United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

September 1, 2005

Via Electronic Transmission
Original via USPS Mail

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

Dear Secretary Leavitt:

A year ago, I wrote former Secretary Tommy Thompson and Administrator Elizabeth Duke with concerns regarding the 340B Drug Discount Program (340B program) and the findings and recommendations of the Office of Inspector General (OIG), Department of Health and Human Services (HHS) related to the 340B program. Administrator Duke responded that the Health Resources and Services Administration (HRSA) had begun to take several actions to improve the 340B program and was developing a comprehensive plan to further strengthen the administration and effectiveness of the 340B program. In addition, she stated that "our plan has and will continue to consider the findings and recommendations in the OIG reports... ." As chairman of the Committee on Finance (Committee), I am concerned that HRSA has neither fully addressed the OIG's recommendations related to problems identified in the 340B program nor made substantial progress toward implementing its comprehensive plan.

In addition to implementing HRSA's plan, there are other important steps to be taken to strengthen the administration of the 340B program. For example, it has come to the Committee's attention that the Office of Pharmacy Affairs (OPA) within HRSA has not had access to the 340B ceiling price data maintained by the Centers for Medicare and Medicaid Services (CMS) for almost a year. It is disturbing that the agency responsible for ensuring that drug companies charge appropriate 340B prices lacks the pricing data to monitor the program.

Beyond concerns regarding the administration of the program, the OIG also found that the 340B program and the Medicaid rebate program were suffering substantial losses due to inaccurate reporting of pricing data by drug companies. A drug pricing violation under the Medicaid rebate program attributable to overstated "best price" may also signal a violation under the 340B program. Recent Medicaid settlements have included substantial payments to the 340B program. For example:

- GlaxoSmithKline [GSK], agreed to pay $88 million to resolve its liability for alleged violations of the Medicaid drug rebate program... [and] also agreed to pay the 340B covered entities $2.5 million to resolve corresponding overcharges.
- Bayer Corporation paid $257 million plus interest as part of a global settlement... [to resolve] allegations that Bayer failed to report accurate best price data. Bayer also agreed to pay the 340B covered entities $9 million for alleged overcharges.
- Schering-Plough Corporation agreed to pay a total of more than $345 million arising from the allegations of fraud against the Medicaid drug rebate and 340B programs... [and] agreed to pay $10.6 million to 340B covered entities.

In response to my letter, Administrator Duke stated that HRSA was sending letters to four drug companies—Aventis, Bristol-Myers Squibb, GSK, and TAP Pharmaceuticals—requesting that each develop "corrective action plans" for refunding or crediting the entities affected by overcharges. It is my understanding that, with the exception of GSK's product Flonase,[1] these companies have not issued refunds to 340B providers or indicated to HRSA that they intend to do so. Likewise, I understand that these companies have not followed through on HRSA's request to determine whether they overcharged 340B entities for other products.

While 340B providers are now being included in best price settlements, I am concerned that there is no mechanism in place to ensure that 340B providers are credited in routine cases where drug companies have recalculated their best price and have sent refunds to the Medicaid program. What steps has HHS/CMS taken to ensure that when drug companies retroactively issue refunds to the Medicaid rebate program, similar refunds are provided to 340B providers?

The Committee is also aware of other problems that hamper the 340B program. As a condition of Medicaid coverage, drug companies are expressly required to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary.[2] The PPA obligates the drug company to charge discounted 340B prices for its products to qualified 340B covered entities. Additionally, the PPA states that "If the Secretary believes that the manufacturer has not complied with the provisions of the Agreement, ... the Secretary may initiate the informal dispute resolution process." According to the OIG, however, no Secretary has ever initiated the dispute resolution process. Further, it has been brought to the attention of the Committee that not all drug companies have entered into PPAs. Some drug companies allegedly assert that not all components of their business, e.g., subsidiary companies, are subject to 340B pricing. Other drug companies allegedly refuse to make certain drugs available to 340B providers at discounted 340B prices. Apparently, these

[1] Specifically, 340B overcharges during fiscal year 1999 for the drug Flonase were refunded to covered entities pursuant to a settlement agreement executed between GSK and the Department of Justice (DOJ) in April 2003. Repayment of 340B overcharges for another GSK drug (Paxil)—the subject of a March 2003 OIG report—were also required under the DOJ settlement, but for a different time period than the fiscal 1999 period to which the March 2003 OIG report pertains.

[2] Under 42 U.S.C. § 256b(a)(1) and § 1927(a)(5) of the Social Security Act, 42 U.S.C. § 1396r-8(a)(5).

drug companies argue that their drug supplies are committed to other purchasers under commercial contracts. Therefore, product "shortages" prevent sales of these products to 340B purchasers at statutory discounts. Simply said, however, drug companies should not be dictating the terms of their PPAs with the Secretary at the expense of taxpayers.

The aforementioned findings and allegations suggest systemic problems in the 340B program beyond the concerns expressed in my letter to Secretary Thompson and Administrator Duke. Given the importance of accurate reporting of best price data under the Medicaid rebate program and the impact of inaccurate reporting on overcharges under the 340B program, CMS and HRSA should be working together to address these issues. I understand that CMS and HRSA have been working together on 340B matters, including data sharing and Medicare Part D implementation. I encourage you to consider forming an interagency task force to address the OIG's recommendations and other issues identified in this letter. It would be advisable, of course, for the task force to regularly meet with the various stakeholders in the 340B program, including drug company representatives and 340B covered entities. Please let me know your position on forming a 340B task force.

With the new Medicare prescription drug benefit set to launch in January, it is absolutely essential that the Federal government prove itself capable of enforcing the requirements of its existing drug programs in an efficient and timely manner. Accordingly, please address in your response whether PPAs need to be revised and strengthened, in order to assure that they can be used as effective tools in enforcing drug companies' obligations under the 340B program and preventing circumvention of Congress's clear intent that qualified 340B providers be able to purchase drugs at deeply discounted prices. Further delay in pursuing these matters is unjust to the American taxpayers who ultimately fund the public hospitals and other government-supported providers entitled to 340B discounts.

Thank you in advance for having your staff coordinate with my staff about this letter by September 9, 2005. I would appreciate your response by October 3, 2005, unless it is available sooner. For your information, copies of this letter were sent to CMS, HRSA and the OIG; attached is a separate letter sent directly to Administrator Duke.

Any questions or concerns should be directed to

All formal correspondence should be sent electronically in PDF searchable format to

All original material should be sent via USPS mail. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley
Chairman

cc: Administrator Duke
Administrator McClellan
Inspector General Levinson