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RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

July 18, 2012

Mary K. Wakefield, BSN, MS, PhD
Administrator
Health Resources and Services Administration
Parklawn Building
5600 Fisher's Lane, Room 14-05
Rockville, MD 20857

Dear Administrator Wakefield:

As Members of the House Committee on Energy and Commerce with specific interest in the 340B Drug Pricing Program, we are writing regarding an issue that has created confusion and uncertainty for pharmaceutical manufacturers as well as 340B safety net providers, pharmacies, and beneficiaries alike. The outdated definition of a 340B patient has contributed to growing concerns with the integrity of the 340B program.

In its September 2011 report, the Government Accountability Office (GAO) found that "HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements." As such, GAO issued several recommendations to the Health Resources and Services Administration for consideration that would strengthen oversight of the program, including a "new, more specific guidance on the definition of a 340B patient."

As you know, the existing definition of a patient was issued in 1996. Since that time, the 340B program has nearly tripled in size. While the program has grown dramatically, oversight of the program has been mostly dependent on a self-policing model with little guidance from HRSA on the program's intent. In its report, GAO also noted: "guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent."

There is growing Congressional interest with the future of the 340B program and its merits in serving the nation's poor and most vulnerable Americans who need access to affordable

prescription drugs. Information received to date from various stakeholders reflects a program that has diverted from its original intent.

The 340B program, as established in the Public Health Service Act (PHSA), was intended to serve individuals who are "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services."[1] Therefore, we believe the definition of a patient must not only be clear in its direction but protective of the beneficiaries we hope the program will serve in the future. As such, we request that HRSA consider and issue an updated definition of a patient that ensures the program's eligibility is for those truly in need and curbs any misuse of the program.

If you have any questions regarding this request, please contact Heidi Stirrup with Chairman Pitts at (202) 225-2927 or Courtney Austin with Representative Cassidy at (202) 225-3901.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

Bill Cassidy, M.D.
Member
Subcommittee on Health

cc: The Honorable Fred Upton, Chairman

The Honorable Henry A. Waxman, Ranking Member

The Honorable Frank Pallone, Ranking Member
Subcommittee on Health

[1] 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.