Where Will the Bulk of Gilead's PrEP Donations End Up?

The Truvada manufacturer's agreement with the Trump Administration is "a tremendous step toward ending the epidemic."

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Ever since it was first authorized for public use in 2012, the principal concerns of public health officials and HIV advocates around Truvada as pre-exposure prophylaxis (PrEP) have focused less on the effectiveness of the med and more on the ability of people who at risk of contracting HIV to access it. Over the past decade, numerous studies have shown that PrEP is extremely effective at preventing sexual transmission of HIV and can be of significant help at preventing HIV transmission among people who inject drugs. However, with a year's supply of the PrEP medication Truvada currently running at over $20,000, PrEP is still inaccessible for those who are uninsured, underinsured or simply unable to pay for the medication.

In an attempt to remedy this, Health and Human Services Secretary Alex Azar announced Thursday, May 9, that the Trump Administration and Gilead Sciences—the manufacturer of Truvada—had reached an agreement for the pharmaceutical manufacturer to donate PrEP to up to 200,000 uninsured individuals annually through 2030. The agreement, which would involve the donation of up to 2.4 million bottles of PrEP to the Centers for Disease Control and Prevention (CDC) each year, could go a long way toward closing the sizable gap that currently exists between those who are on PrEP and those who could benefit greatly from it. Currently, only between 10 and 20 percent of the 1.1 million Americans estimated to be at risk of contracting HIV are on PrEP.

Per the agreement, Gilead will provide the CDC with Truvada initially, but will switch over to donations of their new drug Descovy once it is approved for use in PrEP by the Food and Drug Administration. From that point onward, Gilead will continue to donate Descovy until either the 11-year timeframe of the agreement has ended or a generic version of Descovy becomes commercially available, whichever comes first. AIDS United's Vice President for Policy and Advocacy, William McColl, said that his understanding from a short phone call with representatives from Gilead is that after the switch occurs, Truvada would still be available and that the decision to use either Descovy or Truvada would remain with the physician and client.

With the PrEP donations being earmarked exclusively for at risk individuals who are uninsured, it is likely that the bulk of the donated medications will be people living in states that have not yet expanded Medicaid, particularly in counties and states that have been identified as HIV

transmission hotspots by the Trump administration and which make up the focus of their recently released plan to end the HIV epidemic by 2030. Of the 48 counties targeted by the Trump administration in their ending the epidemic plan, 20 are in states who have refused to expand Medicaid. Similarly, 6 of the 7 predominantly rural states targeted by the Administration also have not expanded Medicaid. With the exception of Missouri, all of the targeted counties and predominantly rural states that have not expanded Medicaid are in the U.S. South.

The announcement of this sizable PrEP donation from Gilead Sciences to the Department of Health and Human Services comes as both the company and the federal government have been under increased scrutiny for the management of patents around Truvada's use in PrEP. The CDC owns 3 patents for the use of 2 drug combinations for PrEP due to funding and conducting the majority of the research on use of Truvada for PrEP. However, critics have stated that the U.S. government is not enforcing the patents and have therefore not received money from Gilead's sales of the drug, which netted the company $3 billion in sales last year. Last month it was reported that the Justice Department had opened a review of the government patent but had not indicated whether they were planning to pursue a patent infringement lawsuit. For their part, Gilead Sciences has said that the discussions of this agreement to donate PrEP medications had been delinked from any negotiations on the CDC's ownership of PrEP use patents.

In a recent article in The Washington Post, AIDS United CEO Jesse Milan, Jr. called news of the deal a "tremendous announcement," adding that the newfound availability of PrEP for so many uninsured individuals, "will make a great difference in the lives of hundreds of thousands of people, and it will be a tremendous step toward ending the epidemic."

Editor's note: For related POZ news, read "Gilead to Donate Up to 2.4M Bottles of HIV Prevention Pills Each Year in the U.S."

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