Oversight & Investigations Subcommittee
"FDA Foreign Drug Inspection Program: A System at Risk"
November 1, 2007
Chairman Bart Stupak's Opening Statement

This hearing is a continuation of this subcommittee's investigations into the safety of imported products. Today we explore the question of whether the FDA is adequately regulating the manufacturing of pharmaceutical products and active pharmaceutical ingredients (API's) for export to the United States.

Most Americans do not realize that today many of the drug products in their medicine cabinets come from overseas. In fact, more than 80% of the active pharmaceutical ingredients that go into drugs come from abroad. India and China account for almost half of these imports. India's pharmaceutical imports into this country have increased 2,400 percent from 1996 to 2006, making it the fastest-growing drug importer and China has doubled its pharmaceutical exports to the U.S. over the last 5 years.

The Food & Drug Administration (FDA) is responsible for regulating foreign-made medicines and ensuring the American public is supplied with safe medications. Despite a 2000 oversight hearing and a critical GAO audit in 1998 which pointed out many of the FDA's weaknesses regarding importation of drugs, the FDA continues to use 20th century tools and resources to address 21st century regulatory challenges. Today's hearing is intended to: 1) determine the effectiveness of FDA in overseeing foreign drug production and 2) explore what resources the agency realistically needs to do the job.

Unlike food products, FDA can't rely on "end testing" to determine if drug products are safe. Instead, FDA's main tool for ensuring that a drug is manufactured safely is to conduct actual on-site inspections of drug-making facilities. FDA is required to conduct a formal "pre-approval" inspection before a firm – domestic or foreign – can begin producing a drug for the U.S. market. After a "pre-approval" inspection, the agency is required to conduct follow-up "surveillance" inspections of domestic facilities to ensure they are continuing to meet U.S. manufacturing regulations.

For U.S drug manufacturers, federal law requires that follow-up inspections be done every two years. Remarkably, there is no law dictating how often the FDA must inspect foreign drug manufacturers. Even though foreign firms pose just as great (if not a greater) risk to the public health than domestic drug firms. In a petition to the FDA, the Synthetic Organic Chemical Manufacturers Association, who will testify today, noted:

> "Foreign facilities, in general, pose a greater risk to public safety because when a facility is inspected infrequently, as is the case for foreign manufacturers, there is a natural tendency for management to become complacent that what was adequate at the last inspection is still adequate…Maintaining [regulatory] compliance requires constant effort and vigilance. Minor deviations may not cause any

apparent lack of quality, but it is a well-paved road from minor deviations to serous quality failures…"

Twenty years ago, the drugs Americans consumed, were made in the United States. Because few firms were overseas, the FDA was reasonably positioned to closely monitor drug production facilities. However, as more foreign drug products enter the U.S. market, FDA's ability to keep pace with inspections and monitoring has become severely limited. This was particularly true when the Committee last examined this matter in 2000. Through the course of that investigation, the Committee found significant shortcomings in FDA's ability to conduct foreign inspections. Back then FDA was under-funded, over-stretched, and poorly coordinated. Among the Committee's principal findings in our 2000 hearing was:

- FDA officials could not determine how often foreign manufacturers were being inspected;

- Drug makers in China and India were inspected, on average, about every 4 to 5 years, which was more than twice FDA's 2 year inspection requirement for domestic pharmaceutical manufacturers;

- FDA had only enough resources to inspect foreign pharmaceutical manufacturers on average once every 11 years.

- Finally, the agency's IT systems were in disarray relying on 15 separate data systems to identify foreign pharmaceutical manufacturers, plan foreign inspection travel, track inspection results, and monitor enforcement actions.

Nearly eight years have passed since our last hearing and surprisingly most of the same problems still plague the FDA today! For example:

- Resources dedicated to foreign drug inspections have actually declined since the GAO's 1998 report while the number of foreign drug manufacturers and imports are on the increase**;**

- Despite more than a decade of warnings from FDA's own internal reviews, the Congress, and the Government Accountability Office, FDA's IT system is still based on multiple databases which lack integration and contain unreliable information.

