HB 248 Proponent Testimony
Ohio House of Representatives Health Committee
5-25-2021

Victoria K. Kerman, BSChemE, MBA, MDiv, MEd

Chairman Lipps, Vice Chair Holmes, Ranking Member Russo, and members of the House Health Committee, thank you for the opportunity to provide proponent testimony on House Bill 248.

My name is Vicki Kerman. I am 65, semi-retired, an Ohio resident, and a mother.

Twenty two years ago this month, my husband and I were in southeastern Siberia adopting our two children. Children who, due to economic circumstances, had been abandoned by their parents and who were a ward of the state in one of their children's homes. I spent ten days among persons who had been beaten down, controlled, betrayed, and abandoned by their government. People who were robotically going through their daily routines without color, without joy, without hope. It was more than unsettling.

Had we not found them, chances are my son would have ended up committing suicide and my daughter would have become a prostitute. Because that's just the way things were.

I have never been so overcome by relief as when we boarded the Delta jet to come home. It meant that we were on our way back to a country driven by opportunity and not by fear.

I am here today to fulfill the promise I made to them twenty one years ago, namely that I would always advocate for what, I believed, would be in their best interests. And in this situation, their best interests align with those of 11 million Ohio residents.

Over the course of the last fourteen months, we have been subjected to a series of egregious mandates and policies implemented in response to Covid 19. This has resulted in a decimated economy, increased incidence of mental health issues, an escalation in drug and alcohol use, and disrupted educational and social environments for our children. We have let this continue even after data and studies have surfaced which raise serious questions regarding the wisdom of these actions.

The passage of House Bill 248 is essential if we are to stop the continued erosion of our personal liberties and our right to control whether or not we choose to subject ourselves to any given medical treatment.

Does anyone remember thalidomide, prescribed in the 1950's to pregnant women to relieve nausea, which was later found to cause irreversible damages to the fetus and thousands of children were born with severe congenital malformations? What about DES, prescribed to pregnant women to prevent miscarriages and where daughters ended up sterile? AZT and the devastating effects it had on those with HIV? The fast-tracked flu vaccine in 1976? The contaminated polio vaccine in 1955? The military's botched anthrax vaccine? (Attachments 1,2,3,4,5)

Cases such as these underscore that critical for persons to insure their and their children's wellbeing is their ability to decide for themselves whether to undertake a medical treatment WITHOUT manipulation, coercion, or discrimination and WITH all of the relevant facts. It is up to each individual to assess his/her own risk/reward profile in making such a decision.

This is particularly true of the Covid 19 injection, a highly invasive treatment which is not, by the CDC's own definition, a "vaccine" at all, but an experimental genetic therapy with documented safety issues and questionable efficacy, one for which we have no knowledge of longer-term consequences because no longitudinal animal studies were performed, and for which the manufacturers have absolutely no liability in the case of injury or death.

Currently, the Governor is trying to bribe the unvaccinated with five million-dollar lotteries and is allocating the responsibility for monitoring and achieving compliance to private sector companies and local governments. Those who choose to turn down the injection are facing discrimination in the form of lost employment, restricted participation in activities, segregated venues, and public shaming.

What is next? The natural progression is to deny non-compliant persons access to those things necessary for survival – credit cards and bank accounts, utilities such as water and electricity, and food. If this sounds totally unthinkable, remember that what started out as "two weeks to flatten the curve" has, over the course of just one year, morphed into discrimination based on vaccination status and the right of the public to know the information in an individual's health record.

We are at a critical juncture in shaping our futures and those of our children and the generations to come.

While in Russia twenty-two years ago, I experienced firsthand the quality of life when nothing is done to stem the usurping of individual rights. And I don't want to visit there ever, ever again.

Down the road – maybe in the not so distant future – my daughter or my son will look me in the eye and ask, "Mom, why didn't you say something?" I will need to be able to look at them and honestly reply, "I did."

I encourage you to vote "Yes" on HB 248. Because you, too, might be confronted with the same moment of truth if not from your own children, then from your constituents.

What do you want to be able to answer?

Thank you for your time.

I would be glad to answer any questions you might have.

Victoria K. Kerman

Attachment 1

HTTPS://HELIX.NORTHWESTERN.EDU/ARTICLE/THALIDOMIDE-TRAGEDY-LESSONS-DRUG-SAFETY-AND-REGULATION

THE THALIDOMIDE TRAGEDY: LESSONS FOR DRUG SAFETY AND REGULATION

By: Bara Fintel, Athena T. Samaras, Edson Carias
Jul 28, 2009

Many children in the 1960's, like the kindergartner pictured above, were born with phocomelia as a side effect of the drug thalidomide, resulting in the shortening or absence of limbs. (Photo by Leonard McCombe//Time Life Pictures/Getty Images)

In a post-war era when sleeplessness was prevalent, thalidomide was marketed to a world hooked on tranquilizers and sleeping pills. At the time, one out of seven Americans took them regularly. The demand for sedatives was even higher in some European markets, and the presumed safety of thalidomide, the only non-barbiturate sedative known at the time, gave the drug massive appeal. Sadly, tragedy followed its release, catalyzing the beginnings of the rigorous drug approval and monitoring systems in place at the United States Food and Drug Administration (FDA) today.

Thalidomide first entered the German market in 1957 as an over-the-counter remedy, based on the maker's safety claims. They advertised their product as "completely safe" for everyone, including mother and child, "even during pregnancy," as its developers "could not find a dose high enough to kill a rat." By 1960, thalidomide was marketed in 46 countries, with sales nearly matching those of aspirin.

Around this time, Australian obstetrician Dr. William McBride discovered that the drug also alleviated morning sickness. He started recommending this off-label use of the drug to his pregnant patients, setting a worldwide trend. Prescribing drugs for off-label purposes, or purposes other than those for which the drug was approved, is still a common practice in many countries today, including the U.S. In many cases, these off-label prescriptions are very effective, such as prescribing depression medication to treat chronic pain.

However, this practice can also lead to a more prevalent occurrence of unanticipated, and often serious, adverse drug reactions. In 1961, McBride began to associate this so-called harmless compound with severe birth defects in the babies he delivered. The drug interfered with the babies' normal development, causing many of them to be born with phocomelia, resulting in shortened, absent, or flipper-like limbs. A German newspaper soon reported 161 babies were adversely affected by thalidomide, leading the makers of the drug—who had ignored reports of the birth defects associated with the it—to finally stop distribution within Germany. Other countries followed suit and, by March of 1962, the drug was banned in most countries where it was previously sold.

In July of 1962, president John F. Kennedy and the American press began praising their heroine, FDA inspector Frances Kelsey, who prevented the drug's approval within the United States despite pressure from the pharmaceutical company and FDA supervisors. Kelsey felt the application for thalidomide contained incomplete and insufficient data on its safety and effectiveness. Among her concerns was the lack of data indicating whether the drug could cross the placenta, which provides nourishment to a developing fetus.

She was also concerned that there were not yet any results available from U.S. clinical trials of the drug. Even if these data where available, however, they may not have been entirely reliable. At the time, clinical trials did not require FDA approval, nor were they subject to oversight. The "clinical trials" of thalidomide involved distributing more than two and a half million tablets of thalidomide to approximately 20,000 patients across the nation—approximately 3,760 women of childbearing age, at least 207 of whom were pregnant. More than one thousand physicians participated in these trials, but few tracked their patients after dispensing the drug.

The tragedy surrounding thalidomide and Kelsey's wise refusal to approve the drug helped motivate profound changes in the FDA. By passing the Kefauver-Harris Drug Amendments Act in 1962, legislators tightened restrictions surrounding the surveillance and approval process for drugs to be sold in the U.S., requiring that manufacturers prove they are both safe and effective before they are marketed. Now, drug approval can take between eight and twelve years, involving animal testing and tightly regulated human clinical trials.

Despite its harmful side effects, thalidomide is FDA-approved for two uses today—the treatment of inflammation associated with Hansen's disease (leprosy) and as a chemotherapeutic agent for patients with multiple myeloma, purposes for which it was originally prescribed off-label. Because of its known adverse effects on fetal development, the dispensing of thalidomide is regulated by the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program. The S.T.E.P.S. program, designed by Celgene pharmaceuticals and carried out in pharmacies where thalidomide prescriptions are filled, educates all patients who receive thalidomide about potential risks associated with the drug.

