HIV Drugmaker Gilead Delayed Newer Version of Tenofovir to Extend Profits

Internal documents show Gilead held off on developing new therapies, such as Descovy, a potentially less toxic version of Truvada.

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It appears the HIV activists were right. For over a decade, they've accused HIV drugmaker Gilead Sciences of delaying the development of a newer, and possibly safer, version of tenofovir, which is included in several blockbuster HIV drugs, such as Truvada and Atripla. The pharmaceutical giant denied the claims and continues to do so. But according to The New York Times, internal documents show that Gilead did in fact utilize a "patent extension strategy" to maximize the older drug's monopoly and profits.

Truvada combines two drugs: tenofovir disoproxil fumarate (TDF, which is sold separately as Viread or generics) and emtricitabine (sold separately as Emtriva). Truvada was approved as HIV treatment in August 2004. It was given the green light as pre-exposure prophylaxis, or PrEP, to prevent HIV, in July 2012. To learn more, see the POZ drug page on Truvada.

Descovy is the updated version of Truvada. It contains a newer version of TDF—tenofovir alafenamide fumarate (TAF)—along with emtricitabine. The Food and Drug Administration approved Descovy as HIV treatment in April 2016 and as HIV prevention in October 2019 (but not for receptive vaginal sex). For more, see the POZ drug page on Descovy as well as the HIV Basics "TAF Versus TDF: What's the Difference?"

Despite knowing that a newer version of the original tenofovir could be less toxic, notably on kidney and bone health, Gilead stopped developing the updated med in 2004, the year the original was approved by the FDA. In such cases, the idea is to delay the release of the better drug until the original patent runs out, then have patients hop, or switch, to the newer, more expensive and better med. The practice is so common in the industry, the Times notes, adding that it even has a nickname: product hopping.

"There's something profoundly wrong that happened here," Christopher Morten, a pharmaceutical patent law expert at Columbia University, told the Times. "The patent system actually encouraged Gilead to delay the development and launch of a new product."

Morten had provided pro bono work in a 2019 lawsuit in which HIV advocates claimed Gilead

delayed the release of newer meds, saying that a proportion of people with HIV who took the meds developed kidney and bone problems, such as osteoporosis (the newer version doesn't cause these side effects). They lost the case.

According to the Times, in the course of other HIV-related cases against Gilead, lawyers unearthed internal documents about the purposeful delay of the newer med, including a 2003 memo regarding "tenofovir exclusivity extension."

To read more about recent lawsuits involving Gilead, see "UPDATE: U.S. Government Seeks New Trial in HIV PrEP Patent Lawsuit" and "HIV Drugmakers Gilead and Teva Didn't Pay to Delay Drugs, Rules Jury."

And for a first-person account of one man's experience with the effects of osteoporosis, check out this 2010 POZ blog post "Did Gilead's Viread Break My Ankle?" from POZ founder Sean Strub.
