Licensing AZT

> *The Americans are certainly hero-worshippers, and always take their heroes from the criminal classes.*
>
> Oscar Wilde

This article takes a look at the Phase II study, the pivotal AZT licensing trial conducted by Margaret Fischl and others, on the basis of which the drug was approved in the US and elsewhere. How AZT complied with what GlaxoSmithKline's South African medical director Peter Moore called 'the most stringent regulations' after Mbeki questioned the drug. All credit to Harvard-graduated survey research analyst John Lauritsen for the original sleuthing. His several knockdown critiques written for the *New York Native* reappeared in his self-published books, *Poison by Prescription: The AZT Story* and *The AIDS War* (Asklepsios, 1993) – now out of print, but given air by *Lancet* and in Britain's Channel 4 *Dispatches* television documentary, *AZT: Cause for Concern*. Lauritsen quotes extensively from FDA director Ellen Cooper's *Medical Officer Review of NDA 19-655* ('the Cooper Review'), reporting widespread irregularities in the conduct of the trial found by FDA inspectors, and I do so in turn. Credit to Duesberg and Rasnick too for their further analysis of the Phase II trial included in *The AIDS dilemma: drug diseases blamed on a passenger virus*, published in *Genetica* in September 1998. The trial itself was reported in 1987 in two concurrent papers in the same issue of 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.*

The Phase II trial was lavishly sponsored by Burroughs Wellcome (now GlaxoSmithKline), to the tune of $10 000 dollars a pop, paid to the principal investigators (supervisors) for every patient on the bus at each of the twelve centres at which it was conducted. Just to keep the doctors onside. Even as they botched their sweetheart study. It involved a mere two hundred and eighty-nine very sick people, nearly all men, of whom half were put on AZT, the rest on placebo. That was how it began anyway, but not for long.

The central finding of the Phase II trial – upon which the FDA based its decision to license AZT – was that it could 'decrease mortality'. Not that it could make the sick better, the usual measure of drug efficacy. There was nothing else to commend it. It was specifically noted that there were no data proving that it actually worked as an antiviral agent in people (there still aren't) – and everyone on the panel knew that what goes on in test tubes is incomparably different from 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 impressive on the face of it: At the point that the trial was ended, nineteen out of the one hundred and thirty-seven-member placebo group had died, against only one of the hundred and forty-five patients administered AZT. The trouble is that the promise goes up in smoke as you take a closer look. In this quick post-mortem, we'll talk about the fatal holes, not the broken bones, cuts and bruises everywhere.

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 own 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's 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 her book, *Positively False*). Lauritsen tells that one very ill patient, identified as '1009', had been on AZT before entering the trial. He was entered among the placebo group. 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. Cooper reported that doctors could tell who was on AZT and who wasn't from a prominent side effect of AZT 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), that is, red blood cells swelling up from AZT exposure before popping off by the ton. Patients themselves quickly cottoned on. If they didn't find out from their doctors, told frankly, or by reading their faces when they asked, they were able to find out easily enough: the AZT, reported the Cooper Review, was bitter, the placebo sweet. Or they went 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 (Channel 4) on 27 January 1988. Chris Babick of the People with AIDS Coalition corroborated this; he told 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 confirms: '..some of the Study Drug had been purchased "on the street".' Some got AZT by mistake, with patients ostensibly on AZT getting the placebo – a bungle picked up by Spitzig in the case of two patients. Or, not to be left out in the cold to die, they procured other dangerous experimental drugs being touted at the time as hope. According to the Cooper Review 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 is 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 we plain folks know it as lying. Shamelessly too: years after the trial, Fischl was still denying to Lauritsen, and again later to Shenton, that the trial became unblinded.

But of course it did – plainly, and for another reason: 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 they did. Obviously.

