# TREATMENT INFORMATION GROUP

# thinking about AIDS drugs

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20 January 2005

Attention: Selloane Khosi

The Advertising Authority of South Africa Willowview Burnside Island 410 Jan Smuts Avenue Johannesburg

Dear Ms Khosi

### TIG response to TAC complaint to ASA

Annexed hereto is the response of the Treatment Information Group to the Treatment Action Campaign's complaint dated 14 December 2004 about our article published jointly with the Dr. Rath Health Foundation in the *Mail&Guardian* newspaper on 26 November 2004 under the heading 'Why should South Africans continue to be poisoned with AZT? There's a natural answer to AIDS'.

Our response is largely confined to answering the TAC's charges concerning our statements about AZT and nevirapine. Regarding the statements in the article about the reported benefits of multivitamin therapy in AIDS, we concur with and accord ourselves with the separately filed submissions of the Dr. Rath Health Foundation.

Yours faithfully

ADV ANTHONY BRINK CONVENER AND NATIONAL CHAIRMAN TREATMENT INFORMATION GROUP

The **Treatment Information Group** is a public interest initiative to promote *research-based* debate of antiretroviral drug policy, alternative non-toxic treatment approaches to AIDS, and HIV testing issues in South Africa. The TIG has entered into a strategic alliance with the **Dr. Rath Health Foundation Africa** to achieve this.

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#### TIG RESPONSE TO TAC COMPLAINT

Ad paragraph 1: We admit that the complainant is who he says he is, although we surmise that he's the TAC's pro forma complainant only, and not the actual author of the complaint. So we don't admit that.

We don't dispute that some doctor has prescribed to the complainant the polypharmacopoeia of drugs that he has listed – a nucleoside analogue (didanosine, in precisely the same chemical class as AZT); a related nucleotide analogue (tenofovir); and a protease inhibitor (ritanovir).

To the extent that the complainant implies that he complies with his prescription and that he takes these drugs repeatedly every day at the doses that have been prescribed to him, the probabilities are that he's not telling the truth, and we accordingly dispute it.

All the drugs listed by the complainant are exceptionally toxic, and most people find their ill effects intolerable with the result that they are unable to ingest the repeated daily doses prescribed.

An article Less is more: Durban International AIDS Conference changes focus of global research effort published in August 2000 by the English AIDS drug promoting organisation NAM (National AIDS Manual) on its website AIDSMAP (funded by the pharmaceutical industry) quoted US National Institute of Allergies and Infectious Diseases director Dr Anthony Fauci pointing out: 'In the four years between the International AIDS Conference in Vancouver and the 13th Conference held in Durban last month, it has become clear that HIV eradication, the hot topic in Vancouver, is not an achievable goal with current drugs. Indeed, many of the same scientists who focused on eradication back then are now engaged with the study of what happens when HAART [so-called highly active antiretroviral therapy] is stopped and then re-started. Interest in structured treatment interruptions (STIs) has grown at precisely the time that the "HAART for life" strategy employed in the developed world has become less popular. For Tony Fauci, Director of the US National Institute of Allergy and infectious Diseases (NIAID), this re-focusing isn't difficult to understand: "For most individuals, continuous HAART, although effective in many patients, can be toxic, difficult to adhere to, and, in many settings, prohibitive in cost."

For the reasons set out later, we dispute that AIDS drugs have been found 'effective in many patients', whatever that's supposed to mean. It is common cause among both their advocates and their critics that they don't cure, which is to say that they don't make ill people better.

In a novel investigation to quantify the **Prevalence of adverse events associated** with potent antiretroviral treatment in single, double, and triple regimens of AIDS drugs, published in *Lancet* on 20 October 2001 (358(9290):1322-7), Fellay et al. reported 'a high prevalence of toxic effects' in a cohort of 1160 patients. More than two thirds of patients on these drugs suffered side effects severe enough to affect treatment adherence – in other words prevent them taking the drugs as prescribed. Forty-seven per cent reported clinical problems like vomiting, diarrhoea, nausea, fat growth, mood swings, insomnia and fatigue. Blood tests revealed 'potentially serious' abnormalities among twenty-seven per cent. The researchers classed a 'significant proportion' of these adverse events as 'serious or severe'. Kidney dysfunction and

severe fatigue that were 'probably or definitely' due to their HIV treatment led to some patients winding up in hospital.

The Fellay paper was preceded by one by Descamps et al. in the *Journal of the American Medical Association* on 12 January 2000, noting somewhat obliquely that 'During the maintenance phase early and late virologic failures appeared to be related more to problems of adherence and antiretroviral treatment potency, respectively, than to selection of resistant mutant viruses.'

