United States Senate
Committee on Finance

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Floor Statement of U.S. Senator Sen. Chuck Grassley of Iowa
Ranking Member of the Committee on Finance
S.1082 – the Food and Drug Administration Revitalization Act of 2007
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Mr. President, today I want to speak about a topic that I have spoken about many times before: drug safety. However today is a little different. Earlier today the Committee on Health, Education, Labor, and Pensions began marking up S. 1082, the Food and Drug Administration Revitalization Act. For the first time in almost a decade we have an opportunity to reform, improve and re-establish the FDA as an institution committed to making patient safety as important as bringing drugs to the market.

S.1082 presents a framework for the future of drug and device safety. I am gratified by some of its current contents and disappointed by others.

First, I am gratified that S.1082 attempts to address some of the overarching issues plaguing the FDA that have been repeatedly revealed by the investigations that I have conducted of the FDA over the past three years. In particular, S.1082 takes a number of steps to address the issues of transparency, accountability and respect for the scientific process that have been lacking for some time at the FDA. S.1082, for example, requires that within 30 days of approval, the "action package" for the approval of a new drug must be posted on the FDA's website. This requirement, however, only applies to a drug with an active ingredient that has not been previously approved by the FDA. The action package would contain all documents generated by the FDA related to the review of a drug application, including a summary review of all conclusions and, among other things, any disagreements and how they were resolved. If a supervisor disagreed with the review, then the supervisor's opposing review would be available to the public. And, to address the many allegations that FDA safety reviewers are sometimes coerced into changing their findings, I greatly welcome the provision that states that a scientific review of an application is considered the work of the reviewer and must not be changed by FDA managers or the reviewer once it's final. The bill also takes steps to bring more resources to the FDA for drug safety, another matter that I have been discussing for years now. In addition, S.1082 requires FDA's Drug Safety and Risk Management Advisory Committee to meet at least two times a year to address safety questions and make recommendations regarding postmarket studies.

I'm also heartened to see that S.1082 incorporated several elements from the

Dodd/Grassley bill entitled the Fair Access to Clinical Trials Act of 2007. S.1082 ensures that the clinical trial registry includes trials of devices approved by the FDA. And, S.1082 requires a drug sponsor to certify, at the time of submission of a drug, biologics or device application to the FDA, that the sponsor has met all of the clinical trial registry requirements. Last but not least, S.1082 attempts to give the FDA some teeth by requiring specific civil monetary penalties for submissions of false certifications and false or misleading clinical trial information. These are in my mind some of the good things that are proposed in S.1082, and I thank both Chairman Kennedy and Ranking Member Enzi in this regard. I hope additions such as these that strengthen S.1082 will make it through the HELP Committee's vote as the Committee considers further changes.

As I said earlier, I am both gratified and disappointed by the contents of S.1082. Let me now turn to some of what is lacking in the bill that in my mind fails to address some of the issues that are critical to re-establishing the FDA's mission and putting John Q. Public, and not big Pharma at the helm of the FDA. I commend the HELP Committee's attempt to ensure that the office responsible for postmarket drug safety is involved in, among other things, decisions made regarding labeling and postmarket studies by making specific references to that office throughout S. 1082. However, the bill does not address the outstanding, critical problem that the office responsible for postmarket drug safety lacks the independence and authority to promptly identify serious safety risks and take necessary actions to protect the public.

As I think we all agree, the FDA is in desperate need of a major overhaul. Over the past three years my investigations have demonstrated the depth and breath of the problems plaguing the FDA on both the drug and device side. Senator Dodd and I have written two bills that we believe will greatly enhance drug and device safety and improve transparency at the FDA and most importantly prevent another Vioxx debacle. The Food and Drug Administration Safety Act of 2007 and the Fair Access to Clinical Trials Act of 2007 are intended to address some of the problems plaguing the FDA at its very core.

Let me be clear; Big Pharma does not like these bills, FDA management does not like these bills, lobbyists are spending hours upon hours lobbying against these bills, and the Food and Drug Administration Revitalization Act does not embrace all the critical elements of these bills. Let me ask each and every member in the Senate the following. What's wrong with establishing a separate center within the FDA whose only job is being a watch dog for those drugs already on the market? What's wrong with supporting a group of committed FDA scientists who only watch for serious adverse events that may pop up only occasionally, perhaps only 1 in 10,000 or 20,000? What's wrong with ensuring that all clinical trial results regardless of their outcome are available to the scientific community, health care practitioners and the public? What's wrong with supporting a clinical trial registry and results database that also require sponsors to reveal their negative trials? And, what's wrong with giving the FDA strong enforcement tools to combat bad players? I say there's nothing wrong with any of these proposals, particularly the proposal that a new, separate and independent center be created to address post-market surveillance, a proposal supported by Senator Dodd and me, not once but twice.

I have heard the naysayers and their many bogus arguments about why a new and

separate postmarket drug safety center will not work. The arguments range from the absurd to the ridiculous and I would like to address a few for you today. One argument is that the creation of a separate center will slow down the drug approval process and delay much needed drugs from those who need them. This argument is a non-starter. Why? Because this new center will be devoted to keeping an eye on drugs once they are already on the market. Another argument is that a new postmarket drug safety center will create an unmanageable bureaucracy at the FDA. Yet another bogus argument. Why would taking an already existing office at the FDA, moving it on an organizational chart and providing it with new authorities to watch for unknown and unexpected adverse events be bad? It just doesn't make sense.

These arguments at first blush made an impression on Dr. Steven Nissen, Chair of the Department of Cardiovascular Medicine at the Cleveland Clinic and Immediate Past President of the American College of Cardiology, who was not an original supporter of establishing a separate center within the FDA to address post-marketing surveillance. But over time his views have changed. As Dr. Nissen probed more, evaluated the facts more and talked to more to on-the-ground FDA staff members, Dr Nissen changed his mind and told America that publicly. Dr. Nissen recently sent me a letter stating that not only does he support the Fair Access to Clinical Trials Act but also the Food and Drug Administration Safety Act. Dr. Nissen said, "In particular, I support the creation of a new and independent center within the FDA called the Center for Post-Market Evaluation and Research for Drugs and Biologics (CPER). Although I had previously expressed some concern about creating this center, I have become convinced that the separation of post-market surveillance from the Office of New Drugs represents the best opportunity to improve the performance of the FDA in handling drug safety issues."

Coupled with Dr. Nissen's letter of support, I also recently received a letter from Dr. Curt Furberg, Professor of Public Health Science at Wake Forest School of Medicine. Dr. Furberg is not only a professor of medicine but he is also a member of the FDA Drug Safety and Risk Management Advisory Committee. Dr. Furberg knows the FDA from the inside. In fact, even Dr. Furberg has written me to say that he is supportive of creating a new center and he is particularly supportive of creating new enforcement tools to be used against bad players in the drug industry. I ask that these two letters be placed into the record with my statement.

If these two thought leaders can come forward and support a new center that is devoted to watching drugs once they are on the market so that American consumers and their doctors know about a problem promptly, then what is wrong with that?

We have seen time and time again that FDA is not as good at this function as it should be. However, the reality is that FDA needs to perform this function well because lives depend on it. I want to see a bill passed that prevents another Vioxx debacle.

In closing, this Congress has an opportunity to make meaningful and positive changes at the FDA. Let's not allow that opportunity to slip through our fingers. Thank you, Mr. President.