Thalidomide has also been associated with a higher occurrence blood clots and nerve and blood disorders. Northwestern University's pharmacovigiliance team, Research on Adverse Drug Events And Reports (RADAR), has launched a joint project with the Walgreens pharmacy at Northwestern Memorial Hospital so that these side effects may be understood and monitored, like those affecting fetal development. RADAR, led by Dr. Charles Bennett of the Feinberg School of Medicine, combines the expertise of clinicians, academics, pharmacists, and statisticians to monitor and disseminate information about adverse drug reactions to cancer drugs.

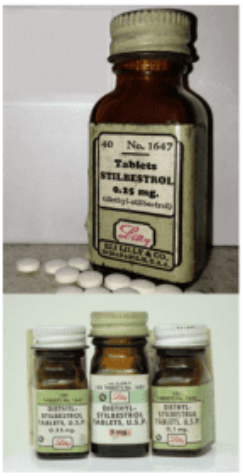
Their project tracks the number of patients who get a blood clot after receiving thalidomide, whether or not the patient received an anticoagulant drug, which are used to help prevent clotting, and if so, which drug was used. Tracking this information will help researchers better identify the incidence and prevention of thalidomide-associated blood clots, allowing the drug to continue to serve as an effective therapy for many patients.

Attachment 2

HTTPS://DESACTION.ORG/WHAT-IS-DES/

WHAT IS DES?

In 1938, DES (diethylstilbestrol) was the first synthetic estrogen to be created.



DES was prescribed to millions of pregnant women, primarily from 1938 – 1971, but certainly not limited to those years. In some cases DES prescriptions were written into the 1980s in the U.S., as well as other countries, in the mistaken belief the drug prevented miscarriage and ensured a healthy baby. But it didn't work and instead DES harmed the mothers who **were prescribed it, the children born of those pregnancies and now possibly their grandchildren and beyond.**

Never patented, DES was cheap and easy to produce, so hundreds of drug companies made it in the U.S. and around the world. DES was marketed under numerous brand names.

DES was prescribed if a woman had a previous miscarriage, diabetes, or a problem pregnancy with bleeding, threatened miscarriage or premature labor.

DES was prescribed primarily in pill form. Up until the mid to late 1950s some women were given DES shots. While the use of injections continued they were given less frequently as time went on. Another form of administration was via vaginal suppositories (sometimes called pessaries). DES also was included in the formulations of some prenatal vitamins, meaning individuals were exposed without actually having had DES specifically prescribed.

Two Harvard researchers dedicated much of their time and energy to studying DES. The husband and wife team of Olive Smith, Ph.D., and George Smith, M.D., developed the DES prescribing protocol that bears their names. The Smith and Smith protocol resulted in the ingestion of massive amounts of DES:

The recommended regimen started at 5mg per day in the 7th and 8th weeks of pregnancy (from first day of last menstrual period), and was increased every other week by 5mg per day through the 14th week. Then the amount was increased weekly by 5mg per day, from 25mg in the 15th week to 125mg per day in the 35th week.

In her book, *DES Voices: From Anger to Action*, DES Action Co-founder Pat Cody described the amount of DES she was given. "My doctor increased the dosage every two and a half weeks and I faithfully took **the Stilbestrol** – the trade name for Eli Lilly's brand of diethylstilbestrol – **for seven months, four times a day, until my 37th week of pregnancy. DES was expensive, $30 a month at a time when our house rent was $75. By the time I had completed this course of treatment, I had swallowed a total of 10,100 milligrams, or more than ten grams of DES – roughly the equivalent of 500,000 of tod**ay's low**-dose birth** control pills."

The Smith's research claiming DES successfully prevented miscarriage had flaws. Their studies used no **control groups and called for bed rest along with DES. Looking back, it seems likely the bed rest, and not the drug prevented miscarriage. But at the time drug makers were enthusiastic about DES. It was cheap and easy to produce so every pill prescribed made money for them. Of note is that DES was never patented, so it was produced by many drug companies and marketed using hundreds of brand names.**

One of the major U.S. DES producers was Eli Lilly and Company, which employed a sales force of drug representatives who heavily promoted DES to doctors, urging them to prescribe DES for their pregnant patients. Armed with copies of the Smith's research they made their case well.

Lilly was proud of its sales force and even ran advertisements touting it in medical journals. This fascinating ad is from the 1940s and was provided by the *American Institute of the History of Pharmacy*. In it Lilly promotes its team of drug representatives ostensibly to help them get a foot in the

door of doctor's offices. In those days, with no direct to consumer marketing, drug companies heavily **marketed their products to doctors. DES is an excellent example of how well that worked in convincing providers to prescribe specific drugs.**

In the late 1960s and early 1970s cases of the specific rare cancer, clear cell adenocarcinoma of the vaginal and cervix, were being diagnosed in young women. A cluster of them at Massachusetts General Hospital in Boston raised alarm among doctors who couldn't figure out what was going on. It took **a persistent DES Mother to unravel the mystery. She told doctors her belief the DES she was prescribed while pregnant was responsible. Ultimately, she was proven right.**

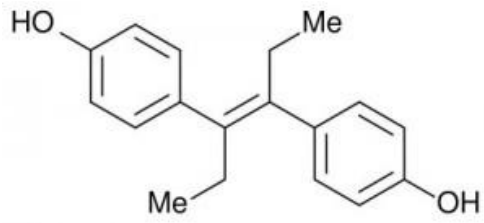
British DES Pill Label

In November 1971, the FDA told doctors to stop prescribing DES for their pregnant patients, however it was never banned. Specifically, the FDA said DES was contraindicated for pregnancy use. In some rare cases American doctors either didn't hear of, or **simply ignored the 1971 message and continued prescribing DES. Internationally, DES use during pregnancy continued for many subsequent years.**

By September 2000, at the urging of drug companies the FDA withdrew approval of DES for use in humans because it wasn't **being prescribed anymore. It is still used by veterinarians, however, to treat incontinence in dogs.**

According to the Centers for Disease Control and Prevention, in the United States an estimated 5 million to 10 million people were exposed to DES, including women who were prescribed DES while pregnant, and the children born of those pregnancies. Now researchers are investigating whether DES health issues are extending into the next generation, the so-called DES Grandchildren, and no estimate of their numbers has yet been made. As study results come in, there is growing evidence that this group has been adversely impacted by a drug prescribed to their grandmothers.

Interestingly, years after developing the chemical formulation for DES, its creator, Sir E. Charles Dodds



was knighted for his accomplishment. It was fully expected in 1938 that his synthetic estrogen would help women worldwide by relieving the estrogen deficiency symptoms of menopause. But almost immediately studies began raising alarms of cancer in animals. Still, those concerns went unheeded in the rush by drug makers to promote this powerful drug for it's **new-found use as a miscarriage preventative.**

As a synthetic estrogen-like compound, the molecular structure of DES differs from natural estrogen, giving it greater potency.

DES was the first compound to be identified as an endocrine disruptor, meaning it interferes with the way a body's endocrine system functions. The results are cancers, infertility and reproductive abnormalities. **Harms caused by endocrine disrupting chemicals are now known to be the most severe when exposure occurs during fetal development. The study of endocrine disrupting chemicals was sparked by the DES experience.**

Research is continuing with new adverse health impacts being identified. The DES experience is a true medical tragedy brought on by less than adequate drug testing, heavy promotion by pharmaceutical companies bent on making a profit, and lax government regulation. While DES is no longer prescribed for human use, those who were exposed to the drug are left dealing with the health and emotional consequences it caused.

Consult this DES Timeline for a historical overview of the DES tragedy.

Attachment 3

https://www.spin.com/featured/aids-and-the-azt-scandal-spin-1989-feature-sins-of-omission/

AIDS and the AZT Scandal: SPIN's 1989 Feature, 'Sins of Omission'

The story of AZT, one of the most toxic, expensive, and controversial drugs in the history of medicine

Written By **Celia Farber** October 5 2015, 3:47 PM ET

At the end of 1989, *two years after we had started the highly controversial AIDS column in* SPIN*, we published an article by Celia Farber called "Sins of Omission" about the truly bad and corrupt science surrounding promoting AZT as a treatment for the syndrome of diseases.*

Celia was the editor and frequent writer of the column and unearthed hard evidence of the cold-bloodedness of the AIDS establishment pushing a drug that was worse than the disease, and killed faster than the natural progression of AIDS left untreated. AZT had been an abandoned cancer drug, discarded because of it's fatal toxicity, resurrected in the cynical belief that AIDS patients were going to die anyway, so trying it out was sort of like playing with the house's money. Because the drug didn't require the usual massively expensive research and trial processes, having gone through that years earlier, it was insanely profitable for its maker, Burroughs Wellcome. It was a tragically perfect storm of windfall profits, something to pacify AIDS activists and the media, and a convenient boom to the patent holders for HIV testing.

