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

Written By Celia Farber

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.

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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.

"I personally do not prescribe AZT. I have continued to experience that people live longer who are **not** on it."

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 results, finally and ironically, are what damns AZT.

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."

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

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."

"This is such shoddy science it's hard to believe nobody is protesting."

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.”

** = “This sentence was changed to correct an error in the original version of this article, which wrongly stated that the FDA had approved Thalidomide”(SPIN-online)*

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