AIDS War. GILEAD
Profiteering with PrEP.

***Full 14-page article online**, with all linked notes and sources:* **www.terrymichael.net/hiv-aids/prep.html**

by Terry Michael – Washington, DC, September 29, 2014

U.S. AIDS czar Dr. Anthony Fauci, director, NIAID

Gilead CEO John C. Martin., with Truvada

Journalism is printing what someone else does not want printed. Everything else is public relations. – *George Orwell*

Abstract

America's AIDS czar for almost 30 years, Dr. Anthony Fauci has promoted and shepherded human experimental research that has exposed HIV negative Third World men and women to toxic chemotherapy, many already health-challenged from lack of clean water, poor sanitation, malnutrition and old diseases like tuberculosis and malaria. The experiments were to demonstrate "Pre-Exposure Prophylaxis" (PrEP) for the anti-viral drug **Truvada**. Like other nucleoside analogs, Truvada has well-assessed adverse ("side") effects. Funded with tax dollars and non-profit grants, including tens of millions from Fauci's National Institute of Allergy and Infectious Diseases, as well as from the CDC and USAID, studies have accrued to the sole benefit of a politically well-connected U.S. drug corporation, **Gilead,** the only company to "donate" pills for the clinical trials**.**

When PrEP was discussed initially in mainstream media, including in a *New York Times* article published January 22, 2006 (later critically reviewed by independent journalist Liam Scheff), human guinea pigs, almost all impoverished Third World subjects, were already in early phase trials, designed to produce results that would allow Gilead eventually to seek FDA approval for re-purposing its "Viread" but later only its "Truvada" chemotherapy for use by HIV antibody negative *Americans,* for theoretical protection from a virus proclaimed by the U.S. government in 1984 as a discrete pathogen responsible for the amorphous health condition described since 1982 as "acquired immune deficiency syndrome," or "AIDS." Under patent protection until 2021, Truvada remains more profitable for Gilead than Viread, for which a generic can be sold as early as December 2016.

Four main Phase 3 trials were initiated before the FDA approved the only drug studied in all four, Gilead's Truvada--two with heterosexual Third World women, one with "discordant" ("one negative, one positive") Third World heterosexual couples, *but only one with the original "risk group,"gay men, over 90% of them in the Third World*. Two of the heterosexual trials were halted early, when investigators began to see no difference between drugged and placebo cohorts. Reports on the gay male study, **iPREX PrEP**, and the discordant straight couples trial, **Partners PrEP**, grossly overstated drug prophylaxis, by using a spurious calculation technique. A valid methodology, dividing sero-conversions in each drug and placebo cohort by cohort size, would have resulted in slight percentage differences between those receiving Truvada and those getting "sugar pills."

[See below full article and summary chart, for a complete explanation.]

Gilead, the worldwide revenue leader in sales of HIV anti-retrovirals--over $9 billion in 2013, in a nearly $20 billion HIV drug sector of the pharmaceutical market--is a Biblically-named ("balm of Gilead," *Jeremiah 8:22*) and politically very well connected company in Foster City, CA. NIAID director Fauci placed the CEO of Gilead, Dr. John C. Martin, on his "advisory council" over 14 years ago, in March 2000, ten months before Gilead's then Board Chairman Donald Rumsfeld resigned to be in President George W. Bush's cabinet as Secretary of the Dept. of Defense. Several years into Rumsfeld's tenure, the DOD stockpiled millions of units of Gilead's then cash-cow drug, *TamiFlu*, which since has been judged as nearly or totally useless as a flu palliative.

When TamiFlu receded as Gilead's big money-maker, the company's extremely expensive ($1,000 to $2,500 a month) single pill, combination drug anti-retrovirals, beginning with Viread, then Atripla, Truvada, and Complera, and now Stribild, have helped catapult the corporation's stock price from the low $20s in early 2012 to approaching $110 by September 2014.

Martin has made *Forbes* magazine's top ten list of highest compensated CEO's in America during several recent years ($40-$50 million in annual compensation.) Fauci, holding the directorship of the National Institute of Allergy and Infectious Diseases for an unprecedented 30 years (as of November 3, 2014,) was *one of the top three highest paid employees, at $335,000, among two million U.S. civil servants in 2011* (according to *Government Executive* magazine.)

