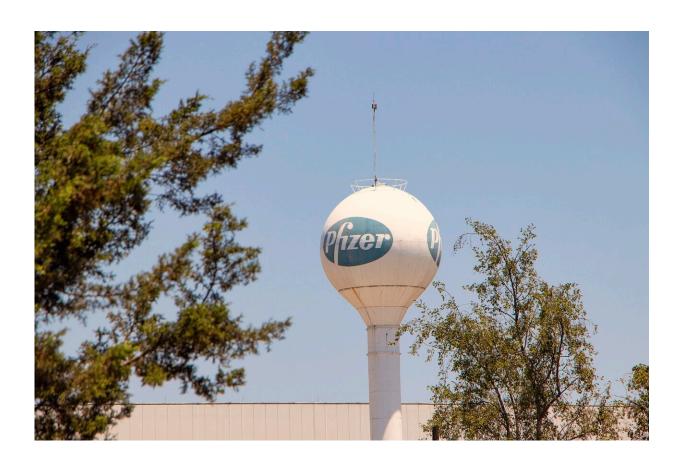


There's only one syphilis medication for pregnant people and the supply is running out

March 25 2024, by Alena Kuzub



The pharmaceutical company Pfizer is the sole manufacturer of penicillin G benzathine, the only medicine that safely treats syphilis in pregnant people. Credit: Pixabay/CC0 Public Domain



The government has a role to play in solving the shortage of the only medication that can treat syphilis in pregnant people, Northeastern University experts say.

"It's leaving people at the risk of serious illness, affecting birthing outcomes and, certainly, the health of infants as well," says Brook Baker, a professor who teaches disability discrimination law at Northeastern.

It is especially concerning, Baker says, because syphilis, a bacterial infection transmitted by <u>sexual contact</u>, can be passed from a mother to her child.

In the United States, cases of syphilis are at the highest levels in 30 years, according to the Centers for Disease Control and Prevention. In 2022, more than 200,000 cases were reported, compared to about 50,000 a decade ago.

Syphilis starts as a painless sore, but can cause serious health problems without treatment. Congenital syphilis, when a mother passes the infection on to her child during pregnancy or at delivery, can lead to stillbirth, miscarriage, infant death and maternal and infant morbidity, according to the CDC.

The CDC registered more than 3,700 cases of syphilis in pregnant people in 2022. Almost 90% of them happened due to the lack of timely testing and adequate treatment during pregnancy. More than 230 babies died at birth and 50 more died in infancy, the CDC reported.

Congenital syphilis can be prevented with timely testing and adequate treatment during pregnancy. But the only drug that is safe in pregnancy, penicillin G benzathine, has been in limited supply in the U.S. since June. That's when Pfizer reported a shortage of its syphilis drug, long-lasting Bicillin L-A.



Pfizer is the only pharmaceutical company to manufacture penicillin G benzathine, according to the CDC.

Pfizer estimates full recovery of its supply no sooner than October for the adult version of Bicillin L-A and early 2025 for the pediatric version of the drug.

There are other generic manufacturers of penicillin G in the world, Baker says, but it is difficult for them to gain approval by the Food and Drug Administration and enter the U.S. market.

In January, the FDA announced temporary approval for the import of Extencilline, the same antibiotic as Bicillin L-A manufactured by Delbert in Italy and marketed in France.

It is unclear whether medical insurance companies will cover the cost of Extencilline, says Brandon Dionne, an associate clinical professor of pharmacy and health systems science at Northeastern.

It's also unclear whether there will be federal support to help defray any cost differences, Dionne says. Distribution of Extencilline was approved through only one company.

"I think people have increasingly started to realize that there probably is a role for the government in at least for certain medications, ensuring that there's adequate supply and adequate manufacturers," Dionne says.

The government could invoke the Defense Production Act, which was used during the COVID-19 pandemic, Baker says, and either nudge Pfizer or enable other producers to pass quality and safety standards for its own use.

"They'd have to help that producer get regulatory approval, which might



be an issue to find a qualified producer," Baker says.

People who are not pregnant can be treated with an oral drug doxycycline. Doxycycline is not safe for pregnant people unlike penicillin G, Dionne says.

"Unfortunately, there's not really an alternative," he says. "Penicillin G is really the preferred and really only option for pregnant mothers and for infants."

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Provided by Northeastern University

Citation: There's only one syphilis medication for pregnant people and the supply is running out (2024, March 25) retrieved 27 April 2024 from https://medicalxpress.com/news/2024-03-syphilis-medication-pregnant-people.html

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