- Due to these poor IT systems, the FDA can not obtain reliable data to run their risk models so they can effectively allocate what limited resources it does have for inspections;

- FDA's IT system has made it nearly impossible to provide the GAO, this Committee, or even its own managers with key data to measure ongoing resource needs.

Let me give you one example. For almost three months our Committee and the GAO have repeatedly asked the FDA for the number of foreign firms the agency is supposed to be inspecting overseas and where they are located. For three months the FDA has on 10 different occasions provided numbers ranging from 2,100 to 13, 800 foreign firms. The database we believe is probably the most accurate shows that about 3,000 firms are registered to ship drug products to the U.S. Yet FDA's own foreign inspection risk model uses data from about 3,300 foreign firms. Another FDA database called OASIS, which captures actual drug shipments to the U.S., now shows an even higher figure of 6,800 foreign firms. That number was revised downwards from 13,800 firms just last week. Frankly, it has been nearly impossible for the Committee staff to calculate what resources FDA needs because its internal data is simply in shambles.

FDA may testify today that they know with some certainty the approximate number and location of every firm that is importing drug product into America, but I am not convinced FDA can accurately calculate the number of foreign firms they should be inspecting. How can we have any confidence FDA is truly managing the risk that may come from foreign-made drug products if the FDA does not know the exact number or location of foreign drug manufacturers?

This most basic data should be available in about an hour, not three months. I don't believe an auto dealership could survive if it was run on an IT system that said there were between 2,000 and 13,000 cars on his lot. But apparently this passes muster at FDA, even though it involves safeguarding the U.S. drug supply.

From the limited data we have gleaned from the agency, FDA's foreign drug inspection program has serious shortcomings. For example, FDA is capable of conducting only 200 to 300 foreign follow-up inspections each year. These are the inspections that by law, FDA attempts to do every two years for domestic firms. But if one assumes that the rough estimate of foreign firms is likely around 3000 a simple mathematic calculation would suggest that FDA can only inspect each foreign drug firm about every13 years.

One must also question whether FDA's limited resources are being properly targeted: For example, we know that China now represents the largest source of production facilities now shipping drug product to the U.S. with more than 700 drug firms. Yet China represents a mere 4% of where FDA is spending its foreign inspection resources.

The Administration believes one of the best ways to solve FDA's lack of inspection resources is to negotiate Memorandums of Agreement (MOA's) with foreign governments. But such efforts will not overcome the lack of FDA funding for on-the-ground foreign inspections. Mutual Recognition of each other's inspection reports would

save considerable money. But neither China nor India – two very large producers of pharmaceutical goods – are anywhere near being ready for such agreements. Perhaps the FDA should open offices in those parts of the world – such as China and India – where many pharmaceutical firms are now located or moving their manufacturing. AstraZeneca, to use just example, is now one of the world's largest pharmaceutical companies and plans on obtaining 90% of its pharmaceutical ingredients from China in the very near future.

FDA does spend considerable resources in India (22%), which is a good thing. Yet, it begs the question of why the administration has not engaged in open discussions with that country as they have been attempting to do with China. This is particularly strange given that Committee staff recently visited India and met with senior government and industry officials who strongly encouraged the FDA to open a permanent office to reduce the backlog of needed inspections.

Every year consumers see more and more counterfeits and poorly made drugs floating around the world. We dodged a bullet this year on tainted toothpaste which could have made many sick. But dozens of Panamanians weren't so lucky last year when they died from taking poisoned medicine that purportedly came from China. That can happen here, and it surely will if we do not get a better handle on ensuring that foreign-made drugs are safe and their plants are inspected regularly. This will require resources and significant restructuring of the program.

Chairman Dingell and I already have legislation designed to give the FDA more resources to do its job. Moreover, we have already sent you bipartisan correspondence delineating certain changes to the program that could be enacted almost immediately. We truly hope it will be sufficient to address what are truly the root causes plaguing the FDA's foreign drug inspection program and not mere window dressing. We have been here before in 1998 and we were told by FDA that these problems would be fixed. Unfortunately, the problems were not fixed and we are here again. To that end, I believe we have an opportunity to fix FDA's foreign drug program before Americans are sickened or killed by contaminated imported drugs.

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