The November/December 2001 issue of *TreatmentUpdate* reviewed a study by Moreno et al. (described as Abstract 93) investigating the *Toxicity profile of antiretroviral drugs in naive patients starting highly active antiretroviral therapy in routine clinical practice*. Noting that 'in the real world, reports of side effects are usually greater than those that are received during clinical trials', Spanish researchers 'reviewed data on 499 subjects with HIV/AIDS who started taking HAART between the years 1996 and 2000. Their aim was to find out about drug-related side effects. These doctors collected data from PHAs [people having AIDS] attending an HIV/AIDS clinic. ... Overall, about 34% of subjects (172 subjects) developed drug-related side effects. In most of these cases (145 of 172 subjects, or 84%), subjects had to stop using the drug that caused the side effect. ... The drugs that caused the most side effects were nevirapine, efavirenz (a similar drug), and the protease inhibitor, indinavir.'

The March 2002 issue of *TreatmentUpdate* discussed a study by Reisler et al. of the US NIH, *Incidence of grade IV events, AIDS and mortality in a large multicenter cohort receiving HAART* (Abstract 36), which looked at data collected from 3227 HIV positive subjects who had been on several clinical trials between 1996 and 2001. They compared the incidence of what they called 'AIDS-related events' (typical infections) and serious or life-threatening drug side effects, which doctors call 'grade IV events', and found three hundred and sixteen 'AIDS-related events' (fourteen per cent of subjects) but double that number of grade IV events: six hundred and sixty three (twenty eight per cent). By about thirty months, ten per cent of subjects had died. The reviewer of the paper accordingly remarked with droll understatement: 'This attests to the severity of such complications.' What were described as 'psychiatric' problems – arising from drug neurotoxicity – joined bone marrow damage, liver disease, pancreatitis, kidney and cardiovascular problems as the most life-threatening drug side effects noted. In short on AIDS drugs patients have twice the chance of succumbing to their toxicities as they do from 'AIDS'.

Numerous other studies have found AIDS drugs intolerably poisonous for a high percentage of people prescribed them. Annexed hereto, marked 'A', is an extensive collation of relevant citations from the medical literature, commencing with further citations reporting the universally recognised problem of adherence to ARV drug prescriptions on account of their life-threatening and frequently fatal toxicity.

A factor detracting from the credibility of the complainant's implication that he adheres to his drug prescription, and that he is 'treatment compliant', is a tendency among poster boys for the pharmaceutical industry to be deceitful about this.

For instance, Zambian AIDS activist Winstone Zulu, an orthodox member of the AIDS Advisory Panel, confessed to interviewer Christine Maggiore during the filming of her documentary film *AIDS in Africa* in mid-2000 (in the possession of the writer and available for viewing): 'I wasn't compliant all the time because the drugs

are difficult to take, you know, they make you sick.' He explained that he didn't want to put others off. 'But in public I was compliant. ... I wasn't taking them all the time. Sometimes I skipped a whole week. ... Every time I took the drugs I felt much closer to death than if I didn't take them.'

The writer witnessed the late Xolani Nkosi ('Nkosi Johnson') mouthing the plea at the behest of his handlers at the opening of the 13th International AIDS Conference in Durban on 9 July 2000: 'I just wish the government can start giving AZT to pregnant HIV mothers to help stop the virus being passed on to their babies. ... I think the government must start doing it because I don't want babies to die.'

The child, however, found AZT unbearably toxic himself.

That he was being forced to take drugs that were making him sick emerged from an article by published online by the AIDS drug promoting news service Health-e on 28 November 2002, *In memory of Nkosi*: 'The scene played itself out three times a day. Nkosi would stand there, a glass of coke in one hand and a pile of pills and potions on the kitchen table in front of him. ... that day Nkosi put on a brave face. "Tonight we'll go and have those prawns," he announced once while trying to swallow the handful of tablets. He would stand there for about three minutes, glass in his slim hand, eyes shut tightly as he tried to coax his frail body into accepting the pills, some of them vitamins, some of them larger and too dry and bulky to swallow. ... After he left we found an assortment of pills scattered under his bed. We realised then that he had not been taking all his medication ...'

The drug that Xolani found particularly intolerable was identified during an interview by Maggiore for her film: 'I'm taking AZT. I'm taking the cocktail. The bitter one I don't like is AZT. There're other pills. I don't really know the names.' Maggiore asked: 'Do you ever not take the pills and not tell anyone? Xolani replied: 'I used to do that but my mom [Gail Johnson] caught me.'

