

**Opening Statement of  
U.S. Senator Michael B. Enzi (R-WY)  
Chairman**

**Senate Committee on Health, Education, Labor, and Pensions**

**Building a 21st Century FDA: Proposals to Improve Drug Safety  
and Innovation**

**November 16, 2006**

Good morning and welcome to today's hearing on ideas and proposals for reforming our nation's regulatory framework for reviewing and approving prescription drugs. For decades, the United States has been the standard bearer in bringing new drugs and medications to the world market. However, over the past few years there have been significant events that have caused the public to lose confidence in our drug safety system.

At the beginning of the 109<sup>th</sup> Congress last year, Senator Kennedy and I pledged to work together to evaluate the Food and Drug Administration and its policies and procedures for bringing new drugs to the marketplace and for ensuring the continued safety of drugs already on the market. In fact, two of the very first HELP Committee hearings of this Congress were focused exclusively on drug safety. Overall, we have held ten hearings on issues involving the FDA.

Senator Kennedy and I pledged to work across party lines to develop a comprehensive response to drug safety issues raised. We incorporated the witness recommendations and comments from a series of stakeholder meetings into our development of the Enhancing Drug Safety and Innovation Act, S.3807.

In addition to the extensive and thorough oversight that we have done on this matter through hearings and meetings with stakeholders, we also took the extra step of posting the draft of the Enzi/Kennedy drug safety bill on the HELP Committee website so that the public could comment before the bill was introduced.

We received dozens of sets of comments from consumer groups, from patient advocates, from industry and from other members of the public in response to the draft. We have incorporated as many of these comments as possible into the introduced bill.

Just like the bipartisan efforts that led to the enactment of our cornerstone drug safety laws, the Prescription Drug User Fee Act and the Food and Drug Administration Modernization Act, now is the time for our bipartisan legislation to

bring more consistency, transparency, and accountability to the drug approval process.

The Enzi/Kennedy legislation, the Enhancing Drug Safety and Innovation Act, would create a more structured framework for resolving safety concerns. It also would leverage advances in science and technology to build a more effective and efficient FDA. It is the right proposal at the right time.

This is further evidenced by the fact that many of the recommendations made by the recent Institute of Medicine report on drug safety were already part of the Enzi/Kennedy bill well before the release of the report.

Throughout our oversight process, we heard repeatedly that all drugs have risks, and the risks and benefits must be weighed together, not separately. We also learned that the FDA has considerable existing statutory authority however the application of that authority can often be too blunt an instrument for the situations currently faced by the agency. Witness after witness recommended that the agency be granted a variety of intermediate authorities so that the agency can more finely calibrate its actions to match the problems and challenges presented to it.

Examples cited by witnesses of potential intermediate authorities include granting FDA special authority for label changes, post marketing studies or delays in direct-to-consumer advertising. However, rather than enact a series of solutions to accommodate each and every potential situation, we must look at a way to accommodate ANY needed change in the drug approval process and postmarket monitoring.

Under our legislation, the FDA would begin to approve drugs and biologics, and new uses for these products, with Risk Evaluation and Mitigation Strategies otherwise known as REMS [*pronounced "rems"*]. The REMS are designed to be an integrated, flexible mechanism to acquire and adapt to new safety information about a drug. The drug company sponsor and the FDA would assess and review an approved REMS at least annually for the first three years, as well as during review of applications for a new use for the drug, when the sponsor suggests changes, or when the FDA requests a review based on new safety information.

Another significant problem faced by the FDA is that the development of tools to evaluate medical products has not kept pace with discoveries in basic science. New tools are needed to better predict safety and effectiveness of the drugs, which in turn would increase the speed and efficiency of applied biomedical research.

Our bill would spur innovation by establishing a new public-private partnership at the FDA to advance what is known as the Critical Path Initiative. This is the FDA's effort to improve the sciences of developing, manufacturing, and

evaluating the safety and effectiveness of drugs, devices, biologics and diagnostics. Senator Kennedy and I support this initiative, but we can accelerate it and ensure its continued vitality by creating a permanent locus at the FDA, which we are calling the Reagan-Udall Institute for Applied Biomedical Research.

Our bill also establishes a central clearinghouse for information about clinical trials and their results to help patients, providers and researchers access these materials so they can make more informed health care decisions.

