



**TESTIMONY OF
GREG SIMON, PRESIDENT
*FASTERCURES / The Center for Accelerating Medical Solutions***

**“BUILDING A 21ST CENTURY FDA:
PROPOSALS TO IMPROVE DRUG SAFETY AND INNOVATION”**

**BEFORE THE
SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS
THURSDAY, NOVEMBER 16, 2006**

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I. Introduction

I want to thank the Committee for the opportunity to present testimony today. My name is Greg Simon, and I am the President of *FasterCures/The Center for Accelerating Medical Solutions*, based in Washington, DC¹.

FasterCures is dedicated to saving lives by saving time in the discovery and development of new therapies for the treatment of deadly and debilitating diseases both in the United States and around the globe. The organization was founded in 2003 under the auspices of the Milken Institute to catalyze systemic change in cure research and to make the complex machinery that drives breakthroughs in medicine work for all of us faster and more efficiently. During our relatively brief history, *FasterCures* has worked with a broad range of individuals and organizations to eliminate barriers to efficiency and effectiveness in our systems of disease prevention, treatment, research and development.

FasterCures is independent and non-partisan. We do not accept funding from companies that develop pharmaceuticals, biotechnology drugs, or therapeutic medical devices. Our primary mission is to improve the lives of patients by improving the research environment, research resources, and research organizations.

I am honored to appear before this Committee, which has a long history of spearheading efforts to protect and promote the health of the public by improving our nation’s process of drug discovery and evaluation. I want to commend Chairman Enzi, Senator Kennedy, and other members on this Committee who have introduced and supported bipartisan legislation to strengthen the FDA’s oversight of drug safety. I commend you for focusing

¹ Before joining *FasterCures*, I served as the Chief Domestic Policy Advisor to Vice President Al Gore from 1993 to 1997, specifically on economic, science and technology issues. In that role, I oversaw a number of initiatives, including the programs of the National Institutes of Health, the National Cancer Institute, the Food and Drug Administration (FDA), the Human Genome Project, and the development of the regulatory framework for biotechnology products. From 1991-1993, I served as Legislative Director for then-Senator Al Gore. From 1985 to 1991, I was Staff Director of the Investigations and Oversight Subcommittee of the House of Representatives Committee on Science, Space and Technology.

this hearing on the broader issue of how to ensure that the FDA is truly prepared to meet the challenges and reap the benefits of 21st Century medicine.

Earlier this year, *FasterCures* provided detailed comments to Chairman Enzi and Senator Kennedy regarding the specific provisions of the “Enhancing Drug Safety and Innovation Act of 2006.” I will touch on some of the major points covered in those comments that we believe deserve continued focus. However, I primarily want to discuss today the broader principles that *FasterCures* believes should guide any effort to strengthen the FDA so that the agency can continue to play a vital role in advancing 21st Century cures.

These principles are as follows:

1. The FDA needs to be able to assess a drug’s impact post-approval, weigh both benefits and risks and take appropriate action to protect the public;
2. To do that the FDA needs much stronger authority to regulate and enforce how an approved drug enters the market, how it is advertised, what claims are made for it and how labels are updated to reflect growing knowledge of a product;
3. To do those things the FDA needs increased appropriations from Congress and should not be forced to rely on industry user fees which the FDA is largely restricted from using on post-approval activities;
4. To do any of this, the FDA needs a confirmed Commissioner to provide strong, effective and professional leadership with a long-term focus and vision; and
5. And for all of this to work, the FDA needs a better understanding of how to communicate its scientific findings to the public to make them better informed participants in our health care system.

II. The FDA at the Dawn of the 21st Century

In the past 10 years, we have witnessed dramatic advances in science that impact the practice of medicine, including the mapping of the human genome, and advances in computational tools and broadband communications. Electronic health records and personalized medicine will likely change the practice of medicine and clinical research in the coming decade, and offer substantial benefits to monitoring adverse events.

