# PrepIsPoison.com

## White Paper by Terry Michael & Thomas Busse

### Executive Summary

Confirmation-biased and cherry-picked clinical trials of Truvada for PrEP grossly misstated results leading to FDA-approval virtually purchased by Gilead Sciences via fast-track "user fees." Truvada and Descovy were chosen for PrEP licensing over Viread based on patent concerns instead of safety and efficacy. Through strategic early termination of trials, study authors fabricated efficacy against a placebo by retroactively tagging Truvada seroconversions as "pre-existing" and throwing them out, turning 0% marginal effectiveness into 2% marginal effectiveness, and statistically spinning 2% as "99% effective." Study authors may even have covered up data indicating Truvada/PrEP INCREASED seroconversions. A compliant and corrupted CDC rubber-stamped guidelines recommending multi-decade toxic chemotherapy for use in HIV negatives without evaluation of long-term use. A naïve Corporate media repeated PrEP clinical trial fabrications and distortions mischaracterizing Truvada's toxicity and failed to report on retraction of "90% efficacy" claim, leading individuals to Truvada's harmful use benefiting a politically hyper-connected drug company profiteering off the health of a gullible and propagandized gay community and increasing insurance premiums for the general population.

### Author Biography

A former newspaper reporter and press secretary to Sen. Paul Simon and the Democratic National Committee and later the Johnson Weld Campaign of the Libertarian Party, Terry Michael in 1989 launched the Washington Center for Politics and Journalism, which he directed until his death in 2017. He was a member of the Washington DC gay community since 1975 and contributed to Politico, Reason, The Washington Examiner, the Washington Blade, ABC News, and RealClearPolitics.

### Supplemental Information

All Sources and Links along with audiovisual resources are available at **PrepIsPoison.com**, a Portland (OR) grassroots-effort by Thomas Busse to educate the gay community about Nucleoside and Nucleotide Analogues.

## BACKGROUND

During the three decades since the United States (U.S.) government proclaimed on April 23, 1984 in a press conference convened by then Health and Human Services Secretary Margaret Heckler that a virus then named HTLV-III was the "probable cause of AIDS," tens of billions of U.S. Taxpayer dollars have been given to multiple thousands of research grantees. These "investigators" report to military organizations within the U.S. Public Health Service including the National Institutes of Health, the Centers for Disease Control, and the National Institutes of Allergy and Infectious Disease (NIAID).

For research and other aspects of HIV and AIDS funding since 1981, federal funding has exceeded **$570 Billion.** This dwarfs investment in all other disease. In 2013, research spending per death[1] was:

- $2,562 for cardiovascular death ($25 per patient)
- $16,010 for diabetes ($47 per patient)
- $5,683 for Alzheimer's ($85 per patient)
- $17,308 for breast cancer ($3,401 per patient)
- $10,146 for prostate cancer ($150 per patient)
- $329,576 for 'Deaths Attributed to AIDS' ($2,818 per patient).

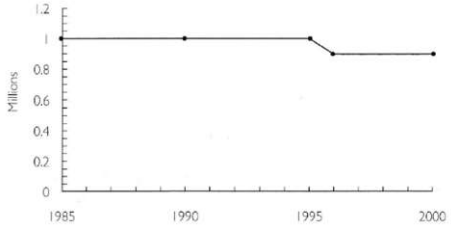

FIGURE 1: Prevalence of HIV in U.S. population

This multibillion dollar investment in "research" mostly subsidizes development of extremely expensive medication treatments with so-called "antiretroviral drugs" (ARV's). Beyond research funding, federal subsidies accrue to drug companies through programs including Medicare, Medicaid, and the "AIDS Drug Assistance Program" (ADAP). These programs are forbidden by law to negotiate with government drug purchasers and pay virtually any price drug companies demand.

Despite this massive investment, the U.S. Center for Disease Control (CDC) reveals that the number of HIV "cases" have remained steady at about 1 Million in any given year for over two decades. Each year, about 45-50,000 new "positives" are counted with an equivalent die-off. In the context of a so-called "epidemic" disease which should follow Farr's law, this paradoxical consistency is simply *not credible*[2]. True epidemic diseases follow a "bell curve" pattern.

## CREATIVE COUNTING OF AIDS, "HIV DIAGNOSIS," AND "CASES"

Deaths attributed to "AIDS" and "HIV Disease" have fallen to 15,000 yearly with many of these clearly attributed to adverse health effects of long-term use of ARV's. Fortunately, this pales in comparison to the silently uncounted scores of thousands of iatrogenic deaths from lethally high doses of AZT and other nucleoside analogues from 1987-1997 fallaciously said by the CDC and major media sources to have been "AIDS Deaths." Today, the CDC states "the deaths of persons **with** an AIDS diagnosis **can be due to any cause –** that is, the death may or may not be related to 'AIDS.'"

For example, the District of Columbia's official HIV/AIDS agency claimed that 251 of its residents died **with** HIV in 2011, but only 69 of those deaths were of **HIV-related causes.** In spite of its purported "transparency" the state of Oregon refuses to release its own statistics[3], but in DC and in Massachusetts, the vast majority of 'AIDS diagnoses' since 1993 have been from a T-cell count under 200 per microliter of blood *with no presenting or AIDS-defining illness* [i.e. opportunistic infection] *at the time of diagnosis*. Thus, in most states (including Oregon) it is possible to be healthy, have no disease symptoms, **get run over by a truck**, and be counted in official statistics and in federal funding applications as an "AIDS death."

Why? **It's the Economy, stupid.** Local agencies such as the Multnomah County Health Department[4] receive about $2500-$3000 in overhead funding each time they count a new "positive," a similar amount each time that positive progresses to 'AIDS,' and yet

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[1] Fair Allocations For Research Foundation, 2013

[2] Chin, James "The AIDS Pandemic: the Collision of Epidemiology with Political Correctness" Radcliffe, 2006. Dr. Chin is the former Infectious Disease Section Chief for the state of California Dept. of Public Health and the WHO's HIV Surveillance Officer.

