Licensing AZT

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Responding to President Mbeki's statement in the National Council of Provinces on 28 October 1999 that there was 'a large volume of scientific literature' showing 'the toxicity of this drug is such that it is in fact a danger to health', and that 'medical researchers' had been issuing 'dire warnings' about it, GlaxoSmithKline's South African medical director Peter Moore claimed he was wrong: 'The President has been gravely misinformed about the safety aspects of AZT.' Why, the drug had been licensed under 'the most stringent regulations'.

This essay looks at the Phase II study, the pivotal AZT licensing trial conducted by Margaret Fischl and others[1], on the basis of which the drug was approved in the US and elsewhere; how AZT met 'the most stringent regulations' as it was being licensed by the Food and Drug Administration[2].

As its name suggests, the Phase II trial was preceded by a preliminary Phase I study, conducted to see whether humans could endure the drug's toxicity. Lauritsen reports that

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1 Reported in July 1987 in two concurrent papers in the *New England Journal of Medicine* by Fischl et al.: 'The efficacy of azidothymidine (AZT) in the treatment of AIDS and AIDS related complex', along with 'The Toxicity of Azidothymidine (AZT) in the Treatment of Patients with AIDS' by Richman et al.

2 For much of the original sleuthing for this article, all credit to John Lauritsen. His several knockdown critiques in the *New York Native* reappeared in his books *Poison by Prescription: The AZT Story* (Asklepsios, 1990) and *The AIDS War* (Asklepsios, 1993). Lauritsen quotes extensively from FDA director Ellen Cooper's *Medical Officer Review of NDA 19-655*, reporting widespread irregularities in the conduct of the trial found by FDA inspectors, and I cite his excerpts in turn. Professor Peter Duesberg and Dr David Rasnick performed a further useful analysis of the Phase II trial in 'The AIDS dilemma: drug diseases blamed on a passenger virus', published in *Genetica* in September 1998. Celia Farber published a seminal exposé of the FDA approval hearing, 'Sins of Omission: The AZT Scandal', in *Spin*, November 1989. Joan Shenton provided important information in her television documentary *AZT: Cause for Concern*, broadcast on Channel 4 in Britain in February 1992, and in her book *Positively False* (IB Taurus, 1998). I have also relied on Bruce Nussbaum's *Good Intentions: How Big Business and the Medical Establishment are Corrupting the Fight Against AIDS* (Atlantic Monthly Press, 1990); Neville Hodgkinson's *AIDS: The Failure of Contemporary Science* (Fourth Estate, 1996); and Steven Epstein's *Impure Science: AIDS, Activism and the Politics of Knowledge* (University of California Press, 1996).

> 12% died in a time period of only six weeks. The four patients who died were replaced, and all 33 patients continued to take AZT in an 'extended trial', during which an additional 21% died. … a cumulative total of one-third (33%) of the patients died either in the Phase I or in the extended trial.

This appalling death rate was read to mean AZT was not acutely toxic, and was therefore safe to give people every day for six months during a Phase II trial to determine efficacy, i.e. to see whether it actually worked.

The Phase II trial was lavishly sponsored by Burroughs Wellcome (now GlaxoSmithKline) to the tune of $10 000 paid to the principal investigators conducting the study for every patient enrolled at each of the twelve centres at which it was run. It involved a mere two hundred and eighty-nine people, nearly all male, all very sick, half of whom were put on AZT and the other half on placebo. That was how it began anyway, but not for long. The central finding of the study, upon which the FDA based its decision to license AZT, was that the drug could 'decrease mortality'. It was specifically noted that there were no data showing that the drug had any antiviral action in people (there still aren't), and everyone on the panel knew that what goes on in test tubes is incomparably different from what happens in the infinitely more complex biological systems of the human body. And, as was obvious from the serious ill effects noted on the trial subjects' clinical case records, AZT was extremely poisonous. But the mortality data were most compelling on the face of it: at the point that the trial was stopped, nineteen of the one hundred and thirty-seven-member placebo group had died, against only one of the hundred and forty-five patients given AZT. Unfortunately things weren't as they seemed.