Finally, the Enhancing Drug Safety and Innovation Act would make great improvements to the FDA's screening process of advisory committee members. Currently, the FDA relies on 30 advisory committees to provide independent expert advice, lend credibility to the product review process, and inform consumers of trends in product development. Our bill would clarify and streamline the overall FDA process for evaluating candidates for service on an advisory committee. This includes addressing the key challenge of identifying a sufficient number of people with the necessary expertise while possessing a minimum of potential conflicts of interest. In addition, the bill would require FDA to undertake additional steps to identify potential financial conflicts that may arise.

When we began our hearings early last year, the FDA asked the Institute of Medicine to conduct a study covering the agency and the U.S. drug safety system. That report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public," was released in late September of this year. As I mentioned earlier, I have been struck by how closely the Institute of Medicine's exhaustive report recommendations parallel provisions in S. 3807. I look forward to hearing more today from Ms. Sheila Burke, Chair of the Institute of Medicine Committee on the Assessment of the U.S. Drug Safety System about those recommendations as well as the other findings and recommendations in the report. I am also very interested to hear the reaction of our second panel to the recommendations raised in the IOM report and pending legislative proposals. I am confident we can continue with the open process we have initiated to address the few areas of difference.

I want to thank the dozens of stakeholders, including the Food and Drug Administration, patient and consumer groups, industry associations, individual companies, and scientific experts who have taken the time and effort to give us their comments and input on the bill. Their assistance has been invaluable.

I also look forward to working with my colleagues to advance this important piece of legislation.

In the upcoming year, we face an exceptionally full agenda with respect to the FDA. Besides updating the FDA's authorities as we have proposed in S. 3807,

we must reauthorize both the drug and device user fee programs, as well as the Best Pharmaceuticals for Children and Pediatric Research Equity Acts. We should not delay tackling the responsibilities we have ahead of us.

I would like to state that in addition to moving drug safety legislation Congress also should move to confirm the nomination of Dr. Andrew von Eschenbach to be Commissioner of Food and Drugs.

Dr. von Eschenbach has a strong record. He is an accomplished scientist, a proven manager, and a man with vision. He is also a cancer survivor, and he has brought that perspective -- and the compassion that goes with it -- to his government service.

He is giving up a job that he loves -- a challenging but rewarding post directing the National Cancer Institute -- to offer his service in what I believe is a much more challenging and often thankless job of leading the FDA.

Dr. von Eschenbach has received significant support from the HELP Committee. I urge my colleagues who are not on our Committee to give Dr. von Eschenbach a chance to effectively run the FDA with full statutory authority.

The FDA needs a leader with the backing and the mandate that Senate confirmation provides. This Congress must take up Dr. von Eschenbach's nomination before we adjourn.

Before I invite Senator Kennedy to make his opening statement, I want to congratulate him and wish him well as he prepares to take the gavel of this Committee in the next Congress. I seem to recall he has served as Chairman of this Committee before, so I imagine he hasn't forgotten how to wield the gavel. But if he wants a refresher course on technique, I would be happy to make the time.

I'm proud that this Committee has worked together to achieve a lot over the last two years. We approved 37 bills. 25 of these bills passed the Senate, and 15 bills were signed into law. Most of these bills passed with overwhelming bipartisan support. And we still have more to do -- we're not done yet!

This Committee has worked together to strengthen our pension system -- update our mine safety laws -- create a national network of cord blood stem-cell banks -- improve our career and technical education programs -- help the chronically ill navigate our healthcare system and afford health insurance -- and allow doctors and nurses to work together in a protected legal environment toward reducing medical errors and improving patient safety.

Clearly, this has been anything but a "do-nothing Committee." We have a record of which we can all be proud. And even in the areas where we disagreed -- such

as over Small Business Health Plans – we handled our disagreements in this Committee with respect for each other’s views and with ample opportunity for the minority to offer and debate amendments.

We have a lot on our plate in the next Congress. Just for starters, we must reauthorize No Child Left Behind, Head Start, WIA, Higher Education, several pieces of food and drug legislation, and provide a reasonable solution for health insurance. If we work together in the same spirit as we did this year, I’m confident we can get all of this done, and more.

So when this Congress comes to a close and the next one begins, I plan to remind my friend Senator Kennedy of the outstanding work we’ve done together in this Congress, and the challenge he faces in matching the record of the 109th Congress here in the HELP Committee. And I’ll stand ready to work with him on the important issues that come before us, as he has worked with me over the past two years.

I now recognize Senator Kennedy for his opening statement.