United States Senate
Committee on Finance

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Grassley seeks feedback on use of registration fees for inspection of foreign manufacturers of pharmaceutical drugs

WASHINGTON — Senator Chuck Grassley is asking the federal agencies charged with drug safety to weigh in on the use of registration fees as a way to help pay for more inspections of foreign pharmaceutical drug manufacturers and also limit the number of facilities that need to be inspected.

Grassley said he's learned that many foreign plants register with the Food and Drug Administration without actually shipping medicine and drug components to the United States, and this bogs down the system within the FDA. At the same time, many foreign plants ship medicine and drug components to the United States without ever registering with the FDA. Grassley also said it's also clear that the FDA needs more resources to meet the massive task of conducting the foreign inspections necessary to protect the American public.

The senator spelled out the issues in a letter sent today to the Secretary of Health and Human Services and to the Commissioner of the FDA. He noted that medical device makers located outside of the United States are currently required to pay registration fees to the FDA.

Grassley has conducted active oversight of the FDA since 2004, and has sought a number of administrative and legislative reforms to improve the performance of the drug-safety agency.

Here is the text of Grassley's letter.

March 11, 2008

Dear Secretary Leavitt and 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 or Agency), Department of Health and Human Services

(HHS). As a senior member of the Senate and Ranking Member of the Committee, I have a duty to ensure that FDA upholds its responsibility to the public's health by properly regulating the nation's drug supply and ensuring that the drugs Americans use are safe and effective.

In December, FDA officials briefed my staff regarding FDA's program for inspecting foreign pharmaceutical manufacturing facilities and ongoing questions regarding inspection funding, emerging exporters, and weaknesses in the inspection process, among other things. This briefing was part of my ongoing inquiry into the FDA's foreign inspection process. In the December briefing, an important point of discussion was the registration of foreign pharmaceutical plants with the FDA.

As I stated in earlier letters, the challenge before the FDA is a daunting one. With limited inspection resources, the FDA is charged with ensuring the safety and efficacy of drugs and pharmaceutical ingredients produced in nearly every corner of the globe. To make matters worse, as the FDA's challenges multiply, its resources for foreign inspections are shrinking. A report prepared last year for the FDA Science Board documented how dwindling resources have led to major reductions in the number of inspections the FDA conducts abroad. The report, "FDA Science and Mission at Risk," stated that the FDA cannot afford to send sufficient inspectors abroad because of "increasing responsibilities… stagnant number of personnel, as well as a lack of travel funds." Looking at all FDA inspections conducted abroad, the report found a 17% drop in the number of inspections since 2000. The Government Accountability Office (GAO) also found decreases in foreign inspection resources. Specifically, the GAO testified on November 1, 2007, that funds for foreign preapproval inspections have dropped from $8.2 million in fiscal year (FY) 2002 to $7.5 million in FY 2007. Funds for foreign postapproval inspections remained stagnant during this same period. In addition, the GAO found that there are approximately 3,000 foreign pharmaceutical manufacturing facilities currently registered with the FDA, but as many as 6,800 facilities importing products into the United States.

It is troubling that the very agency charged with ensuring the safety and efficacy of America's medicines is grossly under-resourced at a time when foreign production of drugs and active pharmaceutical ingredients is growing at record rates. Adding to the difficulty of this task, it appears that many foreign pharmaceutical plants register with the FDA as a means to bolster their own standing and with no intention of exporting products to the United States market. I understand that these registrations can have the effect of increasing the costs and pool of potential inspections for the FDA while providing no benefit at all to American consumers. For example, my staff was informed that in China there are about 578 pharmaceutical facilities registered with the FDA, but only about 200 to 300 of those facilities actually ship products to the United States.

In light of this, I am writing today to ask for your thoughts about the feasibility of introducing registration fees as a way to both augment the FDA's inspection resources and to limit the number of facilities that may register with the FDA without any intention of shipping products to the United States.

Interestingly, registration fees are currently used by the FDA in regard to medical devices. Owners and operators of establishments involved in the production or distribution of

medical devices are required to register with the FDA. This registration includes annual fees paid by the establishment, as required under the Medical Device User Fee and Modernization Act (MDUFMA), and in accordance with a congressionally established schedule of registration fees. For FY 2008, MDUFMA registration fees are listed at $1,706, and are set to increase to $2,364 in FY 2012. Entities required to register and pay fees include both foreign and domestic establishments that manufacture, prepare, propagate, compound, or process a device that is imported to the U.S. market.

There is currently no corresponding requirement that establishments involved in the production of drugs or active pharmaceutical ingredients pay registration fees. Though only a beginning, requiring registration fees for these establishments may help bolster the FDA's inspection capacity while also reducing the number of establishments that register without shipping products to the United States.

As stated above, about 3,000 foreign pharmaceutical manufacturing facilities are registered with the FDA, but other databases suggest that as many as 6,800 are actively importing products to the U.S. market. Collecting registration fees from the lower estimate of foreign facilities that are currently registered with the FDA alone would raise more than $5.1 million for foreign inspection activities, assuming that these facilities paid the same fees required of medical device facilities for FY 2008. This amounts to about a 40% increase for FDA's current foreign inspection budget of roughly $12.7 million. If registration fees were collected from the approximately 6,800 facilities currently importing products to the U.S. market, the FDA could raise more than $11.6 million, nearly doubling the current foreign inspections budget. At the same time, a registration fee requirement may discourage establishments that do not intend to ship products to the U.S. from taking advantage of the registration system. These numbers take into account only foreign pharmaceutical manufacturing facilities-a registration system for pharmaceutical facilities similar to the one established under MDUFMA would require the collection of fees from both foreign and domestic facilities, potentially increasing further the resources available for inspections.

It is critical that we address the inspection resource issues at the FDA if the Agency is to ensure that America's increasingly foreign-produced drug supply is both safe and effective. I would appreciate a written response to this letter as soon as possible. In addition, I am that requesting that HHS/FDA provide a briefing to my Committee staff on the FDA's program for inspecting establishments that manufacture medical devices for the U.S. market.

Thank you for your cooperation and attention to this important matter.

Sincerely,

Charles E. Grassley
United States Senator
Ranking Member, Committee on Finance