United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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Grassley questions government response to the marketing and use of unapproved drugs

WASHINGTON – Sen. Chuck Grassley is asking top officials for the Food and Drug Administration and the Centers for Medicare and Medicaid Services to respond to questions about their agencies' oversight of the marketing of prescription drugs that have not been approved by the FDA and illegitimate billing of the Medicaid program for unapproved drugs.

In response to a Grassley inquiry last year, the FDA acknowledged that its system for finding unapproved drugs is limited, stated that the agency had initiated multiple enforcement actions and would continue to try and get companies to file for marketing approval, and said that it created a website on unapproved drugs to address consumer questions and make available important documents on the issue.

The text of Grassley's November 13, 2007 letter to FDA Commissioner Andrew von Eschenbach and CMS Acting Administrator Kerry Weems follows here.

November 13, 2007

Dear Commissioner von Eschenbach and Acting Administrator Weems:

As Ranking Member of the Committee on Finance (Committee), I have a responsibility to the more than 80 million Americans who receive health care coverage under the Medicare and Medicaid programs to oversee the proper administration of these programs and ensure that taxpayer and beneficiary dollars are appropriately spent on safe and effective drugs and devices.

Last October, I began examining the issue of prescription drugs being sold on the market that have not yet been approved by the Food and Drug Administration (FDA or Agency). Unapproved drugs may pose heightened risks to the American people because their safety, efficacy, labeling, and quality have been not reviewed by the FDA. In a letter to the FDA dated October 11, 2007, I expressed concern about patient safety and noted reports that doctors and pharmacists may be under the impression that all prescription drugs they provide to their patients are FDA-approved.

In the last year, FDA has taken regulatory action against some manufacturers of unapproved drugs. However, according to FDA's own estimates, many more unapproved drugs remain on the market. Furthermore, I have been told that some companies are sending marketing representatives to doctors' offices to promote the use of their drugs, but doctors are not informed that they would be writing prescriptions for drugs that have not been approved by the FDA.

In addition, I have received allegations that Medicaid is being billed inappropriately for unapproved drugs. Medicaid funds cannot be used to pay for drugs that have been classified by the FDA's Drug Efficacy Study Implementation (DESI) program as less-than-effective (LTE) as well as drugs that are identical, related, or similar (IRS) to LTE drugs. All drug manufacturers who want their products to be eligible for Medicaid reimbursement must enter into a Medicaid Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS). To receive an agreement, the manufacturer must provide CMS with specific information regarding its drugs, including a complete list of National Drug Codes (NDCs) and the DESI Codes. The CMS Web site states that CMS compares that information to the information that the manufacturer provides to the FDA to determine if the drug meets the definition of a "covered outpatient drug" for the Medicaid Drug Rebate Program. Yet, I have received troubling allegations that some companies have placed invalid National Drug Codes (NDCs) on the labels of their products, and Medicaid has been billed using these codes.

I brought these allegations to the attention of the Department of Justice (DOJ) in a question for the nomination hearing of Judge Mukasey for Attorney General. If the allegations are true, then not only do we need to strengthen efforts to protect patient safety, but the federal government also should be recouping monies paid for these unapproved drugs. DOJ as well as CMS, FDA, and the Department of Health and Human Services Office of Inspector General (HHS OIG) should be playing key roles in such efforts.

In light of the serious concerns and issues related to the marketing of unapproved prescription drugs, I request that CMS and FDA arrange a joint briefing for my Committee staff by no later than November 21, 2007, to address the allegations discussed in this letter. Please ensure that your staffs are also prepared to respond to the following questions and requests for information:

1. Please provide an overview of current efforts by the CMS and/or FDA to investigate and recover Medicaid and/or Medicare monies paid for unapproved drugs.

2. Please describe how CMS and FDA work with DOJ and HHS OIG to understand and investigate allegations of fraud involving unapproved drugs.

3. In its response dated December 11, 2006, the FDA acknowledged limitations in the accuracy of its Drug Registration and Listing System (DRLS), but stated that the Agency relied on that system as its primary source of knowledge regarding unapproved drugs on the market. In addition to the private data systems cited in FDA's response, does the Agency also compare what is in the DRLS with CMS data on what drugs Medicare and/or Medicaid has actually paid for in the past year?

4. In its December 2006 response, the FDA stated that under the Agency's DESI program, the Agency conducts retrospective evaluations of the effectiveness of drugs previously approved for safety alone from 1938 to 1962. Please describe in detail how FDA determines which DESI classification to assign to a drug approved between 1938 and 1962.

5. According to CMS's Medicare Part D Manual, "the vast majority of the DESI proceedings [for drugs previously approved for safety from 1938 to 1962] have been concluded, but a few are still pending." As of the date of this letter, how many proceedings are pending? What is the status of the pending DESI proceedings?

6. Over the last five years, how often, if at all, has CMS detected or been informed that Medicaid has been inappropriately billed for unapproved drugs? In particular, how often, if at all, has CMS detected or been informed that invalid NDCs have been submitted to CMS?

7. How often, if at all, has FDA detected/identified or been informed or advised in any matter of invalid NDCs that have been submitted to CMS over the last five years?

8. FDA's Website states that the DESI program "ensures that drug products available to Medicaid patients are effective for their intended uses and that federal funds are not expended for drugs that are not maximally effective. The [Division of Compliance Risk Management] reviews various agency publications and documents on a quarterly basis to determine the effectiveness of marketed drug products." In CMS's Release No. 144 regarding changes in drug coverage status/DESI code change, CMS states that labelers had provided inaccurate DESI codes for the listed NDCs as determined by the FDA.[1] Did the FDA identify the incorrect DESI codes in the course of its quarterly review of the effectiveness of marketed drugs or was the Agency informed of the inaccuracies by a third party?

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

Sincerely,
Charles E. Grassley
Ranking Member

CC: The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services

The Honorable Michael B. Mukasey
Attorney General
U.S. Department of Justice

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[1] Available at www.cms.hhs.gov/DeficitReductionAct/Downloads/rel144.pdf