The HIV-AIDS Industry. Thirty years of political science.

by Terry Michael

AIDS war profiteering.

NIH's Fauci and Gilead's Martin: junk science and oligarchic capitalism.

Summary

In medical science research-gone-wild, America's AIDS czar has shepherded experimental use of anti-retroviral drugs in Third World subjects, exposing them to toxic chemotherapy to demonstrate "pre-exposure [to HIV] prophylaxis" or "PrEP." Human guinea pigs were not immune deficient under any clinical or case surveillance definition of AIDS. To qualify for paid participation in experiments, they had to present with *HIV negative* status. For nearly thirty years, Dr. Anthony Fauci has been an un-elected medical science bureaucrat directing the National Institute for Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH.) Not even subject to Senate confirmation, Fauci has amassed informal power over HIV-AIDS research grant proposals funded with billions of taxpayer dollars. Research directed and influenced by Fauci for over three decades has failed to find a cure for HIV disease, as the ever-morphing acquired immune deficiency syndrome is now called, nor has it yielded a vaccine against the purportedly pathogenic retrovirus. Dr. Fauci has mis-used public funds for a narrow view of AIDS research, but especially for recent "PrEP" trials that benefit *one* U.S.-based pharmaceutical corporation, the worldwide revenue leader in sales of HIV anti-retrovirals, the Biblically-named **Gilead Sciences** corporation, with earthly headquarters in Foster City, California. Fauci placed the CEO and Chairman of Gilead, John C. Martin, on his NIAID advisory council in March 2000, ten months before Gilead's then-Chairman Donald Rumsfeld resigned to serve in President George W. Bush's cabinet as Secretary of the Dept. of Defense, which, several years into Rumsfeld's tenure, stockpiled millions of units of Gilead's top-selling Tamiflu, which has been judged by many experts as nearly useless as a flu palliative. The Fauci-Gilead connection is a textbook example of oligarchic capitalism, the legal bilking of taxpayer dollars for the benefit of a single, politically well-connected business enterprise, provided with potentially millions of new customers in a rigged game of confirmation-biased clinical trials, used to justify FDA new-use approval for one of Gilead's top-selling old drugs, which in turn led to May 2014 CDC encouragement of doctors to "PrEP" patients with the company's extremely expensive ($12-$14 thousand per year) big blue pills, known as Truvada.

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During the three decades since the United States government proclaimed on April 23, 1984, in the person of Health and Human Services Secretary Margaret Heckler, that a single retrovirus was the "probable cause" of an amorphous health condition known as AIDS, tens of billions of U.S. taxpayer dollars have been doled out to thousands of HIV-AIDS grantees, "investigators" as they are known in the language of the National Institutes of Health.

Decisions to spend those billions on a theory never properly vetted in an honest peer review process can be tracked to one un-elected medical science bureaucrat, America's de facto AIDS czar, Dr. Anthony Fauci.

Director of the National Institute of Allergy and Infectious Diseases (NIAID) since November 3, 1984, Fauci has never approved grants for anything but the simplistic single pathogen theory of acquired immune deficiency syndrome, the amorphous disease by ever-changing definition. From the beginning of his tenure, he has ignored the "multi-factorial" hypothesis for immune deficiency, including unusual exposure to old pathogens, heavy ingestion of toxins, and chronic and acute stress. He has embraced what can be termed a 19th Century-style, single-germ theory for a complex web of factors that collapsed the immune systems of a subset of gay men in the early 1980s.

Fauci has built a research empire that has funded thousands of studies of every conceivable aspect of the "HIV=AIDS" hypothesis, including clinical trials of so-called "Anti-RetroViral Treatments," chemotherapy known by the acronym "ARV" and sometimes as "ART."

Early AIDS research grants were for studying the theoretical pathogenesis of what Dr. Luc Montagnier and Dr. Robert Gallo claimed to have "discovered" (identified) after a failed decade of research trying to relate retroviruses to cancer. Montagnier labeled his the "Lymphodenopathy Associated Virus" (LAV) and Gallo dubbed his the "Human T-cell Lymphotropic Virus-III (HTLV-III.) To settle the dispute about who discovered what, the U.S. and French governments in 1987 decided to agree that Gallo and Montagnier "co-discovered" the same thing, and that it would thereafter be called the "human immunodeficiency virus," a medical science finding by government proclamation.