Celia — who should get the Congressional Medal of Honor for her brave and relentless reporting, here and throughout the ten years we ran the column — exposed the worthlessness of the drug, the shady studies and deals to suppress the negative findings, and its awful and final consequences. This piece very literally changed the media's view of AIDS and sharpened their discerning and skeptical eye. And soon after, AZT was once again shelved, hopefully this time forever.

Many times over the years since, people have come up to me and said that reading this article saved their lives, that they either stopped taking the drug and their health improved vastly, or they never took it because of what we reported. Nothing ever made me prouder.

— Bob Guccione Jr., founder of SPIN*, October 3, 2015*

[This story was originally published in the November 1989 issue of SPIN*. In honor of* SPIN*'s 30th anniversary, we've republished this piece as part of our ongoing "30 Years, 30 Stories" series.]*

On a cold January day in 1987, inside one of the brightly-lit meeting rooms of the monstrous FDA building, a panel of 11 top AIDS doctors pondered a very difficult decision. They had been asked by the FDA to consider giving lightning-quick approval to a highly toxic drug about which there was very little information. Clinically called Zidovudine, but nicknamed AZT after its components, the drug was said to have shown a dramatic effect on the survival of AIDS patients.

The study that had brought the panel together had set the medical community abuzz. It was the first flicker of hope — people were dying much faster on the placebo than on the drug.

But there were tremendous concerns about the new drug. It had actually been developed a quarter of a century earlier as a cancer chemotherapy, but was shelved and forgotten because it was so toxic, very expensive to produce, and totally ineffective against cancer. Powerful, but unspecific, the drug was not selective in its cell destruction.

Drug companies around the world were sifting through hundreds of compounds in the race to find a cure, or at least a treatment, for AIDS. Burroughs Wellcome, a subsidiary of Wellcome, a British drug company, emerged as the winner. By chance, they sent the failed cancer drug, then known as Compound S, to the National Cancer Institute along with many others to see if it could slay the AIDS dragon, HIV. In the test tube at least, it did. At the meeting, there was a lot of uncertainty and discomfort with AZT. The doctors who had been consulted knew that the study was flawed and that the long-range effects were completely unknown. But the public was almost literally baying at the door. Understandably, there was immense pressure on the FDA to approve AZT, considering the climate of fear and anger all around.*

Everybody was worried about this one. To approve it, said Ellen Cooper, an FDA director, would represent a "significant and potentially dangerous departure from our normal toxicology requirements." Just before approving the drug, one doctor on the panel, Calvin Kunin, summed up their dilemma. "On the one hand," he said, "to deny a drug which decreases mortality in a population such as this would be inappropriate. On the other hand, to use this drug widely, for areas where efficacy has not been demonstrated, with a potentially toxic agent, might be disastrous."

"We do not know what will happen a year from now," said panel chairman Dr. Itzhak Brook. "The data is just too premature, and the statistics are not really well done. The drug could actually be detrimental." A little later, he said he was also "struck by the fact that AZT does not stop deaths. Even those who were switched to AZT still kept dying."

"I agree with you," answered another panel member, "there are so many unknowns. Once a drug is approved, there is no telling how it could be abused. There's no going back." Burroughs Wellcome reassured the panel that they would provide detailed two-year follow-up data, and that they would not let the drug get out of its intended parameters: as a stopgap measure for very sick patients.

Dr. Brook was not won over by the promise. "If we approve it today, there will not be much data. There will be a promise of data," he predicted, "but then the production of data will be hampered." Brook's vote was the only one cast against approval.

"There was not enough data, not enough follow-up," Brook recalls. "Many of the questions we asked the company were answered by, 'We have not analyzed the data yet,' or, 'We do not know.' I felt that there was some promising data, but was very worried about the price being paid for it. The side effects were so very severe. It was chemotherapy. Patients were going to need blood transfusions, that's very serious."

"The committee was tending to agree with me," says Brook, "that we should wait a little bit, be more cautious. But once the FDA realized we were intending to reject it, they applied political pressure. At about 4 p.m., the head of the FDA's Center for Drugs and Biologics asked

permission to speak, which is extremely unusual. Usually they leave us alone. But he said to us, 'Look, if you approve the drug, we can assure you that we will work together with Burroughs Wellcome and make sure the drug is given to the right people.' It was like saying 'please do it.'"

Brad Stone, FDA press officer, was at that meeting. He says he doesn't recall that particular speech, but that there is nothing "unusual" about FDA officials making such speeches at advisory meetings. "There was no political pressure," he says. "The people in that meeting approved the drug because the data the company had produced proved it was prolonging life. Sure it was toxic, but they concluded that the benefits clearly outweighed the risks." The meeting ended. AZT, which several members of the panel still felt uncomfortable with and feared could be a time bomb, was approved.

Flash forward: August 17, 1989. Newspapers across America banner-headlined that AZT had been "proven to be effective in HIV antibody-positive, asymptomatic, and early ARC patients," even though one of the panel's main concerns was that the drug should only be used in a last-case scenario for critically-ill AIDS patients, due to the drug's extreme toxicity. Dr. Anthony Fauci, head of the National Institutes of Health (NIH), was now pushing to expand prescription.

The FDA's traditional concern had been thrown to the wind. Already the drug had spread to 60 countries and an estimated 20,000 people. Not only had no new evidence allayed the initial concerns of the panel, but the follow-up data, as Dr. Brook predicted, had fallen by the wayside. The beneficial effects of the drug had proven to be temporary. The toxicity, however, stayed the same.

The majority of those in the AIDS-afflicted and medical communities held the drug up as the first breakthrough on AIDS. For better or worse, AZT had been approved faster than any drug in FDA history, and activists considered it a victory. The price paid for the victory, however, was that almost all government drug trials, from then on, focused on AZT — while over 100 other promising drugs were left uninvestigated.

Burroughs Wellcome stock went through the roof when the announcement was made. At a price of $8.000 per patient per year (not including blood-work and transfusions), AZT is the most expensive drug ever marketed. Burroughs Wellcome's gross profits for next year are estimated at $230 million. Stock market analysts predict that Burroughs Wellcome may be selling as much as $2 billion worth of AZT, under the brand name Retrovir, each year by the mid-1990s — matching Burroughs Wellcome's total sales for all its products last year.

AZT is the only antiretroviral drug that has received FDA approval for treatment of AIDS since the epidemic began ten years ago, and the decision to approve it was based on a single study that has long been declared invalid. The study was intended to be a "double-blind placebo-controlled study," the only kind of study that can effectively prove whether or not a drug works. In such a study, neither patient nor doctor is supposed to know if the patient is getting the drug or a placebo. In the case of AZT, the study became unblinded on all sides, after just a few weeks.

Both sides contributed to the unblinding. It became obvious to doctors who was getting what because AZT causes such severe side effects that AIDS per se does not. Furthermore, a routine blood count known as a CMV, which clearly shows who is on the drug and who is not, wasn't whited out in the reports. Both of these facts were accepted and confirmed by both the FDA and Burroughs Wellcome, who conducted the study.

Many of the patients who were in the trial admitted that they had analyzed their capsules to find out whether they were getting the drug. If they weren't, some bought the drug on the underground market. Also, the pills were supposed to be indistinguishable by taste, but they were not. Although this was corrected early on, the damage was already done. There were also reports that patients were pooling pills out of solidarity to each other. The study was so severely flawed that its conclusions must be considered, by the most basic scientific standards, unproven.

The most serious problem with the original study, however, is that it was never completed. Seventeen weeks into the study, when more patients had died in the placebo group, the study was stopped, five months prematurely, for "ethical" reasons: It was considered unethical to keep giving people a placebo when the drug might keep them alive longer. Because the study was stopped short, and all subjects were put on AZT, no scientific study can ever be conducted to prove unequivocally whether AZT does prolong life.