[3] See OHA Letter to T. Busse 12/1/2020, posted at prepisopoison.com

[4] In 2009, Multnomah County was added to Title A of the 1990 Ryan White CARE Act. Through that law's grant agreements, the County committed the State of Oregon to expenditures based on a legacy continuing appropriation dating from 1999. This expansion of Federal Policies statewide and ballooning of budgetary commitments was neither discussed nor debated in the legislature, which had until 2001 been resistant to participation in Federal Ryan White programs. A proposed future expansion of the Ryan White Act exposes Oregon to a similar ballooning of policies regarding HCV-positives; unfortunately, the legislature has delegated program participation authority to the Oregon Health Authority, effectively giving up local and state control of public health policy priorities. In 2012, the OHA without consulting the legislature expanded its "reportability mandate" to include CD4 flow cytometry data from laboratories, which increased the state's

more each time Multnomah County records a "death with HIV." As a result, Local Agencies (with a continuing appropriation from Salem outside the Legislature's budgeting process to meet a 10% local match requirement) aggressively pursue testing of all 'adult' residents (starting at age 13). In 2012, I encountered a testing van from the DC-funded "Carl Vogel Center" at my local Safeway. The van paid obviously poor African Americans $15 to take a rapid antibody test. One woman told me she had taken it multiple times for the money.

### America's "AIDS Czar" Anthony Fauci's misguided AIDS Policies

Although Congress has gained P/R credit for allocating AIDS funding, the decisions over how that funding is spent has fallen to NIAIDs and its director, Anthony Fauci, who from the 1980's has employed a theory and disease model never properly vetted in an honest process backed by science. Hired on 11/3/84, Fauci has limited 'AIDS grants' to the study of an HIV monocausal model against the background of an evolving CDC "official definition." Fauci has ignored "multi-factoral" disease models favored by Dr. Luc Montagnier, the discoverer of HIV, and by Dr. Joseph Sonnabend, co-founder of what became AmFAR. Such Co-factoral models include consideration of immunosuppressive "AIDS" triggers from:

- Multiple and repeated exposures to old disease pathogens in brief timeframes, including through the intimacy of sexual activity, and subsequent over-prescription of microbiome-damaging antibiotics
- Frequent injection of toxins inclusive of recreational and prescription drugs that are immune-suppressive. This is inclusive of so-called "antiretroviral drugs" such as AZT.
- Chronic and acute stress that weighs on minority communities – especially closeted homosexual men in so-called 'gay ghettos. This leads to lifestyle and behavioral patterns that can promote oxidative stress similar to malnutrition encountered in the developing world.

Fauci, NIAIDS, and thus the Federal Establishment's oversimplified HIV monocausal disease model may very well be influenced by the director's upbringing. Born in December 1940, Fauci was the son of a Brooklyn, NY pharmacist. Spending over half a trillion dollars NIADS has come up empty except for a dubious ARV therapy known as HAART. Essentially chemotherapies, ARVs theoretically disrupt the reverse transcription of HIV RNA into T-cell DNA, although the clinical basis for this theory is dubious. Interestingly, there is no data that Truvada's ingredients are even effective against HIV because they were originally trialed in the late 90's in accelerated protocols as part of protease inhibitor cocktails, not as monotherapy.

Over the years, ARVs produce a cumulative adverse immunosuppressive effect on the host. This includes damaging the liver, kidney and heart. The number one cause of death in HIV-positives is liver failure from ARVs. Facial wasting, redistribution of body fat, chronic diarrhea, reduction in bone mineral density, lactic acidosis, thinned limbs, protruding veins, cardiopulmonary issues, and abnormal microbiome are all hallmarks of long term ARV use. Often ARVs are initiated without any clinical symptoms of illness, and so called "positive" patients are coerced into HAART without confirmation of actual infection with virus. Because HIV tests only detect antibodies and not virus and molecular PCR tests can amplify HIV sequences that are part of the human genome, it is never quite certain whether "HIV positives" are truly infected. Currently, there are over 103 medical conditions known to cross-react with HIV antibody tests, and the risk of false positives is especially high in a low prevalence population such as Oregon's. Internal medicine doctors often have 5-6 hours total training in HIV/AIDS (heavily influenced by Big Pharma and its agenda to sell specialty pharmacy drugs) and are often unaware of the history, minutae, and problems of HIV test evolution and validation.

### Dangerous Leap into ARV unknown "Test and Treat"

In 1995, Time Magazine labeled Dr. David Ho of the Aaron Diamond Center in New York, "Man of the Year" thus elevating the inventor of "viral load" and "the cocktail" to the ranks of other "men of the year" (including Adolf Hitler). Dr. Ho's "hit Hard hit early" approach, in spite of popular propaganda, is not universally accepted among HIV and AIDS specialists. The math in his paper quickly fell apart[5], but the monster it spawned remains. Dr. Jay Levy (often called the "third discoverer of HIV")[6] authored a basic orthodox textbook *HIV and the Pathogenesis of AIDS.* In 2001, he warned[7] and today still cautions against "early

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transient "AIDS diagnoses" at a cost to the general fund so that Multnomah County's Health Department could claim additional funding under Title A.

