

October 2, 2023

Drug Shortage Task Force  
1600 Pennsylvania Avenue NW  
Washington, DC  
20500

Members of the White House Drug Shortage Task Force,

The undersigned 39 organizations urge the White House Drug Shortage Task Force to take up the penicillin G benzathine (Bicillin L-A) shortage as a priority and work with the manufacturer to ensure adequate supply in the United States. Bicillin L-A remains the preferred treatment for primary and secondary syphilis in adults, infants, and children, and the only approved treatment for syphilis in pregnant women. As the only manufacturer of penicillin G benzathine in the United States, Pfizer's inability to provide adequate quantities of Bicillin L-A has left the Food and Drug Administration, the Centers for Disease Control and Prevention, and many local and state health departments scrambling to ration existing supply of the drug and develop contingency plans.

Only a few months into the shortage, clinics are already reporting that they have been unable to place orders for Bicillin L-A, and those that have been able to place orders are reporting that they are only partially filled or delayed. This is forcing providers to borrow supply from nearby clinics and refer patients elsewhere for care, which delays treatment.<sup>1</sup>

Pfizer first reported a manufacturing delay in June of this year, reporting that the shortage will likely continue through 2024. Given the unreliability of Pfizer's timeline and its vague explanations of why the shortage has occurred, key stakeholders are worried the situation will deteriorate further.

Shortages of Bicillin L-A have been a recurring concern in the US in recent years. In 2002 Wyeth-Ayerst, the previous manufacturer of Bicillin L-A, created shortages in North America when it halted production of the product at a Canadian plant. In 2005, shortages reoccurred and persisted for nearly five years.<sup>2</sup>

Most notably, advocates sent a nearly identical sign on letter to Pfizer in 2017 as part of a two-year shortage that coincided with a significant increase in congenital syphilis cases that has dramatically worsened ever since. Congenital syphilis—syphilis in newborns acquired during pregnancy—is an entirely preventable, yet dangerous disease; it may result in stillbirth or infant death in up to 40% of cases and includes long-term health consequences such as low birth weight, deformed bones, blood and organ abnormalities, blindness, and deafness. In 2015, there were a total of 494 reported cases of congenital syphilis, for a national rate of 12.4 cases per 100,000 live births. Following Pfizer's shortage, the number leapt to 941 cases in 2017 (rate: 24.4 per 100,000 live births), 1,313 cases in 2018 (rate: 34.6 per 100,000 live births), and an astounding 1,875 cases in 2019 (rate: 50.0 per 100,000 live births).<sup>3</sup> As we head into yet another shortage, it is imperative that Pfizer not only invest significant resources to address the manufacturing problems, but be forthcoming with all stakeholders

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<sup>1</sup> National Coalition of STD Directors, "NCSD Releases First Known Survey of the Bicillin L-A Shortage Impact on Clinics." 15 Sep. 2023. <https://www.ncsddc.org/wp-content/uploads/2023/09/NCSD-First-Bicillin-Survey-Results-9.13.23.pdf>

<sup>2</sup> Wyber R, et al. Benzathine Penicillin G for the Management of RHD: Concerns About Quality and Access, and Opportunities for Intervention and Improvement. *Glob Heart*. 2013 Sep;8(3):227-34. doi:10.1016/j.ghheart.2013.08.011.

<sup>3</sup> "Congenital Syphilis, 2017-2020." Centers for Disease Control and Prevention NCHHSTP AtlasPlus. <https://www.cdc.gov/nchhstp/atlas/index.htm>. Accessed July 5, 2023.

impacted by the shortage regarding the reason(s) for the delay. Given that the company's 2017 plans to avoid future shortages have failed, we are also eager to learn more about what the company plans to do differently to safeguard against additional shortages.

