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MEDIA CONTACTS

Dingell: Betsy Barrett (202) 225-4071

Waxman: Karen Lightfoot (202) 225-3641

Pallone: Erin Bzymek (202) 225-4671

DeGette: Juliet Johnson (202) 225-4431

Dingell, Waxman, Pallone, & DeGette Introduce Drug Safety Enhancement Act
Historic Changes to Enhance our Drug Safety Laws

WASHINGTON, D.C. – Today, Rep. Henry A. Waxman, Ranking Member of the Energy and Commerce Committee, Rep. Frank Pallone, Ranking Member of the Subcommittee on Health, and Rep. Diana DeGette, Ranking Member of the Subcommittee on Oversight and Investigations joined Rep. John D. Dingell to introduce The Drug Safety Enhancement Act, which would equip the Food and Drug Administration (FDA) with the authorities and resources it needs to adequately regulate the growing global marketplace for pharmaceuticals.

The Drug Enhancement Act provides tough new directives to protect consumers from unsafe drugs. This legislation builds on H.R. 759, the Food and Drug Globalization Act, which was introduced by Dingell, Pallone and Stupak in 2009, and reflects the reasoned priorities and recommendations of the Food and Drug Administration (FDA). It is imperative that the FDA play a role in improving quality and safety standards of manufacturing facilities. The Drug Safety Enhancement Act seeks to create higher FDA standards and requirements and to construct new funding mechanisms for FDA so oversight and inspectional activities will not place a burden on U.S. taxpayers.

The bill:

- Creates an up-to-date registry of all drug facilities—both foreign and domestic—serving American consumers;
- Generates funding for increased Good Manufacturing Practices (GMP) inspections for brand and generic drugs;
- Requires parity between foreign and domestic inspections;
- Prohibits entry of drugs coming from domestic and foreign facilities that limit, delay or deny FDA inspections;
- Prohibits the entry of drugs into the U.S. lacking documentation of safety;
- Requires manufacturers to know their supply chain, identify and mitigate risk throughout their supply chain, and to document measures taken to secure their supply chain;
- Prohibits false or misleading reports to FDA;
- Provides strong new enforcement tools, including mandatory recall authority, increased civil and criminal penalties, and new FDA authority to subpoena records related to possible violations;
- Provides protection for whistleblowers that bring attention to important safety information; and
- Requires unique identification numbers for drug establishments and importers to improve the ability of the FDA to more quickly identify parties involved in a crisis situation.

“For too long, Americans have suffered from the challenges FDA and the industry face in ensuring the safety of the U.S. drug supply. We must address the deficiencies uncovered by recent recalls,” said Rep. John D. Dingell (MI-15). “The Drug Safety Enhancement Act is a strong and effective response to the troubles we face with an increasingly global and complex drug supply. I look forward to working with my colleagues on both sides of the aisle, consumer advocates, and the regulated industry to ensure we address the safety of the nation’s drug supply in a meaningful way.”

“We need to ensure that the FDA has modern authorities and enforcement tools to help protect the safety of our increasingly global drug supply,” said Rep. Henry A. Waxman (CA-30). “This legislation will provide urgently needed tools and resources, and I urge my colleagues to move this critically important bill as soon as possible.”

“FDA’s pharmaceutical inspection process is still behind the times in recognizing the fact that many of the drugs Americans rely on are manufactured beyond our borders,” said Rep. Frank Pallone (NJ-06). “The Drug Safety Enhancement Act increases enforcement so that FDA can keep pace with an increasingly international marketplace of products and so that Americans can have confidence the drugs they rely on will help them get better, not make them more sick.”

“A few years ago, thousands of American lives were jeopardized by contaminated heparin stock imported from China,” said Rep. Diana DeGette (CO-1). “As pharmaceuticals and their ingredients are increasingly imported from the global marketplace, we must ensure our families can trust the medicines they rely upon, by empowering the FDA with the authority and resources to protect our nation’s drug supply. Congress recently came together on a bipartisan basis to pass a groundbreaking overhaul to our nation’s food safety system, and I look forward to working with my colleagues across the aisle to do the same for our families’ medications.”

With pharmaceuticals and active pharmaceutical ingredients increasingly being produced in foreign countries, often in facilities that have lower standards than U.S. manufacturers, safety risks and an uneven playing field are exacerbated. High-profile risks associated with the globalized drug supply like the heparin crisis of 2007 have put American lives at risk. These alarming risks highlight why FDA needs additional authorities and greater resources to ensure the safety of an increasingly global drug supply.

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