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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

September 25, 2013

Dave Stack  
President, CEO and Chairman  
Pacira Pharmaceuticals  
5 Sylvan Way  
Parsippany, New Jersey 07054

Dear Mr. Stack:

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.<sup>1</sup> 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."<sup>2</sup>

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.<sup>3</sup> 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.

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 Exparel, a Pacira product. Pacira claimed to my

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<sup>1</sup> 42 U.S.C. 256b.

<sup>2</sup> 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.

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

constituent that it “does not participate” in the 340B program and as such would not be offering the qualified covered entity a discounted drug price. However, my staff contacted the Health Resources Services Administration (HRSA), which oversees the 340B program, in an attempt to verify Pacira’s claim that it was not required to provide the 340B discount price.

On September 20, 2013, HRSA confirmed that Pacira “does not participate in the Medicaid program, but *does voluntarily participate in the 340B program* and has signed a Pharmaceutical Pricing Agreement with HRSA. Under this PPA, Pacira *is required* to provide 340B pricing on covered outpatient drugs, including Exparel.”<sup>4</sup> HRSA went on to say that:

If Pacira did not provide an entity the 340B price, it has an obligation to repay the entity or could have its PPA terminated. Pacira has these obligations despite being a voluntary participant in 340B.

Even if Pacira has acquired the original PPA with HRSA from another manufacturer via a sale or merger, the 340B PPA conveys with any transfer of ownership.

HRSA has informed Pacira that, regardless of the fact that it is voluntarily participating in 340B, manufacturers that have a PPA with HRSA must provide the 340B ceiling price or repay covered entities. HRSA has further informed Pacira that it must provide HRSA with a plan to remedy the violation with respect to Exparel.

HRSA is actively monitoring the situation and is assessing whether Pacira has failed to provide 340B pricing on any other covered outpatient drugs.<sup>5</sup>

To better understand Pacira’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 Pacira sales representative 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 Pacira failed to provide 340B pricing?
- 3) Has Pacira 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.

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<sup>4</sup> 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 (emphasis added).

<sup>5</sup> *Id.*

- 4) What steps has Pacira taken to ensure that its sales representatives do not misrepresent its 340B pricing obligations to its customers?

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, flowing style.

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