In a position not even requiring U.S. Senate confirmation, Fauci has amassed informal bureaucratic power and influence over HIV-AIDS medical science research, similar to the clout amassed over decades by the late FBI Director J. Edgar Hoover. Fauci has cultivated a career as the media's face of federal AIDS policy, with the help of an aggressive NIAID public relations effort in his behalf. The billions in NIH/NIAID research dollars he has directed to HIV-AIDS have far exceeded outlays for diseases and conditions that take many more lives and cause much more illness. The son of a Brooklyn, NY pharmacist, the 73-year-old Fauci has aggressively advocated immediate drug treatment of HIV positives, whether or not they have AIDS-defining conditions, *or any disease at all*, as well as drugging HIV negatives for PrEP.

To understand, by analogy, the danger of the PrEP concept, suppose a physician were to give a healthy gay man a standing prescription for daily use of an anti-biotic pill to "protect" him from exposure to gonorrhea on trips to a bath house and from multiple anonymous sexual hook-ups without condoms. Such a drug would certainly damage the intestinal microbiome over time, wiping out many of the trillions of "good gut bacteria" responsible for our first-line of defense from pathogens, our innate immunity, which works together with our adaptive immune system. Use of anti-biotics for "prophylaxis" would most certainly be termed *medical malpractice*, violating the physicians' oath to "*first, do no harm*." Prescriptions for *daily use of Truvada*, with its well assessed short and long-term adverse effects, constitutes *the same malpractice.*

In summary:

(1) ***Confirmation-biased clinical trials*** *of Truvada for PrEP,*
(2) with ***results grossly mis-stated****,*
(3) led to ***FDA approval virtually purchased by Gilead*** *with fast-track "user fees," and*
(4) and a compliant ***CDC rubber-stamping toxic chemotherapy*** *for use in HIV negatives, with*
(5) medical science-naive ***media, repeating PrEP clinical trial fabrications and distortions****, mis-characterizing Truvada's toxicity, and* ***leading individuals to its harmful use****.*

All for the benefit of a politically hyper-connected drug company, Gilead, reaping billions in revenue.

☆☆☆

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Full Article

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 since July 1982 as AIDS, tens of billions of U.S. taxpayer dollars have been given to multiple thousands of HIV-AIDS research grantees, "investigators" as they are known in the language of the National Institutes of Health (NIH.)

For research and all other aspects of HIV-AIDS funding, federal government spending on "HIV-AIDS" has been over $400 billion since 1981, with research outlays dwarfing those for other disease and illness. For example, according to the Fair Allocations In Research Foundation, in 2013 *research spending* per number of *deaths* calculated to $2,562 for cardiovascular disease; $16,010 for diabetes; $5,683 for Alzheimer's; $7,342 for Parkinson's; $17,308 for breast cancer; $10,146 for prostate cancer; and an amazing $329,576 per death *attributed* to AIDS (the CDC acknowledges its figures for AIDS deaths are of individuals *with* AIDS, not necessarily *from* AIDS.) Except for breast cancer, with its aggressive "pink lobby" garnering $3,401 per patient, spending per HIV-AIDS patient has out-paced other single diseases by orders of magnitude. As examples, spending of $2,818 per HIV-AIDS patient contrasts with $25 per cardio patient; $47 per diabetes patient; $85 per Alzheimer's patient; and $150 per prostate cancer patient.

The $400+ billion spending has also included scores of billions for the extremely expensive "anti-retroviral treatments," with federal subsidies that accrue to drug companies when various programs for patient medicine, like Medicare, Medicaid and the AIDS Drug Assistance Program (ADAP,) pay virtually any price Gilead and other drug companies demand. The willingness of federal lawmakers to massively subsidize the drugs allows the pharmaceutical companies to keep prices charged to Americans hugely above the costs to produce the chemotherapy and what they charge customers in other countries.

Despite the massive spending, the government's own figures, from the Centers for Disease Control and Prevention (CDC,) reveal that the number of HIV-conflated-with-AIDS "cases" has remained steady at about a million-or-so each year for over two decades, with an also steady number of about 45-50,000 new "positives" counted each year. That consistency is remarkable--or, candidly put, *simply not credible*--for a claimed "epidemic," which follows a pattern of rising, peaking and then falling--a bell curve.