Later studies associated HIV with a long list of presenting illnesses theoretically related to HIV "infection" and focused on developing possible vaccines against the purported pathogen.

Eventually, much of the research funded at the NIAID and its parent organization, the National Institutes of Health (NIH), centered on the efficacy of ARVs in those who were "HIV positive" and had actual presenting illnesses, and then in those who theoretically had AIDS based only on CD4 T-cell counts under 200, but with no illness, the latter being a definition of AIDS arbitrarily devised by the Centers for Disease Control and Prevention (CDC) and made effective January 1, 1993. That definition was designed only for "case surveillance," a short-cut for counting *potential* cases of actual illness, but not as clinical evidence of AIDS for *treatment* purposes. But it very quickly led non-ill HIV positives, with no defining illnesses, into taking chemotherapy with toxic adverse effects, so-called "side" effects.

Dangerous leap into the ARV unknown: "Test-and-Treat"

By the latter years of the first decade of the 21st Century, Dr. Fauci and his agency had jumped on the "test-and-treat" bandwagon, even after Dr. David Ho's "hit hard, hit early" (with ARVs) theory of the mid-1990s had been discredited among mainstream HIV=AIDS investigators like Dr. Jay Levy of the Univ. of California-San Francisco (sometimes called the "third co-discoverer of HIV.") Levy warned in 2001, and still cautions, against "early intervention" with toxic chemotherapy, before HIV positives present with any illness.

Ho's dangerous advice led scores of thousands of non-ill positives, mostly gay men, to

fall into the AIDS drug trap, and many eventually began to suffer from liver dysfunction, renal failure and heart disease, along with microbiome-damaging chronic diarrhea (weakening the innate immune system in the intestinal tract) and the disfiguring facial fat wasting and fat redistribution that are well assessed effects of the ARVs. (See a well-documented account with video of the long-term toxic effects of ARVs in gay men in *New York* magazine in November 2009.)

Despite the warnings, Fauci began to fund human subject experiments, giving the drugs immediately to those who tested "positive," without regard even to the spurious clinical markers (CD4 T-cell counts and "viral load") let alone presenting illness. (See my report in *The Washington Times* in March, 2010 about one of the studies Fauci funded to experiment on mostly African Americans in the Washington, DC area.)

After criticism of "test-and-treat," that moniker morphed to "Test-and-Lead-to-Care," or "TLC," invoking thoughts of "tender loving care." The HIV-AIDS Industry has been masterful with its use of benign-sounding acronyms. The so-called "drug cocktails" with which David Ho encouraged gay men to "hit hard, hit early" were designated as "Highly Active Anti-Retroviral Treatments" or "HAART," as in the lyrics "you gotta' have heart, lots 'n lots of heart" (from the 1950s Broadway musical, "Damn Yankees.")

A flight of Fauci fantasy: toxic drugs for HIV NEGATIVES

In HIV research-gone-wild, Dr. Fauci then began to finance clinical trials of the toxic drugs in HIV "***negatives***," on the theory the chemotherapy would "protect" them from becoming "positive." Employing another HIV-AIDS drug marketing acronym, aggressive mis-use of the chemotherapy was called "pre-exposure prophylaxis" or the benign-sounding "PrEP."

Tens of millions of dollars in federal outlays from NIAID to study test-and-treat and PrEP (plus grants engineered by Fauci from other agencies like the CDC and USAID, and from non-profits like the Bill and Melinda Gates Foundation) have accrued to the benefit of a little-known pharmaceutical company headquartered in Foster City, California, in the San Francisco Bay area, with the Old Testament/Hebrew Bible-inspired name "Gilead," alluding to the healing "balm of Gilead" (Jeremiah 8:22 – "Is there no balm in Gilead? Is there no physician there?")

Most major drug companies are named after founding families, e.g., Bayer, Glaxo-Smith-Klein, Merck, Johnson & Johnson, Bristol-Myers Squibb, Abbott, Boehringer Ingelheim. Gilead's use of a heavenly-inspired name is testament to its marketing savvy.