There is nothing to indicate that the test subjects were properly randomised. According to Lauritsen, 'the sicker patients may have been placed in the placebo group to begin with. … The FDA documents indicate that this was indeed the case.' A sharply critical *Statistical Review and Evaluation* of the Phase II trial by the FDA's Lawrence Hauptman reported:

> Two patients died very early in the study. … It is arguable that these patients were sick enough at entry that they should not have been included in the study.

Lauritsen notes: 'Both patients just happened to be in the placebo group.' FDA inspector Patricia Spitzig's seventy-six page report of irregularities objected, inter alia, that 'the sponsor unfairly biases against the placebo group', and 'the sponsor makes the analysis look more favourable to AZT' (quoted by Joan Shenton in *Positively False*). Lauritsen tells that one very ill patient, identified as '1009', had been on AZT before entering the trial. He was put in the placebo group, and his death was counted among the placebo deaths.

The trial rapidly became unblinded. The doctors running the trial weren't supposed to know who was on AZT and who was on placebo. Nor were the patients. This is the meaning of a 'double-blind' study. But in her *Medical Officer Review of NDA 19-655*, FDA director Ellen Cooper reported that doctors could readily tell who was on AZT and who wasn't from a prominent side effect of the drug as they looked at patients' blood through their microscopes: macrocytosis (sixty-nine per cent of AZT-treated) followed by severe anaemia (twenty-five per cent), i.e., red blood cells swelling up from AZT poisoning before popping off by the ton. Patients themselves quickly cottoned on to who was on AZT and who wasn't. If they didn't get it from their doctors, they were able to find out for themselves easily enough: the drug, reported Cooper, was bitter, the placebo sweet. Or they went off and had their pills analysed – so a chemist approached for the service told investigative reporters in a television exposé of the corruption of the Phase II trial on NBC News on 27 January 1988. Chris Babick of the People with AIDS Coalition corroborated this, telling Shenton how his organisation had referred trial subjects to three laboratories in New York for the analysis of their pills. If the real thing they'd share it; if dud they'd get it from the lucky guys being prescribed it. Or would buy it. All of which jinks were admitted by trial subjects interviewed for the film. Bought? From where? Spitzig reported that supplies of AZT went missing: eighty-seven bottles from the Boston Centre alone – 'undoubtedly [entering] the black market', concluded Lauritsen. Spitzig confirmed that 'some of the Study Drug had been purchased "on the street"'. Some patients got AZT by mistake, or vice versa, with some ostensibly on AZT getting the placebo – a bungle picked up by Spitzig in the case of two patients. Some, discovering they were on placebo, procured other dangerous

experimental drugs. According to Cooper's report another FDA investigator made the obvious observation: 'The fact that the treatment groups unblinded themselves early could have resulted in bias in the workup of patients.' Lauritsen put it absolutely:

> If there is even the slightest doubt that all 'AZT patients' were really getting AZT, and all 'placebo patients' were getting placebos, then the study has fallen apart at its very core.

But Fischl's report in the *New England Journal of Medicine* was silent about this, claiming the trial to have been a 'placebo-controlled double-blind' study. In design yes, but in execution, it's common cause, not by a long shot. Scientists call this scientific fraud. Lawyers would describe GlaxoSmithKline's assertion of the results of a trial like this, in support of their product, as commercial fraud. But plain folks know it as lying. Shamelessly too: years after the trial, Fischl was still denying to Lauritsen, and again later on to Shenton, that the trial became unblinded. But of course it did – obviously so, and for another reason too: for Fischl and her fellow trial overseers to have made the observation that those ostensibly on placebo were dying faster than those on AZT, they had to have known who was on what. Which they weren't supposed to, until the trial was over. But clearly they did.

The trial was designed to run for six months, i.e. twenty-four weeks, but was prematurely terminated at seventeen weeks, i.e. just more than four months – for ethical reasons, the record has it, since the AZT-treated were doing so well. It would have been wrong to withhold the drug from AIDS sufferers another day. In reality, the reason for the early end of the trial was that it was collapsing into chaos. Apart from having become unblinded, 'protocol violations' were being committed all over the place: patients were taking unauthorised concomitant drugs, thereby skewing the results; 'drug accountability' failures were occurring, i.e. patients took known but unrecorded treatment holidays instead of swallowing the drugs daily as prescribed; patient records were being altered without authority or ostensible reason; and serious adverse effects were not being recorded or were being deleted – all of which was discovered and documented by FDA inspectors in their reports. Cooper reported that the lapses were so widespread that the FDA decided

> to request inspection of all twelve centers which participated in this trial … because one of the early inspections had found significant deviations from FDA regulations regarding the proper conduct of clinical investigations.

