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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

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September 28, 2012

Victor Dzau
Chief Executive Officer
Duke University Health System
2301 Erwin Road
Durham, NC 27710

Dear Mr. Dzau:

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers within our nation's health care safety net (covered entities) have access to outpatient drugs at or below statutorily defined ceiling prices.¹ 340B discounts are available for outpatient drugs only. Drugs used in the inpatient setting do not qualify for savings under the 340B program. The original intent of the program was to extend the Medicaid drug discount to the most vulnerable of patients at PHS Clinics, those who are mostly "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."²

In its September 2011 report on the 340B program, the Government Accountability Office (GAO) notes an inadequate level of oversight by the Health Resources and Services Administration (HRSA) and a lack of necessary direction on program requirements. Of greatest concern is the GAO finding that "the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater." As the improper use of the 340B program increases, so does the financial liability to the federal government. The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize covered entities for providing inpatient services to those who are

¹ 42 U.S.C. 256b.

² Public Health Clinic Prudent Pharmaceutical Purchasing Act, Committee Report to Accompany S. 1729, 102-259, Senate Committee on Labor and Human Resources, March 3, 1992.

covered by private insurance, Medicare, or Medicaid. As such, I have been examining the 340B program.

On September 22, 2012, the News and Observer ran an article entitled *N.C. non-profit hospitals make big money on cancer mark-ups*.³ Specifically, the article references numerous cancer drugs that Duke University Health System has significantly marked-up and sold to its patients. For example, Duke University Health System collected seven times the average sales price for Cisplatin, a drug used to treat a variety of tumors, according to the article. Cisplatin is so cheap (\$1.80 per unit) that Medicare will only reimburse for the infusion fee but not the drug. However, Duke University Health System charges seven times the average sales price. Duke also was paid \$22,680 for a single dose of Avastin, a colon cancer drug. Yet it charged the patient \$32,400. Medicare would have allowed a maximum payment of only \$7,200.⁴

One reason Duke University Health System's huge mark-up of drug prices, as reported by the article, raises serious questions is that it is both a 340B covered entity and non-profit hospital. As such, it receives massive discounts, at manufacturers' expense, for these drugs. However, when selling these deeply discounted drugs, Duke University Health System does not seem to be passing those savings on to its patients. Instead, the 340B discounts appear to be simply subsidizing its bottom line operating margins. In fact, Duke University Health System has been generating record surpluses—\$542 million in 2011.⁵ If “non-profit” hospitals are essentially profiting from the 340B program without passing those savings to its patients, then the 340B program is not functioning as intended.

To help better understand Duke University Health System's participation in the 340B program, please provide the following documents and respond to the below inquires in writing by October 12, 2012:

1. Please provide a summary of all revenue received from participating in the 340B program from 2008, broken down by year.
2. Please explain whether, to what extent, and how Duke University Health System has reinvested those savings for the benefit of uninsured patients.
3. Please provide the payer mix for all 340B drugs from 2008-2012. Please list the price at which Duke University Health System purchased each 340B drug, and the price at which it sold the drug, per payer mix.

³ <http://www.newsobserver.com/2012/09/22/2361661/nc-nonprofit-hospitals-make-big.html>

⁴ <http://www.newsobserver.com/2012/09/22/2361661/nc-nonprofit-hospitals-make-big.html>

⁵ *Id.*

4. Please describe and provide documentation on Duke University Health System's indigent care population and composition. What is Duke University Health System's policy on charitable care? Please provide documents on Duke University Health System's charitable care policies.
5. Has the Health Resources and Services Administration ever audited Duke University Health System's 340B program?

Maintaining the integrity of the 340B program is of the utmost importance, and I trust that you share my concerns. If you have any questions regarding this request, please contact Erika Smith with the Senate Judiciary Committee at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member