The earthly publically held corporation, Gilead Sciences, Inc., has long been politically tied to the Republican Party, as well as to Dr. Fauci, who named its CEO, John C. Martin, to his NIAID advisory council over 14 years ago, in March 2000. Donald Rumsfeld was chairman of the operating board of Gilead from 1997 to January 2001, when he resigned to accept a position in George W. Bush's cabinet as Secretary of the Dept. of Defense, which, several years into Rumsfeld's tenure, stockpiled millions of units of Gilead's best-selling Tamiflu, now regarded by many experts as a nearly or completely worthless flu palliative. In addition to Rumsfeld, who had been on Gilead's

board since 1988, also on the board have been Ronald Reagan's Secretary of State, George Shultz; George H. W. Bush's Special Trade Representative, Carla Hills; and the wife of former California Republican Gov. Pete Wilson.

Four Major Pre-Exposure Prophylaxis (PrEP) Trials
There have been four major "Phase III" PrEP clinical trials, with at least 2,000 and up to 5,000 test subjects each, between 2007 and 2012. The third phase of drug trials are supposed to confirm drug efficacy, monitor side effects to determine protection from long-term poisoning, and check to see if subjects will adhere to "treatment" (take the drug as prescribed.) Phase I and II trials commonly make use of small groups of test subjects, from a few score, to several hundred, to initially evaluate drug safety, determine a safe dosage range, and identify adverse effects.

Summarized in a chart at the end of this article, those four trials have received the greatest media attention since they were begun, concluded or prematurely halted, and then reported. *In each case, **almost all test subjects were Third World**, and **all drugs were "donated" by the Gilead pharmaceutical company**, which stood to gain potentially **billions of dollars** in revenue if their "Truvada" was judged to "protect" test subjects from sero-conversion (from HIV- to HIV+) in assays for antibodies (not actual tests for whole, purportedly pathogenic virions.)*

Two halted and failed clinical trials were ignored by the Food and Drug Administration when it approved, for PrEP, the drug Truvada, the test chemotherapy donated by Gilead in both trials. They were: **FEM PrEP**, 2,120 heterosexual females, all HIV negative, 100% Third World/African; and **VOICE PrEP**, 5,029 heterosexual females, all HIV negative, 100% Third World/African.

Two purportedly "successful" clinical trials served as the basis for the FDA's approval of Truvada for PrEP, OK'd for so-called "at risk populations"--gay males, IV drug users, Africans and other Third World people, and African Americans. (In the Partners experiment, there was also a Viread cohort, a drug also donated by Gilead, but not approved for PrEP by the FDA.) The two trials were designated as: **Partners PrEP**, 4,747 "sero-discordant" couples, one negative, one positive, 100% Third World/African heterosexuals; and **iPREX PrEP**, 2,499 homosexual males, all HIV negative, over half prostitutes, nearly all Third World--more than 50% of them in Peru, with others in Ecuador, Brazil, Thailand and South Africa, and fewer than one-tenth in San Francisco and Boston, apparently added so investigators could claim a few subjects in the U.S., *from where the trials were funded and where the FDA and the CDC would eventually be asked to approve and endorse Truvada for PrEP **for Americans***.

Both the **Fem-PrEP and VOICE PrEP** trials were halted early when investigators saw ***no difference*** in sero-conversions between the Gilead-drugged cohorts and the placebo cohorts. In fact, in some cases, fewer subjects sero-converted in the placebo-taking groups than in the Truvada cohorts. The investigators came up with a variety of excuses for halting the trials, from poor adherence (the paid subjects theoretically lied about taking the drugs) to methodological flaws.

Before the Fem-PrEP study was halted, 33 of the 1,024 subjects in the Truvada cohort sero-converted, compared with 35 among the 1,032 subjects in the slightly larger placebo cohort, a statistically trivial difference.

Before the VOICE PrEP study was abandoned, 94% in the 994 Truvada tablet cohort, 94% in the 1,002 Viread tablet cohort, and 94% in the placebo tablet cohort did not sero-convert--demonstrating absolutely no difference in drugged or un-drugged subjects. The study also used a Viread vaginal gel (cohort of 1,003) and a placebo gel (cohort of 1,003.) There was a statistically insignificant difference, with 94% in the Gilead gel cohort not sero-converting and 93% in the placebo gel cohort not converting.