The trial was designed to run for six months, *i.e*. twenty-four weeks. It was prematurely terminated after seventeen weeks, *i.e*. just after four months – for ethical reasons, the record has it, since the AZT-treated were doing so well. It would be wrong to withhold it from AIDS sufferers another day. In reality the reason for the early end was that the trial was collapsing into chaos. Apart from having become unblinded, 'protocol violations' were being committed all over the place – mostly patients taking unauthorised concomitant drugs, thereby skewing the results; 'drug accountability' failures were occurring, *i.e* patients took known but unrecorded 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 recorded or were cooly deleted – all discovered and documented by FDA inspectors in their reports. The lapses were so widespread that the FDA, according to the Cooper Review, 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. Too 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 *in toto.* The fact that dumping the corrupt data would have considerably thinned out the already small database worried one smart 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? Exlude them or include them? Even the completely fouled Boston returns? Take a guess. A really wild one.

Thirty patients (twenty-one per cent) in the AZT-treated group needed repeated blood transfusions to survive the severe anaemia that the drug was causing. Without them they'd have died. That's why they were repeatedly given replacement blood. Their deaths would have pushed the tally in the AZT-treated group up from one to thirty-one. Versus nineteen in the placebo wing. Add five in the placebo-group who got repeated transfusions too, 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, set against its complaints all day about how poisonous the drug was.

There was a strange thing about that Phase II trial: patients in the control group, officially on sugar pill placebos, also suffered from AZT's toxic effects. With five of them needing multiple blood transfusions too, as we said. Whereas thirty-four per cent of AZT-treated patients suffered the slaughter of more than half their white blood cells, so did six per cent in the control group. Sixty-six AZT-treated patients suffered severe nausea. But so did twenty-five in the love and fruit-juice contingent. Which also seemed to cause the muscles of three of them to atrophy. As AZT did for eleven. Now that we know about the unblinding and pill sharing, the mystery settles. 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 drugs, and not just the dummies. A sentiment voiced by Pascal de Block, diagnosed HIV-positive, in an interview in *A Ray of Hope* – the title from the sales propaganda: 'Retrovir is a major step forward, our first weapon against this deadly virus ... a Ray of Hope for us all.' (Sunshine into the family room. Gleaming out doctor's black bag.) 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.'

The rude fact is that the Phase II trial was a shambles. None other than Project Inform president Martin Delaney in San Francisco – the drug industry's closest friend next to our own Three Stooges, TAC executive president Zackie Achmat, TAC chairman and AIDS Law Project director Mark Heywood, and Judge Edwin Cameron – 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'. This is common knowledge to everyone in the game, even AZT fans and the leading regulatory authority that approved it, the American FDA. Common knowledge to everyone except GlaxoSmithKline's befuddled good ol' boy, Peter Moore, fumbling after drinks with his video remote.

Following the Fischl clinical trial, the FDA appointed a nominally independent panel to review Burroughs Wellcome's application for a licence to market AZT as an AIDS drug. It sat on 16 January 1987. 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. Normally excluded from voting. But not for this one. This is AIDS we're dealing with; forget the rules. Cooper was on the panel too. Someone to count on.

In her exposé, *Sins of Omission: The AZT Scandal*, Celia Farber wrote up panel chairman Itzak Brook's account to her of how the day went: 'There was not enough data, not enough follow-up. 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.' The toxicity of AZT was so severe that Cooper expressed her concern that licensing it 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.' 'An understatement,' thought Lauritsen, 'considering that many AZT patients were treated with the drug for only a few weeks.'

Lauritsen was referring to another eye-popping flaw in the trial: according to the Cooper Review, twenty-three of the AZT-treated group were on the drug for less than four weeks, and fourty-seven for less than twelve, yet 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 have been much higher – if you recall Sigma Chemical Company's warning that the drug is 'TOXIC Toxic to inhalation, in

contact with skin and if swallowed. Target organ(s): Blood Bone Marrow … Wear suitable protective clothing.'

