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Prepared Remarks of U.S. Senator Chuck Grassley of Iowa
Government Accountability Office Briefing on the Food and Drug Administration
"Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process" — GAO-06-402
Monday, April 24, 2006
1:45 pm, Dirksen 215

Thank you for coming. Today I'm joined by Dr. Marcia Crosse of the Government Accountability Office. She's here to answer questions about the GAO's new report on the way the Food and Drug Administration regulates drugs that are on the market.

This report identifies the kinds of problems I've been tracking and investigating for the last two years. The GAO says those problems are real and serious.

American consumers increasingly depend on the FDA for the safety of drugs, medical devices, and even cosmetics.

Despite recent developments, the FDA remains an agency in denial when it comes to the problems addressed in this new report. In fact, many concerns about the agency's post-market review of drugs are not new. GAO says they date back over 30 years. This Washington Post editorial cartoon from 1975 says it better than I can. The problems are long-standing, though what we've seen most recently make the situation ever more egregious and unconscionable.

The new GAO report also echoes the testimony and findings of the Vioxx hearing held in November 2004 by the Finance Committee. At that hearing, the FDA's witness, Dr. Sandra Kweder, responded to the concerns of an FDA whistleblower about the "broken" FDA post marketing safety system by saying, "that's not the FDA I know." Well, it's been 18 months since that hearing, and it's ever more clear that the relationship between the Office of New Drugs and the Office of Drug Safety is broken. So to put it in the terms that Dr. Kweder did, "that is the FDA I know." It's an FDA that took two years to negotiate a Vioxx label. It's an FDA that approved a device even when a team of FDA scientists could not determine if the device even worked. Today, "that's the FDA we all know."

This new Government Accountability Office report provides the evidence. The GAO describes an Office of Drug Safety that is under-funded, lacking independence, and lacking decision-making responsibility. This is unacceptable.

The GAO says that the FDA can't even decide questions such as if drug-safety scientists at the FDA should prepare recommendations for future action when they have concerns about a

drug on the market, or if drug-safety scientists can attend advisory committee meetings. Instead, officials from the Office of New Drugs – which is responsible for approving or disapproving drug applications in the first place – has responsibility for any regulatory action related to the safety of drugs already on the market. The conflict of interest is clear. The new GAO report also says that the FDA's decision-making process doesn't spell out what kinds of drug-safety actions can be taken and when they should be taken.

The FDA needs to make big changes. That's why it's discouraging to see the FDA – which has been the gold standard not just in the United States but around the world – hunker down. We see the agency spend a lot of time on PR and little time on real reform. We get press releases listing accomplishments rather than a meaningful revamping of the way things work inside the FDA. My staff investigators continue to hear from FDA employees who believe in their agency and want to do the right things, but experience intimidation, suppression and reassignments when they raise concerns about the integrity of the FDA's work.

The leadership of the Food and Drug Administration faces tough challenges. The first step is to acknowledge the problems and make a commitment to reform now rather than later. The Acting FDA Commissioner told me recently that he believes in "discipline, rigor and precision." These qualities must be put to work to make sure science and transparency are the top priority at the FDA.

To help make this happen, I'd like to see the Senate act on two pieces of legislation that I've sponsored with Sen. Dodd. We want to establish a mandatory clinical trials registry, and we want to establish and empower FDA scientists to conduct an independent post-market review of drugs. Our legislation has languished in committee. It's time to pay attention to it. It's time to do something .

In addition, the Department of Health and Human Services is sitting on a treasury trove of information about drug safety. Scientists at the FDA and the National Institutes of Health have limited access to drug-safety data from Medicare and Medicaid beneficiaries. This valuable information is not routinely shared at the federal level even though it is shared more frequently at the state level. I'm directing my staff to work with these agencies to see how to make this data available to scientists in a secure way. It's a valuable resource.

Now I'll take a couple of questions, then Dr. Crosse of the GAO will answer questions about her report.

Statement by Sen. Chuck Grassley of Iowa
Friday, April 21, 2006

"The Government Accountability Office report provides solid evidence that everything is not alright at the FDA and calls for long-overdue reform. The FDA's problems are systemic and cultural, not isolated or easily fixed. The public deserves to know the risks when taking a prescription drug, and the FDA's review of drugs already on the market needs to be rigorous, independent, transparent and forthcoming. The bill I introduced with Sen. Dodd would help make that happen by giving the FDA post-market review process real teeth. Consumers shouldn't have to second-guess the safety of what's in their medicine cabinets. The FDA bears

tremendous responsibility as consumers grow increasingly dependent on prescription medicines to cure diseases and maintain a better quality of life."