Investigators in both the gay male **iPREX PrEP** and sero-discordant heterosexual couples **Partners PrEP** studies used calculation techniques that *grossly over-stated* purported "protection" by Truvada in iPREX, and by Truvada and Viread in Partners.

They simply subtracted the small number of drugged sero-conversions from the small number of placebo sero-conversions, and then divided the remainder by the number of placebo sero-conversions, yielding a specious 44% "greater protection" with Truvada in the iPREX trial, and even more spurious results in Partners PrEP, in which the math technique produced 67% "greater protection" in the Viread cohort and 75% "greater protection" in the Truvada cohort.

Buried deep in the iPREX report in the *New England Journal of Medicine* was a claim of over 90% "protection" in Truvada subjects *who faithfully adhered to the drug*--that is, who took it as prescribed, an apparently unintended acknowledgment of the non-real world methodology of a flawed experiment on humans. That 90%+ claim took on a life of its own, and is now the figure most commonly used in popular media reports about Truvada and PrEP.

To use the well-worn but accurate cliché, the study results were cases of **"figures lying and liars figuring."**

An honest way to calculate results would have been to divide the number of sero-conversions in each cohort by the number of subjects in each cohort. In iPREX, that would have yielded 2.9% converting in the Truvada cohort and 5.1% in the placebo group--a slight 2.2% difference. That means 95% of the placebo cohort did not sero-convert, contrasted with 97% not converting in the Truvada cohort. Instead, they claimed the 44% "better" difference for Truvada--but even that suggests over half (56%) of the drug cohort subjects were ***not*** *"protected."* In Partners, 99% of both the Truvada and Viread cohorts did not sero-convert, contrasted with 97% of the placebo cohort--a slight 2% difference.

The creative figuring became the "evidence" used by the FDA to grant Gilead the right to sell its chemotherapy for a new use in *not ill* and *not even "positive"* men and women.

Tens of millions of mostly taxpayers dollars were squandered in behalf of Gilead, so the drug company could reap potential billions in new revenues. A clear case example of oligarchic capitalism is apparent in the company's collusion with Fauci at NIAID; with

FDA advisory panels and commissioners, and their BigPharma conflicts; and with the CDC, reflected in its May 2014 recommendation urging physicians to prescribe Truvada for negatives in the so-called "risk groups," an official government imprimatur for an extremely profitable drug that has helped fuel Gilead's sky-rocketing stock price, from the low $20s to low $80s per share since early 2012.

By contrasting example, if a physician gave a healthy gay man a prescription for a powerful, gut microbiome-damaging anti-biotic, as prophylaxis against exposure to venereal diseases during a night out at a bath house, there would be an outcry of ***medical malpractice*** among responsible health care providers, for a violation of a physician's pledge to "first, do no harm."

Yet such malpractice in HIV negatives has now been endorsed by the NIAID, the FDA and the CDC, ***all for the benefit of one politically connected drug company***.

(Following is a chart I prepared in mid-May 2014 summarizing details of the four trials described above.)

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Comparison of the Four Major PReP Trials (From document research by Terry Michael, as of May 2014.)

