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

September 1, 2005

Via Electronic Transmission
Original via USPS Mail

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 Administrator Duke:

A year ago, I wrote former Secretary Tommy Thompson and you with my 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. You responded on behalf of Secretary Thompson and stated 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, you 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 writing to request a follow-up status report on the implementation of HRSA's plan and additional information and documents related to the 340B program.

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, you 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.

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 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 to

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[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).

you last year. Accordingly, as chairman of the Committee, I request detailed responses to the following requests for information and documents. In responding, please repeat each enumerated request, followed by its accompanying response.

1. With respect to the OIG's body of work related to the 340B program, I am requesting by separate letter that the OIG compile a comprehensive list of recommendations and forward it to HRSA and the Committee, along with the date of each recommendation and the OIG's knowledge of the status of each recommendation as of the date of this letter. Provide a written response to each OIG recommendation, addressing them point by point and explain in detail whether the recommendations have or have not been fully implemented. Finally, if any recommendation will not be fully implemented, provide a detailed explanation for this decision and the policy rationale behind it.

2. Provide a detailed description of HRSA's past efforts and future plans to address the following OIG findings[3]:
   a) HRSA's oversight of the 340B program is inadequate.
   b) 340B entities cannot confirm whether they receive the correct discount because the pricing information is confidential and therefore they must assume that the drug companies' reported price is compliant with the law.
   c) Drug companies' drug price calculations are not verified by either HRSA or CMS.

3. In its comments to the OIG's report,[4] HRSA stated that it was going to request the names of the five drug companies and the eleven drugs examined by the OIG:
   a) State what drugs were examined and what HRSA found to be the full extent of misreporting of best price to CMS.
   b) State how many fiscal years were affected by misreporting.
   c) State whether HRSA identified any other drugs and/or drug companies affected by misreporting.
   d) State the total overcharge for each 340B entity involved.
   e) Describe in detail the refund or credit plan developed for each 340B entity and what refund or credit was recovered from each of the 5 drug companies.

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[3] *Appropriateness of 340B Drug Prices* (OEI -05-02-00070), June 2004. On October 21, 2004, the OIG withdrew this report because of problems with the underlying data used in developing the report's findings. The OIG issued a memorandum to the Administrators of CMS and HRSA, which stated: "The OIG is currently reviewing the data contained in the report. Once the review is complete, any revisions, if appropriate, will be made and the report will be reissued."

[4] *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities* (A-06-01-00060), March 2003.

f) For each of the 5 drug companies, state whether the company has been cooperative or uncooperative with HRSA's requests for information.

In responding to this request, respond with HRSA's actions, findings and determinations made to date.

4. Provide copies of all correspondence, including but not limited to letters and emails, between HRSA and all drug companies related to identifying, determining, and/or recovering drug company overcharges to 340B covered entities.

5. Provide a status report on the negotiations between HRSA and CMS related to 340B ceiling price data. In addition, state the time period to be covered by the pending inter-agency agreement and how soon another agreement will have to be negotiated. Finally, describe in detail why it has taken so long to reach an agreement and state what action will be taken to ensure that OPA will have access to the 340B ceiling price data on a permanent basis.

6. State whether HRSA is aware of any drug companies that have not executed a PPA.

7. State whether HRSA is aware of any drug company that has asserted the position that under its PPA not all components of its business, e.g., subsidiary companies, are subject to a 340B pricing. In addition, identify all drug companies asserting this position and provide copies of all correspondence, including but not limited to letters and emails, between HRSA and all drug companies related to this issue. Finally, state HRSA's program policy with respect to this issue.

8. State whether allegations related to drug companies refusing to make certain drugs available to 340B providers at discounted 340B prices have been raised to or within HRSA, and what action, if any, HRSA has taken or considered to address them. In addition, identify all drug companies and the drug(s) associated with any such allegation and provide copies of all correspondence, including but not limited to letters and emails, between HRSA and all drug companies related to this issue. Finally, state HRSA's program policy with respect to this issue.

9. Provide a detailed explanation of HRSA's efforts to recover from drug companies the drug overcharges identified in the OIG's March 2001 report (*Medicaid Drug Rebates–Sales to Repackagers Excluded from Best Price Determination* (A-06-00-00056)), including the status of any settlement arrangements.

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. If any of the enumerated requests for information or

documents should be directed more appropriately to HHS or to any other agency within HHS, I request that you inform my staff immediately and direct that request to the appropriate departmental agency. 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: Secretary Leavitt
Administrator McClellan
Inspector General Levinson