(After the neuro- and mitochondrial toxicity of AZT (discussed later) that he was forced to take had damaged his muscles and brain to the extent that he'd become blind, insensible, paralysed, wasted and incontinent, and no longer able to swallow the drug, his doctors crushed it into fruit juice and gavaged it into his stomach via pipes stuck up through his nose until he was dead.)

It emerged in the media after South Africa's third democratic election in April 2004 that TAC leader Zackie Achmat had been dishonestly concealing from the people of South Africa and our government the fact that he had been unable to continue taking his triple-combination antiretroviral drug regimen because its severe toxic effects had professionally crippled him, physically and psychiatrically.

A press report in the *Daily Dispatch* on 28 May 2004 highlighted the extent: 'Things have changed in Zackie Achmat's life. Once readily accessible and always quick with a sound bite, a personal assistant now monitors the cellphone and diary of the chairperson of the Treatment Action Campaign (TAC) and screens visitors before ushering them into Achmat's study. ... As much as these changes signify a new level of structure in Achmat's life and the need to manage multiple requests for interviews, the more profound changes emerge from his first six months of anti-retroviral therapy and how this has forced the charismatic activist to review his life. ... a frightening setback..occurred in February and March..which shook Achmat's self-confidence. ... "Going into my fifth month I started feeling a sensation in my feet. At first I dismissed it, thinking I'd done something at the gym. The second week it was clear to

me and I thought, 'I can't let Manto win and I can't let Mbeki win', and I kept quiet for three more weeks." When Achmat finally told his doctor about his symptoms, the nerves in his feet were so sensitive that he could barely walk. A change of drugs (from d4T to AZT) has arrested the situation and his left foot feels better, but he still can't put any weight on his right foot for any length of time, nor can he walk long distances. ... Achmat, who has a clinical history of depression, says that the fact that he was immobile for a week while his doctor tried to bring the side effects under control brought on a terrible depression, the worst he's had in two years.'

In point of fact, AZT is no less neurotoxic than d4T; as nucleoside analogues the drugs are in precisely the same chemical class and have substantially the same toxic pharmacology.

Although not widely known to people whose knowledge of medical science derives largely from what they read in the newspapers, whether the complainant actually lives with anyone, as alleged ('I live with HIV'), is actually a matter of considerable scientific controversy. A scientific paper answering in the negative, **A critique of the Montagnier evidence for the HIV/AIDS hypothesis** by Papadopulos-Eleopulos et al., has just been published by the cutting-edge academic medical journal *Medical Hypotheses* (2004;63(4):597-601). The paper is listed in the US National Library of Medicine's medical research database Pubmed, which has published the easy-to-understand abstract online; see annexure marked 'B'.

The paper, which the writer previewed, is a 'lite' version, a summary of a much more detailed earlier review that was published privately as a monograph and submitted to the South African government in November 2000; see Appendix XI at page 175 of annexure 'C' to this submission. (The writer has a co-authorship credit for the monograph.)

The authors meticulously examine and analyse the microbiological phenomena observed and reported in *Science* in 1983 by Professor Luc Montagnier's research team at the Pasteur Institute in Paris as evidence for their claim to have discovered a new retrovirus (initially named 'LAV'); and they find the evidence defective. And that their claim to have isolated 'HIV' was one hell of a mistake.

The ramifications of the paper for people such as the complainant, who take antiretroviral drugs with life-threatening toxicities, and make a real good living urging them on others via the mass media, in the belief that they are infected by a deadly retrovirus, are obviously gargantuan (not least because, in the specific case of the complainant and his employer Zackie Achmat, they threaten to put them out of their jobs).

We mention this not to be drawn into an exchange of scientific polemics with the complainant, which he is ill-equipped to conduct (and which, with respect, the ASA is equally ill-equipped to adjudicate) but to underscore that all aspects of HIV-AIDS medicine are theoretically insecure, down to the most fundamental existential issue concerning 'HIV' itself. And that the existence of these controversies is acknowledged – controversies recognised as legitimate by informed senior professional scientists. Or else such radical scientific revisionism wouldn't make it past peer-review, past journal editors, and into US National Library of Medicine database. If it was junk. Which is to say that no amount of splenetic frothing about 'denialism' by people with egg heading for their faces will make the persistent scientific challenges just go away.

Even the thinking of AIDS experts about what 'HIV' is, and what it does, is a complete shambles.

