Did HIV Pharma “Pay to Delay” Generic Truvada?

AIDS activists urge the N.Y. attorney general to investigate possible antitrust violations regarding the HIV med used as PrEP.

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Four well-known AIDS activists sent a letter to the New York attorney general urging him to investigate whether Gilead Sciences has violated antitrust laws by seeking deals to delay generic versions of its blockbuster HIV medication Truvada, Stat News reports.

Truvada consists of two different HIV meds—tenofovir disoproxil fumarate and emtricitabine—and is the only drug approved by the Food and Drug Administration (FDA) as an HIV pre-exposure prophylaxis (PrEP), in this case a daily pill to prevent HIV-negative people from contracting the virus.

In the letter to New York State Attorney General Eric Schneiderman, activists James Krellenstein, Peter Staley, Tim Horn and Jeremiah Johnson make the case that Gilead Sciences has reached “pay for delay” settlements with generic drug manufacturers for generic Truvada.

The patent for the tenofovir in Truvada expired in July 2017; the patent for emtricitabine doesn’t expire until 2021. But as POZ reported this summer, the FDA approved a generic version of Truvada in June 2017, and Teva Pharmaceuticals was granted the right to produce it. At the time, Gilead Sciences stated that a generic version of Truvada would not be available soon.

An antitrust expert interviewed in the Stat article said there might be good reason for the attorney general to look into the case. “The question you have to ask yourself is why a generic company would delay entering such a lucrative market,” said Michael Carrier, a professor at Rutgers University School of Law.

The letter to Schneiderman states that Truvada “is an extraordinarily expensive drug—a thirty-day supply costs, on average, over $1,500, despite costing less than $9 to produce. This artificially high price poses a significant burden for payers and patients alike. Indeed, because Gilead’s copay assistance program only covers a maximum of $3,600 in out of pocket expenses—well below the out of pocket maximum established by the Patient Protection and Affordable Care Act (ACA) of $7,150 for individual plans and $13,700 for family plans—even insured patients are often forced to pay significant amounts of money or rely on third party support mechanisms in order to access the

drug. Allowing generic versions of Truvada to be marketed would dramatically reduce the price of the drug."

The letter writers conclude that "due to the confidential nature of the Truvada settlements, and what we believe to be the parties' studied efforts to avoid even basic disclosure of the settlements, it is impossible for us to evaluate whether Gilead in fact paid for delay. We urge you to open an investigation of these settlements."

This summer marked an anniversary for the prevention pill. For more, read "As PrEP Turns Five, the HIV Prevention Pill Is a Major Success."

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