Dr. Brook, who voted against approval, warned at the time that AZT, being the only drug available for doctors to prescribe to AIDS patients, would probably have a runaway effect. Approving it prematurely, he said, would be like "letting the genie out of the bottle."

Brook pointed out that since the drug is a form of chemotherapy, it should only be prescribed by doctors who have experience with chemotherapeutic drugs. Because of the most severe toxic effect of AZT — cell depletion of the bone marrow —patients would need frequent blood transfusions. As it happened, AZT was rampantly prescribed as soon as it was released, way beyond its purported parameters. The worst-case scenario had come true: Doctors interviewed by the *New York Times* later in 1987 revealed that they were already giving AZT to healthy people who had tested positive for antibodies to HIV.

The FDA's function is to weigh a drug's efficacy against its potential hazards. The equation is simple and obvious: A drug must unquestionably repair more than it damages, otherwise the drug itself may cause more harm than the disease it is supposed to fight. Exactly what many doctors and scientists fear is happening with AZT.

AZT was singled out among hundreds of compounds when Dr. Sam Broder, the head of the National Cancer Institute (NCI), found that it "inhibited HIV viral replication in vitro." AIDS is considered a condition of immune suppression caused by the HIV virus replicating and eating its way into T-4 cells, which are essential to the immune system. HIV is a retrovirus which contains an enzyme called reverse transcriptase that converts viral RNA to DNA. AZT was thought to work by interrupting this DNA synthesis, thus stopping further replication of the virus.

While it was always known that the drug was exceedingly toxic, the first study concluded that "the risk/benefit ratio was in favor of the patient."

In the study that won FDA approval for AZT, the one fact that swayed the panel of judges was that the AZT group outlived the placebo group by what appeared to be a landslide. The ace card of the study, the one that canceled out the issue of the drug's enormous toxicity, was that 19 persons had died in the placebo group and only one in the AZT group. The AZT recipients were also showing a lower incidence of opportunistic infections.

While this data staggered the panel that approved the drug, other scientists insisted that it meant nothing — because it was so shabbily gathered, and because of the unblinding. Shortly after the

study was stopped, the death rate accelerated in the AZT group. “There was no great difference after a while,” says Dr. Brook, “between the treated and the untreated group.”

“That study was so sloppily done that it really didn’t mean much,” says Dr. Joseph Sonnabend, a leading New York City AIDS doctor. Dr. Harvey Bialy, scientific editor of the journal *Biotechnology*, is stunned by the low quality of science surrounding AIDS research. When asked if he had seen any evidence of the claims made for AZT, that it “prolongs life” in AIDS patients, Bialy said, “No, I have not seen a published study that is rigorously done, analyzed, and objectively reported.”

Bialy, who is also a molecular biologist, is horrified by the widespread use of AZT, not just because it is toxic, but because, he insists, the claims its widespread use are based upon are false. “I can’t see how this drug could be doing anything other than making people very sick,” he says.

The scientific facts about AZT and AIDS are indeed astonishing. Most ironically, the drug has been found to accelerate the very process it was said to prevent: the loss of T-4 cells.

“Undeniably, AZT kills T-4 cells [white blood cells vital to the immune system],” says Bialy. “No one can argue with that. AZT is a chain-terminating nucleotide, which means that it stops DNA replication. It seeks out any cell that is engaged in DNA replication and kills it. The place where most of this replication is taking place is in the bone marrow. That’s why the most common and severe side effect of the drug is bone marrow toxicity. That is why they [patients] need blood transfusions.”

AZT has been aggressively and repeatedly marketed as a drug that prolongs survival in AIDS patients because it stops the HIV virus from replicating and spreading to healthy cells. But, says Bialy: “There is no good evidence that HIV actively replicates in a person with AIDS, and if there isn’t much HIV replication to stop, it’s mostly killing healthy cells.”

University of California at Berkeley scientist Dr. Peter Duesberg drew the same conclusion in a paper published in *Proceedings*, the journal of the National Academy of Sciences. Duesberg, whose paper addressed his contention that HIV is not a sufficient cause for AIDS, wrote: “Even if HIV were to cause AIDS, it would hardly be a legitimate target for AZT therapy, because in 70 to 100 percent of antibody-positive persons, proviral DNA is not detectable… and its biosynthesis has never been observed.”

As a chemotherapeutic drug, explained Duesberg, AZT “kills dividing blood cells and other cells,” and is thus “directly immunosuppressive.”

“The cell is almost a million-fold bigger target than the virus, so the cell will be much, much more sensitive,” says Duesberg. “Only very few cells, about one in 10,000, are actively making the virus containing DNA, so you must kill incredibly large numbers of cells to inhibit the virus. This kind of treatment could only theoretically help if you have a massive infection, which is not the case with AIDS. Meanwhile, they’re giving this drug that ends up killing millions of lymphocytes [white blood cells]. It’s beyond me how that could possibly be beneficial.”

“It doesn’t really kill them,” Burroughs Wellcome scientist Sandra Lehrman argues. “You don’t necessarily have to destroy the cell, you can just change the function of it. Furthermore, while the early data said that only very few cells were infected, new data says that there may be more cells infected. We have more sensitive detection techniques now.”

"Changes their function? From what — functioning to not functioning? Another example of mediocre science," says Bialy. "The 'sensitive detection technique' to which Dr. Lehrman refers, PCR, is a notoriously unreliable one upon which to base quantitative conclusions."

When specific questions about the alleged mechanisms of AZT are asked, the answers are long, contradictory, and riddled with unknowns. Every scientific point raised about the drug is eventually answered with the blanket response, "The drug is not perfect, but it's all we have right now." About the depletion of T-4 cells and other white cells, Lehrman says, "We don't know why T-4 cells go up at first, and then go down. That is one of the drug mechanisms that we are trying to understand."

When promoters of AZT are pressed on key scientific points, whether at the NIH, FDA, Burroughs Wellcome, or an AIDS organization, they often become angry. The idea that the drug is "doing something," even though this is invariably followed with irritable admissions that there are "mechanisms about the drug and disease we don't understand," is desperately clung to. It is as if, in the eye of the AIDS storm, the official, government-agency sanctioned position is immunized against critique. Skepticism and challenge, so essential to scientific progress and so prevalent in every other area of scientific endeavor, is not welcome in the AZT debate, where it is arguably needed more than anywhere else.

The toxic effects of AZT, particularly bone marrow suppression and anemia, are so severe that up to 50 percent of all AIDS and ARC patients cannot tolerate it and have to be taken off it. In the approval letter that Burroughs Wellcome sent to the FDA, all of 50 additional side effects of AZT, aside from the most common ones, were listed. These included: loss of mental acuity, muscle spasms, rectal bleeding, and tremors.

Anemia, one of AZT's common side effects, is the depletion of red blood cells, and, according to Duesberg, "Red blood cells are the one thing you cannot do without. Without red cells, you cannot pick up ???gen."

Fred, a person with AIDS, was put on AZT and suffered such severe anemia from the drug he had to be taken off it. In an interview in the AIDS handbook *Surviving and Thriving With AIDS*, he described what anemia feels like to editor Michael Callen: "I live in a studio and my bathroom is a mere five-step walk from my bed. I would just lie there for two hours; I couldn't get up to take those five steps. When I was taken to the hospital, I had to have someone come over to dress me. It's that kind of severe fatigue. The quality of my life was pitiful… I've never felt so bad… I stopped the AZT and the mental confusion, the headaches, the pains in the neck, the nausea, all disappeared within a 24-hour period."

"I feel very good at this point," Fred went on. "I feel like the quality of my life was a disaster two weeks ago. And it really was causing a great amount of fear in me, to the point where I was taking sleeping pills to calm down. I was so worried. I would totally lose track of what I was saying in the middle of a sentence. I would lose my directions on the street."

"Many AIDS patients are anemic even before they receive the drug," says Burroughs Wellcome's Dr. Lehrman, "because HIV itself can infect the bone marrow and cause anemia."

This argument betrays a bizarre reasoning. If AIDS patients are already burdened with problems such as immune suppression, bone marrow toxicity, and anemia, is compounding these problems an improvement?