In no other clinical trial were the fabulous 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 1988: *Survival Experience Among Patients With AIDS Receiving Zidovudine*, another mess in which the researchers lost track of fully one quarter of their test subjects – so could hardly comment on how well folk did on the drug, being unable to say how many had died out of sight. But the 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. 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 clashing findings; and a big three-year one conducted by Hamilton *et al*, known as the Veterans Administration Study, reported in the *New England Journal of Medicine* in 1992, whose bottom line was that AZT did not have any life extending benefits: As Shenton summarised simply: '..those who took it longest got sicker and died quicker.' Hamilton told her on film in *AZT: Cause for Concern*, 'I think it is self-evident that our study does not provide the kind of benefit that everyone wished for.' Concerning 'quality of life' on AZT he said, '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.' He was referring to Wu's findings reported in the *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* in 1993 that (as Shenton paraphrased) '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'. Hamilton was right about Wu's being the only reported such study at the time. A few months later, however, Lenderking *et al* backed him up in a most important study, which we'll be looking at soon.

Apart from its superlative cell-killing efficiency, specialist FDA toxicologist Harvey Chernov stated in his *Review & Evaluation of Pharamacology and Toxicology Data* report that AZT 'was at least as active..a carcinogen..as the positive control material, methylcholanthrene.' Which is to say AZT causes cancer as effectively as a known chemical carcinogen used to induce cancer in research laboratories. Would it come as a terrible shock to learn that Chernov recommended against the licensing of AZT accordingly, adding, '..the full preclinical toxicological profile is far from complete … The available data are insufficient to support FDA approval'? No one but Brook was listening.

He told 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.' Its research director David Barry didn't like the sound of that. He'd assumed approval would be a pushover, based on the mortality data. So he applied the squeeze: Brook's suggestion that the panel take more time, and be circumspect about approving the drug, 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 it: '..the implication..was like telling us approve it now or never.' Indeed, asked by the journalists, '..you were consciously putting pressure on the committee for a quick approval?', Barry's frank reply was, 'Yes. Of course.' But the committee wasn't rolled over by Barry's charmless style, a style on display in his reprimand of the BBC journalists for asking a pointed question: 'I don't think taking cynical views really is going to progress medical practice. What we are looking at is what is the best way to provide the most benefit to the most patients for the longest period of time. That is how we acted. I am proud of it. I think we did it ethically, I think we did it right. And I think hundreds of thousands, maybe millions of patients have benefited because of that approach.' Smiling down at us from the clouds. Flapping their wings. You've got to see this bloke on video, his face a shade of green. You can get a sense of him perhaps from his kind of talk: laden with the glib, smug, confident, easy dishonesty of the successful business executive, propagandising for his corporation. Calling black white. He died on 28 January 2002, eulogised by the *Guardian* in a tribute, *David Barry: Key researcher in the development of AZT.* You'd think

reading it that this guy was some kind of Oscar Schindler hero. Rather than the lowest of criminals.

As the panel wavered, unimpressed by Barry's sulky intimidation, and worrying about the extreme toxicity, the company 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. [*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 bucks*.] 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." [*AIDS cases* in extremis *only*.] It was like saying, "Please do it."' As Brook described it to Bruce Nussbaum, author of *Good Intentions* (Atlantic Monthly Press, 1990), 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 top calls to engineer the pep talk saving the day. Brook himself drew that conclusion: 'I think that behind the scenes, something definitely happened.' Unlike the rest of the panel, 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. 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 was a happy one for stock investors. Rapidly rising in anticipation, their 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'.

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'. Just four weeks later, Lauritsen tells us, ten per cent of the AZT-treated were dead. Duesberg and Rasnick report that eighteen months later thirty-two per cent of the AZT-treated had left us. By which time thirty-two per cent of the original control-group guys had joined them. Except that they were now on AZT too: it saves lives. It kills the virus. Look at the amazing numbers. You can live too. The experiment is over. Hop aboard. Here are a few bottles for you as well. Left over. To extend your life. The latter 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 1989. The rest you can just imagine.