[5] https://www.bmj.com/rapid-response/2011/10/30/reply-bennett-david-hos-virological-mayhem-model-has-long-been-debunked

[6] Crewdson, John "Science Fictions" Little Brown (2002) pp 90-91. This book is a neglected classic in the history of AIDS

[7] https://www.sfgate.com/opinion/openforum/article/The-Big-Question-Now-in-Anti-HIV-Therapy-When-2949172.php

intervention" with ARVs, especially in asymptomatics. He repeated this warning in an interview with me in 2011.[8] Although no serious specialist believes Ho's 1995 disease model, Ho's unsubstantiated advice about "surrogate markers" has lead scores of thousands of non-ill HIV positives (including false positives) to fall into the "AIDS Drug trap."[9]

Never in HIV drug trials has a drug been trialed for the expected period of use. One has to look no further than the manufacturer's own small-print disclaimers to their own products:

- Glaxo's Ziagen *"At this time there is no evidence that Ziagen will help you live longer or have fewer of the medical problems associated with HIV or AIDS"*
- Merck's Crixivan: *"It is not yet known whether Crixivan will extend your life or reduce your chances of getting other illnesses associated with HIV"*
- Boehringer's Viramune *"At present, there were no results from controlled clinical trials evaluating the effects of Viramune on the incidence of opportunistic infections or Survival"*
- Glaxo's *Combivir "There have been no clinical trials conducted with Combivir."*[10]

Thus, in an HIV-negative taking co-formulated "Truvada" for prophylaxis over 15+ years, there has never been any scientific evaluation of the long term health impacts of PrEP inclusive of its public cost/benefit. Truvada contains two nucleoside analogues – known carcinogens – and a user would be subjecting himself to a cumulative toxicity never measured in a clinical trial – EVER.

Trial investigators have nothing to say about how long PrEP can be used continuously. At the 19th International AIDS conference in 2012, I confronted proponents of PrEP including Dr. Fauci. The resulting exchange was disturbing and may be viewed at Prepispoison.com.[11] PrEP is a giant experiment in mass chemotherapy. I also reported critically on studies funded by Fauci to the tune of over 26-million dollars to experiment on mostly African Americans in the Washington DC Area.[12]

### Toxic Balms of Gilead for HIV Negatives

By the late 'aughts and with billions of dollars spent, NIAID had come up empty on HIV/AIDS with 190 failed vaccine trials and a lackluster liver-killing HAART regime. With the Ryan White act set to expire in 2010 and budgetary pressures introduced in the wake of the 2008 Financial Crisis and coming 2012 presidential election, Fauci was under pressure to have a success. Thus, the benign-sounding "PrEP" was born. This occurred largely through and to the singular benefit of a Foster City, California pharmaceutical company known as Gilead Sciences. Unlike most large drug companies named after founding families (Lilly, Merck, Bristol-Meyers, etc.) in an astonishing move of marketing savvy, Gilead drew its name from the Hebrew-Bible "balm of Gilead" (Jeremiah 8:22: "Is there no balm in Gliead? Is there no physician there?").

This publicly-held corporation has long been tied to the Republican party and the military industrial complex – as well as to Fauci who named Gilead's CEO John C. Martin to the NIAID advisory council in March 2000.[13] Donald Rumsfeld was chairman of Gilead's board from 1997 to January 2001, when he resigned to become George W. Bush's secretary of Defense. Several years into Rumsfeld's tenure, the DoD stockpiled millions of units of Gilead's Tami-Flu[14], now regarded as completely worthless.[15] In 2020, the same thing happened with Gilead's worthless Remdesivir. Strangely, at the height of the "War on Terror" an "ecoterrorist" who just happened to be the son of Tiburon's City Manager (and who has never been found by the FBI in spite of the massive national security build-out revealed by Edward Snowden), blew up the laboratory and several homes of executives[16] of Gilead's chief competitor, Chiron Corporation. Somehow, Gilead managed to snap up Chiron's critical Hepatitis C patents. [17] In addition to Rumsfeld (who had been on the board since 1988), Gilead's board members have included Ronald Reagan's Secretary

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[8] https://www.washingtontimes.com/news/2010/mar/17/going-too-far-to-battle-disease/
[9] New York Magazine "Another Kind of AIDS Crisis" November 2009 https://nymag.com/health/features/61740/
[10] As a younger man, I remember Combivir ads plastered all over the Castro featuring Magic Johnson. In 2004, Johnson admitted to a German journalist named Torsten Engelbrecht that he had never taken the drug and had never taken any HIV drug since 1992.
[11] https://www.youtube.com/watch?v=tMirE0TNXlQ
[12] https://www.washingtontimes.com/news/2010/mar/17/going-too-far-to-battle-disease/
[13] https://dl.dropboxusercontent.com/u/31816360/FauciAppointsGilead%27sJohnCMartinToNIAIDAdvCouncilMar_20_2000.jpg
[14] http://money.cnn.com/2005/10/31/news/newsmakers/fortune_rumsfeld/
[15] https://www.theatlantic.com/health/archive/2013/02/tamiflu-myth-and-misconception/273167/
[16] A similar fate met the owners of Canadian generic drug maufacturerer Apothek who in December 2017 were found strangled in their Toronto home while they were entangled in a corporate espionage and patent lawsuit against Gilead. The case has never been solved.
[17] https://www.sfgate.com/crime/article/Daniel-Andreas-San-Diego-listed-on-FBI-s-most-5062632.php

of State George Schultz, George HW Bush's trade representative Carla Hills, and the wife of former California governor Pete Wilson. After the mid 2000's, ARVs replaced TamiFlu as Gilead's cash-cow and stock-price mover.

### GILEAD EXCLUDED TWO OF FOUR MAJOR PREP TRIALS BEFORE FDA'S TRUVADA LICENSING

There were four major "Phase II" PrEP clinical trials between 2007 and 2011 **[see chart]**. These involved between 2000 and 5000 test subjects each. Although subsequent "demo projects" and the 2016 "DISCOVER" trial have taken place, these later observational studies were neither placebo controlled nor double blinded. **Efficacy can only be determined through true placebo-controlled trials, and all four PrEP trials purporting to be placebo-controlled are fatally flawed.**