Creative counting of AIDS or "HIV disease" deaths and "cases"

Deaths attributed to AIDS or "HIV disease" in the U.S. have fallen to fewer than 15,000 yearly, with many of those clearly caused by adverse health effects of long-term use of toxic anti-retroviral chemotherapy, such as the drug Truvada, being touted for PrEP. Current deaths related to anti-retroviral induced illness are significant, but are far fewer than the uncounted scores of thousands who succumbed to lethally high doses of AZT and other "nucleoside analogs" in the late 1980s and early 1990s, but were said by the CDC to have died "*with* AIDS." However, the CDC itself acknowledges, and this is an exact quote from a CDC web page (my emphasis added): "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 in its most recent annual report that 251 of its residents died *with* HIV in 2011**,** *but only 69 of those deaths*

were of "HIV-related causes." It was a remarkable admission, listing even suicide cases of HIV "positives" as AIDS ("HIV disease") deaths. The vast majority of new "AIDS diagnoses," since January 1993, have been made on the basis of an antibody test result of "positive" with a CD4 T-cell count under 200 per micro liter of blood--*with no presenting or AIDS-defining illness at the time of diagnosis*. Thus, you can be perfectly healthy, with no disease symptoms, get run over by a truck, and be counted by the CDC (and a local agency that feeds it figures) as an "AIDS death."

Why? It's about money. A local AIDS agency gets thousands more dollars from the federal government when it counts a new "positive" and when it records a death of someone *with HIV*. Money is why the District of Columbia has so aggressively pursued widespread testing of all its adult residents. Just how aggressive, I learned, when I encountered a testing van from the DC government-funded "Carl Vogel Center" in my local Safeway supermarket parking lot in August 2012, paying obviously poor African Americans $15 to take the anti-body test--with one woman telling me she had taken it multiple times *for the money*.

The role of America's "AIDS czar," Anthony Fauci

Many of the decisions to spend scores of billions of research dollars on a theory never properly vetted in an honest peer review process beginning in the mid-1980s 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 studying anything but the simplistic single pathogen theory of acquired immune deficiency syndrome, the amorphous disease by ever-changing U.S. government (CDC) definition. From the beginning of his tenure, he ignored the "multi-factorial" hypothesis for immune deficiency, which includes consideration of the effects of (1) **multiple and repeated exposures to old disease pathogens** in brief time frames, during the intimacy of sexual activity, with subsequent over-prescription of microbiome-damaging, and thus immune suppressive, anti-biotics; (2) **frequent ingestion of toxins**, including "poppers" (nitrites), addictive use of alcohol plus controlled substances like heroine, cocaine and amphetamines, but also the so-called "anti-retroviral treatments" themselves, beginning with the life-threatening AZT in the mid-1980s; and (3) **chronic and acute stress** that weighed heavily on often closeted gay urban males, many not out to their families or friends, and attacked by the emerging religious right in the late 1970s and early 1980s, resulting in chronic release of well-assessed immune-suppressive stress hormones like cortisol.

Fauci 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, beginning in the early 1980s. Born in December 1940, the NIAID director's view of chemicals for healing AIDS victims, by attacking a single germ, may well have been influenced by his upbringing as the son of a Brooklyn, NY pharmacist.

Fauci has built nothing less than a government research empire that has funded thousands of studies of every conceivable and esoteric 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." The drugs disrupt transcription of theoretically pathogenic retroviral code into DNA in a type of white blood cell called CD4 T-cells (with CD4 shorthand for "cluster of differentiation 4," a glycoprotein found on the surface of cells produced in the thymus, thus the "T" in CD4 T-cells.) These disease-

fighting cells are among those that evolved in humans as part of “adaptive immunity” protection from invading pathogens, some capable of causing serious illness, some just harmless passengers. The “CD4" designation for such cells was only introduced in 1984, the very same year the U.S. government proclaimed these cells were being affected by a retrovirus and their numbers in a host’s peripheral blood were used as a clinical marker for AIDS.