Yet, while the personalized medicine era is leaping forward into the 21st Century, the FDA remains tethered to 20th Century technology, regulations and practices as if the Information Age had never happened. Worst of all, it remains mired there because we the people and our elected government have deprived the FDA of the financial and human resources it needs to do the job we have asked it to do in the 90 laws Congress has passed since 1907 setting the FDA’s goals and responsibilities.

There is simply no defending the fact that the FDA budget for providing 300 million Americans a safe food supply and safe and effective medical treatments is the same in real dollars as it was in 1996. The Superintendent of Schools for Montgomery County, Maryland has a budget equal to that of the FDA. This speaks well of Montgomery

County's commitment to education but calls in question our national commitment to food and drug safety and the approval of new cures for diseases.

Each year, the FDA receives minimal new dollars and yet its costs increase, missions evolve, the scope of science expands, and inflation erodes the budget. In addition, innovative, future focused programs of the FDA such as the Critical Path Initiative that would bring the agency into the 21st century have not been given full financial support, and the impact of new technologies such as nanotechnology cannot be measured and evaluated. The budget is holding the FDA back and preventing the agency from maximizing the benefits of these historical advances in science for the American public. The staff of the FDA are dedicated public servants who are ready to tackle these problems.

The FDA plays a central role in American medicine. It has an incredibly challenging role to protect and promote the public's health. The agency must ensure that products are safe, but also effective. It must help speed lifesaving drugs to patients, yet ensure that those same patients have the safest drugs possible. We expect the FDA to be committed to protecting our health and well-being. But we have not been committed to giving the agency the tools and resources it needs to meet our expectations.

So how do the Institute of Medicine (IOM) report *The Future of Drug Safety* and the Enzi-Kennedy bill address this gap between where we would like the agency to be and where it is?

The recommendations contained in the IOM report would go a long way toward helping the FDA meet the goal of speeding to patients innovative cures that are both safe and effective. Last month, shortly after the IOM report was released, *FasterCures* and the National Health Council hosted a forum for patients and medical research advocates to consider and debate the report's findings and recommendations. Sheila Burke, who chaired the IOM committee, as well as IOM Study Director Kathleen Stratton, participated in the meeting. The conference was our attempt to help focus involved members of the patient and research communities on the implications of the proposed policy changes. We believe the meeting was an important first step in ensuring that the perspectives of patients and researchers have a prominent place in any future debate on drug safety. A brief summary report on that meeting will be submitted for the hearing record later this week.

We urge the Congress to put the work of the IOM Committee front and center in its deliberations. As Ms. Burke stated at our meeting on the report, "We've revolutionized how we care and manage people with illness, but the FDA has not been able to keep up with that complexity. Delaying approval until certainty is reached is not always a good option. Patients depend on these drugs and yet there is an all or nothing environment."

We appreciated the opportunity to provide comments on your proposed legislation prior to introduction, and we look forward to continuing to draw on our experience to be a

resource to the members of this Committee as you consider any policy that will strengthen the FDA. Some specific comments are as follows:

- On the Risk Evaluation and Mitigation Strategies (REMS) process, we are concerned that this process has the potential to slow down product reviews if not constructed correctly and with precision. We believe scarce FDA resources should be concentrated on *activities* that actually mitigate safety risks for designated products rather than be focused on reviewing risk mitigation *plans* for all products and label changes.
- We welcome the draft bill's focus on using www.clinicaltrials.gov to support mandatory reporting of clinical trial data in a manner that is useful to both medical professionals and patients.
- The Reagan-Udall Institute for Applied Sciences concept for advancing the Critical Path Institute is an exciting development. We are pleased that the bill recognizes the importance of federal funding and the importance of having representatives of the National Institutes of Health in this partnership.
- Finally, we believe strengthening the FDA Advisory Committee process is a very important goal, however we do not believe the bill goes far enough. Extricating all potentially perceived conflicts of interest will in fact “dumb down” these committees through overly broad definitions of conflict of interest. Conflicts can never be eliminated from panels of experts, but they can be disclosed and balanced.

III. *FasterCures*' Prescription for Change

I want to elaborate on our key principles that *FasterCures* believes are essential to strengthening the FDA and ensuring that our federal drug approval and oversight processes are fully prepared to harness the promise of 21st century medical progress.