Every PrEP trial experienced **early termination** prior to the FDA's 2012 decision to license Truvada for PrEP. The consistent Early Termination raises several red flags in the context ARV drug development going back to the 1987 approval of AZT. As reported in the early 1990's by journalist John Lauritsen, AZT's manufacturer unblinded the "Fischl" trial and terminated it the moment it got a statistical blip showing efficacy for AZT and this was known to the FDA which approved the toxic drug anyway – leading to the death of 300,000 healthy gay men between 1987 and 1997 from AZT poisoning incorrectly described as "AIDS" in the popular press.[18] Even though the Concorde Study[19] of 1994 (still the only legitimate placebo-controlled trial of ARVs ever performed – all others being controlled against earlier ARVs) proved conclusively that AZT and the entire class of Nucleoside Analogues have **only adverse efficacy against the key clinical endpoint of extending life,** AZT and its progeny remain on the market. Also notable about the PrEP trials was they **took place in the developing world** and are hardly comparable to the intended U.S. Patient base. African trials should also raise red flags in the context of ARV drug development in light of the HIVNET whistleblower complaint of Jonathan Fishbein at the NIH[20]. Fishbein revealed **a culture of willfull disregard for scientific integrity** in African ARV clinical trials, and subsequent retaliation against him indicates the NIH, NIAID, and allied subcontractors have not cleaned up their act. Furthermore, early termination of a 1996 trial (NIAID ACTG-320), considered to be "definitive" in establishing efficacy of David Ho's ARV cocktail was later admitted by study authors to have been too premature for statistical significance (Boston Globe Feb 25, 1997). The so-called "Lazarus effect" was more related to ceasing lethally toxic doses of AZT, d4T, ddI, etc.

**Two of the halted PrEP trials were ignored by the FDA** and their data was not submitted with Gilead's Truvada Expanded Use Authorization. These were **FEMPrEP** involving 2,120 HIV negative heterosexual females and **VOICEPrEP** involving 5,029 HIV-negative heterosexual females. **Both found 0% Effectiveness.** Information on both was not released until 2013.

In 2012, the FDA only saw data for two "successful" trials: **PartnersPrEP[21]** involving 4,747 heterosexual serodiscordant couples and most importantly **iPREX[22],** a multi-center trial of 2,499 HIV-negative gay/bisexual ("MSM") males, two-fifths of whom were prostitutes unscreened for drug use. 9% of the trial participants were American – at two centers in San Francisco and Boston – and these were obviously added so investigators could claim to the FDA and the public at least some testing was done in the U.S.

The FDA's "Anti-Viral Drugs Advisory Committee" voted on May 10 2012[23] to endorse Truvada for PrEP in:

1. Gay Men (vote of 19-3)
2. Serodiscordant heterosexual couples (vote of 19-2 with one abstention)
3. A vaguely-defined "other individuals at risk" category (vote of 12-8 with two abstentions)

Two committee members voted "no" on all three proposals: Dr. Elaine H. Morratio, an assistant professor at the University of Colorado, Denver, and Dr. Laruen V. Wood, a captain in the US Public Health Service. Their comments take up four pages in the transcript of the meeting. Morratio voted no *"… because I believed that the risk management elements proposed were inadequate to ensure the safety and efficacy that was observed in the trials could be adequately translated in the real world."* Morratio has proved prescient, especially in regard to risk management of kidney function monitoring. In 2019, California state Senator Scott Wiener, who receives contributions from Gilead, sponsored SB 159[24] allowing for pharmacist-dispensed Truvada and bypasses all safety guidelines of regular tests for kidney function including Glomeruler Filtration Rate (GFR) and Serum

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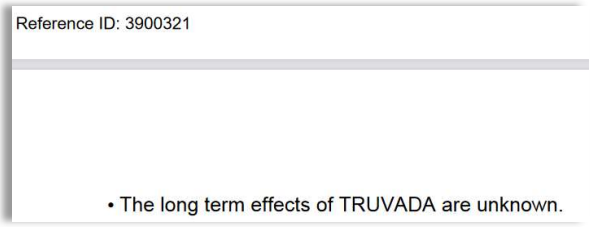
[18] Lauritsen, John "AZT: Poison By Prescrption" Asklepios, New York (1990).
[19] Concorde's PI received death threats in the months prior to publication of trial results (personal communication, 2009)
[20] Farber, Celia "Out of Control: AIDS And the Corruption of Medical Science" Harpers, March 2006 (available at prepispoison.com)
[21] https://www.nejm.org/doi/full/10.1056/NEJMoa1108524
[22] https://www.nejm.org/doi/full/10.1056/NEJMoa1011205
[23] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/ucm295937.htm
[24] https://www.nytimes.com/2019/10/09/us/california-hiv-drugs-prep.html

Creatinine as well as HIV (for the important issue of resistance – see below). The scenario is very similar to the post-marketing of AZT, which took on a life of its own in stark contrast to limitations promised in the 1987 FDA Advisory transcript.[25]

Dr. Elaine Wood noted only a handful of Americans were involved in the study. She pointed out only 117 gay African American men were in the iPrex Study out of a total of only 225 Americans of all races. Wood noted not a single African American woman was included in the Partner's Trial, which comprised 100% developing world subjects. She noted that Americans of African heritage are those "considered by the CDC" to be most "at risk" in the United States but this "consideration" was unsubstantiated in the published scientific literature. Wood stated, ***"I have significant safety concerns because it's well-known that African Americans have an extreme disproportionate risk for end-stage renal disease, chronic kidney disease and dialysis."***

Again, Wood's remarks have proved prescient. Starting in 2017, Gilead, the CDC, and National Public Radio started aggressively promoting PrEP to African American Women[26], in spite of NOT ONE CLINICAL TRIAL EVER INVOLVING THIS POPULATION. Evidently, "African American Women" are "other individuals at risk" targeted for PrEP marketing <sarcasm>because Black insatiable sexual desires are in the genes of jungle people and they do funny things with monkeys including the consumption of "bushmeat."</sarcasm> The reality is numerous studies show African Americans are more likely to practice responsible ("safe") sex[27] and that genetic factors make HIV tests less specific in people of African ancestry,[28] meaning Black Americans are at higher risk for false positives. [29] The term "Human Guinea Pig" resonates in the African American community, and one does not have to look further than the package insert of Truvada to see that long-term use of Truvada for PrEP is a giant scientific experiment pushed on marginalized minority populations:




The ostensible reason FemPrep and VoicePrep were halted was low adherence[30]; however, in the supplementary report to iPREX on page 33 in a revision published only after the FDA's 2012 approval, iPREX's study authors belatedly disclose that low-adherence in their trial was also frequent[31]. Of course, adherence is something studies are supposed to assess about a nauseating nephrotoxic diarrhea-inducing chemotherapy. The authors of FemPrep and VOICEPrEP told Reuters they blamed adherence on "bad African discipline," yet iPREX also had African trial participants. Either iPREX just managed <sarcasm>to pick better Africans, </sarcasm> or Gilead's convenient "choice" to be concerned about African Discipline on ethical grounds seems motivated when Ethics can be used to ignore studies whose results Gilead doesn't like.