Over years of use, various ARVs can produce adverse, immune-suppressive effects in a host, including damage to the liver, kidney failure and heart disease, facial fat wasting, redistribution of body fat, chronic diarrhea negatively impacting the microbiome, reduction in bone mineral density, lactic acidosis that can result in cardiopulmonary failure, thinned limbs with protruding veins, and a host of other maladies. The conditions can result in serious illness and death in so-called “HIV positive” patients, most talked into taking the drugs *without presenting with any illness*. The “positive” description is given to anyone whose blood sample is reactive to a test for antibodies, *not a test for virions*. And antibodies from scores of host conditions can cross-react with an antigen, such as “p24," used in a test kit; the “p” stands for “protein” and “24" signifies a molecular weight of 24,000 daltons. Because of the potential for cross-reactions, a so-called “HIV test” does not prove that an antibody or antibodies that caused an indicator color change in a test strip resulted from “HIV.” (A dalton is an *extremely* tiny unit, used to measure the mass of atoms; 24,000 daltons = $3.985272000003 \times 10^{-20}$ gram--note, ten-to-the-*minus*-20 power.)

Brief history of AIDS research

Early AIDS research studied the theoretical pathogenesis of what Dr. Luc Montagnier and Dr. Robert Gallo both claimed to have “discovered” (identified) after a failed decade of investigations trying to relate retroviruses to cancer. In fact, no disease before and no disease after the amorphous AIDS has been credibly claimed to be caused in humans by a retrovirus.

Montagnier labeled his the “Lymphodenopathy Associated Virus” (LAV) and Gallo dubbed his the “Human T-cell Lymphotropic Virus-III (HTLV-III.) *Note that neither name uses any form of the word “immunodeficiency.”* In fact, in seminal papers Montagnier and Gallo published, respectively, in the journal *Science* in May 1983 and May 1984, they and colleagues did no more than assert (see the paper abstracts linked above) that their claimed viruses ***“may be involved”*** with or ***“suggest”*** a possible cause of what was being described by the U.S. Centers for Disease Control (after July 1982) as AIDS.

To settle the dispute about who discovered what--and to divide substantial profits from an anti-body test each attempted to patent for their retroviruses--the U.S. and French governments in 1987 decided to agree that Gallo and Montagnier “co-discovered” the same thing, and it would thereafter be called the “human *immunodeficiency* virus,” or “HIV,” *a medical science finding by government proclamation*. As American writer Willa Cather observed a century ago, “Give the people a new word, and they think they have a new fact.” In this case, it wasn’t even a word, just a couple of acronyms joined by a hyphen: “HIV-AIDS.”

Later studies made claims of associating HIV “infection” and its purported immune suppression with a long list of presenting illnesses, eventually numbering almost 30. Many clinical trials of drugs were conducted to assess whether chemotherapy could disrupt “HIV infection” of CD4 T-cells, even though, to this day, there is no unqualified assertion by mainstream HIV-AIDS researchers that CD4 T-cells are killed, disabled, programmed for self-destruction (apoptosis) or even reduced in total numbers (between the lymph system

and peripheral blood) by a retrovirus. Still other research has been funded over the years for developing a vaccine against the purported pathogen. *All of the research has yielded thirty years of failed effort to develop a "cure" or produce a vaccine.*

Much of the early research financed by the NIAID/NIH and other units of the Dept. of Health and Human Services (to which the NIH, FDA and CDC are all attached) centered on the efficacy of ARVs in those who were "HIV positive" and had actual presenting illnesses. Research then shifted to those who theoretically could have immune deficiency based only on CD4 T-cell counts under 200, *but with no illness*, the latter being a definition of AIDS arbitrarily devised by the 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 frightened, non-ill HIV "positives," with no AIDS-defining illnesses--and in many cases antibodies from something other than HIV--into taking chemotherapy with toxic adverse effects, the so-called "side" effects. The response was similar to that which occurred beginning in the 1980s when victims of "positive" anti-body assays immediately began taking high doses of toxic AZT and other nucleoside analogs, even though they had no presenting illness, leading to thousands of anti-viral drug-induced deaths.

