June 18, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar,

The 340B Drug Pricing Program was created in 1992 to help qualifying hospitals and safety net clinics get access to discounted prescription medicines for uninsured or vulnerable patients. While this program was created to be a small component of the nation's safety net, the lack of adequate oversight has led to exponential growth in the 26 years since its enactment, leading to increased spending across the health care system and allowing many participating hospitals to prioritize profits over patients. We are writing to you today to applaud actions the Department of Health and Human Services (HHS) has already taken on the 340B program and request that HHS continue using its authority to fix the 340B program so patients, not hospitals, are the ones benefitting.

The undersigned organizations represent thousands of patients, providers, community advocates and taxpayers who are committed to fixing the 340B program. We recognize the important role the program plays for true safety net facilities such as federally qualified health centers, Ryan White HIV/AIDS clinics, black lung clinics, and other federal grantees and are dedicated to ensuring the program reaches the vulnerable or uninsured patients it was intended to help. Our organizations believe in fixing 340B so patients and true safety net facilities are the ones benefitting.

The 340B program has seen outsized growth in recent years, far surpassing the scope and size of the program as it was originally envisioned by Congress. It has grown from $6.9 billion in sales at the 340B price in 2012 to $19.3 billion in 2017, a nearly 200 percent increase in just 5 years.[i] From 2013 to 2017, the number of hospital entities participating in the program tripled.[ii] In 2017, 340B represented nearly 8 percent of branded outpatient drug sales.[iii] This growth has not been accompanied by evidence that patients are more likely to benefit from the 340B discounts. In fact, the program's growth is not associated with 340B hospitals providing additional safety-net services.[iv]

This explosive growth is set against a backdrop of historically weak oversight and lax program rules, which have allowed hospitals and middlemen to profit without any requirement that they help low-income patients. In contrast, grantees are required to redirect revenue from programs like 340B back to their grant services to the patients they serve. These lax standards for 340B DSH hospitals, which represent 80 percent of program sales,[v] are not only diverting money away from vulnerable patients, but are allowing the 340B program to drive up health care costs and cut off convenient options for care.

Economists writing in the *Journal of the American Medical Association* found the 340B program may cause a "shift toward more expensive drugs because profit margins will in general be larger,"[vi] due to the "spread" hospitals can make on the program. Additionally, the Community Oncology Alliance[vii] has shown that to generate more profit through increased 340B prescriptions, 340B hospitals are acquiring independent community practices at an alarming rate and consolidating care into the costlier hospital setting – where treatment is 60 percent

more expensive than in a community clinic.[viii] This trend results in patients being forced to pay more in a hospital setting and having to incur higher cost sharing.

By utilizing the authority the administration already has to provide the needed oversight that the HHS Office of the Inspector General and Government Accountability Office agree the program needs, this administration has a chance to protect patients from rising drug prices and an ineffective bureaucracy.

The 340B program must be fixed to ensure that it is helping and not hurting patients within DSH hospital settings and is protecting community providers. The administration has taken an important first step towards lowering Americans' drug prices through the 340B policies outlined in the "American Patients First" blueprint. We urge the administration to take action and consider reforms to the 340B program as part of their plan. Economists have specifically recommended that "lawmakers could lower the price of prescription drugs by reforming the federal 340B Drug Pricing Program."[ix]

Our organizations are dedicated to fixing the 340B program so it can benefit the patients it was created to serve. We hope HHS will harness its current authorities to provide increased oversight of the 340B program via guidance or other means, and clarify the program's vague rules so that it operates in the best interests of patients, not hospital profits.

We are happy to answer any follow-up questions from your office and would be more than willing to meet to discuss this important issue.

Sincerely,

AIDS Response Seacoast
Alzheimer's Texas
Americans for Tax Reform
Arizona Bioindustry Association, Inc.
Arthritis Associates PLLC
Asthma and Allergy Foundation of America - New England Chapter
Biocom
BioForward WI
BioNJ
Bioscience Association of North Dakota
California Association of Area Agencies on Aging
California Health Collaborative
California Hepatitis C Task Force
CancerCare
Citizens Against Government Waste
Colorado BioScience Association
Colorectal Cancer Alliance
Cutaneous Lymphoma Foundation
Glut1 Deficiency Foundation
HERO House
Illinois Biotechnology Innovation Organization
INDUNIV Research Center, Inc/Bio Alliance PR
International Association of Hepatitis Task Forces
International Cancer Advocacy Network
International Foundation for Autoimmune & Autoinflammatory Arthritis

Iowa Biotechnology Association
Kentucky Life Sciences Council
Log Cabin Republicans
Lupus and Allied Diseases Association
Lupus Foundation New England
Lupus Foundation of America
Medical Oncology Association of Southern California, Inc.
Mental Health Association of Middle Tennessee
MichBio
Montana BioScience Alliance
National Grange
National Infusion Center Association
National Taxpayers Union
New Mexico Biotechnology & Biomedical Association
Northwest Parkinson's Foundation
One in Four Chronic Health
Prescription Drug Assistance Network
RetireSafe
Rheumatoid Arthritis Support Group of Central Oregon
Rheumatology Nurses Society
SC Manufacturers Alliance
SCBIO
Scleroderma Foundation Washington Evergreen Chapter
Sherie Hildreth Ovarian Cancer Foundation
South Carolina Cancer Alliance
Southeast Alabama Sickle Cell Association, Inc.
Texas Healthcare and Bioscience Institute
The ALS Association Evergreen Chapter
Transplant Recipients International Organization of the Pacific Northwest
Valley AIDS Information Network
Washington State Alliance for Retired Americans
Washington State Oral Health Coalition
Wyoming Epilepsy Association

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[i] http://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html
[ii] https://www.help.senate.gov/imo/media/doc/Draper1.pdf
[iii] https://www.thinkbrg.com/media/publication/928_928_Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf
[iv] S. Desai, J McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018; 378:539-548.
[v] Chris Hatwig, Apexus Update – 340B Health Summer Conference, July 2016.
[vi] R. Conti, P. Bach, Cost Consequences of the 340B Drug Discount Program, JAMA : The Journal of the American Medical Association, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.
[vii] Community Oncology Alliance, "The Value of Community Oncology Site of Care Cost Analysis," September 2017. https://www.communityoncology.org/wp-content/uploads/2017/09/Site-of-Care-Cost-Analysis-White-Paper_9.25.17.pdf
[viii] Ibid,.
[ix] R. Conti and M. Rosenthal, "Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation," N Engl J Med 2016; 374:703-706.