### Creative Massaging of PrEP Clinical Trial Results: -2% becomes 0% becomes 2% becomes 90% becomes 99% Effective

Before FemPrep was halted, 33 of the 1024 subjects in the Truvada cohort seroconverted compared to 35 among the 1032 subjects in the placebo cohort – a meaningless difference.

Before VOICEPrEP was memory-holed, 94% of the 994 Truvada tabled cohort, 94% of the 1002 Viread tablet cohort, and 94% in the 1008 placebo tablet cohort did not seroconvert – demonstrating absolutely no difference. What is strange is the cohorts were originally equal, so why did the Truvada cohort shrink? It turns out there were disproportionate seroconversions in the Truvada cohort retroactively tagged as "pre-existing." How such assignment bias was introduced is unknown, but "occult" infections not detected at enrollment by HIV specialists who should know what they're doing raise the real possibility that Truvada cohort seroconverted at a greater rate than the placebo cohort! *Was the strategic early termination intended to avoid making such an outcome beyond-obvious had the trial run its intended course, risking hundreds of millions in drug sales?* The New York Times published an apologia regarding VOICEPrEP', but "low adherence" was based in serology, not in the more critical hair analysis which would have confirmed the serology. Hair analysis was not published until 2016 – contradicting the NYTimes.

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[25] Nussbaum, Bruce "Good Intentions: How Big Business and the Medical Establishment are Corruption the Fight against AIDS" pp 150-182 Atlantic Monthly Press (1990). This book, like "And the Band Played On" has important significant factual information but is an undisclosed industry-funded propaganda work. The reality not discussed in the book is that ACT-UP's Treatment and Data committee was an Astroturf effort funded by Burroughs Wellcome to weaken regulatory approval standards. Today, Treatment and Data is known as the Treatment Action Group (TAG) and receives funding from Gilead and the Gates Foundation. It was TAG that created the marketing lie Descovy is 'safer.'

[26] https://thewestsidegazette.com/spreading-the-word-about-hiv-prevention-for-african-american-women/

[27] Bussell, et. Al. "Public Perceptions Regarding the AIDS Epidemic" AIDS Research 2 (1986) 253-58

[28] Bauer, H.H. "Demographic Characteristics of HIV: Why Does HIV Discriminate by Race?" J. Scientific Exploration (2006) 255-288

[29] Bauer, H.H. "Demographic Characteristics of HIV: What determines the Frequency of Positive HIV tests?" J. Sci. Exploration (2006) 69-94

[30] See Reuter's Article from 2013 at prepoison.com. Reuters has now scrubbed it from the internet.

[31] The supplementary appendix is at prepispoison.com

In addition to stacking the deck by casting out the two multimillion dollar studies that didn't yield pro-PrEP results, investigators in the other studies seen by the FDA (Partners and iPREX) resorted to calculation techniques grossly overstating the alleged "protection" of Truvada. In iPREX, investigators simply subtracted the 36 drugged seroconversions from the 64 placebo seroconversions (totaling just 4% of 2,499 total subjects). They then divided the remainder by the number of placebo seroconversions, yielding a specious 44% "greater protection." Partners followed a similar procedure alleging 67% greater protection in the Viread cohort and 75% "greater protection" in the Truvada cohort. Because both studies were stopped early, one really wonders if the 28 serocoversions the Partners/iPrex methodology alleges wouldn't have happened *but for Truvada* would simply have happened later and if study authors stopped the trial once it was able to get the results it wanted. For instance, upon initial use, Truvada's side effects could cause that cohort to have less or different sex, deferring potential exposure to when participants would have adjusted to the drug. Even worse, two years after the iPrEX study went before the FDA, the NEJM quietly updated its Supplementary appendix to iPrEX (which nobody reads) and quietly disclosed that it too had occult pre-existing seroconversions only in the Truvada cohort – the same problem as with VOICEPrEP, but not disclosed to the FDA. If the conveniently discarded "occult seroconversions" are added back in, Truvada may have INCREASED HIV transmission. This makes sense – a chemotherapy weakens the body and thus its natural defenses against infection.

An honest way to calculate results would have been to divide the number of seroconversions in each cohort by the number of subjects in each cohort. In iPREX, that would have yielded 2.9% converting in the Truvada cohort vs. 5.1% in the placebo group: a 2.2% difference, which itself could be accounted for by chance and the brief duration of the trial – and given the pervasive lack of blinding controls in African drug trials, could have been fabricated via early-termination. Put another way, 95% of the placebo cohort did not seroconvert, contrasted with 97% in the Truvada Cohort. In Partners, 99% of both the Truvada and the Viread cohorts did not sero-convert, contrasted with 97% of the placebo cohort – a 2% difference. Hardly "99% Effective."