1. **The FDA needs to be able to assess a drug's impact post-approval and take appropriate action to protect the public.** The IOM report cited the need for a “lifecycle” approach to drug oversight. FDA's regulatory authority should not end with a drug's approval, because that is just the beginning of what we can learn about a medical treatment in the marketplace. Rather, we believe that FDA should have a greater role working with industry, doctors, and others to communicate what is learned about products once they have been introduced into real medical practice. As a drug moves from controlled trials in several hundreds or thousands of people to a potential market of millions, both its benefits and risks may be magnified. This will require more resources for the FDA. If the post-approval authority is exercised properly, we believe it will help speed the approval process because the agency, policymakers, and the public would have greater confidence that safety issues that are not apparent during the pre-approval phase—or that *cannot be detected* in pre-approval clinical trials -- would be detected and addressed quickly post-approval. This knowledge should be captured and analyzed in a way that doctors can better communicate treatment

benefits and risks to their patients so more informed decisions on options can be made.

2. **To do proper post-market surveillance, the FDA needs much stronger authority to regulate and enforce how an approved drug enters the market, how it is advertised, what claims are made for it and how labels are updated to reflect growing knowledge of a product.** As the IOM report recognizes, safety and efficacy are the yin and yang of every drug and are best weighed together. We need a flexible system of approval and post-approval that helps consumers, physicians, and patients more appropriately weigh and respond to those risks and benefits. We specifically commend to the Committee the important role highlighted by the IOM for nonprofit research organizations and the patient advocacy community in helping to bridge the gap between FDA and the public when discussing the benefits and risks of new medicines.
3. **To do any of this, the FDA needs a confirmed Commissioner to provide strong, effective and professional leadership with a long-term focus and vision.** *FasterCures* supports the confirmation of Dr. Andrew von Eschenbach to be the Commissioner of the FDA and urges he be confirmed as soon as possible.
4. **And for all of this to work, the FDA needs a better understanding of how to communicate its work to the public to make them better informed participants in our health care system.** Patients and consumers need timely information to help them make informed decisions. Toward this end, the FDA should take more aggressive steps to ensure that labeling information and supplemental safety and efficacy information are more patient-centered. Moreover, *FasterCures* supports proposals found in legislation before this Committee and embraced by the IOM to give the FDA more authority to require sponsors to register data at a centralized independent website, www.clinicaltrials.gov. We believe that posting appropriate information at a single, credible, widely available source will go a long way toward providing consumers, patients, providers, scientists and researchers with data they need to help analyze safety and efficacy information and make more informed decisions.
5. **To do all these things the FDA needs increased appropriations from Congress and should not be forced to rely on industry user fees which the FDA is largely restricted from using on post-approval activities.** The FDA needs greater resources to carry out its mission. Many of the improvements recommended by the IOM and included in several legislative proposals will simply not be possible without additional resources. The IOM recommended that Congress approve a substantial increase in both FDA funding and personnel. *FasterCures* strongly believes that any additional funding should come from appropriated funds, rather than user fees. Because *FasterCures* believes this is critical, we are actively participating in two coalitions that are aggressively advocating for additional funding for the agency: The FDA Alliance and the Coalition for a Stronger FDA.

IV. Conclusion

There is no agency or aspect of our government that touches more lives everyday than the FDA. Its mission is the highest and best example of the government's core mission – to protect the health and safety of the American people. Historically, the FDA has done its work so well that it represents the gold standard all other countries rely upon and seek to emulate. There can be no resting on our laurels. Either we provide the FDA the tools and resources it needs to thrive in the 21st Century or it will begin to atrophy and our nations' health will begin to atrophy with it. Many of the proposals contained in both the IOM report and the Enzi-Kennedy legislation will help position the FDA to meet the medical challenges of the 21st Century. But those proposals will not succeed if we are not committed as a nation to valuing the health of our people far greater than is now the case and to acting accordingly.

Thank you for the opportunity to testify. *FasterCures* looks forward to continuing to be a resource to the members of the HELP Committee and to Congress as you address these important issues.