, as we have more effective cures earlier on and more effective treatments to manage the progression of many chronic illnesses.

We need to encourage more treatments like this. We need to encourage this kind of medical progress, but for new technologies like this to be used as effectively as possible, we need product labels and an environment for developing information both before products are approved and after they are on the market that promotes as much accurate and complete information as possible. We need regulatory methods that encourage accurate and understandable communication about information to everyone in the health care system. We cannot afford higher costs or reduced access to these treatments as a result of lawsuits that do not protect patient health and do not promote or advance the health of the public. Patients should have access to high quality care without avoidable medical errors and complications, and there are many steps that we can and should take to achieve these goals. Our liability system for both physicians and medical products can be a very positive force to help us meet these critical medical challenges, but we are not there now.

Today our liability system is threatening quality care. In order to continue to improve the health of the public through affordable access and to help professionals through the development of better clinical practices and better medical technology, we need to have a tort system that is as reasonable and as modern and as up-to-date as our technologies. At the FDA, my main job is to help protect and advance the health of Americans, and I see the current situation as a real threat to those goals. I believe we can do much better. I believe that our tort system can be, once again, an important part in protecting the public health by providing an important and up-to-date deterrent to bad medical care. So I hope you all will think about this and join us and help the FDA and other government agencies fulfill our mission of protecting and promoting the public health. In these areas of law and health, as in many other areas of law and health and medicine, there are more opportunities than ever to make real differences in the health of Americans. Thank you.