In many ways, the placebo groups of all studies re-created part of the famous Padian study of 1997 observing no seroconversions over ten years in a cohort of serodiscordant couples in Northern California *after entry into the study*.[32] The deficient brief duration of the four PrEP studies may simply have echoed the study-entry effects observed by Padian. Also, given seroconversion in heterosexual couples was observed in the placebo cohorts unlike in Padian, the neglected multifactorial AIDS model suggests seroconversion observed in the PrEP studies may have been due to "co-factors" not present in Padian's Northern California cohort such as oxidative stress due to developing world poverty.[33] HIV tests (including nucleic acid tests) are notoriously unreliable in Africa, registering over 70% false positives due to cross reactions with tropical microbes.[34] Africans reverse-seroconvert quite often, although this is almost never reported in the press. Long-term post-study confirmation of true seroconversions was lacking prior to Truvada approval and is not planned by iPREX study authors.

Buried deep in the iPREX supplementary Appendix as initially published in the NEJM was a claim of over "90% Protection" in a few Truvada subjects who were said to faithfully adhere to Truvada as prescribed. This 90% figure was not backed with supporting data, which study authors promised to publish with a post-trial update. This 90% claim took on a life of its own in the press, and it is commonly used in popular accounts pushing Truvada as "the new condom,"[35] and 90% is still being reporting in *The Los Angeles Times* as of December 2020.[36] In Rwanda, Truvada was hailed as "Wonder Drug reduces HIV by 90%" [37] However, after giving the press a Juicy 90% figure (which somehow grew to 99% on the website of the Gilead-funded San Francisco AIDS Foundation[38]), in 2015, the NEJM quietly updated the Supplementary Appendix and the unsupported 90% claim disappeared from the web simultaneous with the debut of the non-adherence disclosure and the mysterious occult pre-existing infections.[39]

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[32] Padian, et al *Heterosexual transmission of human Immundeficiency virus (HIV) in Northern California: Results from a ten-year study.* American Journal of Epidemiology, 146:350-357

[33] Dr. Luc Montagnier, Nobel prize winner for the discovery of HIV and supporter of the Multi-factoral model of AIDS, stated in 2008, *"I think this is one way to approach, to decrease the rate of transmission, because I believe HIV we can be exposed to HIV many times without bring chronically infected, our immune system will get rid of the virus within a few weeks, if you have a good immune system; and this is the problem also of the African people."*

[34] Sacramento Bee, October 30, 1994, and conversation with Dr. Christian Fiala who worked for many years in Uganda.

[35] https://www.out.com/news-opinion/2013/09/09/hiv-prevention-new-condom-truvada-pill-prep

[36] https://www.latimes.com/business/story/2020-12-22/hiv-prep-prevention-drugs-insurance-no-copay

[37] https://www.newtimes.co.rw/section/read/182104

[38] https://www.sfaf.org/resource-library/side-by-side-comparison-truvada-and-descovy-for-prep/

[39] The evolution of the Supplementary Appendix with all supporting documentation is posted at prepispoison.com

Given the persistent fraud in HIV drug trials going back to the 1980's, it appears **study authors dangled the RETRACTED 90% claim in the seldom-read appendix as a sound-byte for the media**.

### CRONY CAPITALISM MEETS BIG PHARMA AND JUNK SCIENCE

Gilead, Fauci, and the FDA share a revolving door. The FDA qualified Gilead to receive expedited (6 months or less) consideration of its late 2011 application for "supplemental" use of its Truvada for "PrEP" despite the fact it targeted users who were not ill and users for which there were established prophylactics (condoms, education, etc.) on the market. The authors of this white paper contacted the FDA's public affairs office to ask if Gilead paid a **"user fee**" for consideration of this expedited application. The FDA replied that law and regulations do not allow the figure to be made public. A rejection of a FOIA request is posted at prepispoison.com. An FDA document (see table 6) [40] reveals average FDA income of $771,000 for "supplements requiring clinical data."

So, why the rush for expedited approval backed by four prematurely terminated studies holding problematic data? The July 2012 vote by five FDA commissioners allowed AIDS czar Fauci to characterize PrEP in the media as "an important addition to our toolkit of HIV prevention interventions," just days before the 19th International AIDS conference in Washington, DC[41] attended by as many as 20,000 individuals heavily connected to K-street … during a tight U.S. presidential election where a "victory over AIDS" and new profits for the Pharmaceutical Industry would help influence the outcome.

In the wake of this hasty decisions, the PrEP industry has bloomed. The US Public Health Service took action on May 14, 2014 setting guidelines[42] and urging physicians to prescribe Truvada for negatives in so-called Risk groups. The result: Gilead's stock rose from the low $20's to almost $110 per share between January 2012 to September 2014. None of this investor equity was used to fund the 4 PrEP clinical trials. All the risk was borne by Fauci's NIAID and the Bill and Melinda Gates Foundation. As of 2019, Gilead's retail price for a one-month supply of Truvada is $1,845/month,[43] and the foundation does not make grants to individuals or to programs such as high risk pool subsidies. **Is the Gates Foundation truly operating as a charity worthy of a tax exemption?**

The FDA was once the agency that protected Americans from Thalilomide, but post-AIDS it is the agency that unleased Vioxx onto the public. A major culprit is the **1992 Prescription Drug User Fee Act**. In a February 26, 2007 Boston Globe Op/Ed **Taking Back the FDA,** former NEJM editor-in-chief Marcia Angell wrote that the user fee practice "*put the FDA on the payroll of the industry it regulates .. [it] puts the fox in the chicken coop….The agency's coziness with industry is underscored by the composition of its 18 advisory committees – outside experts who help evaluate drugs. Incredibly, many of these advisors work as consultants to drug companies*" [44]

Though members of the advisory committees are supposed to file statements of any potential conflicts of interest, **those disclosures by law and regulation are not available to the public under the Freedom of Information Act.** The only way a possible conflict is disclosed is if the FDA grants a waiver to the committee member for a potential conflict and allows him or her to sit in judgement of a filing by the company with which the potential conflict exists.

