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FDA should make anti-HIV drug over the counter

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Secretary of Health and Human Services Alex Azar announced last week a federal suit against Gilead Sciences, makers of pre-exposure prophylaxis against HIV, also known as PrEP, claiming the company is infringing on government patents while selling these prescription-only drugs at high prices. The case could devolve into a protracted legal battle hinging on arcane patent law and the validity of government patents.

But both parties could avoid that if the Food and Drug Administration would simply make PrEP and post-exposure prophylaxis, also known as PEP, available over-the-counter.

The Centers for Disease Control and Prevention reports sexual activity is the predominant cause of HIV transmission in the U.S. Studies show PrEP can reduce risk of HIV transmission from sex by 99 percent, and reduces HIV transmission from needle sharing by 74 percent when taken daily. PEP is also effective in preventing HIV transmission, but must be taken within 72 hours of exposure and continued for 28 days, and should be followed by repeated HIV testing from a health care provider.

Experts recommend that regular users of PrEP get semiannual blood tests to check their kidney function, because long-term use can cause renal impairment. But that doesn't mean the drug shouldn't be available over the counter. People taking nonsteroidal anti-inflammatory drugs long-term, such as ibuprofen, can harm their kidneys and should probably periodically check their kidney function. And people on long-term acetaminophen can harm their liver. These drugs are already available over the counter.

In October, recognizing the need to make these drugs more available, California Gov. Gavin Newsom signed into law a bill allowing pharmacists to prescribe PrEP and PEP. While the FDA decides whether a drug is classified as prescription-only or over the counter, states get to determine the scope of practice of their licensed health care practitioners. State legislatures have increasingly expanded pharmacists' scope of practice, allowing them to prescribe a prescription-only drug, as a means of working around the federal prescription requirements in order to improve access (and decrease cost) to medications and vaccinations their residents want and need.

Making PrEP and PEP over the counter will greatly increase access to these lifesaving products. At-risk individuals won't have to spend the time and money going to a doctor's office to get a prescription. Their access won't be limited to retail pharmacies, because over-the-counter drugs can be obtained at thousands of other retail and convenience stores. They might even become available in vending machines, as is the case with Plan B, also known as "the morning after pill" for birth control.

Numerous studies show substantial price reductions when drugs move from prescription-only to over the counter. It is reasonable to expect the same to happen with PrEP and PEP.

In his last State of the Union Address, President Trump set the laudable goal of eliminating new transmissions of HIV by the year 2030. Increased access to PrEP and PEP is critical to reaching that goal.

The U.S. Department of Health and Human Services oversees the Food and Drug Administration. If HHS Secretary Azar is serious about making HIV prophylaxis cheaper and more available, he doesn't have to get bogged down in a multi-year lawsuit with a pharmaceutical manufacturer, with an uncertain outcome, while new cases of HIV mount up every day. He can press the FDA to make PrEP and PEP over the counter.

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