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Press Release

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DELAURO ON REGULATORY SCIENCE AT THE FDA, AVANDIA

Agriculture Appropriations Subcommittee Hearing

(As Prepared for Delivery)

The hearing is called to order. First, I want to welcome today's speakers. On our first panel, we have the Ranking Member of the Senate Finance Committee, Senator Charles Grassley of Iowa. And on Panel Two, Dr. Harlan Krumholz, Harold H. Hines, Jr., Professor of Medicine at Yale University School of Medicine; and Dr. Sidney Wolfe, director of the Health Research Group at Public Citizen.

Thanks to all three of you for being here today, and for your hard work on the issue of drug safety. And Senator, thank you in particular for taking the time to join us on this side of the Hill, and for your leadership in producing the staff Committee report we discuss today.

This report poses many questions which, as the subcommittee with jurisdiction over the FDA, it behooves us to address. While we did not invite representatives from Glaxo and FDA to discuss this matter today on account of their own pending negotiations, we do have two independent experts here, along with the Senator, of course, to help us sort through this information today.

Regarding this troubling report, let me say first. By bringing life-saving drugs to the marketplace, pharmaceutical companies are applying our country's greatest resource – its innovative spirit – to help more people live longer, healthier, more productive lives. Most people at some point experience the direct reach and power of these drugs to cure illness, heal wounds, or halt disease. I am here today as someone who has felt that power, when more than 20 years ago, I was diagnosed with and survived ovarian cancer.

And so when the FDA is weighing whether or not a particular drug is safe enough to be on the market, I understand that there are often many competing issues in play. Sometimes, people suffering from a given illness, after consultation with their doctors, will willingly accept some extremely severe side effects for a chance at relief or recovery.

Case in point: chemotherapy, where we factor in some truly terrible consequences only because the disease of cancer is still more life-threatening than the cure.

So, as both the preeminent guardian of the public health and an agency whose mandate emphasizes innovation, part of the FDA's responsibility is to carefully weigh these sorts of pros and cons, before coming to a conclusion about the safety of a given drug.

But to be able to make these important – indeed, life-or-death – decisions on behalf of the public health, the FDA's scientists and regulators need to have all the pertinent information about a given drug at their disposal. They need the regulatory tools and the regulatory science capacity to draw their own independent and unbiased assessments of a drug's safety. And, if a drug is in fact deemed unsafe by the agency, the agency needs the structural and the political capacity to ensure its recommendation is subsequently put into action, followed, and enforced.

Which brings us to the case before us today, concerning the diabetes drug Avandia. As you all know, the Senate Finance Committee's staff investigative report revealed that for many years the manufacturer knew much more about the risks of the drug than it revealed to the FDA.

This report poses several troubling questions for this subcommittee. Most obviously, if Avandia is unsafe, how did it ever get on the market in the first place? For that matter, why is it still on the market, right now? And what does the case of Avandia tell us about the FDA's current ability to conduct its drug safety responsibilities?

Looking at the details of the Avandia story, the major study suggesting this drug was safe was the RECORD trial, sponsored by its makers, GlaxoSmithKline. As we now know, and as the Senate Committee's staff report reaffirms, serious questions have been raised about this clinical trial's scientific merit. And last month the Mayo Clinic released an analysis which found 90 percent of the scientists who published articles supporting Avandia had financial ties to Glaxo! This is astonishing.

Also astonishing to me is the fact that, in June of 2007, two scientists at the FDA's drug safety office, after going over all the evidence, recommended that Avandia be removed from the market. But nothing came of this decision, and in fact Avandia is on the market right now, pending the findings of the TIDE study, which is expected to be published in 2015.

2015! We should not take so long to study a drug about which such serious safety issues have been raised. As the Senate report and others have noted, lives are at stake. And one has to wonder, what is the purpose of a drug safety office if its recommendations are ignored at the agency?

Consider how long this process has already taken. When this drug was approved in 1999, the FDA requested that Glaxo conduct a post-market study, ADOPT, which

finally came out in 2006. In the intervening years, Glaxo continued to praise their new drug, even as scientists on their staff began to recognize and flag serious problems with Avandia. And now we are talking about waiting until 2015 before a reevaluation. Simply put, this process should not take 16 years, and particularly not when the drug-maker in question has such a record of promoting a drug even in the face of dire warnings.

We are here today to ascertain what the Avandia case tells us about drug safety at FDA. But in many ways, this is not a new story. We saw very similar problems with Merck, who used ghostwriters to promote their own studies of their pain medicine, Vioxx. Or consider Trasylol, the heart surgery drug linked to kidney failure that the FDA failed to remove from the market in a timely fashion, resulting in an estimated 22,000 preventable deaths. Cases and controversies like these, or Ketek – the list goes on – are alarming to all of us. And, with every new case, they look less and less like outliers and more and more like symptoms of a dangerous and systemic failure in our regulatory apparatus.

In testimony before the Senate Finance Committee in 2004, Dr. David Graham, an epidemiologist at FDA testified that, because of the culture at the Center for Drug Evaluation and Research, the U.S. was virtually defenseless against another drug safety disaster like Vioxx, and it was only a question of time before another disaster would strike. It would appear that Avandia is that disaster. From every indication we have seen, Avandia looks to be an instant replay of what transpired with Vioxx.

So, I hope that today we can work to identify exactly what happened here with Avandia – what went wrong, when, and who knew about it. And, even more importantly, I hope we can begin to figure out ways to address these continuing drug safety problems at the agency.

On one hand, we clearly need to establish more independent regulatory science capability, so that the agency can make evaluations about drug safety free of industry pressure. And we obviously need more disclosure and transparency from the pharmaceutical companies themselves, so that we do not have another situation where the only safety assessment of a given drug is one as clearly compromised as the RECORD trial.

In restructuring the FDA towards a more scientific bent, and in mandating that industry post summary-level results of clinical trials online, the FDA Amendments Act we passed in 2007 has and should continue to make a difference on these fronts. But, as we now know, increased scientific capacity and more industry transparency are only parts of the solution.

We also need to change the culture at FDA – to make it more proactive rather than reactive – and to ensure that there are clean, consistent, and well-delineated lines of communication between the scientists examining these drugs and the regulators making decisions. In this last regard, the evidence suggests that we should look into

strengthening either the independence or the powers of the FDA's drug safety office, so that its recommendations no longer go unheeded.

So, thank you again, Senator Grassley, Dr. Krumholz, and Dr. Wolfe, for being with us today to help us get to the heart of these continuing problems. Ranking Member Kingston, would you like to make a statement?

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