“Yes, AZT is a form of chemotherapy,” says the man who invented the compound a quarter-century ago, Jerome Horwitz. “It is cytotoxic, and as such, it causes bone marrow toxicity and anemia. There are problems with the drug. It’s not perfect. But I don’t think anybody would agree that AZT is of no use. People can holler from now until doomsday that it is toxic, but you have to go with the results.”

The results, finally and ironically, are what damns AZT. Several studies on the clinical effects of AZT — including the one that Burroughs Wellcome’s approval was based on — have drawn the same conclusion: that AZT is effective for a few months, but that its effect drops off sharply after that. Even the original AZT study showed that T-4 cells went up for a while and then plummeted. HIV levels went down, and then came back up. This fact was well-known when the advisory panel voted for approval. As panel member Dr. Stanley Lemon said in the meeting, “I am left with the nagging thought that after seeing several of these slides, that after 16 to 24 weeks — 12 to 16 weeks, I guess — the effect seems to be declining.”

A follow-up meeting, two weeks after the original Burroughs Wellcome study, was scheduled to discuss the long-range effects of AZT and the survival statistics. As one doctor present at that meeting in May 1988 recalls, “They hadn’t followed up the study. Anything that looked beneficial was gone within half a year. All they had were some survival statistics averaging 44 weeks. The p24 didn’t pan out and there no persistent improvement in T-4 cells.”

HIV levels in the blood are measured by an antigen called p24. Burroughs Wellcome made the claim that AZT lowered this level, that is, lowered the amount of HIV in the blood. At the first FDA meeting, Burroughs-Welcome emphasized how the drug had “lowered” the p24 levels; at the follow-up meeting they didn’t even mention it.

As that meeting was winding down, Dr. Michael Lange, head of the AIDS program at St. Luke’s-Roosevelt Hospital in New York spoke up about this. “The claim of AZT is made on the fact that it is supposed to have an antiviral effect,” he said to Burroughs Wellcome, “and on this we have seen no data at all… Since there is a report in the *Lancet* [a leading British medical journal] that after 20 weeks or so, in many patients p24 came back, do you have any data on that?”

They didn’t.

“What counts is the bottom line,” one of the scientists representing Burroughs Wellcome summed up, “the survival, the neurologic function, the absence of progression and the quality of life, all of which are better. Whether you call it better because of some antiviral effect, or some other antibacterial effect, they are still better.”

Dr. Lange suggested that the drug may be effective in the same way a simple anti-inflammatory, such as aspirin, is effective. An inexpensive, nontoxic drug called Indomecithin, he pointed out, might serve the same function, without the devastating side effects.

One leading AIDS researcher, who was part of the FDA approval process, says today: “Does AZT do anything? Yes, it does. But the evidence that it does something against HIV is really not there.”

“There have always been drugs that we use without knowing exactly how they work,” says Nobel Prize winner Walter Gilbert. “The really important thing to look at is the clinical effect. Is the drug helping or isn’t it?”

A physician with extensive experience with AIDS patients who asked to remain anonymous told *SPIN*, point blank: “I personally do not prescribe AZT. I have continued to experience that people live longer who are not on it.”

“I’m living proof that AZT works,” says one person with ARC on AZT. “I’ve been on it for two years now, and I’m certainly healthier than I was two years ago. It’s not a cure-all, it’s not a perfect drug, but it’s effective. It’s slowing down the progression of the disease.”

“Sometimes I fee like I’m swallowing Drano,” says another. “I mean, sometimes I have problems swallowing. I just don’t like the idea of taking something that foreign to my body. But every six hours, I’ve got to swallow it. Until something better comes along, this is what is available to me.”

“I am absolutely convinced that people enjoy a better quality of life and survive longer who do not take AZT,” says Gene Fedorko, President of Health Education AIDS Liaison (HEAL). “I think it’s horrible the way people are bullied by their doctors to take this drug. We get people coming to us shaking and crying because their doctors said they’ll die if they don’t take AZT. That is an absolute lie.” Fedorko has drawn his conclusion from years of listening to the stories of people struggling to survive AIDS at HEAL’s weekly support group.

“I wouldn’t take AZT if you paid me,” says Michael Callen, cofounder of New York City’s PWA coalition, Community Research Initiative, and editor of several AIDS journals. Callen has survived AIDS for over seven years without the help of AZT. “I’ve gotten the s–t kicked out of me for saying this, but I think using AZT is like aiming a thermonuclear warhead at a mosquito. The overwhelming majority of long-term survivors I’ve known have chosen not to take AZT.”

The last surviving patient from the original AZT trial, according Burroughs Wellcome, died recently. When he died, he had been on AZT for three and one-half years. He was the longest surviving AZT recipient. The longest surviving AIDS patient overall, not on AZT, has lived for eight and one-half years.

An informal study of long-term survivors of AIDS followed 24 long-term survivors, all of whom had survived AIDS for more than six years. Only one of them had recently begun taking AZT.

In the early days, AZT was said to extend lives. In actual fact, there is simply no solid evidence that AZT prolongs life.

“I think AZT does prolong life in most people,” says Dr. Bruce Montgomery of the State University of New York at Stony Brook, who is completing a study on AZT. “There are not very many long-term survivors, and we really don’t know why they survive. It could be luck. But most people are not so lucky.”

“AZT does seem to help many patients,” says Dr. Bernard Bahari, a New York City AIDS physician and researcher, “but it’s very hard to determine whether it actually prolongs life.”

“Many of the patients I see choose not to take AZT,” says Dr. Don Abrams of San Francisco General Hospital. “I’ve been impressed that survival and lifespan are increasing for all people

with AIDS. I think it has a lot to do with aerosolized Pentamadine [a drug that treats pneumocystis carinii pneumonia]. There's also the so-called plague effect, the fact that people get stronger and stronger when a disease hits a population. The patients I see today are not as fragile as the early patients were."

"Whether you live or die with AIDS is a function of how well your doctor treats you, not of AZT," says Dr. Joseph Sonnabend, one of New York City's first and most reputable AIDS doctors, whose patients include many long-term survivors, although he has never prescribed AZT. Sonnabend was one of the first to make the simple observation that AIDS patients should be treated for their diseases, not just for their HIV infection.

Several studies have concluded that AZT has no effect on the two most common opportunistic AIDS infections, Pneumocystic Carinii Pneumonia (PCP) and Kaposi's Sarcoma (KS). The overwhelming majority of AIDS patients die of PCP, for which there has been an effective treatment for decades. This year, the FDA finally approved aerosolized Pentamadine for AIDS. A recent Memorial Sloan Kettering study concluded the following: By 15 months, 80 percent of people on AZT not receiving Pentamadine had a recurrent episode of pneumocystis. Only 5 percent of those people who did get Pentamadine had a recurring episode. "All those deaths in the AZT study were treatable," Sonnabend says. "They weren't deaths from AIDS, they were deaths from treatable conditions. They didn't even do any autopsies for that study. What kind of faith can one have in these people?"

"If there's one resistance to AZT in the general public at all, it's within the gay community of New York," says the doctor close to the FDA approval, who asked to remain anonymous. "The rest of this country has been brainwashed into thinking this drug really does that much. The data has all been manipulated by people who have a lot vested in AZT."

"If AIDS were not the popular disease that it is — the money-making and career-making machine — these people could not get away with this kind of shoddy science," says Bialy. "In all my years in science I have never seen anything this atrocious." When asked if he thought it was at all possible that people have been killed as a result of AZT poisoning rather than AIDS he answered: "It's more than possible."

August 17, 1989: The government has announced that 1.4 million healthy, HIV antibody-positive Americans could "benefit" from taking AZT, even though they show no symptoms of disease. New studies have "proven" that AZT is effective in stopping the progression of AIDS in asymptomatic and early ARC cases. Dr. Fauci, the head of NIH, proudly announced that a trial has been going on for "two years" had "clearly shown" that early intervention will keep AIDS at bay. Anyone who has antibodies to HIV and less than 500 T-4 cells should start taking AZT at once, he said. That is approximately 650,000 people. 1.4 million Americans are assumed HIV antibody-positive, and eventually all of them may need to take AZT so they don't get sick, Fauci contended.

The leading newspapers didn't seem to think it unusual that there was no existing copy of the study, but rather a breezy two-page press release from the NIH. When *SPIN* called the NIH asking for a copy of the study, we were told that it was "still being written."

