



National Association of County & City Health Officials

The National Connection for Local Public Health

October 16, 2023

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

Dear Members of the White House Drug Shortage Task Force,

The National Association of County and City Health Officials (NACCHO) urges the White House Drug Shortage Task Force to take up the penicillin G benzathine (Bicillin L-A) shortage as a primary concern and work to ensure adequate supply in the United States. NACCHO represents the 3,000 local health departments across the country, the vast majority of which provide clinical services to address sexually transmitted infections. Bicillin L-A is a critical treatment for syphilis and the only treatment approved for use in pregnant people. Unfortunately, it is already in shortage, and the situation is projected to worsen without intervention.

The nation is currently facing a public health crisis. In recent years, syphilis cases have surged. According to the Centers of Disease Control and Prevention (CDC), reported cases of syphilis increased 74 percent between 2017 and 2021 (the most recently reported timeframe). Even more alarming is the rise in congenital syphilis, increasing 203 percent during the same period, which tracks the rise of syphilis in pregnant people.¹ These individuals should be treated immediately; however, the current Bicillin L-A shortage is leading to rationed or delayed care.

Bicillin L-A is the preferred treatment for primary and secondary syphilis in adults, infants, and children. It is also the **only** approved treatment for syphilis in pregnant people. While alternative regimens for primary and secondary syphilis infections are possible in other populations, treatment becomes much 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 Food and Drug Administration (FDA), CDC, and many local and state health departments are currently forced to ration the existing supply of Bicillin L-A and develop contingency plans. We have heard from local health departments in communities across the country about current or future projected shortages of the treatment, causing concerns for continued spread and more severe health outcomes. Additionally, many local health departments are 340B providers, and we are concerned about how the shortage may impact 340B and commercial supply differently.

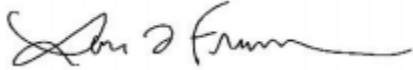
Pfizer is currently the only manufacturer of Bicillin L-A in the United States, and we urge you to work with them to share the exact causes of the current shortage, plans to fix this situation (including efforts to provide higher quantities of this drug); and ensure it does not happen in the future. Similarly, we ask for your help to ascertain whether the 340B stock of Bicillin L-A is or will be more severely impacted and if so, how the company will alleviate the strain on safety-net providers that rely on the 340B program to access this expensive medication.

Action by the Task Force is both important and timely. Rising trends in syphilis rates are clear, and demand for Bicillin L-A has been and will continue to increase for the foreseeable future. Existing public

health data and trends must be used to forecast future burden and adjust manufacturing capacity accordingly. At the same time, investments in shortage prevention efforts must be prioritized.

Therefore, we respectfully request that the Task Force take up the Bicillin L-A shortage as a priority and work with both public health providers as well as the manufacturer to address and clearly communicate about current shortages and prevent them in the future. If you have any questions, please contact Adriane Casalotti, Chief of Government and Public Affairs for NACCHO, at acasalotti@naccho.org.

Sincerely,



Lori Tremmel Freeman
Chief Executive Officer

<https://www.cdc.gov/std/statistics/2021/overview.htm#:~:text=The%20national%20congenital%20syphilis%20rate,syphilis%20among%20reproductive%20aged%20women.>