

STANDARD DEVIATIONS: The Truth about Truvada

Techs,

While there is still no true cure for HIV, medication known as antiretroviral therapy exists to control HIV infections. When taken properly, antiretroviral medication can help someone infected with HIV maintain good health, live a long, normal life, and potentially even prevent the spread of HIV to others. Studies have shown that pre-exposure prophylaxis (PrEP) reduces the risk of getting HIV from sex by more than 90% when used consistently. Among people who inject drugs, PrEP reduces the risk of getting HIV by more than 70% when used consistently.

One PrEP drug dominates the HIV landscape, **Truvada**, a fixed-dose combination of two antiretrovirals: tenofovir disoproxil and emtricitabine. The drug is manufactured by Gilead Sciences.

On Thursday, 5/16/19, the company's new CEO Daniel O'Day took the congressional hot seat for a grilling about the drug maker's preventive option for the disease, Truvada for PrEP. Here's the statement made in the House Committee on Oversight and Government Reform hearing last week.

“We have taken the disease from a death sentence to a manageable clinical condition, but we're not done yet,” Gilead CEO Daniel O'Day told committee members. **“We have to be sure that Americans get our medicines at a price that allows us to invest in research.”**

Okay, I can get behind the first part of that, but I struggle with the second sentence.

The company's drug, **Truvada**, a pre-exposure prophylactic, for the prevention of HIV is a controversial topic. In viral suppression and HIV prevention, is the recommended formula for preventing HIV. Over 1,000,000 (a million) Americans at risk of getting HIV. Only 20% (200,000) of the targeted population can afford or use the drug here. The cost for taking **Truvada is \$20,000/yr., or \$70 per daily dose.**

Gilead Sciences is the manufacturer and has no competitor in the U.S. market. They have cleared over 35 Billion \$ since 2004 in Truvada sales (U.S). Pretty good cash if you hold the patent! Right?

You do.

Actually, we all do. The CDC holds that patent; you, me and every American. Gilead recently admitted as much; and in recognition, has agreed to provide free Truvada for 200,000 persons



until 2030 (or, another 20% of the needy). Well, you wouldn't expect them to just reduce the cost, would you? Yay for America! Right?

Not so fast.

Patent law is territorial, the same drug is sold as a generic across the world (HIV is a pretty big deal). In Africa, **the \$20,000 regimen here costs around \$60**, or 0.3% the cost we see in the States. Only one in five of the Americans who should use this retro-viral can afford it. The good news is: the patent expiry is September of 2020. Then other companies can market their generic Truvada and the price should plummet to affordable levels? Hurray for the system! Right?

Whoa, pard,

You see, those clever kids over at Gilead have a better, safer, drug just waiting to hit the shelves! Yes, the new drug has a safer active ingredient (tenofivir disoproxil vs. tenofovir alafenamide, TDF vs TAF in the formula). And in, oh, about eleven months, we can all switch to Descovy, for about that same 20 LARGE/yr. Meanwhile, no problem with giving away the warehouse full of Truvada (it only cost <\$60/yr. to make, anyway & the patent is almost up). All that money invested in that research paid off for mankind! Right?

About Face, Soldier!

The legwork on the new drug, **Descovy**, was done years ago. Gilead has suppressed distribution in order to maximize profit from the Truvada deal. Now that its peddled monopoly is ending, the new patent will extend their market and exclusive pricing for years. Gilead recently **lost a motion to dismiss** a case claiming the company delayed safer TAF-based HIV drugs to protect sales for its older generation of TDF-based medicines. And all that research was funded through the CDC studies done years ago at the expense of us, the taxpayer, not Gilead. Shame on Gilead but good news for HIV prevention! Right?

As if it weren't weird enough, man.

Between 2011 and 2016, the rate of new HIV diagnosis in the US has not changed, statistically. It has remained at around 12-13 cases per 100,000 for years. Even with PrEP available (if you've got the do-ray-me) the rate of incidence hasn't gone down. What's with that? The fact is that the therapy has not made an impact on HIV, here. But, out there? Where PrEP is affordable for a much greater portion of susceptible people the rate has dropped 16% percent in the same time. Keeping the cost of Truvada or Descovy at current levels enriches Gilead and its stockholders but does nothing to address the HIV epidemic in America. Yeah, but that doesn't affect me, right?

Well, here's the deal.

HIV emerged in the 1980's and woke the world up to the threats of Bloodborne Pathogens. We, as laboratory scientists have become intimately familiar with HIV and its risks. Unlike the drug company, the price of our "PrEP" is minimal. Like the drugs, we use biosafety principles and practices as our pre-exposure prophylaxis every day. And also like the drugs, biosafety offers



protection from acquiring disease. Caution, reason and access to information, protection and guidance keep the incidence of disease at a low risk for labs that recognize biosafety.

The work we do in the lab for HIV awareness, prevention, and management is the true return on our investment in biosafety. The questionable future of the business of HIV therapy and prevention in the United States remains to be decided.

That's just the truth.

Have a great week and be safe,

Bryan

p.s. "In recent years we have made remarkable progress in the fight against HIV and AIDS. Scientific breakthroughs have brought a once-distant dream within reach. My budget will ask Democrats and Republicans to make the needed commitment to eliminate the HIV epidemic in the United States within 10 years. Together, we will defeat AIDS in America." President Trump's 2019 State of the Union Address 2/5/2019.

References

www.cdc.gov/hiv/research/biomedicalresearch/prep/index.html

www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis

www.nytimes.com/2019/05/09/health/gilead-truvada-hiv-aids.html
health.utah.gov/epi/diseases/hivaids/

www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf

www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf

www.unaids.org/en/resources/fact-sheet

www.gilead.com/news-and-press/press-room/press-releases/2019/5/gilead-sciences-to-provide-free-truvada-for-prep-to-support-us-initiative-to-end-the-hiv-epidemic

www.fiercepharma.com/pharma/gilead-s-o-day-takes-congressional-hot-seat-to-defend-truvada