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

By the last years of the first decade of the 21st Century, Dr. Fauci 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 A. Levy of the Univ. of California-San Francisco (sometimes called the "third co-discoverer of HIV.") Author of the basic, orthodox textbook, *"HIV and the Pathogenesis of AIDS, 3rd Edition*," Levy warned in 2001, and still cautions, against "early intervention" with toxic chemotherapy, before HIV positives present with any illness, as he did in an interview with me four years ago. Even HIV "co-discoverers," Robert Gallo and Luc Montagnier, were critical of Ho's theory.

Ho's dangerous advice led scores of thousands of non-ill positives, mostly gay men, to fall into the AIDS drug trap starting two decades ago, and many eventually began to suffer from the well assessed effects of the ARVs (as described above.) See a documented account, with video, of the long-term toxic effects of ARVs in gay men, published in *New York* magazine in November 2009. These serious "side" (a pharmaceutical industry euphemism for "adverse") effects come mostly with long-term use of the ARVs over years, not reflected in the very short-term clinical trials (as few as 18 months or less) that were designed to justify PrEP. Thus, an "HIV negative" taking Truvada, with its speciously claimed prophylaxis, for three, four, five, ten, fifteen, twenty or more sexually active years *would be subjecting himself to its cumulative toxicity*, never measured by the PrEP trials. *And the trial investigators, along with the NIAID, FDA and CDC, have nothing to say about how long PrEP can be used continuously*. At the XIX International Aids Conference in Washington, DC in July 2012, I confronted proponents of PrEP, resulting in this exchange. *(A YouTube video.)*

Despite the warnings, by the end of the first decade of the 21st Century, 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 (also linked above in the reference to Dr. Levy) in *The Washington Times* in March, 2010 about one of the studies Fauci funded (with

about 26 million tax dollars) 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 visions of "tender loving care." The HIV-AIDS Industry has been masterful in its use of benign-sounding acronyms. The "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 "Damn Yankees" lyrics, "You gotta' have heart, lots 'n lots of...HAART."

A flight of Fauci fantasy: toxic "balms of Gilead" 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 use of the chemotherapy was called "pre-exposure prophylaxis" or the benign-sounding "PrEP."

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

Almost all 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, publicly-held corporation, Gilead Sciences, Inc., has long been politically tied to the Republican Party, as well as to Dr. Fauci, who named its CEO, Dr. 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 (DOD.) Several years into Rumsfeld's tenure, the DOD stockpiled millions of units of Gilead's then best-selling TamiFlu, now regarded 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. Gilead's army of political influence peddlers were bestowed with millions of dollars in company stock and directors' compensation. After the mid-2000s, HIV ARVs displaced TamiFlu as Gilead's cash-cow drugs.

And now (since late 2013) the company has FDA approval for marketing its mega-expensive $84,000/regimen *Sovaldi* (sofosbuvir) for treating so-called "Hepatitis C Virus" (HCV) claimed by anti-body testing as a potential pathogen for a potential illness, which theoretically can damage your liver twenty or thirty or forty years after an "infection"--or never. But of course, your liver disease could also have been caused by long-term use of alcohol and various drugs in those same time periods. (A recent report calculates that 24 million Americans consume *10 or more alcoholic drinks a day*.) What is now eponymously named "Hepatitis C," after the purported HCV, used to be called hepatitis non-A non-B, with "hepatitis" just a general description of liver dysfunction. HCV seems to be the new HIV, each claimed to be identified only by an anti-body test, each said to be capable of

lurking in your body for years before resulting in sickness (which can be attributed to various causes, like alcohol, other than a mysterious virus) and both of which mysterious viruses are said to be "treat-able" with extraordinarily expensive "anti-virals."

Four major PrEP trials before FDA decision

There were four major "Phase III" PrEP clinical trials, with at least 2,000 and up to 5,000 test subjects each, between 2007 and 2011, the results of which *or the early termination of which* were reported before the FDA decision in 2012 to allow Truvada for PrEP. The *third phase* of a drug trial is supposed to: (1) confirm drug efficacy (does it do what it claims?); (2) monitor adverse effects to determine short-term and over-time safety, which is impossible if the duration of the trials is brief, as were the PrEP Phase III trials; and (3) 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 potential for efficacy, determine a safe (non-sickening, non-lethal) dosage range, and identify immediate or short-term adverse effects.