We are also highly skeptical of the company's attempts to primarily blame the shortage on increasing demand, which appears to unfairly deflect blame to communities affected by syphilis. However, trends in syphilis rates are clear and demand has been and will continue to increase for the foreseeable future; if Pfizer was truly caught completely off guard, it raises significant questions about the competency of the company to forecast obvious infectious disease trends. According to the CDC, the rate of primary and secondary syphilis has increased almost every year since 2000, increasing 28.6% between 2020 and 2021.<sup>4</sup> Rates have increased among both males and females, in all regions of the United States, in all age groups, and in all racial and ethnicity groups. Gay and bisexual men made up almost half (46.5%) of all P&S cases among men in 2021.

Additionally, we are concerned about how the shortage may impact 340B and commercial supply differently, and we ask for your help in working with Pfizer to ascertain whether the 340B stock of Bicillin L-A is more severely impacted and if so, how Pfizer intends to alleviate the strain on safety-net providers that rely on the 340B program to access this expensive medication.

Because Bicillin L-A is the only approved syphilis treatment for pregnant women, they remain an extremely vulnerable population when shortages occur. While alternative regimens for primary and secondary syphilis infections are possible in other populations, treatment becomes more complicated—with patients having to adhere to multiple daily doses over two weeks—and inferior to the penicillin G benzathine standard of care, particularly from a public health perspective.

The syphilis epidemic has already proven challenging to control. If affected communities and public health officials in the United States must rely on a single manufacturer for the standard of care, that manufacturer must be able to maintain adequate supply. Unexplained and repeated manufacturing delays not only endanger the successful treatment of syphilis, they endanger efforts to cure people in a timely manner, stop onward transmission, and bring down rising levels of new infection rates.

Affected communities and key stakeholders need to know the exact causes of the current shortage, including how Pfizer plans to fix this situation quickly and prevent it from happening again. Investments in shortage prevention efforts must be prioritized and we hope the company is already making progress toward resolving the Bicillin L-A shortage sooner than stated. But, we require support from the Drug Shortage Task Force to ensure accountability.

NCSD can be reached by emailing Rachel Deitch at [rdeitch@ncsddc.org](mailto:rdeitch@ncsddc.org) and PrEP4All can be reached by emailing Jeremiah Johnson at [Jeremiah@PrEP4All.org](mailto:Jeremiah@PrEP4All.org). At a minimum we request that the Bicillin L-A shortage be taken on as a priority of the task force, that members of the task force meet with us to discuss additional opportunities for next steps, and that you work with Pfizer to share prompt, transparent communication about the shortage with affected communities. We must rectify this unacceptable situation and prevent future recurrences.

Sincerely,

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<sup>4</sup> "Sexually Transmitted Disease Surveillance 2021: National Overview of STDs." Centers for Disease Control and Prevention. <https://www.cdc.gov/std/statistics/2021/overview.htm>. Accessed July 5, 2023.

AccessHealth MA (formerly Community Research Initiative)  
Act Now: End AIDS (ANEA) Coalition  
AIDS Action Baltimore  
AIDS Alabama  
AIDS Cure Research Collaborative  
AIDS Foundation Chicago  
AIDS Treatment Activists Coalition (ATAC)  
AIDS United  
Allentown Health Bureau  
American College of Nurse-Midwives  
amfAR  
Association of Maternal & Child Health Programs  
AVAC  
Big Cities Health Coalition  
Center on Halsted  
Desert Oasis Healthcare  
Equality California  
Five Horizons Health Services  
HealthHIV  
HIV+Aging Research Project-Palm Springs  
ICHANGE  
Jacobs Institute of Women's Health  
LKA Palm Springs  
NASTAD  
National Coalition for LGBTQ Health  
National Coalition of STD Directors  
National Family Planning & Reproductive Health Association  
National PrEP Program - PrEP4ALL  
National Working Positive Coalition  
NMAC  
Palmtree Clinical Research, Inc.  
Prevention Access Campaign  
Renegade.bio  
San Francisco AIDS Foundation  
The AIDS Institute  
Treatment Action Group  
U=U plus  
Valley AIDS Council  
West Virginia Department of Health