We asked a few questions about the numbers. According to the press release, 3,200 early ARC and asymptomatic patients were divided into two groups, one AZT and one placebo, and

followed for two years. The two groups were distinguished by T-4 cell counts; one group had less than 500, the other more than 500. These two were then divided into three groups each: high-dose AZT, low-dose AZT, and placebo. In the group with more than 500 T-4 cells, AZT had no effect. In the other group, it was concluded that low-dose AZT was the most effective, followed by high-dose. All in all, 36 out of 900 developed AIDS in the two AZT groups combined, and 38 out of 450 in the placebo group. "HIV-positive are twice as likely to get AIDS if they don't take AZT," the press declared.

However, the figures are vastly misleading. When we asked how many patients were actually enrolled for a full two years, the NIH said they did not know, but that the average time of participation was one year, not two.

"It's terribly dishonest the way they portrayed those numbers," says Dr. Sonnabend. "If there were 60 people in the trial those numbers would mean something, but if you calculate what the percentage is out of 3,200, the difference becomes minute between the two groups. It's nothing. It's hit or miss, and they make it look like it's terribly significant."

The study boasted that AZT is much more effective and less toxic at one-third the dosage than has been used for three years now. That's the good news. The bad news is that thousands have already been walloped with 1,500 milligrams of AZT and possibly even died of toxic poisoning — and *now* we're hearing that one third of the dose would have done?

With all that remains so uncertain about the effects of AZT, it seems criminal to advocate expanding its usage to healthy people, particularly since only a minuscule percentage of the HIV-infected population have actually developed ARC or AIDS.

Burroughs Wellcome has already launched testing of AZT in asymptomatic hospital workers, pregnant women, and in children, who are getting liquid AZT. The liquid is left over from an aborted trial, and given to the children because they can mix it with water — children don't like to swallow pills. It has also been proposed that AZT be given to people who do not yet even test positive for HIV antibodies, but are "at risk."

"I'm convinced that if you gave AZT to a perfectly healthy athlete," says Fedorko, "he would be dead in five years."

In December 1988, the *Lancet* published a study that Burroughs Wellcome and the NIH do not include in their press kits. It was more expansive than the original AZT study and followed patients longer. It was not conducted in the United States, but in France, at the Claude Bernard Hospital in Paris, and concluded the same things about AZT that Burroughs Wellcome's study did, except Burroughs Wellcome called their results "overwhelmingly positive," and the French doctors called theirs "disappointing." The French study found, once again, that AZT was too toxic for most to tolerate, *had no lasting effect on HIV blood levels, and left the patients with fewer T-4 cells than they started with*. Although they noticed a clinical improvement at first, they concluded that "by six months, these values had returned to their pretreatment levels, and several opportunistic infections, malignancies, and deaths occurred."

"Thus the benefits of AZT are limited to a few months for ARC and AIDS patients," the French team concluded. After a few months, the study found, AZT was completely ineffective.

The news that AZT will soon be prescribed to asymptomatic people has left many leading AIDS doctors dumbfounded and furious. Every doctor and scientist I asked felt that it was highly unprofessional and reckless to announce a study with no data to look at, making recommendations with such drastic public health implications. “This simply does not happen,” says Bialy. “The government is reporting scientific facts before they’ve been reviewed? It’s unheard of.”

“It’s beyond belief,” says Dr. Sonnabend in a voice tinged with desperation. “I don’t know what to do. I have to go in and face an office full of people asking for AZT. I’m terrified. I don’t know what to do as a responsible physician. The first study was ridiculous. Margaret Fischl, who has done both of these studies, obviously doesn’t know the first thing about clinical trials. I don’t trust her. Or the others. They’re simply not good enough. We’re being held hostage by second-rate scientists. We let them get away with the first disaster; now they’re doing it again.”

“It’s a momentous decision to say to people, ‘If you’re HIV-positive and your T-4 cells are below 500, start taking AZT,'” says the AIDS doctor who wished to remain anonymous. “I know dozens of people that I’ve seen personally every few months for several years now who have been in that state for more than five years, and have not progressed to any disease.”

“I’m ashamed of my colleagues,” Sonnabend laments. “I’m embarrassed. This is such shoddy science it’s hard to believe nobody is protesting. Damned cowards. The name of the game is to protect your grant, don’t open your mouth. It’s all about money… it’s grounds for just following the party line and not being critical, when there are obviously financial and political forces driving this.”

When Duesberg heard the latest announcement, he was partially stunned over the reaction of Gay Men’s Health Crisis President Richard Dunne, who said that GMHC now urged “everybody to get tested,” and of course those who test positive to go on to AZT. “These people are running into the gas chambers,” says Duesberg. “Himmler would have been so happy if only the Jews were this cooperative.”

Attachment 4

https://www.cnn.com/2020/09/01/health/eua-coronavirus-vaccine-history/index.html

Past vaccine disasters show why rushing a coronavirus vaccine now would be 'colossally stupid'

By Jen Christensen, CNN
Updated 11:34 AM ET, Tue September 1, 2020

(CNN) Vaccine experts are warning the federal government against rushing out a coronavirus vaccine before testing has shown it's both safe and effective. Decades of history show why they're right.

FDA signals vaccine could green light early

Their concern that the FDA may be moving too quickly heightened when FDA Commissioner Dr. Steven Hahn told the Financial Times that his agency could consider an emergency use authorization (EUA) for a Covid-19 vaccine before late stage clinical trials are complete if the data show strong enough evidence it would protect people.

The commissioner has the authority to allow unapproved medical products to be used in an emergency when there are no adequate or approved alternatives. An EUA is not the same as full approval and it can be withdrawn.

That's what happened with hydroxychloroquine and chloroquine. The FDA granted an EUA to the drugs -- much praised by President Donald Trump -- on March 28. It subsequently revoked its EUA in June after studies showed they were not effective and could also potentially cause serious heart problems.

Vaccine approval

For a vaccine to be FDA approved, scientists must gather enough data through clinical trials in large numbers of volunteers to prove it is safe and effective at protecting people against a disease. Once the data is collected, FDA advisers usually spend months considering it.

An EUA is much quicker. Only once before has the FDA given a vaccine this lesser standard approval of an EUA, but it was in an unusual circumstance. Soldiers had sued, claiming a mandatory anthrax vaccine made them sick, and a judge put a hold on the program. The Department of Defense asked for an EUA that then overrode the court ruling in 2005, so it could continue vaccinating military personnel -- this time on a voluntary basis.

Otherwise, vaccines have had to go through the entire clinical trial process and FDA approval process, which can take months or years.

When the vaccine making process has been rushed, there have been bad outcomes.

The Cutter incident

On April 12, 1955 the government announced the first vaccine to protect kids against polio. Within days, labs had made thousands of lots of the vaccine. Batches made by one company, Cutter Labs, accidentally contained live polio virus and it caused an outbreak.

More than 200,000 children got the polio vaccine, but within days the government had to abandon the program.

"Forty thousand kids got polio. Some had low levels, a couple hundred were left with paralysis, and about 10 died," said Dr. Howard Markel, a pediatrician, distinguished professor, and director of the Center for the History of Medicine at the University of Michigan. The government suspended the vaccination program until it could determine what went wrong.

Monkey trouble

However, increased oversight failed to discover another problem with the polio vaccine.

From 1955 to 1963, between 10% and 30% of polio vaccines were contaminated with simian virus 40 (SV40).

"The way they would grow the virus was on monkey tissues. These rhesus macaques were imported from India, tens of thousands of them," medical anthropologist S. Lochlann Jain said. "They were gang caged and in those conditions, the ones that didn't die on the journey, many got sick, and the viruses spread quickly," added Jain, who taught a history of vaccines course at Stanford and is working on a publication about the incident. Scientists wrongly thought the formaldehyde they used would kill the virus. "It was being transferred to millions of Americans," Jain said.

"Many believe this issue wasn't adequately pursued," Jain said. Some studies showed a possible link between the virus and cancer. The US Centers for Disease Control website, however, said most studies are "reassuring" and find no link.

No current vaccines contain SV40 virus, the CDC says, and there's no evidence the contamination harmed anyone.

The epidemic that never was

In 1976, scientists predicted a pandemic of a new strain of influenza called swine flu. More than 40 years later, some historians call it "flu epidemic that never was."

