

Chairman Dingell at the Subcommittee on Oversight and Investigations Hearing Entitled, "FDA Foreign Drug Inspection Program: A System At Risk"

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

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED, "FDA FOREIGN DRUG INSPECTION PROGRAM: A SYSTEM AT RISK"
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Mr. Chairman, today's hearing could not be timelier given the unremitting bad news regarding the safety of imported products. I am struck, however, by how little has changed in the seven years since our last hearing on the Food and Drug Administration (FDA) foreign drug inspection program like d@j vu all over again.

Seven years ago, this Subcommittee heard FDA Commissioner Jane Henney testify that:

- FDA could not provide a complete list of foreign drug producing facilities;
- FDA lacked an information technology (IT) system able to effectively manage the foreign drug inspection program; and
- FDA lacked the resources to inspect foreign drug manufacturing firms that imported to the U.S. at the recommended two-year intervals, as is required for domestic companies.

Mr. Chairman, you may think you are hearing an echo in the room, but let me summarize today's findings:

- FDA still cannot calculate the number of foreign drug producing facilities shipping products into the U.S.;
- FDA's IT system still is as broken as it was back then, unable to provide critical data for regulating foreign drug production; and
- FDA still lacks the necessary resources to effectively conduct foreign inspections to ensure that the medicines made abroad are safe for U.S. consumers.

There is one slight change since our last hearing. Unfortunately, it is a change for the worse. Despite the dramatic increases of drug imports into the U.S. indicating even more foreign drug facilities requiring inspection the agency's resources have actually decreased since our last hearing.

I believe that the American people generally assume that the FDA ensures that foreign-manufactured drugs sold in this country are safe. They assume incorrectly.

For example, most experts recommend that drug-producing firms be inspected about every two to three years, which is generally how often domestic drug firms by law are required to be inspected. The rules for foreign firms, however, are completely different.

According to testimony we will hear today, FDA only has the resources to inspect foreign firms once every 13 years on average. China, for example, now has more facilities manufacturing drug products for the U.S. market than any other country, some 714.

Yet given the FDA's anemic resources, only 13 inspections were conducted in China in 2007. At this rate, it would take the FDA 55 years just to clear this backlog.

The bottom line is that the FDA has no clue what the condition is of most foreign drug-manufacturing facilities that import into the U.S. market. The agency is using an antiquated regulatory system from the last century, when the global economy was very different. It is time that FDA both receives and dedicates enough resources so as to effectively carry out its mission in today's global market.

Mr. Chairman, I have introduced a bill that will give FDA adequate resources to do its job. I hope the Members of this Committee will work together on this legislation to see to it that it becomes enacted into law. This hearing should serve as a wake-up call to FDA that it's time to seriously address the restructuring and funding the foreign drug inspection program. Nothing less will restore the confidence of the American people in the safety and efficacy of our drug supply.

Prepared by the Committee on Energy and Commerce
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