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# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6115

MAJORITY (202) 225-2927  
FACSIMILE (202) 225-2525  
MINORITY (202) 225-3641

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### Opening Statement of Rep. Henry A. Waxman Chairman, Committee on Energy and Commerce Drug Safety: An Update from FDA Subcommittee on Health March 10, 2010

Thank you, Chairman Pallone, for holding this hearing today and giving us the opportunity to hear from the FDA on the critically important issue of drug safety.

Although it has been some time since the Committee focused on drug safety, that pause does not represent any lessening of our collective commitment to this issue. When we took up the food safety bill last year, we made it clear that the legislation was just a first step. As the Senate prepares to take up its version of the food safety legislation passed by the House last July, we turn next to drug, medical device, and cosmetic safety issues. We start that process with today's hearing – knowing already that there is much work to be done in the area of drug safety.

We cannot forget the lessons of the 2007 heparin contamination catastrophe which resulted in numerous severe allergic reactions and the deaths of at least 80 Americans. In that case, the active ingredient was manufactured in China. Thanks to the excellent work of the Subcommittee on Oversight and Investigations in 2008, we know that this is not a unique situation: the U.S. drug supply is increasingly sourced from abroad.

In order to market a drug in the U.S., FDA must ensure that the drug meets our appropriately high safety standards. So when ingredients or finished drug products are manufactured abroad, FDA needs to expand its reach if the Agency is to meet its responsibilities.

As heparin illustrated, FDA clearly needs more authorities and more resources to do a better job policing the safety of imported products. But what heparin also demonstrated is that we cannot expect FDA alone to do this job. We need to place a greater onus on all manufacturers to oversee the safety of their own products. This principle is reflected in the work that Mr. Dingell, Mr. Pallone, and Mr. Stupak did on their Food and Drug Administration Globalization Act. For instance, the bill would require drug manufacturers to implement "Quality Risk Management Plans" to incorporate risk identification and control into their production processes. We need that.

This is a principle that should be familiar to all of us – the Food Safety Enhancement Act reflects this kind of approach with respect to food manufacturers. So I am confident we can get the same kind of bipartisan agreement to incorporate this concept into a bill on drug safety as well.

I hope FDA will tell us today about what the Agency believes it needs to protect us from another heparin disaster.

I am also eager to hear about FDA's implementation of the 2007 FDA Amendments Act. Congress made some major strides toward improving the safety of our drug supply in enacting this legislation. For the first time, FDA was given the authority to require manufacturers, among other things, to conduct post-market studies, implement "Risk Evaluation and Mitigation Strategies" or "REMS," and make safety-related drug labeling changes. This hearing will be a great opportunity to learn about FDA's challenges and successes with the use of these authorities three years after the enactment of this landmark legislation.

I want to thank Dr. Sharfstein for being here today and look forward to his testimony.