

Submitter: Thomas Busse
On Behalf Of: HEAL - Testimony Part II
Committee: Senate Committee On Health Care
Measure, Appointment or Topic: HB2942

The first portion of my testimony focused on why expanding PEP access is bad policy. This second part focuses on why pharmacist-prescribed PrEP is bad policy and how this bill will raise the cost of health insurance for everyone while providing no clinical benefit to anyone.

PrEP was FDA-approved in 2012 based upon faulty clinical trial data. It opened up a completely new market selling expensive drugs to perfectly healthy people with no insurance. 2012 was also an election year and the first year the International AID\$ Conference returned to the United States, and the Obama Administration was trying to curry favor with Big Pharma by opening up an entirely lucrative new market as part of the multibillion dollar AID\$ drug lobby. As such, the Obama Administration pushed through the idea of PrEP by bypassing normal FDA safeguards. PrEP completely failed in two randomized placebo controlled trials in heterosexual women (Trials the FDA never saw and that were only revealed to have failed in 2017), and in order to get PrEP approved, the indicator trial, IPREX was strategically terminated early after becoming unblinded and finding a statistical blip where there was a 2% absolute risk reduction for "high risk gay men." Most worrisome, 40% of trial participants dropped out, raising the question of whether investigators simply excluded their data to get the results they wanted. Only 112 Americans participated in the trial which took place in multiple sites and the site-level data was not published - a probable indicator of fraud (i.e. only one site cooks the data), with some participants only enrolled for fewer than five weeks. Since 2012, there have been no true placebo controlled trials of PrEP on the basis of "ethics" - every new PrEP medication is trialed against the previous PrEP medication. Seroconversions among PrEP users are quite common, but this is a fact covered up by the AID\$ establishment because when they happen, clinicians blame the patient for "poor adherence" and they are reported as not being on PrEP. In other words, given the rushed data in 2012, it is unknown whether PrEP works at all or whether the people who are taking PrEP are the same people who would not seroconvert anyway.

PrEP initially came out at about \$8,000/month. It was approved under political pressure by an FDA panel for "High Risk Gay Men" - but the definition of "high risk" was left unstated. It was also approved for "serodiscordant couples" even though the FDA did not know about or see the data from the trials showing it failed in this official risk group. It was finally approved on a 60-40 vote for "others at risk." The FDA was wise to be hesitant about PrEP and until 2019 put it under a REMS agreement where pharmaceutical companies could not market it. What PrEP's manufacturer, Gilead Sciences, did is to fund "seeding trials" - phony clinical trials with no research benefit

to promote PrEP's usage among gay men such as the SF Public Health Department's "Demo Project." Trial recruitment turned into PrEP advertising. In Multnomah County, a Gilead Sciences Vice President's mother sat on the County board of Commissioners and ran through a \$500,000 grant to Cascade AID\$ - effectively bypassing the REMS agreement because it was "public health." Gilead Sciences also funds an army of Cascade AID\$ "PrEP Navigators" who are little more than pharmaceutical sales reps.

PrEP went off patent in 2020, and with "authorized generics" coming out at about \$400/month, Gilead's lobbying program turned twofold: 1. Trash that generic drug Truvada as more toxic than their "me-too" drug Descovy by launching a phony lawsuit with the AIDS Healthcare Foundation and a journalist shill for the Los Angeles Times and then weaponize fake patient groups such as Cascade AID\$ to lobby for laws that require insurance coverage of all ARV's so insurers would be forced to cover Descovy, and 2. Broaden the market by convincing people who are not at risk of HIV that they are.