But it was a bit late. The panel appointed to consider the data was scheduled to meet a month later. FDA officials met twice to resolve what to do about all the corrupted case reports – so rank at the Boston centre that FDA inspectors recommended that all data from it be canned completely. The fact that dumping the corrupt data would have considerably thinned out the already small database worried one bureaucrat more than the fact that they were junk: 'if exclusion of all patients with protocol violations were strictly applied, quite a few patients would probably be deleted from the database.' Too bad, you might have answered, but you weren't there to insist. So what do you think the FDA resolved to do? Exclude them or include them? Even the completely fouled Boston returns? Take a guess. A really wild one.

Thirty patients in the AZT-treated group (twenty-one per cent) needed repeated blood transfusions to survive the severe anaemia that the drug was causing. Without these repeated infusions of replacement blood they'd have died during or soon after the study, and their deaths would have raised the death toll in the AZT-treated group from one to thirty-one. That's thirty-one dead in the AZT-treated group versus nineteen in the placebo wing. Add five in the placebo-group who got repeated transfusions as well (we're coming to this), and you get twenty-four. Thirty-one AZT deaths versus twenty-four placebo deaths wouldn't have looked so impressive on the blackboard at the FDA's licensing panel hearing, especially set against the complaints all day about how very poisonous the drug was.

A strange thing about that Phase II trial is that patients in the control group, officially on placebos, also suffered from AZT's toxic effects, with five of them needing multiple blood transfusions too, as mentioned. Whereas thirty-four per cent of AZT-treated patients suffered the loss of more than half their white blood cells from the drug's haematological toxicity, so did six per cent in the placebo group. Sixty-six AZT-treated patients suffered severe nausea. But so did twenty-five in the placebo contingent – three of whose muscles were found to have atrophied, like

those of eleven AZT-treated men. Now that we know about the unblinding of the study, the mystery resolves. Many in the placebo group were being poisoned by AZT too. In the terrified hysterical atmosphere, everybody wanted a chance to live, a chance to take the new drug – a sentiment voiced by Pascal de Block, diagnosed HIV-positive, in the BBC Panorama documentary *A Ray of Hope*. De Block said, 'I was desperate to sort of cling on to anything that would bring me life or that would somehow sustain my life.' Such as AZT, advertised as 'a Ray of Hope for us all … Retrovir is a major step forward, our first weapon against this deadly virus.'

Fact is the Phase II trial was a total mess. None other than Martin Delaney, president of the drug industry-funded, ARV-promoting organization Project Inform in San Francisco, flayed the 'multicenter clinical trials of AZT [as] perhaps the sloppiest, most poorly controlled trials ever to serve as the basis for an FDA licensing approval'.

On the strength of the Phase II study Burroughs Wellcome applied to the FDA for a licence to market AZT as an AIDS drug. The FDA appointed a nominally independent panel to review the data. How independent it was you can decide from the fact that some of its members were in the company's pay as consultants involved in the AZT trial whose data were on the table for consideration. The panel sat on 16 January 1987. In 'Sins of Omission: The AZT Scandal' Celia Farber related panel chairman Itzak Brook's account to her of how the day went:

> There was not enough data, not enough followup. 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 [*the impressive mortality figures*], but I 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.

Indeed, the toxicity of AZT was so severe, said Cooper at the hearing, that licensing the drug would mean a 'significant and potentially dangerous departure from our normal toxicology requirements', particularly since she'd noted in her review that 'The majority of patients randomized to receive AZT in this trial experienced significant

toxicity.' This was an 'understatement,' thought Lauritsen, 'considering that many AZT patients were treated with the drug for only a few weeks.' Lauritsen was referring to another critical flaw in the trial: according to Cooper's report, twenty-three of the AZT-treated group were on the drug for less than four weeks, and forty-seven for less than twelve, yet they were counted in among the rest, officially on it for seventeen weeks. Had this bunch, close to half the AZT group, been on the drug for as long as the others, the total mortality tally among the AZT group would certainly have been very much higher.