"President Ford was basically told by his advisers, that look, we have a pandemic flu coming called swine flu that may be as bad as Spanish flu," said Michael Kinch, a professor of radiation oncology in the school of medicine at Washington University in St. Louis. His latest book, "Between Hope and Fear," explores the history of vaccines.

"Ford was being cajoled to put forward a vaccine that was hastily put together. When you have a brand new strain situation like that, they had to do it on the fly," Kinch said.

Ford made the decision to make the immunization compulsory.

The government launched the program in about seven months and 40 million people got vaccinated against swine flu, according to the CDC. That vaccination campaign was later linked to cases of a neurological disorder called Guillain-Barre syndrome, which can develop after an infection or, rarely, after vaccination with a live vaccine.

"Unfortunately, due to that vaccine, and the fact that it was done so hastily, there were a few hundred cases of Guillain-Barre, although it's not definitive that they were linked," Kinch said.

The CDC said the increased risk was about 1 additional case of Gullain-Barre for every 100,000 people who got the swine flu vaccine. Due to this small association, the government stopped the program to investigate.

"It was kind of a fiasco," Markel said. "The good news is that there never was an epidemic of swine flu. So we were safe, but that shows you what could happen."

Growing distrust in the US

It took several incidents for people to start distrusting vaccines. Even after thousands of kids got sick from the first polio vaccine in 1955, when the program restarted, parents made sure their children got vaccinated. They had clear memories of epidemics that paralyzed between 13,000 and 20,000 children every year. Some were so profoundly paralyzed that they could not even breathe easily on their own, and relied on machines called iron lungs to help them breathe.

"Parents were pushing their kids to get to the head of the line to get the polio vaccine, because they had seen epidemics every summer for years, and saw kids in iron lungs and they were terrified," Markel said.

Markel said people's attitudes started to change between 1955 and the problematic 1976 swine flu vaccination project.

"You've got civil rights, when people see the cops beating the hell out of people on TV. You've got the Vietnam War where people start to get disgusted with the killing. You've got Watergate when the president is literally lying through his teeth," Markel said. "That led to a real distrust of authorities and federal government, and it extended to doctors and scientists. And, that's only progressed as time has gone along."

A 'colossally stupid' move

Markel said people's mistrust of the system makes the idea that the FDA would rush this process before late stage clinical trials are complete "colossally stupid."

"This is one of the most ridiculous things I've heard this administration say," Markel said. "All it takes is one bad side effect to basically botch a vaccine program that we desperately need against this virus. It's a prescription for disaster."

FDA Commissioner Hahn said that the vaccine decision will be based on data, not politics, but Kinch shares Markel's concern.

"This could do substantial damage," Kinch said. Kinch, who is a patient in one of the vaccine trials himself, said the clinical trial process needs to be followed to the end. A too-early EUA for a vaccine could cause a "nightmare scenario," for a few reasons.

One, the vaccine may not be safe. Two, if it is not safe, people will lose faith in vaccines. Three, if a vaccine doesn't offer complete protection, people will have a false sense of security and increase their risk. Four, if a substandard vaccine gets an EUA, a better vaccine may never get approval, because people would be reluctant to enroll in trials and risk getting a placebo instead of a vaccine.

"People are going to die unnecessarily if we take chances with this," Kinch said. "We've got to get this right."

CNN Health's Jamie Gumbrecht contributed to this story

Attachment 5

https://childrenshealthdefense.org/defender/covid-vaccine-military-botched-anthrax/
10/21/20

BIG PHARMA › VIEWS

What COVID Vaccine Policymakers Can Learn From Botched Military Anthrax Vaccine Program

It's time to re-evaluate recommendations related to the approval, mandating and monitoring of vaccines.

By Pam Long

In 2002, the U.S. Government Accountability Office (GAO) issued a report to Congress on the Anthrax Vaccine Immunization Program (AVIP), a mandatory program created by the military in the late 1990s.

The 55-page report detailed a litany of adverse reactions to the anthrax vaccine, and the subsequent mass exodus of military pilots and other highly valuable military personnel who refused the mandated vaccine.

Why revisit a report, written nearly two decades ago, on how the military handled the anthrax vaccine?

First, the report validates many of the concerns parents have voiced for decades about childhood vaccine schedules. It should serve as a warning to parents, especially in light of the rush to develop a COVID-19 vaccine. After all, the Centers for Disease Control and Prevention is directing the Childhood Immunization Program under the same dysfunctional decision-making paradigm as the one used by the military.

Second, the report's insights into the military's poor handling of the anthrax program are valuable today — when the threat of a SARS-CoV-2 vaccine mandate looms large — for their potential to reshape our current approach to vaccines and mandates.

We've seen recently how a corrupt pharmaceutical industry, just by putting a few letters in the mail and incentivizing the media to broadcast panic, can manipulate officials at the highest level of the federal government into endorsing the need for fast-tracking a vaccine.

It's time to re-evaluate how the U.S. Food & Drug Administration (FDA), the Department of Defense (DOD) and the Department of Health and Human Services (HHS) make recommendations related to the approval, mandating and monitoring of vaccines.

If government officials do undertake this reevaluation process, they would do well to consider the GAO's critique of the military's handling of the anthrax vaccine — including the GAO's assessment of how one man's actions needlessly put an entire military population at risk of experiencing a dangerous reaction to an unproven vaccine.

Here's a look back at the concerns raised by the GAO in 2002 about anthrax, the military and vaccine safety programs.

1. Did the risk of anthrax justify mandating the vaccine for all military members?

The anthrax vaccine had been in development and limited use in the military since 1970. As of 1997, there was talk of making the vaccine compulsory for all 2.4 million military service members, including active duty and reserve personnel and civilian contractors.

The events of September 11, 2001, and subsequent anthrax letter attacks through the U.S. postal system, bolstered calls for mandating the anthrax vaccine throughout the military. As of 2001, more than 500,000 service members had received at least one dose of the vaccine, which was designed to be administered in six doses.

From 2000 to 2018, the military anthrax mandate was challenged several times in court for lacking FDA approval and licensure, and for lacking proven potency against fatal inhalation of anthrax. During this time, DOD restricted the anthrax vaccine to a smaller group of "at risk troops" and halted and resumed the program several times, without transparency.

In addition to the legal challenges, the GAO report identified that the military had a serious retention crisis due to the anthrax vaccine. The most experienced pilots left or planned to leave the military to avoid the anthrax vaccine — they were even willing to walk away from retirement benefits.

"According to our survey, between September 1998 and September 2000, when AVIP was mandatory, about 16 percent of the guard and reserve pilots and aircrew members had transferred to another unit (primarily to non-flying positions), moved to inactive status, or left the military altogether. In addition, 18 percent of those still participating in units indicated their intention to transfer, move, or leave in the near future. About one-fifth of those who had already left did so knowingly before qualifying for military retirement."

The pending loss of pilots was undeniable. According to the report, 69% of those pilots who changed their status ranked the anthrax vaccine as the main factor, and 72% of those pilots who planned to leave the military ranked the anthrax vaccine as the main factor. More than half of the losses and potential future losses of aircrew members in the guard and reserve were pilots. These personnel losses included more experienced positions of flight evaluator, flight instructor and aircraft commander, in whom the military had invested years of training.

If the narrowing of the anthrax vaccine program was designed to retain pilots and officers, the data should be investigated. What were the "at risk" criteria? Did the anthrax program target enlisted personnel because officers were refusing the anthrax vaccine twice as frequently as enlisted personnel? Did the anthrax program target personnel with less experience and training, and subsequently less value to the military?

Prior to 2001, DOD had concluded that biological agents such as anthrax were not a threat for mass casualties due to the limited number of countries with the expertise and sophistication required to weaponize and disseminate anthrax. In October 2001, a few letters mailed with anthrax spores became the primary justification for the anthrax vaccine mandate in the military, with media coverage of disrupted businesses and government operations inducing panic. If the mailings originated from

someone in the industry with a conflict of interest, then the anthrax vaccine program was based on a manufactured crisis.

As of 2020, the risk of death from the inhalation of anthrax, which was used to justify the program, has never been substantiated.

2. Anthrax manufacturer fraudulently reported mild adverse reactions with low rates

The GAO report documented that overall injuries, both localized and systemic, from the anthrax vaccine were double the reported rate from the manufacturer. The data also revealed that more serious and long-lasting adverse events were 100 times more frequent than the manufacturer reported.

