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December 11, 2017

The Honorable Lamar Alexander
Chairman
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Alexander and Murray:

On behalf of the HIV Medicine Association, thank you for holding the full committee hearing on “The Cost of Prescription Drugs: An Examination of The National Academies of Sciences, Engineering, and Medicine Report *Making Medicines Affordable: A National Imperative.*” HIVMA represents more than 5,000 physicians, researchers and other healthcare professionals working on the frontlines of the HIV epidemic in communities across the country.

HIVMA agrees with the National Academy of Medicine report’s conclusion that, “the impact of the unaffordability of prescription drugs on people in the United States is very clear: it ultimately harms people’s health, sometimes even resulting in death.” As HIV and infectious diseases specialists, we see firsthand how high drug prices can impede access to treatment. We too, like the report authors, recognize the important role the drug industry plays in drug development and innovation and appreciate the need for a balanced approach to addressing drug prices. We are optimistic that, working collaboratively, industry, health insurers, providers, policymakers and other stakeholders can identify solutions that improve access to critical medications without compromising drug development.

We write today to highlight a case study that illustrates how high drug prices can negatively impact public health. Specifically, the price and shortage of benzathine penicillin G (BPG) (brand name Bicillin LA) are impeding effective treatment of syphilis in some patients at a time when syphilis cases are spiking, including among pregnant women. BPG is the recommended treatment for syphilis, and the *only* recommended treatment for pregnant women exposed to syphilis. Treatment of sexually transmitted infections (STIs) is an important intervention not only for the health of the affected individual but also to prevent the spread of STIs to sexual partners and newborns.

Cases of syphilis and other STIs are increasing in the United States

Today, there is an urgent need to mount a much more aggressive response to the unprecedented rise in rates of STIs across the country, as described by the Centers for Disease Control and Prevention (CDC) in its annual Sexually Transmitted Disease Surveillance Report (September 2017). The CDC reported that more than 2 million cases of chlamydia, gonorrhea and syphilis were reported in the United States in 2016, the highest number ever. The majority of these new diagnoses (1.6 million) were cases of chlamydia, but there were also 470,000 new gonorrhea cases and almost 28,000 cases of primary and secondary syphilis. If left undiagnosed and untreated, all three of these preventable diseases can have serious health consequences, including infertility, life-threatening ectopic pregnancy, infant stillbirth, multisystem organ disease due to syphilis including ocular disease and neurosyphilis, and increased risk for HIV transmission.

Dr. Jonathan Mermin, director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, said that STIs are "outpacing our ability to respond." While the rise in reported syphilis diagnoses in the previous decade was primarily attributed to men who have sex with men, the rate of new diagnoses in 2015-2016 increased 36% among women and 28% among newborns. In 2016, there were more than 600 congenital syphilis cases, resulting in 40 infant deaths and severe health complications among the others. CDC said this "represents a tragic systems failure," noting a simple STI screening test and antibiotic treatment can prevent these consequences.

Given these findings, HIVMA and the Infectious Diseases Society of America have previously recommended the declaration of a *national public health emergency* to more urgently address this growing epidemic. One component of a comprehensive response to these issues is ensuring access to STI screening and affordable BPG treatment to cure syphilis, especially for at-risk populations. Improving access to this drug and incentivizing the expansion of its supply are paramount to reversing the course of this epidemic.

Price and supply are impeding access to curative treatment

Since May 2016, the Food and Drug Administration (FDA) has sounded the alarm about a dangerous shortage of BPG. This shortage seriously hampers efforts to treat syphilis. Currently there is only one supplier of BPG in the United States. Public and transparent engagement with that supplier is urgently needed among federal and local officials, advocates and professional organizations.

Even when BPG is available, however, its cost can be a barrier to accessing treatment that we urge you to address. Penicillin is an old and inexpensive drug that costs only pennies per dose to manufacture. Drug shortages have contributed to the manufacturer's price increases, resulting in skyrocketing prices. As an example, at an Atlanta-based clinic, the clinic's cost for BPG is \$318 per dose. As a consequence of BPG's high price, insurers are not fully covering provider costs or are not covering BPG at all. An internal analysis of the top ten major health insurers (Coventry, UnitedHealth, Aetna, Humana, Health Net, Molina, WellCare, Centene, Blue Cross Blue Shield, Cigna) demonstrated that a significant proportion of their formularies place BPG on their highest tier. This can increase out-of-pocket costs by hundreds of dollars, making the drug essentially unaffordable to patients, preventing them from becoming cured, and resulting in the continued spread of a staggering number of new infections that can be fatal to newborns. Due to price and coverage restrictions, many physicians, including obstetricians and gynecologists, are referring their patients to local health departments for treatment, causing treatment delays and loss to follow-up which is essential to determining that treatment has been successful.

BPG is on the World Health Organization's *List of Essential Medications*, a list of the safest and most effective medications that should be available to all health systems globally. That Americans are experiencing both shortage of and usurious prices for one of our oldest antibiotics is simply unacceptable.

We urge the committee to continue to evaluate solutions to drug pricing issues, and request that the Committee hold hearings to explore the impact of high drug costs on public health, including the growing STD epidemic.

Thank you for your leadership on these issues. We welcome the opportunity to discuss these issues further with your staff, and can be reached through the HIVMA Executive Director Andrea Weddle at (703) 299-0915 or aweddle@hivma.org.

Sincerely,



Melanie Thompson, MD
Chair