In no other clinical trial were the wonderful results of Fischl's Phase II study ever reproduced. Not in another big one that followed, reported by Creagh-Kirk et al. in the *Journal of the American Medical Association* in November 1988: 'Survival Experience Among Patients With AIDS Receiving Zidovudine: Follow-up of patients in a compassionate plea program', another mess in which the researchers lost track of fully one quarter of their test subjects – so could hardly comment on how well people did on the drug, being unable to say how many had died out of sight. But the alleged life-saving efficacy of AZT reported in that useless study still turned out nowhere near as terrific as the Phase II trial suggested. In short, the Phase II numbers were too good to be true, something discovered over and over in other trials, such as in a similar one in France at the Claude Bernhard Hospital, discussed in *Debating AZT*, which returned contradictory findings. And 'A controlled trial of early versus late treatment with zidovudine in symptomatic human immunodeficiency virus infection: Results of the Veterans Affairs Cooperative Study', a big one conducted over three years by Hamilton et al. and reported in the *New England Journal of Medicine* in February 1992, found AZT did not have any life extending benefits, and that as Shenton summarised it, 'those who took it longest got sicker and died quicker'. Hamilton confirmed to her on camera in her documentary *AZT: Cause for Concern*: 'I think it is self-evident that our study does not provide the kind of benefit that everyone wished for.' He dismissed the notion that AZT affords 'quality of life' to those treated with it:

> There has been no formal demonstration of quality of life. … In fact the only study that has been done on this point and published

> to my knowledge has failed to demonstrate an improvement in quality of life.

Hamilton was referring to the findings of Wu et al. in 'Functional status and well-being in a placebo-controlled trial of zidovudine in early symptomatic HIV infection' reported the *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* in May 1993 that 'patients on AZT had an inferior quality of life compared to those on a placebo in terms of overall health, well-being, energy, mental health and pain' (Shenton's paraphrase). Hamilton was right about Wu's study being the only one reported at the time. A few months later, however, Lenderking et al. backed Wu up in a most important study, to which we'll be returning shortly.

Apart from its superlative efficiency at killing cells, specialist FDA toxicologist Harvey Chernov pointed out in his *Review & Evaluation of Pharmacology and Toxicology Data* report that AZT 'was at least as active … a carcinogen … as the positive control material, methylcholanthrene'. This is to say AZT causes cancer as effectively as a known carcinogen used to induce cancer in research laboratories. Chernov recommended against the licensing of AZT accordingly, adding that 'the full preclinical toxicological profile is far from complete … The available data are insufficient to support FDA approval.' No one but Brook was paying attention. He told the BBC journalists investigating AZT for their *Ray of Hope* exposé:

> I had serious doubts whether we had all the information we needed about toxicity, about the dose, and even how effective it was. And I felt we needed a few more months to get answers from the company.

Burroughs Wellcome research director David Barry didn't like the sound of that. Based on the impressive mortality data, he'd assumed prompt approval was a foregone conclusion. Brook's suggestion that the panel be circumspect and take more time over the licence application caused his company 'great chagrin,' he said. The cost of preparation for the approval process had been

> a tremendous burden to us. … we have invested more than $80 million … in the program so far. … We would definitely prefer not to continue that program as it is for any significant period of time.

Brook saw through this: 'the implication … was like telling us approve it now or never.' Indeed, put to Barry by the BBC journalists that he was 'consciously putting pressure on the committee for a quick approval', he frankly admitted it: 'Yes, of course.'

As the panel wavered, worrying about the evident extreme toxicity of the drug, and unimpressed by the pressure Barry was applying, Burroughs Wellcome drew a secret ace. Brook told Farber:

> The committee was tending to agree with me 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. [*This was Paul Parkman, with whom Barry had co-written a paper while they were office pals in the FDA, before Barry switched jobs for the big salary and stock options*.] 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.'