The four trials that preceded FDA approval of Truvada for PrEP are summarized in a chart at the end of this article. In each trial, almost all test subjects were Third World people, 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 all but 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, OK'd in the U.S. for so-called "at risk populations"--gay males, sero-discordant heterosexual couples, plus others with vaguely defined possible risks for infection. In one of the trials, there was also a cohort given Viread, an older drug also donated by Gilead, but not sought by Gilead for PrEP approval by the FDA, probably because Viread would lose patent protection in 2016, five years before the ultra-expensive Truvada, giving Gilead nine years to cash in on Truvada for PrEP as well as its continued use to "treat" HIV.

The two "successful" 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 gay (including bi-sexual) males, all HIV negative, two-fifths 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. The American 9%, about 225 of the 2,499, obviously were added so investigators could claim at least 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.

Based largely on the Partners and iPREX studies, the FDA's "Anti-Viral Drugs Advisory Committee" voted May 10, 2012 (scroll down to May 10 materials) to endorse Truvada for PrEP (1) in gay men, by a vote of 19-3; (2) in sero-discordant heterosexual couples, 19-2, with one abstention; and (3) in a poorly defined "other individuals at risk" category, 12-8,

with two abstentions. Only two committee members voted "no" on all three propositions, Dr. Elaine H. Morratio, an assistant professor at the Univ. of Colorado-Denver, and Dr. Lauren V. Wood, MD, a Captain in the U.S. Public Health Service. Their reasons for voting "no" can be found on pages 514-517 of the transcript of the meeting.

Morratio said she voted against all three "...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 into the real world."

Wood's concerns went directly to the fact, as cited above, that only a handful of Americans were involved in the studies. She pointed out that only 117 gay African American men were in the iPREX study, out of a total of only 225 Americans of all races, included among the 2,499 subjects in iPREX--making African American gay males only four-and-a-half percent of the study subjects. And, Wood observed, not a single African American woman was included in the Partners trial, which was comprised of 100% Third World subjects. She noted that Americans of African heritage are those considered by the CDC "most at risk" for HIV in the United States. And, she said, "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." Renal (kidney) problems are among the most serious adverse ("side") effects seen over time in those using Truvada.

Both the **Fem-PrEP** and **VOICE PrEP** trials were halted early when investigators began to see no difference in sero-conversions between the Gilead-drugged cohorts and the placebo cohorts. In halting the trials, investigators focused on poor adherence (some of the paid subjects apparently didn't tell the truth about taking the drugs.) Of course, adherence to the often nauseating and diarrhea-causing drugs was one of the things the trials were supposed to assess. The study proposals were written with language to assure that, if the investigators were not seeing "protection" from the drugs, they could halt the trials by claiming poor adherence--though major adherence problems were also seen in many test subjects in iPREX and Partners, and those trials were not halted.

Creative massaging of the PrEP trial results

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 meaningless 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 1,008 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 (one percent) difference, with 94% in the Gilead gel cohort not sero-converting and 93% in the placebo gel cohort not converting.

In addition to stacking the research deck by shutting down the two multi-million dollar studies that weren't yielding pro-PrEP results, investigators in both the gay male **iPREX** and sero-discordant heterosexual couples **Partners** studies used calculation techniques that grossly over-stated purported "protection" by Truvada in iPREX, and by Truvada and Viread in Partners.

In iPREX, investigators simply subtracted the small number, 36, of drugged sero-conversions from the small number, 64, of placebo sero-conversions, totaling just 4% of

2,499 total subjects. They 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, in which the math technique produced 67% "greater protection" in the Viread cohort and 75% "greater protection" in the Truvada cohort.

