Generic PrEP to Arrive in September 2020, but Will Big Savings Follow?

Only one company will sell a version of the HIV prevention pill Truvada. When others go to market, prices will likely drop further.

May 9, 2019 By Trent Straube

A generic version of the HIV prevention pill Truvada as PrEP, or pre-exposure prophylaxis, will be available in September 2020, a year before expected, according to an announcement by the drug's manufacturer, Gilead Sciences, reports NBC News.

The approval of generic versions of meds is usually met with praise because it means significant cost savings to the consumer—and therefore more access to people who need the medicine. But the case of generic Truvada seems to raise more questions than acclaim.

For starters, only one company, the Israeli-based Teva Pharmaceutical Industries, will be allowed to sell the generic version of Truvada in the U.S. market, starting September 30, 2020.

The agreement with Teva was made in 2014 but only announced now. Why is that, activists want to know. Is it because groups such as ACT UP, Health GAP and the PrEP4ALL Collaboration have been urging the federal government to #BreakThePatent on Truvada, a call that has intensified after the recent revelation that the federal Centers for Disease Control and Prevention holds patents on the drug?

That is not the case, according to a statement from Gilead, which reads: "Gilead reached an agreement with Teva Pharmaceutical in 2014 to allow the early launch of a generic version of Truvada into the market in the United States in 2020, a year earlier than required. This agreement is not related to current discussions with the federal government to determine the best ways to broaden access to Truvada for PrEP for vulnerable populations in the United States and support the federal plan to end the HIV epidemic."

Regardless, Gilead's agreement could give Teva exclusive rights to generic Truvada for about a year. That's because Truvada is made of two different meds: tenofovir disoproxil fumarate (TDF) and emtricitabine. The patent on TDF has already expired (an updated version, tenofovir alafenamide, TAF, is on the market), but the patent for emtricitabine isn't set to expire until September 2021, according to Gilead.

This means Teva will have no competition to force its generic prices much lower than the brand-name version, explains Tim Horn, the director of medication access and pricing at the National Alliance of State & Territorial Directors (NASTAD), in an email exchange with POZ (full disclosure: Horn is a former editor at POZ).

“Historically,” Horn says, “when there’s only one generic manufacturer in the field, the price difference is a miniscule 10% to 15%. The real savings for all purchasers and payers won’t begin until there’s robust generic competition.”

A month’s supply of Truvada in the United States is priced from $1,600 to $2,000 (despite costing only a fraction of that amount to manufacture). This means that Teva’s generic med could still be out of reach for those who need it most, such as young gay Black men and transgender women.

Of course, it must be pointed out that many insurance providers, including Medicaid, cover Truvada and that Gilead offers a copay card. So the oft-repeated price tag of $1,600 shouldn’t deter anyone from trying to access Truvada today.

Other issues will come into play and affect the meds’ costs, says Horn, who raises the possibility that Gilead may discontinue its copay assistance program for Truvada at the end of September 2020 and that Teva may elect not to set up its own program. At this point, it’s impossible to predict the resulting price tags for the meds.

AIDS activist Peter Staley, in a Facebook post about generic Truvada, warned that “Teva can expect to become PrEP4All’s next target if they don’t launch their own patient assistance programs.” Staley’s post, embedded below, also includes text from a correspondence with Douglas Brooks, Gilead’s senior director for community engagement.

What’s more, Gilead’s HIV pill Descovy (made of emtricitabine and the updated tenofovir) will likely be approved for PrEP by the end of 2019, well before the generic Truvada hits the market. If that happens, NASTAD’s Horn says, Descovy will have a robust copay assistance program. “It’s unclear if the end result will be cost savings and improved access with a generic versus mass exodus to high-cost Descovy,” Horn says.

Meanwhile, Aaron S. Lord, MD, with the PrEP4All Collaboration, issued a statement on the announcement of Teva’s generic Truvada. It reads in part:

> “While Gilead’s announcement that generic Truvada will be made available in the United States a year early is a victory for the LGBTQ+ community, for HIV activists and for U.S. taxpayers, this should only be the beginning. Even their announcement today leaves Gilead with exclusive rights to Truvada as PrEP for another 15 months and Teva as the only generic manufacturer on the U.S. market. This will do little to reduce the price in a way that will increase access, and PrEP4All remains suspicious of the terms and lack of transparency surrounding the Teva settlement. I have to ask, what’s to stop them–other than a desire for profit margins–from releasing the rights now?

> “Furthermore, Gilead’s statement…that the agreement to allow Teva to manufacture a generic a year early was made in 2014 runs afoul of statements made to shareholders by their former CEO John F. Milligan on their Q2 2017 earnings call. In that call, he said, ‘We don’t expect generic Truvada in the United States until 2021.’ If this agreement was made in 2014, why did he lie to shareholders?”

To read more about Gilead’s Descovy as PrEP, click here; to read about efforts to #BreakThePatent, click here; and for news that the CDC owns the patent to Truvada as PrEP, click here.

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