



NCSDDC
National Coalition
of STD Directors

Promoting Sexual Health
Through STD Prevention

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Division of Dockets Management (HFA – 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

RE: [Docket No. FDA-2018-N-3272] - Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments

To Whom it may concern:

The National Coalition of STD Directors (NCSDDC) respectfully submits these comments in response to the Food and Drug Administration's (FDA) request for comments on identifying the root causes of drug shortages and finding enduring solutions. NCSDDC is the only national public health membership organization representing health department STD programs, their directors and support staff, as well as community-based partners across all 50 states, seven large cities, and eight US territories. Our mission is to advance effective sexually transmitted disease prevention programs and services in every community across the United States. We appreciate the opportunity to provide: 1) information regarding the impact on patients and health care providers resulting from a recent shortage of Bicillin-LA for the treatment of syphilis; and 2) recommendations for preventing and mitigating future shortages.

Assessing the Adverse Consequences of Drug Shortages to Patients, Health Care, Providers, and the Drug Supply Chain

The FDA declared a national shortage of Bicillin-LA (Penicillin G) from April 29, 2016 until May 18, 2018. Bicillin-LA is the preferred treatment for syphilis and is the only therapy with documented efficacy for syphilis during pregnancy. This shortage occurred during a period when syphilis has shown a sharp and distressing rise. From 2013 to 2017, reported syphilis rates in the U.S. increased from 76 percent with rates of congenital syphilis increasing an alarming 154 percent. In 2017, during the heart of the shortage, 30,644 cases of infectious (primary and secondary: P&S) syphilis were reported. Rates increased in all demographics and in three-quarters of states and the District of Columbia. Although men accounted for almost 90 percent of all reported cases of P&S syphilis, men who have sex with men (MSM) comprised 68.2 percent of reported P&S syphilis cases among men and women who were able to provide information on the sex of their partners. In the U.S. approximately half of MSM with P&S syphilis are more likely to be infected with HIV in the future.¹

¹National Academy of Public Administration. *The Impact of Sexually Transmitted Diseases on the United States: Still Hidden, Getting Worse, Can Be Controlled*. 2018



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The shortage of Bicillin-LA during this time period led to many adverse consequences for health care providers and patients. During the shortage when Bicillin-LA was in limited supply, many health care providers were forced to prescribe doxycycline or tetracycline for non-pregnant patients, a suboptimal 14 to 30-day treatment, that often causes adverse side effects resulting in patients discontinuing treatment or not adhering to optimal dosing. The number of persons treated with suboptimal regimens during this shortage period is unknown but believed to be significant. Another impact of the shortage was that many health care providers (including HIV care providers) were unable to procure a supply of Bicillin-LA to treat their infected patients at the time of their diagnosis and subsequently had to refer them to another health care provider. Anecdotal data suggest that some patients did not seek treatment at alternative health care facilities because of accessibility issues or stigma concerns, possibly resulting in continued infection and transmission of syphilis and HIV.

Identifying the Root Causes and Drivers of Drug Shortages

Bicillin-LA is the preferred treatment for syphilis (and the only treatment for pregnant women). It is solely manufactured by Pfizer, Inc. in one facility in the United States. When this facility became inoperative due to a problem with the supply of raw materials and an equipment malfunction in 2016, the production of Bicillin-LA was halted for a protracted period resulting in a national shortage. This problem was exacerbated because the existing stockpile or supply of Bicillin-LA was unevenly distributed among drug wholesalers, resulting in geographic areas with extreme shortages. In addition, the 340B program's drug procurement and distribution rules made it difficult and sometimes impossible for public health agencies and other community-based organizations to redistribute their supply of Bicillin-LA to geographic areas in their jurisdictions experiencing shortages or providing medications to health care providers not enrolled in the 340B program.

Identifying Strategies for Preventing or Mitigating Drug Shortages

NCSO recommends that the FDA consider the following strategies:

- 1) Create a specialized designation for medications used to treat infectious disease of critical public health importance (including syphilis, gonorrhea, and chlamydia) where it is in the public health interest to ensure that an adequate supply and stockpile is always available and accessible in all communities.
- 2) Encourage and incentivize drug manufacturers to have at least two facilities where any public health critical drug is manufactured, preferably in different geographic regions, to promote redundancy and resilience.
- 3) Encourage and incentivize drug manufacturers to maintain a two to three year supply or stockpile of raw materials needed to manufacture public health critical drugs and to report the status of this stockpile to the FDA on an on-going and periodic basis.
- 4) Ensure that U.S. trade policies facilitate the importing of raw materials used in the manufacturing of public health critical drugs.
- 5) Develop a mechanism to extend the expiration date for public health critical drugs on an emergency basis to boost supply during periods of shortage while maintaining drug viability.

- 6) Develop policies that enable public health critical drugs manufactured in foreign countries to be imported and used in the U.S. during periods of shortages while ensure their safety and efficacy.
- 7) Review and revise the 340B Program policies and rules to allow public health critical drugs to be redistributed among health care providers within and among communities during periods of shortage.
- 8) Ensure that systems are available for health care providers to easily report shortages and procurement problems for public health critical drugs.
- 9) Ensure that a readily accessible communication system is available for drug manufacturers and wholesalers/distributors to keep health care providers and the public aware of the status of shortages of public health critical drugs.

Thank you again for the opportunity to provide input on this important issue. For any questions or comments on please contact Kyra Miller, Manager, Policy and Government Relations, at (202) 618-4035 or kmiller@ncsddc.org.

Sincerely yours,



David C. Harvey
Executive Director