For the first ten years they said it was a 'lentivirus', a latent, dormant slow virus 'with a long period of silent infection' (Shoub: *AIDS and HIV in perspective*. Cambridge, 1994).

Then in January 1995 on the pages of *Nature* (373:113) they said, no, no, that's all wrong, 'HIV' is actually an extremely busy virus producing billions of copies of itself every day from the start and fighting, they said, 'a titanic struggle' with the CD4 cells of our immune systems. 'Billions of infected cells can be destroyed every day,' went the accompanying editorial under the dramatic title 'Virological Mayhem'.

Thus was revived the long-abandoned notion that 'HIV' virulently attacks CD4 cells – in total conflict with the reigning model at the time that 'HIV' somehow persuaded them to die off by way of some undefined, indirect mechanism: programmed cell suicide, they called it, **Apoptosis in AIDS** – asserted on 28 May 1993 by Montagnier (and Gourgeon) in *Science* (260: 1269), that is by none other than the bloke who claimed to have isolated 'HIV' ten years earlier. The top expert.

Inspired by these revolutionary new martial fantasies, AIDS experts now proposed that HIV-positive people be treated immediately and aggressively; and it was in this theoretical milieu that the new 'hit hard, hit early' approach of HAART was launched: multiple drug combinations, in bracing doses, administered without delay.

No less than eight pages of letters were published in *Nature* on 18 May 1995, taking Ho and Wei's new theory to pieces by exposing their childish mathematical and scientific blunders. Further debunks continued to be published, culminating in two articles in the February 1998 issue of *Nature Medicine*, in which immunologist Dr Mario Roederer of Stanford University commented: 'There has been considerable debate about this simple hypothesis. The *Nature* papers ignited a heated controversy that resulted in publication of several well-designed and informative studies, which raised serious doubts ... In this issue of *Nature Medicine*, reports by Pakker et al. and Gorochov et al. provide the final nails in the coffin for [Ho and Wei's] models of T-cell dynamics.'

Another close investigation by Warner, Greene and associates at the University of California at San Francisco and at Berkeley, put paid to 'a core tenet in the scientific dogma of AIDS, a view that has dominated the field ever since a landmark 1995 study co-authored by famed New York AIDS expert David Ho', reported the *San Francisco Chronicle* on 5 January 1999; they'd found the Ho thesis to be 'an illusion of faulty assumptions and poor measurement techniques'. (For which rubbish he's still got his 1996 TIME Man of the Year prize on the wall.)

So now, no one knows what's going on, what sort of virus 'HIV' is supposed to be, quick or slow, active or passive.

Despite the collapse of the theoretical justification for HAART, it remains terrifically popular among AIDS doctors and drug industry promoting activists. As we see from this complaint and the clowns who supported it. (See later.)

Such is the quicksilver fluidity of HIV-AIDS medicine – at other times its leaden inertia and intransigence.

The current theoretical crises, instability, and rapid flux in HIV-AIDS medicine in regard to aetiology and pathogenesis dynamics, are echoed in wildly unstable treatment convention.

What's important to appreciate is that AZT and nevirapine have been in use as AIDS drugs – as 'mother to child prevention' drugs especially – for a relatively short time; and medical opinion on what's good and right for the treatment of 'AIDS sufferers' is constantly changing – quickly and radically, year to year, like the fashions in Milan.

For instance, the 32<sup>nd</sup> edition of *Martindale: The Complete Drug Reference* published in 1999 intoned authoritatively: 'Treatment options for patients with HIV infection are changing rapidly with a trend towards initiating therapy with combinations of antiretroviral drugs at an early stage of the infection. Until recently zidovudine [AZT] was given as monotherapy.'

Treatment protocol is now 'changing rapidly with a trend' in the opposite direction.

Just a year or so later, on 5 February 2001, top US government AIDS experts were urging the delay of treatment initiation for as long as possible in their radically revised *HIV Treatment Guidelines Updated for Adults and Adolescents* – fairly described as a 'sea change' in treatment convention by prominent AIDS drug lobbyist Mark Harrington, senior policy director of the New York-based, drug company funded Treatment Action Group (an early financial sponsor of the TAC).

New Scientist anticipated the news of the radical reversal of AIDS treatment convention in a report in even stronger terms on 16 December 2000, under the headline, **No More Cocktails**: 'Four years of "hit hard, hit early" HIV treatment may be on the way out in the US, as evidence mounts of the drugs' serious side effects. AIDS experts in the US are about to complete a humiliating U-turn when the Department of Health and Human Services launches its revised HIV treatment guidelines in January.'

