

The Truvada Lawsuit

Dear Participants,

You may have recently seen or heard about lawsuits filed against [Gilead Sciences](#), the manufacturer of [Truvada](#). This 2-drug tablet was [approved by the FDA in 2004](#) to treat HIV, and in 2012, it was [approved for HIV prevention](#) (as [pre-exposure prophylaxis or PrEP](#)). Since Truvada is a medication that is being used in our prevention research studies, we want to share information that may answer questions you have about Truvada.

Is Truvada safe?

Truvada is a combination of two drugs: emtricitabine (abbreviated FTC) and tenofovir disoproxil fumarate (abbreviated TDF). We have known for years that TDF can cause some thinning of the bones (a decrease in bone density). For most people, the amount of bone thinning that TDF causes does not meaningfully increase the chance of a broken bone (fracture). There are [clear guidelines for when and how to check bone density for people living with and without HIV](#), and healthcare providers take these guidelines into account when they're deciding whether to check bone density. So far, studies of people taking Truvada for PrEP [have not shown any increased risk of broken bones](#). We also know from studies of [people living with HIV taking Truvada](#) and [people who take Truvada as PrEP](#) that if someone stops taking the drug their bone density recovers close to where it was before they started Truvada.

[TDF can also cause kidney problems in some people](#) – especially those with diabetes, high blood pressure, or other medical problems that put them at risk for kidney disease. Fortunately, this is uncommon, [occurring in around 2 of every 100 people who take TDF for treating their HIV](#). It's also [reversible for the majority of patients](#) living with HIV who have a change in their kidney function related to Truvada. Among participants in studies of Truvada for PrEP, there were just as many people who had kidney function changes taking TDF as those taking the placebo – meaning that [it didn't look like Truvada was causing any significant kidney issues](#). It's important for you to know our research studies include regular blood tests to check on kidney health. Overall, we agree with the FDA that Truvada should be considered safe for the treatment and prevention of HIV. What we know about Truvada and kidney and bone health has not changed since you entered the UNC research study.

What are the lawsuits about?

The lawsuits we are aware of allege that the maker of Truvada ([Gilead Sciences](#)) delayed coming out with a new combination drug that appears to have a better safety profile than Truvada. The new drug, called [Descovy](#), contains FTC and an alternative version of TDF called tenofovir alafenamide fumarate (abbreviated TAF). TAF is very similar to TDF but [has less effect on bone density and a lower likelihood of causing kidney problems](#). The lawsuits do not claim that Truvada has any new or previously undisclosed side effects – only that the drug company should have come out with the new version (TAF) drug sooner.

How have the HIV prevention research studies conducted at UNC changed since the lawsuits were filed?

Our team works hard to make sure that our participants are monitored closely for any safety issues throughout all of our studies, so these lawsuits have not changed anything that we do for our participants. Blood tests are done routinely, and bone scans are part of many of our prevention studies – even though they are not part of usual practice for people taking Truvada as PrEP outside of a research study. We are also obligated to inform you if there is any new information that could change the risk of participating in a study (plus it's just the right thing to do). But the information that your study coordinator reviewed with you during the informed consent process is the same today as it was when you entered the study. There is no new information to share regarding Truvada's safety.

As of August 2019, Truvada is the only FDA-approved drug for HIV prevention, but newer prevention drugs are being compared to Truvada as the “standard.” When new options for pre-exposure prophylaxis (PrEP) are approved by the FDA, we are obligated to let you know, so that you can decide whether to continue in the study or to switch to the new medication. We expect some new options to become available over the next several years.

We hope this addresses questions or concerns you may have about Truvada. Please let a study team member know if you have other questions we have not covered.

Thanks,

Study Team