U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Monday, July 26, 2004

Grassley Seeks Agency Action on Drug Company Overcharges

WASHINGTON -- Sen. Chuck Grassley, chairman of the Committee on Finance, has asked Secretary Tommy Thompson, Department of Health and Human Services (HHS), and Administrator Elizabeth Duke, Health Resources and Services Administration (HRSA), to describe what action HRSA has taken to recover overcharges from drug companies.

Grassley pointed to reports issued in June, and another last year, by the Inspector General for HHS. The Inspector General found that during a single month in 2002, public hospitals and clinics participating in HRSA's 340B drug discount program for low-income patients overpaid drug companies more than $41 million for prescription drugs. Last year, the OIG reported that five drug companies overcharged 340B-covered entities $6.1 million for sales of 11 drugs during a single year.

"In light of the pennies-on-the-dollar settlements some drug companies have paid to settle federal government cases in recent years, it seems to me the taxpayers continually are being taken to the cleaners," Grassley said. "At some point the federal government needs to say enough is enough and put some real teeth into regulating its drug programs."

The text of Grassley's letter follows. The relevant reports are attached.

July 23, 2004

The Honorable Tommy G. Thompson
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Elizabeth M. Duke, Ph.D.
Administrator
Health Resources and Services Administration
U.S. Department of Health & Human Services

Room 14-05 Fishers Lane
Rockville, MD 20857

Dear Secretary Thompson and Administrator Duke:

The Committee on Finance (Committee) is taking a close look at the drug pricing practices of many drug companies participating in federal health care programs. Earlier this month the Department of Health & Human Services (HHS), Office of Inspector General (OIG) issued two reports after inspecting the administration of the 340B Drug Discount Program (340B program). (1) According to the OIG: "We conducted these inspections because of concerns about the appropriateness of prices that 340B covered entities are paying for outpatient drugs and the efficiency of the program's administration." The New York Times summarized the OIG's findings straightforwardly, stating "that drug companies had repeatedly overcharged public hospitals and clinics for low-income patients, making them pay more than the maximum prices allowed by federal law."

The OIG found that during a single month in 2002, 340B entities overpaid drug companies more than $41 million for prescription drugs. As you are aware, this is not the first time the OIG found that drug companies overcharged 340B entities. In a report, dated March 10, 2003, the OIG stated:

"We estimated that five manufacturers, makers of the 11 prescription drugs in our review, overcharged 340B-covered entities $6.1 million for sales occurring during the 1-year period ending September 30, 1999. The overcharges occurred because the drug manufacturers inappropriately excluded sales to health maintenance organization (HMO) repackagers from their best price determinations, thereby increasing the prices charged to 340B entities. We are recommending that the Health Resources and Services Administration (HRSA) require the five drug manufacturers to identify the exact amount of the overcharges for each of the affected 340B-covered entities and apply the overcharge amounts as offsets or credits to each entity's future purchases."

HRSA fully concurred with the OIG's recommendation and outlined a plan for its implementation. HRSA's plan included determining if overcharges occurred in years outside the scope of the OIG's review and whether any other drugs were affected. As chairman of the Committee, I request that HRSA provide a complete, detailed, written accounting of how it did or did not implement the OIG's recommendations in this report. Please respond to the following questions specifically:

(1) In its comments to the report, HRSA stated that it was going to request the names of the five drug manufacturers and the eleven drugs examined in the report from the OIG-did the OIG provide that information to HRSA? If so, what drug companies were involved and what drugs were examined?

(2) What did HRSA find to be the full extent of misreporting best price to CMS?

(3) How many fiscal years were affected by misreporting?

(4) What other drugs and/or drug companies did HRSA identify?

(5) What was the total overcharge for each 340B entity?

(6) What refund or credit plan was developed for each 340B entity and what refund or credit was recovered from each drug company?

In addition, please provide copies of any and all correspondence between HRSA and any drug companies associated with HRSA's implementation of the OIG's recommendations. With respect to the OIG's recommendations in its report entitled, Appropriateness of 340B Drug Prices (OEI-05-02-00070), I am disturbed by the brevity of HRSA's response to them. Therefore, I request that HRSA provide a written explanation, which addresses the OIG's recommendations point by point, and elaborate on whether the recommendations will or will not be fully implemented.

It is also of great concern to me, Mr. Secretary, that the OIG believes: (1) that HRSA has no authority to enforce the terms of the Public Health Service Act; and (2) that your ability to require drug companies to reimburse 340B entities for discounts withheld and ability to terminate Pharmaceutical Pricing Agreements with drug companies are both "ineffectual." Please state whether you concur with the OIG's interpretation of your authority as Secretary of HHS. In addition, please explain why HRSA should not have the ability to impose fines and civil penalties on drug companies to ensure that 340B entities receive full discounts.

In light of the pennies-on-the-dollar settlements some drug companies have paid in recent years, it seems to me that America's taxpayers are continually being taken to the cleaners. At some point the Federal government needs to say enough is enough and put some real teeth into regulating its drug programs. Do you not agree?!
For your information, I am forwarding this letter and my concerns about whether drug companies are being investigated in association with the 340B program to the OIG and to the Department of Justice.

Thank you in advance for having your staff coordinate with my staff about this letter by July 28, 2004. And please provide the requested information, explanations and documents by August 18, 2004, unless it is available sooner. In responding to my requests, please repeat each enumerated request, followed by its accompanying response.

Sincerely,

Charles E. Grassley
Chairman

cc: John Ashcroft, Attorney General
Dara Corrigan, Acting Principal Deputy Inspector General

(1) Appropriateness of 340B Drug Prices (OEI -05-02-00070); *Deficiencies in the 340B Drug Discount Program s Database* (OEI -05-02-00071)