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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

September 25, 2013

Mr. Paul Perreault
Chief Executive Officer and Managing Director
CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Dear Mr. Perreault:

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program required for all Medicaid participants 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 I have long supported the program and its goal, to extend the Medicaid drug discount to the most vulnerable of patients at covered entities, those who are mostly, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."²

The 340B program requires pharmaceutical manufacturers that want to sell their products to state Medicaid programs to agree to provide price discounts or rebates on covered outpatient drugs purchased by qualified covered entities. Pharmaceutical manufacturers agree to provide discounts to 340B qualified covered entities when they enter into pharmaceutical pricing agreements (PPAs) with the Secretary of the Department of Health and Human Services.³ Through these PPAs, the 340B program enables qualified covered entities to reduce their outpatient prescription drug expenditures and pass the deeply discounted drug to those patients in need of low cost prescription drugs.

¹ 42 U.S.C. 256b.

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

³ The Pharmaceutical Pricing Agreement is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf>.

On July 17, 2013, I was informed by a qualified covered entity in my state that your company failed to provide the 340B price for Kcentra, a CSL Behring product. CSL Behring claimed to my constituent that Kcentra “is not available at 340B pricing, due to the fact that it is an in-patient biotherapy.” However, my staff contacted the Health Resources Services Administration (HRSA), which oversees the 340B program, in an attempt to verify CSL Behring’s claim that it was not required to provide the 340B discount price.

On September 17, 2013, HRSA confirmed that “340B pricing should be available to eligible covered entities.”⁴ HRSA went on to say that:

HRSA has contacted the manufacturer and has confirmed that they are offering 340B pricing.

This drug is indicated in an acute major bleeding situation; therefore, its use in the outpatient setting may be limited. A covered entity may only request 340B pricing if the drug is used on an outpatient basis.⁵

As my constituent explained to your representative, the drug is used by hospitals in emergency settings when the patient first arrives and prior to being admitted as an inpatient, or instead of being admitted as an inpatient. Thus, according to HRSA guidance, it would qualify for 340B pricing in those instances.

To better understand CSL Behring’s compliance with its obligations to provide 340B pricing, please provide the following documents and response to the below inquires by October 9, 2013:

- 1) Why did a CSL Behring claim to my constituent that it was not required to provide 340B pricing in light of the information to the contrary provided by HRSA?
- 2) To how many other qualified 340B covered entities has CSL Behring failed to provide 340B pricing?
- 3) Has CSL Behring reimbursed any 340B covered entities for its failure to provide 340B pricing? If not, please explain why not and explain when the reimbursements will be processed.
- 4) What steps has CSL Behring taken to ensure that its sales representatives do not misrepresent its 340B pricing obligations to its customers?

⁴ September 20, 2013 email between Shannon Dunn, Health Resource Services Administration Office of Legislation, Leslie Atkinson, Health Resource Services Administration Office of Legislation, and Erika Long, Senior Investigator, Senate Judiciary Committee.

⁵ September 17, 2013 email between Shannon Dunn, Health Resource Services Administration Office of Legislation, Leslie Atkinson, Health Resource Services Administration Office of Legislation, and Erika Long, Senior Investigator, Senate Judiciary Committee.

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

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive style with a large, prominent "C" at the beginning.

Charles E. Grassley
Ranking Member
Committee on the Judiciary
U.S. Senate