

PATRICK J. LEAHY, VERMONT, CHAIRMAN

HERB KOHL, WISCONSIN
DIANNE FEINSTEIN, CALIFORNIA
CHARLES E. SCHUMER, NEW YORK
RICHARD J. DURBIN, ILLINOIS
SHELDON WHITEHOUSE, RHODE ISLAND
AMY KLOBUCHAR, MINNESOTA
AL FRANKEN, MINNESOTA
CHRISTOPHER A. COONS, DELAWARE
RICHARD BLUMENTHAL, CONNECTICUT

CHARLES E. GRASSLEY, IOWA
ORRIN G. HATCH, UTAH
JON KYL, ARIZONA
JEFF SESSIONS, ALABAMA
LINDSEY O. GRAHAM, SOUTH CAROLINA
JOHN CORNYN, TEXAS
MICHAEL S. LEE, UTAH
TOM COBURN, OKLAHOMA

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

BRUCE A. COHEN, *Chief Counsel and Staff Director*
KOLAN L. DAVIS, *Republican Chief Counsel and Staff Director*

September 28, 2012

Dr. William Roper
Chief Executive Officer
University of North Carolina Hospital
101 Manning Drive
Chapel Hill, NC 28025

Dear Dr. Roper:

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 University of North Carolina Hospital (UNC Hospital) has significantly marked-up and sold to its patients. For example, UNC Hospital was paid \$267 for a dose of taxol used to treat breast and ovarian cancer. That's more than 600 percent higher than the Medicare allowance of about \$36, according to the article. More shockingly is that UNC Hospital billed one patient \$9,184 for a dose of Doxorubicin. The patient had private insurance, which paid \$6,328 for the drug.

One reason UNC Hospital'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, UNC Hospital 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. 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 UNC Hospital's participation in the 340B program, please provide the following documents and respond to the below inquiries 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 UNC Hospital 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 UNC Hospital purchased each 340B drug, and the price at which it sold the drug, per payer mix.
4. Please describe and provide documentation on UNC Hospital's indigent care population and composition. What is UNC Hospital policy on charitable care? Please provide documents on UNC Hospital's charitable care policies.

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

5. Has the Health Resources and Services Administration ever audited UNC Hospital'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,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley
Ranking Member