Here's How We Can Get Universal Access to PrEP

U.S. activists unveil a national action plan to #BreakThePatent. It points out that taxpayers funded the research behind Truvada as PrEP.

July 25, 2018 By Trent Straube

A group of grassroots activists called The PrEP4All Collaboration released a report that outlines a national path to create universal access to pre-exposure prophylaxis (PrEP), the daily HIV-prevention tablet that's sold under the brand name Truvada.

Released at the 22nd International AIDS Conference (AIDS 2018) in Amsterdam and available as a free download here, the 40-page white paper is titled A National Action Plan for Universal Access to HIV Pre-Exposure Prophylaxis (PrEP) in the United States.

The paper's executive summary lays out its issues and goals. Here is that text in full:

> HIV pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) is the most effective method of HIV prevention for HIV negative persons known. Approved for use in the United States in 2012, when taken daily, TDF/FTC PrEP is more than 99% effective in preventing HIV infection.
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> Despite its proven efficacy for both individuals and at population scale, the potential for TDF/FTC PrEP to dramatically decrease rates of HIV in the United States has not been fully realized. More than six years after FDA [Food and Drug Administration] approval, utilization and access in the U.S. remains abysmal. Less than ten percent of people with indications for PrEP are accessing it and major disparities along racial lines, geographic regions, and sex have already emerged. We believe the root cause of this problem is the price. Gilead Sciences, the manufacturer of the only domestically available version of TDF/FTC PrEP, charges in excess of $1,600 a month, despite FDA-approved versions of generic TDF/FTC costing less than $6 internationally, a markup of over 25,000%.
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> None of the research used to support the FDA approval of Truvada for its use as PrEP was meaningfully funded by Gilead but rather by the U.S. taxpayers via the National Institutes of Health (NIH), as well as by the Bill and Melinda Gates Foundation. Remaining patents on Truvada are based on research that was funded by taxpayers through federal grants.

> This white paper was developed by a small group of HIV activists in New York City. The following document outlines our plan for universal PrEP access. This plan would provide free TDF/FTC and clinical care to every American who needs PrEP for a cost less than what our healthcare system currently spends to get PrEP to less than ten percent of the people who need it. In addition, this plan would provide over half a billion dollars a year to address systemic and individual barriers to PrEP access. In order for this to occur, the federal government needs to act, using existing law, to break the patents that enable Gilead's monopoly on TDF/FTC. We present this plan as a request for additional leadership and thought partners. How do you see a universal PrEP rollout affecting your community? How can we work together to end the HIV epidemic in the United States while also tackling non-cost-related barriers to PrEP access? We welcome your leadership and input.

Chapter titles outline the focus of the paper, which lays out the PrEP access problem in the United States and offers solutions. A few samples:

- "The Low Rate of PrEp Utilization Is One of the Greatest Public Health Implementation Failures in the History of This Country"
- "The PrEP Pricing Problem"
- "Why Is Truvada So Expensive in the United States?"
- "Gilead Is Likely Engaging in Illegal 'Pay for Delay' Settlements"
- "The Price for TDF/FTC in the United States is Vastly Inflated"
- "At Current Prices, It Is Cheaper to Let People Get HIV Than to Scale-Up PrEP"
- "The Need for a National PrEP Program"
- "Government Paths to Access Generic PrEP"

What are the paths to universal PrEP access? The authors cite two: march-in rights and the Bayh-Dole Act.

Congress passed the Bayh-Dole Act in 1980 “to address concerns about the lack of commercialization of scientific advances made using public funds,” according to the white paper. Another purpose of the legislation is to “ensure that government obtains sufficient rights in federally supported interventions to meet the needs of the government.” (The march-in right is a provision of the act that allows the government to basically ignore exclusivity patents and to grant licenses to other drug manufacturers.)

In other words, when a medicine is developed using federally funded research and when that medicine is pivotal to the health and safety of the citizens, the government can step in to expand access to the drug.

In the past, the NIH has stated that it’s not within its purview to control the prices of drugs. A solution to this, the white paper authors note, is for the NIH to exercise its march-in rights and issue more licenses to drug manufacturers to make TDF/FTC for PrEP, which would increase the supply and competition.

The paper’s authors detail many other ways the federal government can infringe on U.S. patents without permission.

The following members of the PrEP4All Data and Strategy Working Group collaborated on the white paper:

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You can learn more about their efforts at BreakThePatent.org. The site includes a petition you can sign, calling on the NIH to break the patent around Truvada as PrEP.

In related news, three members of PrEP4All recently penned an opinion piece in The New York Times titled “Why Don’t More Americans Use PrEP? that makes for an excellent summary of the white paper.

“A critical component of this plan [for universal PrEP access] is insisting that federal agencies use their statutory authority to break Gilead’s undeserved monopoly,” write the authors of the opinion piece. “With low-price, generic Truvada, the cost to cover every American who needs

PrEP—including both drug costs and clinical care—would be less than a tenth the amount that the federal government already spends on HIV care. The billions saved could pay for vital services to ensure those who need PrEP the most can get it and those living with HIV can keep the virus suppressed. If the patent on Truvada remains, the plan will cost over $20 billion."

You can read more from Peter Stately, one of the coauthors of the Times opinion piece, in his POZ Blog. Don't miss his latest post, "Pics & Notes From Amsterdam."

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