



October 24, 2017

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)  
c/o Jonathan Mermin, M.D., M.P.H., Designated Federal Officer  
Director, National Center for HIV/AIDS, Viral  
Hepatitis, STD, and TB Prevention  
Centers for Disease Control and Prevention  
CORP BLDG 8 Room 6171  
Atlanta, GA 30329

Dear Members of the CHACHSPT:

We would like to thank the Committee for the opportunity to provide public comments on behalf of the Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS). IDSA represents more than 11,000 physicians, scientists and other health care professionals who specialize in infectious diseases. HIVMA is a professional society nested within IDSA representing more than 5,000 HIV clinicians and researchers working on the front lines of the HIV, HCV and other STD epidemics. The 1,100 PIDS members are the core professionals advocating for the improved health of children with infectious diseases both nationally and around the world, participating in critical public health and medical professional advisory committees that determine the treatment and prevention of infectious diseases, immunization practices in children, and the education of pediatricians.

We would like to focus our comments today on the urgent need to mount a much more aggressive response to the unprecedented rise in rates of STD cases across the country, as described by the Centers for Disease Control and Prevention (CDC) in their September, 2017 annual [Sexually Transmitted Disease Surveillance Report](#).<sup>1</sup> The CDC reported that 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, stillbirth in infants, multisystem organ disease due to syphilis including ocular disease and neurosyphilis, and increased risk for HIV transmission.

These findings should serve as a wakeup call that business as usual will no longer suffice with regard to addressing the STD crisis and concerted timely action from the federal government is of the essence, including [declaration of a national public health emergency](#) on this issue. We urge HRSA and the CDC to take the lead in articulating a national STD control strategy to mount a comprehensive accelerated response that would include the following components:

**Support an FY2019 budget request for a \$40 million increase in STD funding to provide a much needed jump-start for state and local health departments and clinics to fight the rise in STDs:** Federal funding for

State and local public health infrastructure and personnel is insufficient to allow for the necessary follow-up and partner services for the more than two million new STD cases, including HIV, that are reported annually. We will not be able to curtail these epidemics without a significant boost in the resources to stop the spread of STDs and enhance our preparedness for emerging threats such as drug-resistant gonorrhea.

**Commit to ending congenital syphilis, the significant increase in which may be linked to opioid use:** The CDC has indicated its intention to strengthen the congenital syphilis response with focused efforts to improve diagnosis and treatment of pregnant women and ensure prompt treatment of newborns in the ten states hardest hit by congenital syphilis. This should include activities consistent with [WHO recommendations](#) to achieve the goal of eliminating mother-to-child transmission of syphilis or congenital syphilis,<sup>ii</sup> with benchmarks and an estimation of resources required to achieve this end point. Every case of congenital syphilis should be considered a sentinel public health event, including investigation of missed opportunities for diagnosis and treatment by healthcare providers. We have the tools to eliminate congenital syphilis and must invest the resources necessary to do so.

**Support expanded provider education on STD screening recommendations and clinical presentation of STDs:** We must accelerate efforts to educate clinicians about the importance of STD screening, including extra-genital screening, periodic screening for those who are HIV-infected, and screening every three months for those on PrEP. Ways to reach clinicians could include partnerships with medical provider and public health organizations, CME and training opportunities, flyers or posters for clinics, podcasts, smartphone apps, social media outreach and other resources.

**Support measures to address price and supply issues for penicillin:** We urge the CDC and HRSA to undertake measures to ensure timely availability of appropriate medications for treating STDs. Since May 2016, the Food and Drug Administration (FDA) has sounded the alarm about a dangerous shortage of Bicillin L-A (Penicillin G benzathine or BPG). This shortage seriously hampers efforts to treat syphilis. Currently there is only one supplier of BPG in the U.S. Public and transparent engagement with that supplier is urgently needed among Federal and local officials, advocates and professional organizations. We urge a federal review of this shortage to assess its causes and develop solutions to address immediate issues and help ensure a reliable supply of this important medicine.

