CDC Has Patents on PrEP, Advocates Find

Activists want future and retroactive royalties to pay for a national PrEP program.

March 28, 2019 By Liz Highleyman

The Centers for Disease Control and Prevention (CDC) holds patents on the use of Truvada (tenofovir disoproxil fumarate/emtricitabine) for HIV pre-exposure prophylaxis (PrEP), according to a report in The Washington Post.

Truvada, manufactured by Gilead Sciences, is the only approved medication for HIV prevention. The combination pill was initially approved for HIV treatment, and Gilead provided the drug for government-funded studies to test whether it could also prevent infection.

After a series of successful studies in monkeys, Robert Grant, MD, of the University of California at San Francisco and colleagues showed that once-daily Truvada reduced new infections by 92 percent among mostly gay and bisexual men who used it consistently. In numerous follow-up studies and demonstration projects, no one who took PrEP at least four times a week has become infected.

Grant's research received $50 million in federal grants from the National Institutes of Health (NIH), as well as $17 million from the Bill & Melinda Gates Foundation, according to the Post.

Although Gilead holds patents on the Truvada coformulation and the two drugs it contains, the U.S. government separately patented the use of the pill for PrEP, an indication approved in 2012. Yet the government is not receiving revenue for this use and has not moved to make less expensive generic alternatives available.

"With the amount of effort and time and taxpayer money that went into it, for CDC and Gilead not to come to an agreement, so the taxpayer could get some of that money, is really unconscionable," Thomas Folks, PhD, a retired CDC researcher who worked on the early PrEP studies, told the Post.

BOOM. @PrEP4AllNow got this story placed on the front page of tomorrow's Washington Post.

Gilead owes royalties to the CDC from all its Truvada PrEP sales since 2012, which should amount to hundreds of millions of dollars. 1/3 https://t.co/ebmTceOaMU

— Peter Staley (@peterstaley) March 27, 2019

Truvada sells for around $1,600 to $2,000 per month, and it brought in $3 billion in sales last year, the report says. Although Gilead offers a patient assistance program and co-pay card that keep out-of-pocket costs low for many individuals who use PrEP, the cumulative cost for public health programs that aim to expand the use of the prevention pill remains considerable.

CDC researchers estimate that only around 10 percent of the 1.14 million people who are at high risk for HIV and eligible for PrEP are using it, with the proportion falling to low single digits for Black and Latino people, who have higher rates of new infections.

While many barriers stand in the way of more widespread PrEP use, many people have reported that cost is a factor. Advocates contend that if Truvada or a generic equivalent were cheaper, it would be possible to provide it to many more people.

“The CDC has all these patents and is allowing Gilead to rip off the American people at the expense of public health,” James Krellenstein, cofounder of the advocacy group PrEP4All, told the Post.

The report stems from an investigation by PrEP4All advocates, who researched the government patents, commissioned an outside review by Christopher Morten, a patent expert with the Global Health Justice Partnership (GHJP) at Yale Law School and the Yale School of Public Health, and turned over their findings to the Post.

“I have no reason to believe that these patents are not valid and enforceable, and moreover, they seem to be infringed [by Gilead] by the use of Truvada for PrEP,” Morten told the Post. “These are public assets that were generated with public money that effectively are going to waste here.”

Morten’s full statement notes that the CDC’s patent on Truvada for PrEP, which was issued in 2015, is expected to remain in effect until 2031. If the claim is enforced, the U.S. government “could possibly be entitled to collect money damages,” according to the statement.

“If the CDC asserted its patents against Gilead, the revenue generated could be used to fund a program to create universal access to PrEP within the United States, which could dramatically reduce new HIV infections,” Yale law professor and GHJP codirector Amy Kapczynski said in a

statement.

> GHJP joins @PrEP4AllNow in calling on @CDCgov to use its patents for PrEP to promote universal access to PrEP within the United States. https://t.co/qurxemjo5M
>
> — Yale GHJP (@YaleGHJP) March 27, 2019

As described in a statement from the Treatment Action Group (TAG), widespread PrEP rollout as a public health intervention in Australia and England have only been possible thanks to negotiations that dramatically reduced the cost of Truvada and use of inexpensive generic versions.

"Were the CDC to effectively slash the cost of [tenofovir DF/emtricitabine] at a time when public outrage on drug pricing is at an all-time high, taxpayer dollars for HHS [the Department of Health and Human Services] would go much further," the TAG statement reads. "The CDC has everything it needs to dramatically lessen these financial barriers and more effectively use anticipated new HHS funding to get access for hundreds of thousands of Americans who need PrEP."

PrEP4All and GHJP are calling on Gilead to pay royalties on the use of Truvada for PrEP both going forward and retroactively to 2012. They want the CDC's royalty revenue to be used to fund a national PrEP program that includes provision of low-cost PrEP—either Truvada or a generic equivalent—and wraparound services such as lab tests and clinical care, with a focus on vulnerable people and communities where PrEP is now underutilized. (See the BreakThePatent petition here.)

Gilead asserts that the government's patents for Truvada for PrEP are invalid. The company told the Post in a statement that it has discussed the patent issue with CDC representatives, but declined to provide details. The company said Truvada was already being used off-label for HIV prevention before the CDC's patent application and that the patents "do not reflect the contributions of Gilead scientists" to the government's monkey PrEP research.

The CDC did not respond to the Post's requests for comments, and an NIH patent official said he could not discuss conversations with companies.

As the PrEP patent debate continues, the clock keeps ticking toward the expiration of Gilead's original patent on the Truvada coformulation in 2021, which will likely open the doors to generic competitors, several of which are already available in other countries.

[Editor's note: This article has been updated to add new information as it becomes available.]