

For Immediate Release  
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Grassley works for prescription drug and medical device safety

WASHINGTON --- Senator Chuck Grassley today introduced legislation with Senator Ted Kennedy to give the Food and Drug Administration (FDA) more resources to inspect domestic and foreign-made prescription drugs and devices.

The bipartisan legislation also responds to concerns about medical device reviews by the FDA and calls for an Institute of Medicine study to examine the FDA's system for approving devices.

The Drug and Device Accountability Act of 2009 is similar to legislation introduced last year by Grassley and Kennedy.

“An increasing number of drugs and ingredients for pharmaceuticals are being manufactured in other countries, yet studies show the FDA doesn't know how many foreign plants are subject to inspection, and the FDA conducts relatively few foreign inspections each year,” Grassley said. “Our legislation is a practical solution to beefing up the FDA's inspection work, both domestically and abroad, and holding the FDA accountable for its review of medical devices, where questions have been raised about the agency's work.”

The Drug and Device Accountability Act would augment the FDA's resources through the collection of inspection fees. The bill also would expand the FDA's authority, including new subpoena powers, for ensuring the safety of drugs and medical devices made domestically and in other countries. Finally, the bill would require certification of applications for drugs and devices needing FDA approval and establish civil and criminal penalties for false or misleading certifications.

Grassley's floor statement detailing the need for this legislation is below. He is Ranking Member of the Senate Committee on Finance, where he's conducted extensive oversight of the FDA's performance. Kennedy is Chairman of the Senate Committee on Health, Education, Labor and Pensions, which is responsible for FDA legislation.

Floor Statement of U.S. Senator Chuck Grassley of Iowa  
Ranking Member of the Committee on Finance  
Introduction of the Drug and Device Accountability Act of 2009  
Thursday, April 23, 2009

Mr. President, over the last five years I have conducted extensive oversight of the Food and Drug Administration. As a result of my oversight activities, I identified serious problems at the FDA that included:

- The quashing of scientific opinion within the agency;
- Delays in informing the public of emerging safety problems;

- Too cozy a relationship between the FDA and the industries it is supposed to regulate; and
- A failure to be adequately transparent and accountable to the public

The FDA will require strong leadership to rebuild public confidence and tackle the cultural and organizational problems that have plagued the agency.

Strong leadership alone, however, will not fix all the problems.

The agency needs additional tools, resources, and authorities to fulfill its mission of protecting the health and safety of the American people.

In September 2007, the Congress passed the Food and Drug Administration Amendments Act to provide FDA some of the needed tools, resources, and authorities.

This legislation was a positive step forward in strengthening the agency and restoring the public's trust in the FDA, but Congress' work is not done.

Today, I am here to talk about another FDA bill.

In the summer of 2007, I started examining FDA's program for inspections of foreign pharmaceutical manufacturing plants.

I expressed concerns to the FDA regarding, among other things, inspection funding, emerging exporters, and severe weaknesses in the inspection process.

An increasing amount of the drugs and active pharmaceutical ingredients Americans use are being manufactured in foreign countries; primarily in China and India.

Yet, as reported by the Government Accountability Office in November 2007, the Food and Drug Administration does not know how many foreign establishments are subject to inspection and the agency conducts relatively few foreign inspections each year.

According to the FDA, from fiscal year 2002 through fiscal year 2007, the agency conducted fewer than 1,400 inspections of foreign pharmaceutical facilities.

And these inspections were often conducted in countries with few reported quality concerns.

In China, the world's largest producer of active pharmaceutical ingredients, and where we have seen increasing reports of contaminated products, only 11 inspections were conducted during FY 2007—that is way too few.

During the same year, FDA conducted 14 inspections in Switzerland, 18 in Germany, and 24 in France—all countries with advanced regulatory infrastructures.

In addition, FDA officials estimated that the agency inspected foreign class II device makers every 27 years and foreign class III device makers every 6 years.

Class III devices are devices that support or sustain human life or present a potentially unreasonable risk of illness or injury, such as pacemakers and heart defibrillators.

In January 2008, we saw too well what happens when we have a broken inspection system.

Baxter International Inc. temporarily suspended production of its blood thinner Heparin because of an increase in reports of adverse events that may be associated with its drug.

Then recalls were announced.

There were serious concerns about whether or not this country would have enough Heparin to meet patient needs as a result of the contamination.

After several months, FDA's investigation found that the active ingredient in Heparin, which was made at a facility in China, was contaminated.

And the serious adverse events in patients who received Heparin were linked to the contaminated blood thinner.

The recalls and investigation of contaminated Heparin highlighted significant weaknesses in FDA's oversight of the production and supply chain and emphasized the need to improve FDA's protection of the safety of products made in this country and abroad.

The FDA is charged with ensuring the safety and efficacy of drugs, pharmaceutical ingredients, and devices produced around the world despite its inadequate budget for inspections, in particular foreign inspections.

It is troubling that the FDA is grossly under-resourced at a time when foreign production of drugs and active pharmaceutical ingredients is growing at record rates.

Last Congress, I introduced the Drug and Device Accountability Act of 2008 with Senator Kennedy, Chairman of the Committee on Health, Education, Labor, and Pensions.

The Congress did not have an opportunity to act on that legislation.

So, today Senator Kennedy and I are introducing the Drug and Device Accountability Act of 2009.

Senator Kennedy is not able to join me here on the Senate floor but I want to thank him for his cooperation and work with my office on this important legislation.

I also want to take this opportunity to express my appreciation for his commitment and efforts over the years to reform and improve the FDA.

I'm going to spend the next few minutes highlighting some of the things the Drug and Device Accountability Act of 2009 would do.

This bill would augment FDA's resources through the collection of inspection fees.

It also expands the agency's authority for ensuring the safety of drugs and medical devices, including foreign manufactured drugs and devices by:

- Expanding FDA's authority to inspect foreign manufacturers and importers;
- Allowing the FDA to issue subpoenas; and
- Allowing the FDA to detain a device or drug when its inspectors have reason to believe the product is adulterated or misbranded.

In addition, the bill would require individuals responsible for submitting a drug or device application or a report related to safety or efficacy to certify that the application or report complies with applicable regulations and is not false or misleading.

Civil as well as criminal penalties could be imposed for false or misleading certifications.

I believe this is an important provision given the troubling findings over the last few years: that is that some companies have withheld important safety information from the FDA or buried that information in their submissions to the agency.

In addition, in light of recent, serious allegations that have been raised by scientists within the FDA regarding the agency's handling of medical device reviews, the bill calls for an Institute of Medicine study to examine FDA's system for clearing and approving devices for marketing.

During President Obama's weekly address last month, the President stated, "There are certain things only a government can do. And one of those things is ensuring that the foods we eat, and the medicines we take, are safe and do not cause us harm."

I concur and the Drug and Device Accountability Act is an opportunity for Congress to help FDA do a better job of ensuring that our increasingly foreign-produced drug and device supply is safe and effective.

I look forward to working with my colleagues in the Senate and with the Obama Administration to ensure that FDA has the necessary tools and resources to meet its oversight responsibilities.