December 11, 2019

Members of the House:

We are writing on behalf of governmental public health organizations representing the nation's public health officials with oversight for HIV, hepatitis, and sexually transmitted diseases (STDs) to support HR3, the *Lower Drug Costs Now Act*. the National Alliance of State & Territorial AIDS Directors (NASTAD) represents public health officials overseeing HIV and hepatitis programs in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, seven local jurisdictions receiving direct funding from the Centers for Disease Control and Prevention (CDC), and the U.S. Pacific Island jurisdictions. NASTAD's singular mission is to end the intersecting epidemics of HIV, viral hepatitis, and related conditions. The National Coalition of STD Directors (NCSD) represents health department STD directors, their support staff, and community-based partners across 50 states, seven large cities, and eight US territories. NCSD's mission is to advance effective STD prevention programs and services in every community across the country.

We believe that legislative efforts to reduce the high cost of drugs in this country are imperative to our ability to address HIV, hepatitis, and STDs. The high and increasing prices for critical public health medications – including HIV antiretrovirals used to both treat and prevent HIV infection, hepatitis C direct acting antivirals that cure hepatitis C, and essential STD treatments – hinder the ability of state and local health departments to purchase and deliver these drugs in public health settings. We applaud efforts in both the House and Senate to create legislation that reins in drug list prices, penalizes manufacturers for price hikes, and reduces consumer out-of-pocket costs for Medicare Part D. We urge Members of the House to consider the following:

High list prices must be reduced to increase access to medications to vulnerable populations

We support HR3's provisions selecting a number of drugs for direct government negotiation and setting parameters for a maximum fair price across Medicare, individual, and group health coverage. We believe this intervention is necessary given the failure of the market to create a fair, transparent, and efficient mechanism for the pricing of many brand-name drugs without interchangeable multiple-source generics, including HIV antiretrovirals and critical STD medications. For example, the mean average price of recommended initial regimens for most people with HIV in 2019 is more than $3,600 a month–a 77% increase over the mean price for standard-of-care options in 2009.

Similarly, we support inflation penalties in the Medicare Part B and D programs aimed at curbing drug prices that outpace inflation. HIV antiretrovirals are typically subject to annual price increases of 6% to 9%, far exceeding the Consumer Price Index for All Urban Consumers (CPI-U). While these price increases trigger additional rebates to ensure cost containment for federal purchasers and state Medicaid programs, Medicare is not afforded statutorily defined protections. Also consider Bicillin L-A, the preferred treatment for primary, secondary, and early latent syphyilis. Since its launch in 2006 at an

average wholesale price (AWP) of $25 per 4 mL unit, the price has nearly quadrupled to more than $96 per unit.

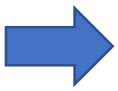
Despite an intricate patchwork of public and private programs to maximize access to costly prescription drugs for diseases of public health significance, increasing list prices have been a barrier to sustainable, widespread access, particularly for vulnerable populations. We need bold efforts to address our broken drug pricing system, which adversely affects people living with, and at risk for, HIV, STDs, and viral hepatitis.

As list prices are reduced, savings must be reinvested to preserve the public health safety net

We support the detailed plan released for reinvestment of savings generated from HR3 to expand Medicare benefits, fund programs to address health workforce shortages, and invest necessary resources to NIH for research and development. We also urge members of Congress to consider the unintended consequences of drug pricing reforms that reduce list prices, particularly on the impact to 340B Ryan HIV/AIDS Program (RWHAP) grantees and STD and other 318 grantee clinics. Any drug pricing provision that dramatically reduces list prices must take into account the decreased savings public health 340B entities are able to reinvest in critical programs and services. These savings constitute non-federal resources for these entities. We therefore urge Congress to reinvest savings generated from drug pricing reforms to ensure that RWHAP grantee and 318/STD clinic 340B entities are able to continue to provide vital services.

The current system of HIV care and prevention depends on the program income generated through 340B to provide vital care, prevention, and support services that cannot otherwise be financed by federal dollars or health insurance billing. The below chart illustrates the program income differential for just one ARV with an estimated ~$20,000 U.S. list price and includes analysis across the six countries proposed for comparison in HR3.

Price Comparison for Example ARV	
U.S. estimated AMP price	$20,000
U.S. estimated 340B discounted price	$10,200
U.S. price at the 120% cap	$10,140
Australia price	$6,500
Canada price	$5,300
France price	$9,000
Germany price	$10,500
Japan price	$10, 900
United Kingdom price	$8,400



Estimated 340B savings generated at current U.S. AMP price	~$9,800
Estimated 340B savings generated at 120% cap-adjust price	~$2,300

While reducing list prices is crucial, it is also important to ensure that we preserve the HIV care and prevention infrastructure currently being funded via 340B savings. HHS Assistant Secretary for Health Admiral Brett Giroir has noted the significant role the 340B program will play in the Ending the HIV Epidemic initiative, particularly with the recent expansion of 340B eligible prevention grantees. Specifically, HHS intends “to use the 340B program, which allows [pre-exposure prophylaxis] PrEP to be obtained at a much lower cost to the government” to expand access so more patients can obtain HIV

preventive care. Without specific reinvestment of drug pricing reform savings, 340B covered entities will not have the resources to engage communities that would benefit from increased access to PrEP. Similarly, RWHAP grantees, including AIDS Drug Assistance Programs (ADAPs), have helped to address the myriad barriers that keep people living with HIV from achieving viral suppression by investing savings generated from 340B into core services. Comprehensive drug pricing reforms may mean that the entire financing model for these public health programs should change, and we urge Congress to ensure stability in these vital programs as these changes occur, and we transition to a sustainable financing model.

Similarly, we urge Congress to assess the impact of any proposed drug pricing proposal on Medicaid. As a study developed by Milliman indicates changes in the list price to some Medicaid drugs may inadvertently increase the net price in the Medicaid program (see Milliman, *Impact of potential changes to the treatment of manufacturer rebates*, January 2019). Careful attention must be paid to both intended and unintended consequences of the direct regulation of drug list prices, including solutions for instances where vital safety net programs may see overall funding losses.

Consumer out-of-pocket costs in Medicare Part D must be lowered

We support the provisions in HR3 that expands access to Medicare's Low-income Subsidy (LIS) program and Medicare Savings Program (MSP). As more people living with and at higher risk for HIV age into the Medicare program, the high out-of-pocket costs associated with medications has become a significant barrier to care and treatment. Similarly, hepatitis C direct acting antivirals are typically covered on a Part D plan's specialty tier, with significant consumer cost sharing. We strongly support provisions that cap consumer out-of-pocket spending in Medicare Part D.

Please contact Amy Killelea at NASTAD (akillelea@nastad.org) or Stephanie Arnold Pang at NCSD (sarnold@ncsddc.org) if we can be of assistance.

Sincerely,

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NASTAD

Sincerely,

David C. Harvey, Executive Director
National Coalition of STD Directors