U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Friday, October 13, 2006

Grassley asks FDA for more information about unapproved prescription drugs

WASHINGTON – Sen. Chuck Grassley has asked the Food and Drug Administration for more information about its review of prescription drugs that are currently on the market without an FDA approval.

"There are many physicians and pharmacists under the impression that drugs they administer to patients are safe, and approved by the U.S. government," Grassley said. "That's not always the case, and these health care workers ought to be educated and made aware of that."

In a letter sent this week, Grassley asked the acting commissioner of the Food and Drug Administration how the FDA will inform health providers, pharmacists and the general public that not all prescription drugs currently on the market are FDA approved.

Here is a copy of Grassley's letter.

October 11, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. 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 ensure that beneficiaries receive drugs that are both safe and effective.

Last month, USA Today reported that the Food and Drug Administration (FDA) "estimates that several hundred unapproved active ingredients, including antihistamines, narcotics and sedatives, are in prescription drugs sold in the USA," and these drugs make up almost 2% of all prescription drugs on the market. In that article entitled, "Hundreds of unapproved drugs sold by prescription," FDA's director of compliance stated, "We have concerns about their safety, about their quality, about their labeling." I echo those concerns.

These drugs are being marketed without the FDA's review of scientific data demonstrating that the products are safe and effective.

What further troubles me is that many physicians and pharmacists may be under the impression that all of the drugs they provide to patients are FDA-approved. The FDA website states that unapproved drugs are often advertised in medical journals and listed in pharmaceutical references such as the Physician's Desk Reference, and the drug labels do not disclose that the drugs have not been approved by the FDA. In addition, according to USA Today, URL/Mutual Pharmaceuticals of Philadelphia surveyed 500 pharmacists and found that 91% of those pharmacists thought all of the products they dispense are FDA-approved.

Several months ago, the FDA issued new guidance, "Marketed Unapproved Drugs — Compliance Policy Guide," and took regulatory action against manufacturers of unapproved prescription drugs containing the antihistamine carbinoxamine. According to the FDA press release, dated June 8, 2006, the carbinoxamine-containing products were labeled for cough and cold symptoms despite never receiving approval from the FDA for such indications.

While I am heartened to hear that FDA is taking this important matter seriously, I remain concerned about patient safety. There are many more unapproved drugs that the FDA has yet to act on while health care providers continue to prescribe some of them to their patients. Furthermore, the FDA stated to USA Today that it lacks the resources to remove all unapproved drugs from the market. Accordingly, I request that the FDA respond to the following questions:

1. According to the FDA website, many of the unapproved drugs were developed and marketed before the 1962 amendments to the Federal Food, Drug, and Cosmetic Act. Since many of these drugs have been on the market for decades, I am interested in the impetus for FDA's recent actions. What led to the FDA's decision to take action now to ensure that unapproved drugs meet FDA's standards for safety, efficacy, and quality or be removed from the market? How many unapproved drugs did the FDA remove from the market over the last 10 years and prior to the release of the new guidance?

2. How did FDA arrive at its estimation that there are several hundred unapproved active ingredients in drugs currently on the market?

3. FDA stated that it issued the guidance to "encourage" companies to comply with FDA's drug approval process. Given that some of the companies may have been manufacturing and selling unapproved drugs for many years, what assurances do you have that the guidance will improve compliance?

4. The new guidance states that the FDA does not have complete data on illegally marketed products. Given this lack of data, please describe in detail how the FDA identifies unapproved drugs.

5. Please describe in detail how FDA identifies which drugs require immediate attention and regulatory action. For example, how does FDA determine which unapproved drugs have potential safety risks if there is incomplete data and the universe of unapproved products is "constantly changing"?

6. According to the Bloomberg article, "Drugs Slip Past FDA, Sell Unapproved by the Millions," dated October 11, 2006, the FDA "may not act against beneficial drugs for which alternatives aren't available." How does the FDA determine which unapproved drugs may be beneficial and not require regulatory action?

7. What actions, if any, is the FDA taking to inform health providers, pharmacists, and the public that not all prescription drugs currently on the market are FDA-approved? If a provider, pharmacist or patient discovers that a marketed drug lacks FDA approval, is there a system in place for reporting that information to the FDA?

8. FDA's website states that the new guidance "is the next step in an FDA initiative to ensure that all marketed U.S. drugs have required approval." What other actions are planned, and how will FDA ensure that all marketed drugs are approved drugs if the agency believes it lacks the resources to remove all unapproved drugs from the market?

I look forward to hearing from you regarding the concerns and questions set forth in this letter by no later than October 31, 2006.

Sincerely,
Charles E. Grassley
Chairman