Whatever Happened With That PrEP Patent Lawsuit?

In a letter to federal officials, PrEP4All and HIV advocates demand an update on the drug patent lawsuit "United States v. Gilead."

January 28, 2022 By Trent Straube

On November 6, 2019, the federal government filed a complaint against drugmaker Gilead Sciences over the patent of Truvada and Descovy—two meds used as pre-exposure prophylaxis (PrEP) to prevent HIV. More than two years later, the case remains a big question mark.

Seeking answers, PrEP4All and 24 other HIV advocacy groups sent letters to U.S. Attorney General Merrick Garland and Health and Human Services (HHS) Secretary Xavier Becerra demanding an update on the lawsuit. (You can read the full letter on PrEP4All.org.) In addition, the advocates want federal officials to meet with them to discuss how the government will use royalties from the lawsuit to expand access to HIV prevention via PrEP

"Nearly a decade after PrEP was approved [by the Food and Drug Administration], many of the communities that need PrEP the most are still not able to access it," said James Krellenstein, PrEP4All's managing director of strategy and policy, in a PrEP4All press release about the letter.

> PrEP4All and 24 other advocacy organizations send a letter to @TheJusticeDept and @HHSGov with the following 3 demands. #USvGilead #PrEP4AllNow https://t.co/8t7umudKqR pic.twitter.com/TnQo5AYWg2
>
> — PrEP4All (@PrEP4AllNow) January 20, 2022

The lawsuit, filed by the Department of Justice on behalf of HHS, centers on the question of who owns the patent to these PrEP meds. The letter to the government summarizes the situation as such:

PrEP is a highly effective medical technology, and it exists thanks to taxpayer-funded research conducted by constituent agencies of HHS. PrEP was invented by scientists at the Centers for Disease Control and Prevention (CDC) in the 2000s. PrEP was then first proven safe and effective in humans in a clinical trial funded by the National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation in the late 2000s and early 2010s. This trial and subsequent trials have shown that PrEP is over 99% effective at preventing sexual transmission of HIV.

Gilead relied on this taxpayer-funded research when it sought and received approval from the Food & Drug Administration (FDA) to market commercial PrEP products. The FDA approved Gilead's first version of PrEP in 2012, and Gilead has marketed PrEP products continuously since then. Since 2012, Gilead has earned at least $10 billion from PrEP sales in the United States. Gilead's manufacturing costs on PrEP are low—estimated at less than $6 per bottle—and its profits have been massive. As HHS stated in 2019, when it filed the lawsuit, "Gilead has profited from research funded by hundreds of millions of taxpayer dollars and reaped billions from PrEP through the sale of Truvada and Descovy."

However, while Gilead profited, there was little progress at curtailing the HIV epidemic in the United States, largely because of a lack of access to PrEP. Despite PrEP's incredible efficacy, U.S. HIV diagnoses have fallen by less than 10% since 2012. Nearly 40,000 Americans become newly infected with HIV every year. This lack of progress is not because PrEP doesn't work; it is because PrEP is still grossly underutilized by people who would benefit from it. Fewer than 25% of people indicated for PrEP currently use the drug. Hundreds of thousands of Americans who are indicated for PrEP do not get the drug and remain at risk of HIV. A myriad of barriers inhibit its use among the communities most vulnerable to HIV....

As of 2019, Gilead sold Truvada at a price of $21,600/patient/year. Today, Gilead charges even more for Truvada—$22,500/patient/year. It charges the same price for another PrEP product, Descovy. Lower cost generic versions of Truvada have become available in the United States, but there is no generic version of Descovy available to patients in the United States.

Since 2019, the U.S. government's leverage over the company seems only to have increased. First, Gilead tried to invalidate HHS's patents outside of the United States v. Gilead litigation, but Gilead's efforts failed. Second, the judge presiding over United States v. Gilead denied Gilead's motions to dismiss. Third, the amount of money that Gilead could owe the U.S. government for infringement of HHS's patents has increased substantially since 2019. In 2019, an analysis published in The New York Times estimated that Gilead's potential infringement liability could reach $3 billion. In 2020, an independent article published in JAMA found that Gilead's liability could exceed $4 billion. Since then, Gilead has earned billions more in revenues from PrEP sales within the United States. With each and every new sale, Gilead's potential liability increases.

> While we applaud DOJ's and HHS's decision to bring the United States v. Gilead lawsuit, two years have passed, and the suit has yet to produce any concrete benefits for people with and vulnerable to HIV. United States v. Gilead is not scheduled to go to trial until 2023. At current infection rates, by mid-2023, over 100,000 Americans will have been newly diagnosed with HIV since DOJ and HHS brought the lawsuit.

Timing is essential for another reason: PrEP programs face a devastating loss of funding for HIV prevention. In fact, beginning this month, HIV clinics and nonprofits serving those at highest risk for HIV—notably, Black, brown, queer and Southern communities—stand to lose over $100 million year. That's because Gilead is ending a reimbursement system, related to the 340B federal law on drug pricing, that helps fund the clinics.

Although health insurers must now cover PrEP and generic versions are available—as is an injectable form of PrEP that lasts two months—many clinics rely on the 340B reimbursement system to remain open.

For more about PrEP disparities and which population groups and regions are using PrEP, check out this AIDSVu.org video "What Is PrEP?" (also viewable on YouTube):

Click the hashtag #PrEP for a collection of related articles including:

- "Apretude Approved—the First Long-Acting Injectable PrEP Option"
- "2021 Was a Year of HIV Progress; Now Let's Focus on PrEP Access"
- "Black and Latino Folks Are Less Likely to Be Referred for PrEP"
- "Take This Article With You When You Request HIV PrEP"

Scientists estimate PrEP to be about 99% effective among men who have sex with men and 88% to 90% among heterosexual men and women (though researchers believe this latter number is likely higher). For more details, see "How Well Do U=U and PrEP Work? The CDC Updates Its Answers." For more general information, see "What's the Difference Between Truvada and Descovy for PrEP?" and POZ Basics on HIV Prevention.

We are delighted to announce that @ActivistJohnson has joined PrEP4All as PrEP Program Manager! As PrEP Program Manager, Jeremiah brings a wealth of

experience including working to promote universal access to treatment and comprehensive HIV prevention. https://t.co/6mpvgR3O5o pic.twitter.com/WDs2QeHFmm

— PrEP4All (@PrEP4AllNow) January 27, 2022

And in related news, PrEP4All announced this week that activist Jeremiah Johnson has joined the team as its PrEP program manager. Johnson appeared on the cover of POZ in 2008 regarding his lawsuit against the Peace Corps, which had dismissed him from service when he tested HIV positive. For similar articles, see "Peace Corps Lifts HIV Restrictions" and the 2018 article "Peace Corps Volunteer Claims He Was Sent Home After Contracting HIV and Another Says He Was Denied PrEP."

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