### CHOICE TO SEEK LICENSING OF CO-FORMULATED TRUVADA OVER VIREAD WAS BASED ON PATENTS OVER PATIENTS

Phase I and Phase II investigations of PrEP and early P/R[45] from around 2006 focused on Viread – a monoformulation of the prodrug TDF, and this was the drug used in early studies by Susan Buchbinder in the San Francisco Dept. of Public Health.[46] TDF went off patent in 2016. FTC (brand name Entriva) is patented by Gilead through mid-2021, and thus Truvada, a co-formulation of FTC/TDF. Both PARTNERSPrEP and VOICEPrEP trialed Viread in addition to Truvada.

It appears Truvada's co-formulation (TDF/FTC) was chosen over Viread (TDF only) to **extend Gilead's exclusive marketing period for TDF/PrEP from 2016-2021**. TDF is a prodrug that metabolizes into a nucleoside/tide analogue of Adenosine. It has the exact

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[40] https://www.govinfo.gov/content/pkg/FR-2010-08-04/html/2010-19116.htm

[41] This was funded by Fauci with a $7 million dollar grant from NIAID to the International AIDS society, an NGO in Geneva Switzerland.

[42] If history is any guide, guidelines have a history of becoming mandates: this lays the Orwellian foundation for public health policy where gay negatives black women negatives who test positive for reportable STI's are deemed "at risk" and then forced into taking HIV medication and monitored with routine blood-work under the name of "pharmacovigilance."

[43] https://www.sfaf.org/resource-library/side-by-side-comparison-truvada-and-descovy-for-prep/

[44] http://www.boston.com/yourlife/health/diseases/articles/2007/02/26/taking_back_the_fda/

[45] https://www.nytimes.com/2006/01/22/magazine/protect-or-disinhibit.html

[46] https://www.sfgate.com/health/article/Antiviral-drug-used-to-treat-AIDS-to-be-tested-as-2632078.php

same mechanism of action[47] as FTC (an analogue of Cytosine – the C and the A of DNA's ACTG). Prodrugs create a more regular bioavailability, meaning pills can be taken less frequently. In contrast, the body clears FTC quickly. Such co-formulations are notorious for **breeding drug resistance[48].** In fact, the Supplementary Appendix to iPREX noted FTC resistance in the observed seroconversions. Similarly, post marketing studies of PrEP seroconversions indicate multi-drug resistance.[49] This could have been avoided had Gilead applied for an expanded use authorization of Viread as a less toxic and equally (in?)effective option instead of the more profitable Truvada. The cronyism of Fauci's NIAID leadership shows through in that Fauci, in spite of his huge budget for funding political AIDS conventions, could have issued a contract instead of RFP to study Viread further, bringing a less toxic generic PrEP option to market.

As a result of Truvada's co-formulation, Gilead's successor patented product, Descovy, also similarly co-formulated. Market perception now exists that two nucleoside/tide analogues are somehow necessary. There was much marketing buzz that somehow Descovy was "safer." This is not true. In a separate white paper at prepispoison.com, we discuss how this marketing buzz was manufactured using astroturf funding, a friendly lawsuit with the AIDS Healthcare Foundation, bribes to a Stanford doctor to make incorrect public statements, and how Gilead used the friendly lawsuit and under-the-table payments to astroturf activist Eric Paul Leue to coerce social media companies to institute censorship policies to silence PrEP Critics (including PrepIsPoison.com and the personal account of its founder as well as personal accounts of attorneys bringing lawsuits against Gilead) in order to hide any discussion of the risks of PrEP toxicity from the public.

## Closing Observations

Without actual clinical trial data about long-term use of the toxic chemotherapies in Truvada and Descovy, members of the heavily propagandized gay community are allowing themselves to be turned into human guinea pigs, and the regulatory bodies that are supposed to protect them are using gay men to line Big Pharma's pocketbooks for no health benefit. We are told to "fight AIDS," What does this mean? AIDS, Inc. is a trillion-dollar industry. Since HIV diagnosis became reportable in 2001, new cases have hovered at about 250 a year and prevalence estimates have remained essentially unchanged. Yet in that time, the Ryan White program expanded, Oregon joined the CDC's medical monitoring program, the Affordable Care Act was passed, PrEP came out, and local AIDS service agencies expanded. **Something is not working.** Oregon's official goal is "suppression," (i.e. get people on drugs), but Dr. Jay Levy writes about HAART in his standard HIV medical textbook that it is a "misconception that this treatment will prevent HIV transmission.[50]" MacArthur Genius Robert Root-Bernstein wrote in 1993, "We do not understand AIDS." We still do not. There are very powerful forces at work preventing us from acknowledging our ignorance.

Studies by Kerwin and Witte[51] show doctors are the most authority minded of all professionals. They are paid to have answers, not ask questions. For the ideologists, fraud is taboo, yet fraudulent results in science are likely to be accepted if they are plausibly presented, if they conform with prevailing prejudices, and if they come from suitably qualified authorities affiliated with elite institutions. Precisely because medical and public health professionals believe themselves to be scientific and thus immune from the nonrational elements that govern scientific process (including intuition, attachment, bias, rhetoric, money, and propaganda), they are more susceptible to them. Perhaps the greatest barrier to asking questions is apathy. People are content to live in the reality created by our media, government, and advertisers. Our most important goal is to make people *care*. We must reach their hearts and minds. It is up to each person to acknowledge their own ignorance and do their own homework, because if they do not, as we have been told from the beginning by the AIDS Inc. mainstream, **SILENCE = DEATH.**

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[47] Visit PrepIsPoison.com for an extensive article on how nucleoside analogues work and why they're toxic and carcinogenic

[48] A notable example is Septra/Bactrim which is a mixture of sulfamethoxazole and trimethoprim. Technically chemotherapies instead of antibiotics, the formulation was jointly trialed in the 1960's by Hoffman LaRoche and Burroughs Wellcome who mixed them together in proportion to their March, 1958 market share in order to avoid "excess competition" (this is why it has two names: Roche's was Bactrim and their product was sulfameth). The medical literature is filled with articles deploying circular reasoning to explain why the co-formulation exists. In fact, Trimethoprim alone is safer and more effective and the co-formulation creates resistance to both at a greater rate. Given antibiotic resistance is a global health concern, Fauci's NIAID as the US Government's official investment vehicle for combatting infectious disease could have contracted for the necessary studies to license one or both antibiotics as generics without co-formulation. Septra is an important AIDS medication used to treat PCP Pneumonia. What Fauci actually did was get the co-formula re-patented in 1988 in an aerosolized form, with the marginal toxicity of Sulfamethaxole "killing thousands" (Sunday Times of London February 27, 1994), allowing both Hoffman LaRoche and Burroughs Wellcome to jack up the price charged to AIDS patients.