Even when BPG is available, its cost can be a barrier to access that we urge you to address. One way to do this would be by declaring the STD epidemic a public health emergency, which might allow additional flexibility regarding the use of 340B medications. The 340B program offers discounted prices for outpatient prescriptions for certain safety-net providers. This would be extremely helpful to improve treatment access in areas where price and supply are barriers. Penicillin is an old and inexpensive drug that costs only pennies per dose to manufacture and yet the price of benzathine penicillin G (BPG) has skyrocketed. As an example, at an Atlanta-based clinic without access to 340B pricing, the price 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. We offer two specific examples but there are likely many more, the Aetna Medicare 2017 Comprehensive Formulary considers BPG a non-preferred (Tier 4) drug<sup>iii</sup> and Anthem's national formulary does not include BPG on its formulary.<sup>iv</sup> 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 even loss to follow-up for treatment. These high prices and the insurance industry's response to them

are unacceptable, in general, but unconscionable in the context of a public health crisis. One way to immediately address this would be to allow health departments to use their 340B procurement authority to buy BPG at the significantly lower 340B price and then distribute the medication to local public health designated providers and sites diagnosing and treating syphilis. We also urge HHS to work with private insurers to consider additional opportunities to expand access to BPG.

**Increase efforts to educate providers on partner notification and treatment services and encourage the use of expedited partner therapy (EPT):** Most states require treating providers to make a good faith effort to notify partners of patients with STDs including syphilis. Given the limited or absence of local public health resources to conduct partner notification activities, enhancing provider awareness of their responsibility could help facilitate timely and effective partner notification and treatment. In August 2006, CDC recommended the practice of EPT for certain populations and specific conditions and CDC continues to recommend it in [Sexually Transmitted Diseases Treatment Guidelines, 2015](#).<sup>v</sup> According to CDC analysis, EPT is currently permissible in 41 states, potentially allowable in 7 states, and prohibited in 2 states (Kentucky and South Carolina).<sup>vi</sup> However more clinician training is needed to engage them in partner notification services and encourage the use of EPT where appropriate. Continuing to address reimbursement issues for EPT in the private sector also will be crucial to implementation.

**Advocate for re-establishment of clinical quality measures for STD screening:** When the National Quality Forum (NQF) last undertook review of the infectious diseases measures set (the clinical quality measures that are used in the various federal quality improvement and value-based incentive programs), many measures were retired or dropped including the measure for STD screening. We recommend that CDC and HRSA work with the NQF to develop and submit for NQF endorsement updated STD screening measures in order to promote clinician adherence to treatment guidelines with regard to STD screening.

Thank you for your consideration of our views, and please call on us as a resource as the Committee considers ways to better address the STD epidemics. We can be reached through Colin McGoodwin of IDSA at [cmcgoodwin@idsociety.org](mailto:cmcgoodwin@idsociety.org), Kimberly Miller of HIVMA at [kmiller@hivma.org](mailto:kmiller@hivma.org), or Christy Phillips of PIDS at [cphillips@idsociety.org](mailto:cphillips@idsociety.org).

Sincerely,



Paul Auwaerter, MD, MBA, FIDSA  
IDSA President



Melanie Thompson, MD  
HIVMA Board Chair



Paul Spearman, MD, FPIDS  
PIDS President

---

<sup>i</sup> Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016*. Atlanta: U.S. Department of Health and Human Services; 2017.

<sup>ii</sup> World Health Organization. The Global Elimination of Syphilis: Rationale and Strategy for Action. 2007.  
<http://www.who.int/reproductivehealth/topics/rtis/syphilis/en/>.

<sup>iii</sup> Aetna Medicare 2017 Comprehensive Formulary. Available online at:  
[https://www.aetnamedicare.com/documents/individual/2017/formularies/FORM\\_2017\\_17020AET\\_a1\\_EN.pdf](https://www.aetnamedicare.com/documents/individual/2017/formularies/FORM_2017_17020AET_a1_EN.pdf).  
Accessed 10/19/17.

<sup>iv</sup> Anthem Tiered National Formulary. Available online at: [https://www.anthem.com/health-insurance/nsecurepdf/pharmacy/abcbs\\_anthem\\_natl\\_dl\\_tiered](https://www.anthem.com/health-insurance/nsecurepdf/pharmacy/abcbs_anthem_natl_dl_tiered). Accessed 10/19/17.

<sup>v</sup> Centers for Disease Control and Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines. Online at:  
<https://www.cdc.gov/std/tg2015/default.htm>. Accessed 10/24/17.

<sup>vi</sup> Centers for Disease Control and Prevention, "Legal Status of Expedited Partner Therapy (EPT)," <https://www.cdc.gov/std/ept/legal/default.htm> Accessed 10/24/2017.