



October 1, 2020

AbbVie
Attn: **Tara Southwell**, Gov't Affair Director
Therapeutic Area Strategies, Oncology & Specialty
1 North Waukegan Road
North Chicago, IL 60064

Janssen Global Services | Johnson & Johnson
Attn: **Marcus Wilson**, Director
National Policy & Advocacy
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Theratechnologies
Attn: **Jonathan Haas**, Director
Market Access National Business
2015 rue Peel, Bureau 1100
Montréal (Québec) H3A 1T8, Canada

Gilead Sciences
Attn: **Coy Stout**, Vice President
US Commercial Access & Reimbursement
333 Lakeside Drive
Foster City, CA 94404

Merck
Attn: **Phil Rinnander**, Executive Director
Global Human Health Finance
351 N Sumneytown Pike
North Wales, PA 19454

ViiV Healthcare
Attn: **Lynn M. Baxter**, Senior Vice President
Head of North America ViiV Healthcare
5 Moore Drive
Research Triangle Park, NC 27709

RE: INDUSTRY'S PROPOSED CHANGES TO 340B DRUG DISCOUNT PROGRAM

Dear Colleagues,

The ADAP Advocacy Association and the Community Access National Network ("CANN") are deeply concerned over the pharmaceutical industry's proposed changes to the 340B Drug Discount Program. Our concerns that any attempt to limit the discounts through contract pharmacies or increase data collection requirements could have adverse impact on certain Covered Entities, namely the Ryan White Clinics serving clients living with HIV/AIDS. We write to voice our collective concern on how the proposed changes would affect smaller AIDS Service Organizations ("ASOs") and community-based organizations ("CBOs") who use contract pharmacies. We urge you to adopt a carve-out for Ryan White Clinics, thus avoiding possible damaging effects on the safety-net programs crucial to the HIV-positive community.

RE: INDUSTRY’S PROPOSED CHANGES TO 340B DRUG DISCOUNT PROGRAM

Ryan White Clinics cannot afford to get stuck in the crossfire between pharmaceutical companies and contract pharmacies. The access-to-care and service-provider-networks developed from scratch by AIDS advocates in the 1980s and 1990s remain critical to the national system of care developed under the original Ryan White CARE Act legislation. In particular, many smaller ASOs also remain critical to underserved populations and impoverished areas, especially in the rural South.

ASOs will have to make arrangements for the necessary expertise and services to comply with the proposed changes, and in most cases smaller ASOs are unlikely to afford them. In today’s treatment-driven world of HIV care, access to anti-retroviral medication is by far the most essential link to effective care. However, many ASOs lack the capital and resources to open their own pharmacies. Thus, contract pharmacy services all too often provide that essential link.

The patchwork of existing federal regulations and guidance on exactly what business arrangements might be appropriate are somewhat lacking from the U.S. Department of Health & Human Services’ (“HHS”) Health Resources and Services Administration (“HRSA”); whereas larger organizations may possess enough business volume to insure equitable and fair contracts many CBOs lack the capital, staff resources, and the legal expertise to engage fairly in the complexities of the current drug distribution system. This is particularly true for many federally funded safety-net programs. Both the ADAP Advocacy Association and Community Access National Network speak from decades of experience in the HIV care continuum but recognize that similar circumstances may exist for other patient populations.

Some of the proposed changes to 340B – as currently understood – seek to address the problems associated with the rapid expansion of contract pharmacies by adding new procedures, reporting requirements and other changes for organizations who do not have their own pharmacies, including ASOs. These community-based service providers are already burdened with ever-changing funding streams and under-funded public health infrastructure. Any attempt to limit access to 340B-related discounts, or impose new reporting requirements would cause irrevocable damage to the fragile safety net serving the HIV community

Over the decades the HIV advocacy community and pharmaceutical industry have negotiated many arrangements to ensure access to care and treatment for the HIV-positive patient population living in the United States. Many of the arrangements still exist today, but they could be inadvertently weakened by these proposed changes.

With the aforementioned concerns in mind, we respectfully request that any proposed changes to the 340B Drug Discount Program include a designated carve out for federally funded safety-net programs, such as Ryan White Clinics. Now is not the time to weaken or undermine the HIV care delivery system.

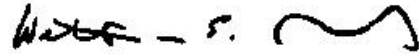
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Please feel free to contact us at brandon@macsata.org and weaids@ticann.org. Thank you.

Respectfully submitted,



Brandon M. Macsata
CEO
ADAP Advocacy Association
PO Box 846
Nags Head, NC 27959



William E. Arnold
President & CEO
Community Access National Network
1724 Florida Avenue, NW
Washington, DC 20009