Name of trial, funding source/s, drugs used.	Number of subjects in trial. Description and size of cohorts.	Geographical location/s*** of subjects.	Time frame of study and report release date.	Findings claimed by investigators	Alternative view of what the data demonstrate.
iPREX PReP NIAID & Gates F. Truvada# /TDF-FTC Placebo	2,499 total MSM* All HIV- Truvada =1,251 Placebo = 1,248 over 1/2 prostitutes	Peru (56%) plus Ecuador, Brazil, Thailand, S. Africa, US (9% SF/Boston) **91% 3rd World**	Enrolled between July '07 - Dec. '09; halted May '10 Article NEJM+ 12/30/10	Truvada =36 Sero-Conv. Placebo =64 Sero-Conv. formula^: 64-36/64 = 44% claimed as greater protect. than placebo	97% of Truvado cohort ***did not*** sero-conv.; 95% of placebo cohort ***did not*** sero-conv. **2% *"better"* with drugs?** Buried in report is claim 90% + better for absolute adherence.##
Partners PReP Gates F. Viread#/TDF Truvada# /TDF-FTC Placebo	4,747 hetero *couples*, sero-discordant** Viread=1,584 Truvada = 1,579 Placebo = 1,584	Kenya and Uganda **100% 3rd world**	Enrolled between July'08-Nov.'10 halted early, 5/31/11 Article NEJM 8/2/12	Viread x=17 (67%) Truvada x=13 (75%) Placebo = 52 formula^: 52-x/52 = % claimed "more protected"	99% of drugged cohorts did not sero-conv. 97% of placebo cohort did not sero-conv. **2% *"better"* with drugs?**
~~**Fem-PrEP**~~ ~~Gates F. & USAID~~ ~~Truvada#/TDF-FTC~~ ~~Placebo~~	2,120 female HIV- Truvada=1,024 Placebo = 1,032 (had planned 3,900)	South Africa, Kenya, Tanzania **100% 3rd world**	Enrollment began 2009, **halted 4/2011** Halting explained CROI# March 2012	Truvada = 33 (3.2% Sero-C.) Placebo = 35 (3.4% Sero.C) "Protection" statist. **identical** formula: x/cohort size	96.8% Truvada cohort and 97.6% of placebo cohort did not sero-conv. **<1% "better"?**
~~**VOICE PrEP**~~ ~~NIAID~~ ~~Truvada#/TDF-FTC~~ ~~Viread#TDF; Viread gel~~ ~~Placebo tabs & gel~~	5,029 female HIV- Truvada=994; Viread=1002; Viread gel=1003; placebo tab=1008; placebo gel=1003	South Africa (80%), Uganda, Zimbabwe **100% 3rd world**	Enrollment between 9/'09 - 6/'11; **halted 10/2011.** Halting explained CROI 3/'13	Sero-C's:Truv.=61, Viread =60, placebo tabs=60. ***Equal*** "protection." Viread gel=61, placebo gel=70; statist. insig. difference	94% Truv., 94% Viread and 94% placebo tab cohorts did not Sero.C. 94% Viread gel and 93% placebo gel did not Sero-C. 1% **"better"?**

NOTES.....

NIAID = Nat. Institute of Allergy and Infectious Diseases; Gates F. = Bill and Melinda Gates Foundation;
USAID = U.S. Agency for International Development. Truvada = TDF-FTC = tenofovir disoproxil fumarate and emtricitabine.
Viread = TDF = tenofovir disoproxil fumarate. Drugs are chemotherapy, called "anti-retroviral treatments" or ARVs or ARTs.

# Gilead donated ALL drugs used in all trials ~~X~~ = HALTED when results didn't match conf. biases of investigators	*MSM = Men Sex with Men. ** 1 partner HIV+ and 1 HIV-	*** All funded by U.S. entities, with U.S. drugs, seeking U.S. FDA approval, yet almost 100% 3rd world subjects??	#Conf. on Retroviruses and Opportunistic Infections +New England Journal of Medicine	^ Placebo sero-con.'s minus drug sero-con's divided by placebo Sero-Cs = % "less" sero-con. than placebo	##This 90%+ is a non-real world condition of not missing single dose, yet news stories cite it instead of already spurious 44%

NOTE: iPReX trial (gay men,) and Partners PReP (hetero discordant couples) were at the heart of Gilead's effort to obtain "fast-track" FDA approval for Truvada for HIV *negatives*. Paying a "user fee," Gilead got 6-month action -- clearly not a "fast track"-worthy emergency use for non-"positive," non-ill individuals, for a drug retailing $12-$14,000/year. Even orthodox HIV experts warn against "premature" use of toxic chemicals in *positives*, because of adverse effects over time to liver, kidney and heart, meaning 10 or 15 years, often less. None of the PReP trials lasted much more than a year or two. Thus, there was no evidence on long-term adverse effects in negatives. The trials were a collusion between Gilead, NIAID, FDA and CDC, which put its stamp of approval on prescription in May 2014. It was all about the money, subjecting gay men, IV drug users, 3rd world people, and African Americans (the "risk groups") to lethal chemotherapy.