United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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For Immediate Release
Thursday, Aug. 9, 2007

Grassley Seeks FDA Briefing on Steps to Ensure Safety of Foreign-made Medicine

WASHINGTON – Sen. Chuck Grassley, ranking member of the Committee on Finance, is asking the Food and Drug Administration for an explanation of its steps to ensure the safety of foreign-made medicine. In a letter to the agency commissioner, Grassley said he is disturbed by reports of the inadequacy of FDA inspections of foreign pharmaceutical manufacturing facilities, especially given the growing predominance of overseas manufacturing of such products.

The text of Grassley's letter follows here.

August 8, 2007

Via Electronic Transmission
The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs, including the payment for prescription drugs regulated by the Food and Drug Administration (FDA). As Ranking Member of the Committee, I have the duty to ensure that the FDA upholds its responsibility to the public's safety by properly regulating the nation's drug supply and ensuring that the drugs Americans use are safe.

I have been troubled by a number of recent articles discussing the FDA's failures in inspecting

foreign pharmaceutical manufacturing plants. In fact, in a recent *Washington Post* article, William Hubbard, a former FDA associate commissioner, characterized the problem as "dire and deteriorating." Given the fact that nearly 80 percent of the active pharmaceutical ingredients used in the U.S. are manufactured abroad, this is a significant problem that needs to be addressed immediately.

Even more troubling is that this problem is not a new one. Congress has expressed concerns about the FDA's oversight of foreign drug manufacturing facilities in the past. In 1998, the Government Accountability Office prepared a report to the United States House Committee on Commerce responding to concerns about the FDA's "ability to ensure the safety and quality of the increasing volume of foreign-produced drugs imported daily into the United States." The fact that this problem persists nearly ten years after this report was published is unacceptable.

Accordingly, I am requesting that the FDA provide information about how it is handling this serious problem. I would like to know the measures the FDA has in place today to inspect foreign drug manufacturing facilities, as well as how it intends to improve these measures in the future. Specifically, I ask the FDA to brief my staff and provide formal responses to the following questions:

1) What protocols does the FDA currently have in place regarding inspection of foreign pharmaceutical manufacturing facilities? What specifically does the FDA do when it inspects a foreign pharmaceutical manufacturing facility? Please include copies of the protocols in your response.

2) How many on-site visits of foreign pharmaceutical manufacturing facilities has the FDA performed since 2002 and who performed them? In what countries were these inspections performed? How many inspections were performed in each country? What were the results? When an inspection results in negative findings, what kind of follow-up occurs? How much does the FDA spend on foreign inspections annually? How many of these inspections were for pre-approval purposes rather than ongoing inspections of existing sites? How many were for facilities producing generic drugs, and how many were for those producing brand name ones? In India, what number were for PEPFAR Aids programs?

3) What kinds of cooperative relationships does the FDA have with its foreign counterparts or other foreign regulatory bodies? How does the FDA measure the efficacy of the inspections performed by these foreign agencies? By those measures, how well are these agencies performing the function of thorough inspection of drug manufacturing facilities?

4) What strategies is the FDA developing to improve the inspection of foreign pharmaceutical plants, and what is the timeline for the implementation of these strategies? What, if any, are the barriers to implementing these strategies?

5) How long do FDA inspectors typically remain abroad? How long do inspections of foreign facilities usually last?

6) Does the FDA currently have any plans to create an agency outpost in India? If so, what is the status of these plans?

7) A report by PriceWaterhouseCoopers recently stated that, in the near future, pharmaceutical manufacturers will make a large shift from domestic facilities to ones in Asia. How is the FDA preparing to respond to this possibility?

I look forward to your cooperation and assistance on this important matter, and would greatly appreciate a briefing for my staff. Please have your staff contact my Committee staff to schedule a meeting.

Sincerely,

Charles E. Grassley
Ranking Member

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