HIV Drugmaker Can Be Sued for Delaying Release of Safer Med, Court Rules

24,000 people with HIV who took an older form of tenofovir (TDF) are suing Gilead Sciences for delaying development of a safer version.

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Pharma giant Gilead Sciences, which manufactures numerous blockbuster HIV meds, can be sued by customers claiming that the drugmaker caused them harm when it delayed the development of a newer and safer version of the drug Viread (tenofovir disoproxil fumarate, or TDF), according to a ruling by the 1st District Court of Appeals in San Francisco.

Specifically, 24,000 plaintiffs—people living with HIV—claim they were harmed by taking TDF, which was approved for HIV treatment in 2001 and has potential side effects, such as bone and kidney damage. According to the lawsuit, Gilead knew about a newer and less damaging version of TDF but delayed work on it so that the drugmaker could profit from the older med.

As Justice Jerry Goldman sums up in the 3–0 decision:

> "While Gilead was developing TDF, it discovered a similar, but chemically distinct, potential drug, tenofovir alafenamide fumarate (TAF). Plaintiffs allege that Gilead's early testing indicated TAF could be as effective as TDF at treating HIV/AIDS, while carrying a lower risk of adverse effects. According to plaintiffs, however, Gilead elected to defer development of TAF because it was concerned that the immediate development of TAF would reduce its financial return from TDF. Years later, Gilead resumed the development of TAF and obtained FDA [Food and Drug Administration] approval for its sale in 2015.

> "Although plaintiffs are seeking compensation for injuries caused by their use of TDF, they do not assert any claim seeking to prove that TDF is defective. Instead, they characterize their claim as one for ordinary negligence, contending that Gilead's decision to defer development of TAF to maximize its profits breached its duty of reasonable care to users of TDF. They also assert a claim for fraudulent concealment, reasoning that Gilead had a duty to disclose information about TAF to users of TDF."

Gilead countered that the plaintiffs must prove that the drug was defective and that the drugmaker had no duty to disclose facts about the development of the newer tenofovir (TAF, known by the brand name Vemlidy).

Given the facts of the case, the judge ruled that a trial could move forward and Gilead could be held to account for the delay "if the reason was solely to maximize Gilead's profits."

According to The San Francisco Chronicle, this marks the first time that a California appellate court has ruled that a manufacturer can be liable for a product that isn't defective. (Despite possible side effects, the older tenofovir, TDF, was an effective part of HIV treatment.)

Deb Telman, Gilead's general counsel told the newspaper that if the ruling stands, it will have "widespread, negative consequences across all fields of innovation and manufacturing, undermining the development of new products and discouraging improvement of existing products."

Gilead can appeal the ruling to the state's Supreme Court.

Both TDF and TAF are used not only in several combination HIV treatments but also as pre-exposure prophylaxis (PrEP), which HIV-negative people take to prevent contracting the virus. To learn more about these medications, see "TAF Versus TDF: What's the Difference?" For a quick-reference chart that compares antiretroviral options, check out our latest HIV Drug Chart.