Brook told Bruce Nussbaum, author of *Good Intentions: How Big Business and the Medical Establishment are Corrupting the Fight Against AIDS* that until that point 'the tide was against approval'. Since the FDA had no inherent interest in seeing any particular drug approved, you can put money down that the manufacturer had placed a couple of calls to the top to engineer the pep talk saving the day. Brook himself drew that conclusion: 'I think that behind the scenes, something definitely happened.' Brook didn't buy Parkman's pitch and voted against approval. But the others all raised their hands, Cooper included. In his book Nussbaum recounts in detail the proceedings of the panel meeting from the minutes kept. It reads like a script from a Marx Brothers movie. Your eyes bulge. Like Harpo's. You can't believe it. Not so much when they were hammering on the toxicity and the missing and conflicting

data, which they did all day, especially Cooper, but the quality of the discussion, the level of the debate thereafter.

The decision to approve AZT was a happy one for stock investors. Rapidly rising in anticipation of approval, Burroughs Wellcome share prices thereafter doubled. AZT was formally licensed on 20 March 1987, after a 'review and approval', according to a Public Health Service press release, 'accomplished within less than four months – one of the shortest approval actions on record'.

Just four weeks later, Lauritsen tells us, ten per cent of the AZT-treated were dead. Duesberg and Rasnick report that by eighteen months the figure had climbed to thirty-two per cent. According to Farber all original test subjects on AZT were dead by the end of 1989. Death was never intended as endpoint criterion for the assessment of drug efficacy in the Phase II study, with the result that causes of death were frequently not positively identified and recorded. The reports consequently abounded in speculations and presumptive diagnoses, thereby masking fatal drug intoxication as a cause of death. Nobody thought to biopsy the tissues of the dead to see whether they'd died of muscle rot, an epidemic of which broke out among HIV-positives after AZT was approved, along with neurological damage, resulting in what AIDS experts call AIDS dementia. Neither of which is any coincidence to scientists who've investigated how well AZT poisons off muscle and nerve cells. (Some leading studies are reviewed in *Debating AZT*.)

A week after the licensing trial was terminated an FDA press release reported the approval of a special dispensation allowing 'expanded distribution of the drug to AIDS patients who had been shown to benefit from AZT in the controlled trial'. Eighteen months later, thirty-two per cent of the subjects in the original placebo group now on AZT had joined the original AZT-treated group in Heaven. (The data you can find in 'Prolonged zidovudine therapy in patients with AIDS and AIDS-related complex' by Fischl et al. in the *Journal of the American Medical Association* in November 1989.)

Lauritsen reports that on 17 January 1990, three years after it approved AZT, the FDA announced a new officially recommended AZT treatment dose of 600 mg daily, half of its previous recommendation of 1200 mg,

although doses of 1500 mg and 1800 mg were being routinely prescribed too:

> Health and Human Services Secretary Louis Sullivan said in a statement that the change 'means that fewer patients may have to discontinue AZT therapy because of serious side effects.'

(In South Africa they never got the message; the AZT package insert still recommends mediaeval doses of up to 1500 mg of AZT daily.) According to Sullivan the new dose recommendations were based on 'preliminary findings' that half as much was as effective as the former full dose. Nobody got to see them, because they hadn't been published and never were. Lauritsen commented:

> According to those 'preliminary findings', nearly half of those receiving the high dose (1200 milligrams) had side effects that were so serious that they had to discontinue AZT treatment. At the same time, fully a quarter of those receiving the low dose also had to discontinue treatment, for the same reasons.

This then was how AZT was licensed under the most 'stringent regulations' in the US as a treatment for sick people diagnosed with AIDS. In no time at all AZT was being prescribed to HIV-positive people in perfect health too – a treatment trend that began to set in with all the panic almost as soon as AZT came onto the market, but which was officially sanctioned by the FDA on 30 January 1990 when it recommended AZT administration to anyone with a CD4 cell count of less than 500, no matter how healthy.