[49] https://www.nejm.org/doi/full/10.1056/NEJMc1611639

[50] https://www.sfgate.com/opinion/openforum/article/The-Big-Question-Now-in-Anti-HIV-Therapy-When-2949172.php

[51] Kerwin MH et al "A Curriculum on Medical Ignorance" Med Ed. 23:24-29

## SUPPLEMENTARY DISCUSSION: THE WONDERFUL WORLD OF P-HACKING

iPrex's published study[52] is titled "Pre-exposure Chemoprophylaxis for HIV Prevention." Because Chemoprophylaxis is Chemotherapy, and because Chemotherapy is Poison, it follows that PrEP Is Poison.

The iPrex Truvada seroconversions over time appear to be converging with the placebo. **Had the trial not been terminated early and gone to 196 weeks as planned**, would the total seroconversions have converged? One possibility is Truvada (FTC-TDF) may have simply caused a detectability lag as a post-exposure prophylactic, and this effect could harness the protocol (section 13.8.3) to trigger an automatic termination when the predictable study-entry effect became manifest, guaranteeing study "success." A closer look at the protocol indicates termination and thus success could be manufactured simply by recategorizing 5-8 seroconversions – and study authors cast out 11 in the Truvada group, unrandomizing the assignment. Early termination of studies is a well-known way to "p-hack" data. With PrEP, hundreds of billions of dollars in gross potential revenue from a new market was at stake.

**Study authors are disingenuous when not mentioning or discussing early termination at all in their published NEJM paper.** In the context of two other studies where these lines *DID* converge (i.e. the finding was not replicable), iPREX should not be blindly accepted as scientific evidence of Truvada's efficacy for PrEP. A bedrock of science is replicability. With PrEP, this has not happened. In fact, with VOICEPrep and FemPrep, the opposite happened.

Moreover, looking at the graph, what reasonable person would say Truvada is 90% or 99% or 45% effective? Why is the media not asking questions? Would the bottom line have continued "catching up" had the study run its course? Prescribing doctors should show this graph to patients requesting PrEP.

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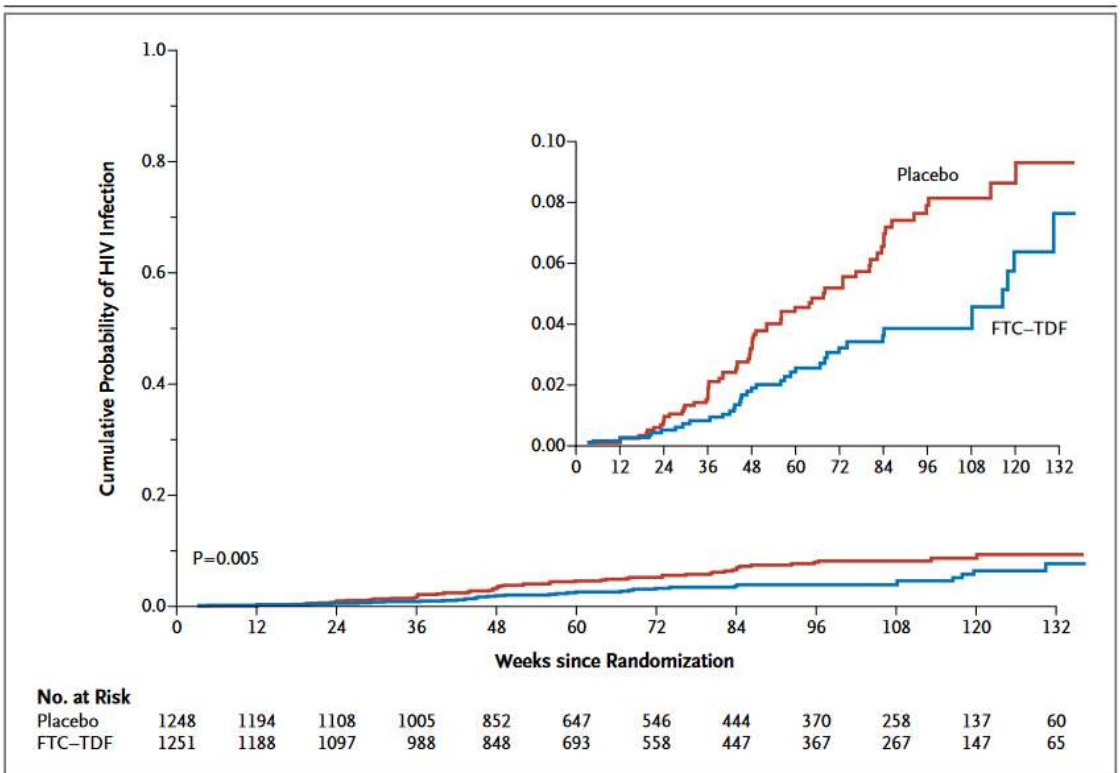


**Figure 2. Kaplan–Meier Estimates of Time to HIV Infection (Modified Intention-to-Treat Population).**
The cumulative probability of HIV acquisition is shown for the two study groups. The efficacy of preexposure prophylaxis with emtricitabine and tenofovir disoproxil fumarate (FTC–TDF) was 44%, as compared with placebo (P=0.005). The inset graph shows a more detailed version of the overall graph up to a probability of 0.10.

52