To understand why the results were specious--that they looked deceptively impressive--suppose there were two cohorts of 1,000 each in a clinical trial, one getting drugs and the other placebos for 18 months. Then suppose 1 subject converted in the drugged group and 3 in the placebo cohort, and investigators decided to end the trial at that point. Subtract 1 from 3 and divide the remainder by 3, and *you would get a seemingly impressive 67% "greater protection*" with the drug. Then, suppose you let the trial run 1 more month, and one more drugged subject happened to sero-convert, but no more did in the placebo cohort. If you chose to stop the trial then, the "protection" would drop by half, *to 33%*. Then, to see even more clearly how the "results" were subject to chance and to rigging, in terms of time length, divide 999 (drugged, and not converting) by 1,000, and 997 (placebo, and not converting) by 1,000, and you would have the extremely un-impressive results of 99.9 percent not converting in the drugged group and 99.7 percent not converting in the placebo group. A two-tenths of one percent difference, rather than the 67% difference using the creative math.

Buried deep in the iPREX report in the *New England Journal of Medicine* (NEJM) was a claim of over 90% "protection" in a few Truvada subjects who were said to faithfully adhere 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. The 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--even though the formal "Results" summary section at the beginning of the iPREX report in NEJM cited only the spurious 44% protection claim.

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, as in the above hypothetical example, 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, which could have been accounted for by chance and the brief duration of the trial. Put another way, that means 95% of the placebo cohort did not sero-convert, contrasted with 97% not converting in the Truvada cohort. Instead, the investigators, seeking confirmation of their self-fulfilling prophecy, claimed a 44% "better" difference for Truvada. But a less than 50% difference between the two cohorts suggests a significant failure of "protection" for the drugged subjects. In Partners, 99% of both the Truvada and Viread cohorts did not sero-convert, contrasted with 97% of the placebo cohort--a 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 positive* men and women.

Crony capitalism meets bureaucratic junk science

Tens of millions of mostly taxpayers dollars were squandered in behalf of Gilead, so the drug company could reap potential billions in new revenues, by exposing untold numbers of HIV negatives to toxic chemotherapy. Crony capitalism is apparent in the company's

connections with Fauci at NIAID; with an FDA anti-viral advisory panel and the full FDA compromised by Gilead paying for its fast-track approval; and with a compliant third agency, the CDC, accepting the biased research and the pay-to-play FDA approval process, resulting in the U.S. Public Health Service action on May 14, 2014, setting guidelines and urging physicians to prescribe Truvada for negatives in the so-called "risk groups." It amounted to an official government imprimatur for an extremely profitable drug, a rubber stamp of approval derived from a corrupt process, that has helped fuel Gilead's sky-rocketing stock price, from the low $20s to almost $110 per share, between January 2012 and September 2014.

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 that the targeted users of the drug are not ill. Asked for this article what Gilead paid as a "user fee" for consideration of its supplemental use of Truvada for PrEP, the FDA public affairs office replied that law and regulations do not allow the figure to be made public--very convenient for the drug company, not so transparent for the public. But an FDA document (see "Table 6") reveals an average fee of $771,000 for "Supplements requiring clinical data."

So, what was the rush? Simple. The early July 2012 vote by the five FDA commissioners allowed AIDS czar Dr. Anthony Fauci to characterize PrEP as "...an important addition to our tool kit of HIV prevention interventions," just days before the XIX International AIDS Conference in Washington, DC--attended by as many as 20,000, a conference Fauci funded with a $7 million NIAID U.S. taxpayer grant to the International AIDS Society, a foreign-based (Geneva, Switzerland) NGO that lobbies for the tens of thousands of researchers who make their livings studying the endless mysteries of "HIV-AIDS."

Allowing Gilead to fund its fast-track approval with a "user fee" is a prime example of the corrupt practice created by Congress in 1992, at the behest of the pharmaceutical industry's powerful Washington lobby. In a February 26, 2007 essay in *The Boston Globe*, titled "Taking Back the FDA," former *New England Journal of Medicine* editor-in-chief Marcia Angell wrote that the user fee practice "...put the FDA on the payroll of the industry it regulates." The "Prescription Drug User Fee Act," Angell asserted, "put the fox in the chicken coop." The industry now funds over half of the FDA's expenses in assessing the efficacy and safety of drugs submitted for approval by the user fee payers. And, Angell wrote in that 2007 article: "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 advisers work as consultants for drug companies."

Though members of the advisory committees are supposed to file statements of any potential financial conflicts of interest, those disclosures, by law and regulation, are not available to the public. 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 judgment of a filing by the company with which the potential conflict exists.

