Congress of the United States

Washington, DC 20510

March 5, 2012

John J. Castellani
President and Chief Executive Officer
Pharmaceutical Research and
Manufacturers of America (PhRMA)
950 F Street, NW
Suite 300
Washington, DC 20004

James C. Greenwood
Biotechnology Industry
Organization (BIO)
1201 Maryland Avenue, SW
Suite 900
Washington, DC 20024

Dear Mr. Castellani and Mr. Greenwood:

We are writing to you to request information to assist Congress in its oversight over the 340B drug discount program. We raise this issue as an area of mutual concern given the significant expansion of the program's scope in recent years and the risks of improper diversion and poor oversight recently identified by the Government Accountability Office (GAO).

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers, known as covered entities, within our nation's health care safety net have access to outpatient drugs at or below statutorily defined ceiling prices.[1] The original intent of the program was to extend the Medicaid drug discount to the most vulnerable patients receiving services at Public Health Service clinics, including individuals who are, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."[2]

The GAO report issued in September 2011 outlined several findings related to the 340B program that are concerning to us. The GAO also stated that Federal oversight of the program is "inadequate" to ensure that covered entities and manufacturers are in compliance with program requirements. With the reliance on self-policing among participating manufacturers and covered entities and the increase in the number of new settings in which the program is offered, the risk of improper purchases or diversion of 340B drugs has significantly increased. The problems

[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.

identified by the GAO as it relates to the oversight responsibilities of each party and the expansion of the program need resolution.

Therefore, to better understand how the program operates as it relates to these risks, to facilitate Congressional oversight over this important program, and to ensure that it is operating within the parameters of the law, we respectfully request that you please respond to the below inquiries in writing by March 15, 2012:

1. Have your associations issued comments or policy positions on the definition of a 340B patient to your membership or the Administration? If so, please provide copies.
2. Are you aware of any examples of diversion within the 340B program where discounted drugs are being transferred to facilities or individuals beyond a covered entity? If so, please identify them and provide any supporting materials.
3. Are you aware of any examples of diversion within the 340B program where drugs primarily used in an inpatient setting are being purchased for outpatient use? If so, please provide any available data and any supporting materials.
4. Are you aware of any audits of covered entities conducted by drug manufacturers to ensure program compliance? If so, please provide details on what companies conducted such audits and which covered entities were involved.
5. Have your associations provided information to the Health Resources and Services Administration regarding the incidents of hoarding of the 340B program. Specifically, please share examples when hoarding of a certain drug has disrupted market supply.
6. Do your associations provide any information to manufacturers related to verification of covered entity eligibility?
7. What information has either of your associations provided to your members to ensure covered entities can access 340B discounts for eligible products?
8. What protocols do your members have in place to ensure the avoidance of duplicative discounts and/or federal overpayments of drugs purchased at 340B prices?
9. Do your associations provide manufacturers any information related to the nondiscrimination requirement under the law to ensure covered entity access to 340B discounted products? If so, please provide those documents.

Further, we ask that you please provide the following documents:

1. Documents provided by your associations to the Government Accountability Office (GAO) during their most recent investigation of the 340B program.
2. Documents provided by your associations to the Health Resources Services Administration (HRSA) regarding any concerns of drug diversion or program misuse.
3. Documents provided to HRSA regarding audits conducted by companies that are members of your associations.
4. Materials you are able to access through the 340B University offered through the prime vendor program.

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 Heidi Stirrup with the House Energy and Commerce Committee at (202) 225-2927, Erika Smith with the Senate Judiciary Committee at (202) 224-5225, Riley Swinehart and Melissa Pfaff with the Senate Health, Education, Labor, and Pensions (HELP) Committee at (202) 224-6770 or Hayden Rhudy and Kimberly Brandt with the Senate Finance Committee at (202) 224-4515.

Sincerely,

Joe Pitts
Member of Congress

Michael Enzi
U.S. Senator

Orrin G. Hatch
U.S. Senator

Charles E. Grassley
U.S. Senator

cc: Ranking Member Frank Pallone
Health Subcommittee
House Energy and Commerce Committee

cc: Chairman Max Baucus
Senate Finance Committee

cc: Chairman Patrick Leahy
Senate Committee on the Judiciary

cc: Chairman Harkin
Senate Health, Education, Labor, and Pensions Committee