

Chairman Dingell at the Subcommittee on Oversight and Investigations hearing entitled, "FDA's Foreign Drug Inspection Program: Weaknesses Place Americans at Risk"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED "FDA'S FOREIGN DRUG INSPECTION PROGRAM: WEAKNESSES PLACE AMERICANS AT RISK"
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Mr. Chairman, thank you for holding this important hearing.

Today we again explore whether the Food and Drug Administration (FDA) is adequately able to protect American citizens from the unscrupulous or incompetent foreign manufacture of pharmaceutical products. Given the findings of this Subcommittee and the recent disturbing events surrounding tainted heparin, I believe FDA is not up to the task, as it cannot or will not undertake the reforms needed to protect Americans from this threat from abroad.

Let me summarize some of the Committee's key findings from its investigations:

Significant and growing amounts of pharmaceutical products used by Americans are manufactured overseas.

At least 80 percent of all active pharmaceutical ingredients are now imported, much of it from countries lacking competent regulatory systems, such as China and India.

Current U.S. law requires that FDA inspect domestic drug manufacturing firms once every two years, but there is no law requiring the same for foreign firms.

While FDA is able to inspect domestic firms about once every 2.7 years, the inspection rate of foreign firms is once every 13 years. In fact, at this time FDA is only able to inspect about 7 percent of the existing foreign firms shipping drug products to the U.S. annually.

What does this mean? More than 700 Chinese firms are currently registered to export drug product to the U.S., but FDA can only inspect about 10 to 20 of them per year. In other words, it would take FDA more than 30 years to inspect each Chinese firm a single time, assuming no new firms are added to the list.

The information technology (IT) system FDA uses to track and manage data on foreign manufacturers and the drugs they export to the U.S. is archaic and fraught with inaccuracies. FDA is unable to say how many foreign firms are subject to inspection globally, or where they are located. GAO reports that FDA cannot determine how many firms are exporting drugs to the United States.

The last time the Commissioner of Food and Drugs was here, he promised to return and give us the details of how he was going to fix this mess. I hope that his testimony will not resemble what he told the Senate Appropriators last week, which appeared short on substance and heavy on bureaucratic buzzwords.

I am hoping the Commissioner will finally tell us what additional resources he needs. The President's 2009 budget does little to materially close the gap in foreign inspection rates. To this point, neither I nor the American people have any reason to believe that this Administration is serious about protecting us from dangerous foreign-made drugs.

Until the Commissioner frankly tells Congress what new regulatory tools are needed, what it will take to truly fix the broken IT systems, and how many more personnel it will take to inspect foreign firms with meaningful frequency, I fear we will continue to see contaminated products entering both our food and drug supply. That is a simply intolerable situation that this Committee intends to address with legislation this year.

Prepared by the Committee on Energy and Commerce
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