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. I mean the prescribed one. 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-positive patients after the drug was approved. Along with neurological damage, resulting in what 'AIDS experts' call AIDS dementia. By pure coincidence. Since the thought that AZT caused it is unthinkable. Except to the scientists who've investigated how successfully AZT poisons off muscle and nerve cells. Whose studies are reviewed in *Debating AZT.*

Before we leave the 'stringent' Phase II trial on the basis of which AZT was licenced in the US and everywhere else, here's a brief look at a preceding preliminary Phase I trial – the trial (without placebo control) conducted to see whether humans could endure the drug's toxicity. Lauritsen tells: '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.' The conclusion? AZT was as safe as houses. The data were read, in the face of the appalling death rate, to mean AZT was not acutely toxic. The researchers

forgot that toxicity also comes in another form, chronic or cumulative toxicity. Meaning, if it doesn't knock you over right away, the longer you're on it, the sicker you get. On the basis of the Phase I trial, the drug was found fit to take to a six-month Phase II trial, to see whether it actually worked, *i.e*. to determine efficacy. Whether the sick would get better on it. None did.

Lauritsen reported that on 17 January 1990, three years after approval, the FDA announced a new officially recommended AZT treatment dose: half of what it was before, 600 mg, down from 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 medieval 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 full dose. Nobody got to see them, because they hadn't been published. Lauritsen picked it up: '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.'

These then were the 'stringent' trials on the basis of which AZT was licensed as a treatment for sick people diagnosed with AIDS. But as you know, AZT is prescribed to people diagnosed HIV-positive in perfect health, in other words, not just as an AIDS drug, but as an anti-HIV one. A trend that began to set in with all the panic almost as soon as AZT came onto the market, but officially sanctioned by the FDA on 30 January 1990, when it recommended admininistration to anyone with a CD4 cell count of less than 500. No matter how healthy. The futility of CD4 cell counting we've already touched on. And we recall that the large-scale European Concorde trial overseers found the exercise irrelevant.

The study founding the FDA's new treatment indication for AZT, led by researchers from the sour cream of the AIDS research club, Paul Volberding and others, *Zidovudine in Asymptomatic Human Immunodeficiency Virus Infection: A Controlled Trial in Persons with Fewer than 500 CD4-Positive Cells per Cubic Millimeter*, was eventually published in the *New England Journal of Medicine* in April 1990. It was another abortion. In both senses. On 3 March 1990 Lauritsen was present at a 'State of the Art Conference on AZT Therapy for Early HIV Infection' in Washington, at which Volberding publicly admitted to 'a strong suspicion' that participants knew who was on the drug and who wasn't. Steven Epstein reports in *Impure Science* 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 holidays – Volberding's answer was that this actually buttressed the findings since it 'would tend to give results that underestimate the the true effect of zidovudine'. It certainly would, sport, since your claims about how insignificant the toxicity of AZT proved to be was a big selling point to HIV-positive asymptomatics and the FDA. When the latter approved it for the former, expanding the AZT market by a factor of ten, 'the stock price of parent company Wellcome plc [in England got an instant lift of] 1.4 billion pounds'.

Concerning the basic flaws in this study, ACGT 019, poking around the garbage any longer would be too dull even for this book; it's surely enough just to point out that the Concorde trial, superior in every respect – in scale, duration, control, completion – refuted the 'stringent' Volberding study outright. And that when William Lenderking of the Harvard School of Public Health put together a team, including Volberding, to reappraise the study, a whole set of different conclusions were arrived at.

In *AIDS: The Failure of Contemporary Science* (Forth Estate, 1996) Neville Hodgkinson quoted American AIDS research boss Anthony Fauci, director of the National Institute for Allergies and Infectious Diseases, saying in a press statement in August 1989, after the premature termination of the Volberding 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.' 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.' But moreover, 'after investigators paid more attention to the drug's side-effects...[a] very different picture' emerged, as compared with what Volberding and Fauci had claimed about them. 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 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' mean by 'quality of life' was clarified by Australian 'AIDS expert' 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*].'

Prefatory to his re-analysis and debunk, in *Genetica* in 1995, 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: '..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].' But the big trouble with Lenderking's fluffy conclusion is that the Concorde trial results published a month later showed that treating asymptomatic HIV-positives with AZT has no benefits, and does not 'delay progression of HIV disease' as Volberding had claimed, and Lenderking believed. If we go back to Lenderking's conclusion, with the bad bit severed, what we're left with is his finding concerning the hard facts: AZT is so poisonous that it can kill you. But GlaxoSmithKline's Moore claims conversely that the drug delivers 'quality of life'. Makes you feel great.