The study founding the FDA's new treatment indication for AZT, 'Zidovudine in Asymptomatic Human Immuno-deficiency Virus Infection: A Controlled Trial in Persons with Fewer than 500 CD4-Positive Cells per Cubic Millimeter', by Volberding et al., was eventually published in the *New England Journal of Medicine* in April 1990. It was another abortion – in both senses. Lauritsen attended a 'State of the Art Conference on AZT Therapy for Early HIV Infection' in Washington on 3 March 1990, at which Volberding publicly admitted to 'a strong suspicion' that study participants knew who was on the drug and who wasn't. Steven Epstein mentions in *Impure Science: AIDS, Activism and the Politics of Knowledge* that when challenged about the 'non-compliance'

problem in the trial – patients not taking AZT daily in terms of the trial design, i.e. taking drug treatment holidays – Volberding's answer was that this actually buttressed the findings since it 'would tend to give results that underestimate the true effect of zidovudine'. He was right about that, but in a sense he didn't think of: the extent of AZT's toxicity would have been masked – and Volberding's claim that AZT was insignificantly toxic was a big selling point to the FDA. When the latter approved it for HIV-positive asymptomatics, thereby expanding the market for AZT tenfold, 'the stock price of parent company Wellcome plc [got an instant lift of] 1.4 billion pounds'.

Poking around the basic flaws of this study, ACGT 019, would be tedious; it's surely enough to point out that the Concorde trial, superior in every respect – in scale, duration, control, completion – refuted the Volberding study outright. And that when William Lenderking of the Harvard School of Public Health put together a team, Volberding included, to reappraise the study, a whole set of different conclusions were arrived at. In *AIDS: The Failure of Contemporary Science* Neville Hodgkinson quotes American AIDS research boss Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, saying in a press statement in August 1989, after the premature termination of Volberding's ACGT 019 trial:

> This study has clearly demonstrated that early treatment with [AZT] can slow disease progression without significant side effects in HIV-infected persons with fewer than 500 T4 cells who do not yet have symptoms.

But as Hodgkinson noted: 'Four and a half years later, however, a new analysis of the trial data reached a similar conclusion to Concorde: that AZT was essentially useless.' Moreover, as compared with what Volberding and Fauci had claimed about them, a 'very different picture' emerged 'after investigators paid more attention to the drug's side-effects'. Revisiting Volberding's data, Lenderking et al. concluded in 'Evaluation of the Quality of Life Associated with Zidovudine Treatment in Asymptomatic Human Immunodeficiency Virus Infection' published in the *New England Journal of Medicine* in March 1994:

> For asymptomatic patients treated with 500 mg of zidovudine, a reduction in quality of life due to severe side effects of therapy ['life-threatening in some cases'] approximately equals the increase in the quality of life associated with a delay in the progression of HIV disease.

What 'AIDS experts' like these mean by 'quality of life' was clarified by their colleague Andrew Carr in an article he wrote for *Lancet* in the first week of July 2002 (to which we'll later return for a closer look):

> Patients prevented from dying or developing AIDS by HAART [*assuming they are*] can be thought of as having an increased quality of life. The same cannot be said, however, for asymptomatic patients at low risk of AIDS. And yet, as with adherence, quality of life was reported in only two of the 23 HAART studies; perhaps not an unexpected figure in view of the fact that only 4% of clinical studies in any medical discipline report data for quality of life [*in the normal sense of the expression*].

Preliminary to his re-analysis and debunk of two more junk trials, the Australian European Collaborative Group Study and the San Francisco Men's Health Study, purporting to show benefits from AZT treatment among HIV-positive asymptomatics with CD4 cell counts above 500/mm^3, Malcolm Zaretsky summarised the Lenderking findings in plainer language in *Genetica* (96(3)) in 1995:

> the harmful effects of AZT on quality of life, concomitants of its toxicity, resulted in no net benefits to these patients [with CD4 cell counts below 500/mm^3 at the start of the trial].

The Concorde trial results published in *Lancet* in April 1994 showed that treating asymptomatic HIV-positives with AZT has no benefits and does not 'delay progression of HIV disease' as Volberding claimed and Lenderking believed. So if we go back to Lenderking's conclusion, and cut out the bad bit, what we're left with is the fact that AZT is completely useless as a medicine, and what's more it's so exceptionally toxic that it can kill you.

No, said GlaxoSmithKline, 'AZT has extended and improved the quality of life of millions of people living with HIV/AIDS around the globe.' It offers you 'A world of antiretroviral experience.'