"According to our survey results, the reported rate and severity of adverse events experienced by personnel who had received the anthrax shots were considerably higher than those published in the vaccine manufacturer's product insert in use at the time of the survey or reported by DOD. For example, an estimated 84 percent of the personnel who had had anthrax vaccine shots between September 1998 and September 2000 reported having side effects or reactions. This rate is more than double the level cited in the vaccine product insert. Further, about 24 percent of all events were classified as systemic—a level more than a hundred times higher than that estimated in the product insert. The reaction rates from our survey were also consistent with the results of two earlier DOD studies of the anthrax vaccine. In addition, we found that most events were not being reported to either official or informal DOD channels, partly because most individuals were unaware of the reporting process for documenting any such occurrences."

The report cited two other DOD studies, in Hawaii and Korea, which replicated these findings. The manufacturer's product insert recommended the vaccination be discontinued when systemic reactions occurred. But most respondents to the military survey had received four doses of anthrax vaccine, and had reacted to each dose. It is unlikely that any victims knew how to identify or report a systematic reaction linked to the vaccine.

3. Vaccine adverse reaction surveillance does not exist in the U.S.

How can a highly reactive vaccine continue to be administered for more than 20 years?

The GAO report validated what thousands of parents of vaccine-injured children describe via the Vaccine Adverse Event Reporting System (VAERS) — that VAERS is a passive, failure-by-design system incapable of detecting hot lots of vaccines.

The anthrax program administered millions of doses to military members without an active surveillance system acting as a watchdog to monitor health outcomes. The GAO report provided alarming data on the difference in reporting under passive and active monitoring methods:

"DOD continued to use data from VAERS to monitor adverse events or reactions to anthrax vaccination, even though it is a 'passive' surveillance system that relies on vaccine recipients or their health care providers to report adverse events after vaccination. Studies show that significantly fewer adverse events are reported under such a system when compared to an active surveillance approach in which vaccine recipients are actively monitored to identify and track any adverse reactions to a vaccine or medication.13 For example, we estimated that almost three-fourths of vaccinated guard and reserve personnel experienced burning in the vaccinated arm and a knot or lump in the vaccinated arm,

compared with DOD's report that 0.007 percent had such reactions. In November 2001, DOD reported that after more than 2 million doses of anthrax vaccine had been administered to more than 522,000 people, only 1,685 VAERS reports were submitted for possible adverse events associated with the vaccine. In contrast, the approximately 380 shot recipients in our survey disclosed more than 6,000 reactions (almost 1,300 of which were systemic) from slightly more than 1,300 shots."

The GAO report recommended that the Secretary of Defense establish an active surveillance program to identify adverse events, to monitor those affected with adverse reactions and to provide treatment protocols for health care workers. It asserted that VAERS was incapable of any of these functions, and thereby substantiated that a functioning watchdog over the CDC's Childhood Immunization Schedule is non-existent.

4. DOD information on anthrax safety and efficacy wasn't credible

The GAO report quantifies the high level of distrust that military personnel had with the anthrax vaccine information provided by DOD. Sixty two percent of respondents were highly dissatisfied with the anthrax vaccine's effectiveness in battlefield exposures. Sixty two percent were highly dissatisfied with the vaccine's short-term safety, and 69% were highly dissatisfied with long term safety. According to the report, 69% were highly dissatisfied with information on reactions to the anthrax vaccine.

Despite an extensive DOD campaign to communicate the anthrax as a serious threat, and the anthrax vaccine as safe and effective, most technically proficient military personnel remained unconvinced of either. Overall, 77% of the respondents indicated that they would not have taken the anthrax vaccine if they hadn't been required to. Only 11% of the respondents reported that they would have taken the shot on a voluntary basis, and 12% percent were uncertain.

The main concerns expressed about the anthrax vaccine were increased risk for autoimmune disease (80%), effects on offspring (63%) and effects on male fertility (51%). The civilian community under state vaccine mandates expresses this same distrust of vaccines in the affluent and educated populations who are most likely to exempt themselves from vaccines.

5. Fear of retaliation from employers and doctors for reporting vaccine adverse reactions

From the report:

"In addition, our survey estimated that about 57%of those who experienced an adverse reaction did not discuss it with anyone in military health care or their individual supervisors. Some 49% cited concern about the loss of flight status, possible adverse effects on their military or civilian careers, and the fear of ridicule as reasons for not discussing vaccination shot reactions with others."

6. Denial of vaccine-induced disease regarding Gulf War Syndrome

The GAO report noted that anthrax adverse reactions were very similar to Gulf War Syndrome symptoms. These symptoms include skin disorders, chronic fatigue, headache, memory problems, muscle and joint pain, insomnia, gastrointestinal problems, respiratory problems, neurological problems and tumors.

"In addition, some Gulf War veterans are suffering from unexplained illnesses that they believe might have been caused by anthrax vaccinations received during the war."

The report cites several studies in the U.S. and the UK that showed a relationship between the anthrax vaccine and Gulf War Syndrome, and implicated the squalene, an ingredient in the vaccine. Gulf War Syndrome occurred in 34% of Persian Gulf War veterans, and 12% of non-Persian Gulf War veterans who reported receiving vaccines during the war but who did not deploy, indicating that the vaccines used during the war may be a contributing factor.

The number of inoculations were associated with increased symptoms of skin and musculoskeletal complaints in UK Gulf War veterans. Declines in long-term subjective health were associated Gulf War veterans who had received the anthrax vaccine. Vaccination against biological warfare was associated with the CDC multi-symptom syndrome in the Gulf War cohort in the UK. The production of anti-squalene antibodies in Gulf War Syndrome patients is linked to the presence of squalene in certain lots of the anthrax vaccine.

The Department of Veterans Affairs (VA) lists potential toxins that could cause Gulf War Syndrome, but dismisses the fact that the squalene-containing anthrax vaccine could be the cause. The VA also omits the plausibility of aluminum, another vaccine ingredient, which has been linked to Gulf War Syndrome. Neurotoxins in vaccines are never considered by healthcare providers for neurotoxic effects in children and adults.

7. Corruption and collusion in the vaccine industry, FDA, DOD and HHS

DOD did not concur with the GAO report. The Pentagon claimed there was no data to justify a new active surveillance program of the anthrax vaccine. DOD also stated that there was no difference between pilot separations from the military before and during the mandatory AVIP program. DOD has maintained that the anthrax vaccine was very safe and needed.

To date, there is no surveillance system to know how anthrax vaccine reactions manifested over time, or how many people are living with a chronic disease as a result.

In 2008, the federal court affirmed that the FDA, HHS and DOD allowed an illegal AVIP program by mandating an experimental anthrax for military personnel that was not licensed for use against inhalation anthrax, nor approved for use by a presidential waiver.

Later in 2008, the FBI accused U.S. Army scientist Bruce Ivins of being responsible for the 2001 anthrax letter attacks. In 2010, the Amerithrax investigation portrayed Ivins' motive as dedicating 20 years of his life to a dwindling anthrax vaccine program with failing potency tests that would not meet criteria for FDA approval and to being under scrutiny for allegations that the anthrax vaccine contributed to Gulf War Syndrome.

The FBI evidence was based on emails. The FBI alleged that the FDA had suspended the production of the anthrax vaccine just prior to the letter attacks, but the attacks were the basis for the FDA fast-tracking the vaccine that did not meet standards. The FBI affidavits also document that Ivins was honored by DOD for getting the anthrax vaccine into production. HHS allowed the AVIP program to continue until 2018, likely until stockpiles were depleted.

To date, DOD has not considered correcting the records of court-martialed and punished soldiers who refused an illegally-mandated experimental vaccine based on a manufactured crisis.

Can we really believe that one dead man is to blame for the entire anthrax vaccine program while there is evidence that the FDA acted illegally in approving an experimental vaccine that did not meet standards, DOD responded negligently when adverse reactions were overwhelming in the first year of the program, and HHS allowed the program to continue for eight more years after the FBI reported a crime of treasonous bioterrorism originating from the vaccine industry for financial benefit?

In the likelihood of a near-future SARS-CoV-2 vaccine mandate, the anthrax vaccine program failures should be studied for all of the above reasons, but mainly for the allegation that one man's actions put an entire military population at risk for a reactive vaccine without demonstrated benefit or necessity — and for the lessons that should be applied to any future COVID-19 vaccine program.