Closing observations...

It is important to note that only iPREX, of the four trials (two completed and two abandoned) attempted to assess the impact of PrEP on the first and still by far the greatest "risk group," gay males. And 91% of the test subjects in iPREX and 100% of the

human guinea pigs in the other three trials were Third World people, despite the fact the trials were financed from the U.S. and the claimed results were used to justify decisions by the FDA and CDC for U.S. citizens.

Finally, consider the following scenario for another kind of potential illness in gay men. Suppose, say in the year 1980, a physician gave a healthy gay man a standing prescription for a powerful, gut microbiome-damaging anti-biotic, for daily use, as prophylaxis against exposure to bacterial venereal diseases--after the man noted to his doctor that he goes to the local bath house every Saturday night, doesn't always use condoms, hooks up frequently with multiple partners, and intends to continue doing so, maybe for years. If a doctor wrote such a prescription, there would be an outcry of *medical malpractice* among responsible health care providers, for 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*.

Appendix

Following is a chart prepared by the author in May 2014 summarizing details of the four clinical trials described above, and **a WebMD.com summary** of serious short and long-term adverse effects of Truvada use.

All adverse effects and warnings for Truvada, many cited in the above article, and also on the WebMd page, can be found at *Gilead's own web site*:
http://www.truvada.com/truvada-faqs

As noted above, for those first reading this article on paper, the entire piece, with all hyperlinks, can be found at: www.terrymichael.net/hiv-aids/prep.html

Profile of author Terry Michael
http://www.terrymichael.net/PDF%20Files/TerryMichaelBiographyContactInfoForWeb.pdf

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*from **WebMD.com** article assessing Truvada "side effects"*

Note: Truvada consists of 300 milligrams of tenofovir disoproxil fumarate (of which 245 mg is tenofovir) plus 200 milligrams of emtricitabine. Re-printed verbatim from WebMD.com site, accessed September 14, 2014.

Comparison of the Four Major PrEP Trials (From document research by Terry Michael, as of May 31, 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 2/5 prostitutes	Peru (56%) plus Ecuador, Brazil, Thailand, S. Africa, US (9% SF/Boston) ***91% 3rd World***	Enrolled between July '07 - Dec. '09; halted early 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 96.6% of placebo cohort did not sero-conv. **two-tenths of 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 who have 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 -- 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 of Truvada for PrEP 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.

Truvada “Side Effects”

Nausea, vomiting, diarrhea, headache, dizziness, trouble sleeping, back pain, or change in the color of skin on your palms or soles of your feet may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Some people with HIV infection may experience worsening of a previous medical condition (such as an old infection) as their immune systems improve, or develop new conditions because their immune systems have become overactive. This reaction may occur at any time (soon after starting HIV treatment or many months later). Tell your doctor right away if you have any serious side effects, including: unexplained weight loss, persistent muscle aches/weakness, joint pain, numbness/tingling of the hands/feet/arms/legs, severe tiredness, vision changes, severe/persistent headaches, signs of infection (such as fever, chills, trouble breathing, cough, non-healing skin sores), signs of an overactive thyroid (such as irritability, nervousness, heat intolerance, fast/pounding/irregular heartbeat, bulging eyes, unusual growth in the neck/thyroid known as a goiter), signs of a certain nerve problem known as Guillain-Barre Syndrome (such as difficulty breathing/swallowing/moving your eyes, drooping face, paralysis, slurred speech).

Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as depression, anxiety), loss of appetite, stomach/abdominal pain, pink/bloody urine, change in the amount of urine.

Changes in body fat may occur while you are taking this product (such as increased fat in the upper back and stomach areas, decreased fat in the arms and legs). The cause and long-term effects of these changes are unknown. Discuss the risks and benefits of treatment with your doctor, as well as the possible use of exercise to reduce this side effect.

Tenofovir may increase the risk of bone loss. Discuss the risks and benefits of treatment with your doctor, as well as the possible use of calcium and vitamin D to reduce this side effect. If you are at risk for bone loss, your doctor may monitor your bone mineral density. Tell your doctor right away if any of the following serious side effects occur: bone pain, easily broken bones.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

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