Anthony Fauci, director of NIAID in the US, and one of the Co-Chairs of the panel convened to review the official treatment regime, conceded: 'It's clear we're not going to eradicate the virus with the drugs we have now. And we're starting to see a greater and greater realization of the accumulation of toxic side effects.'

Dogma about 'resistance' is another illustration of the chaos in AIDS treatment orthodoxy: AIDS experts have persistently frightened their patients into staying on their drugs, notwithstanding their terrible ill effects, by threatening that unless they do drug-resistant strains of HIV will appear, due to their 'propensity to induce resistance when not taken with absolute consistency' as Professor Susan Ball put it in **Patients Who Want to Stop Their Medications: Treatment Interruption in HIV Infection**, published in the *AIDS Reader* in August 2003.

But **Accrued HIV evidence turns treatment dogma on its head**, wrote Erika Check in *Nature* in the same month: 'A series of studies has dispelled the widespread notion that patients who don't take every dose of their anti-HIV medication create a publichealth risk by helping to nurture HIV strains that resist therapy. The findings suggest instead that some patients who do not take all of their medicine are actually less likely to become resistant to therapy than those who adhere rigidly to their doctors' instructions.'

Please.

AIDS treatment orthodoxy is even moving beyond this recent fad of 'structured intermittent therapy' (typically one week on, one week off) down to reduced single doses a day when on the drugs; see the citations discussed on pages 20 and 21 of annexure 'P7', and the endorsement of big-time AIDS experts for this.

This latest retreat in dosing convention has been driven by the recognition that HAART is unendurably toxic for most people, as Fauci, quoted above, pointed out five years ago.

Information about the serious toxicity of AIDS drugs is constantly being published in the medical and scientific press, but it rarely features in the popular press. There are several reasons for this.

Public Relations firms retained by the pharmaceutical industry package and feed favourable reports into the news system about 'promising' treatments and developments 'giving hope', but research findings, such as the most recent reported late last year, finding yet again that AZT and similar 3TC cause brain damage to babies exposed to it in the womb (see annexure 'D'), do not reach the media, because no one in the popular press is looking out for this sort of bad news – bad for business, bad for advertising and bad for newspaper profits.

The TAC has become the darling of the white liberal media for constantly working to undermine the authority and reputations of the leadership of the ANC in power, and consequently it enjoys the unqualified warm support of what the late Peter Mokaba described in *Umrabulo* 10 as 'the media which forms part of the most reactionary forces among those offering consistent ideological resistance to transformation. It is a powerful tool of manipulation, information and propaganda.' For the same reason the TAC enjoys the lavish financial support of US foreign policy supporting American foundations.

In the particular case of the internationally influential but locally impotent *Mail&Guardian*, the newspaper has an avowed policy of promoting AIDS drugs, and will not publish any material critical of them; see our Press Release on the ins and outs of this, annexure 'E'.

In this drug-promoting endeavour, the TAC and the media, especially the *Mail&Guardian*, operate as invaluable instruments of US foreign policy (and its covert executive operatives) on 'AIDS' in Africa, which centres on the forced dumping of useless, toxic drugs, whose gleam is fading in Western markets, in African countries like ours, despite the informed, strenuous opposition of our democratic government.

In the circumstances, the TAC's attempt, by abusing the ASA, to stifle the publication of information about the toxicity of drugs that it champions so profitably (in riches and honours, and in corporate fifth column political influence in our new democracy) is especially deplorable, and it poses a grave threat to the lives of the people of South Africa.

The TAC wants the ASA to ban the publication of the fact that AZT and nevirapine are extremely toxic and can poison and in some cases kill people in the most horrible way.

It's unbelievable. But then again, we couldn't help noticing that the Pharmaceutical Manufacturers Association of South Africa, to which AZT and nevirapine manufacturers GlaxoSmithKline and Boehringer Ingelheim both belong, is a leading

member of the ASA. Even though the ASA bills itself as 'an independent body set up by the marketing communication industry'. And the business of peddling drugs is not part of the 'marketing communications industry' by any stretch of the imagination.

No prizes for guessing why the drug companies are in there.

Since the control of information is vital to the survival and prosperity of their fraudulent and murderous business.

Ad paragraph 2: We note with interest, from his job description, that the complainant is a professional 'career patient', to quote the moniker coined by Susan Showalter in her study of modern epidemics of mass hysteria, Hystories: Hysterical Epidemics and Modern Culture (Picador, 1997). Showalter describes this syndrome where the 'patient career may be a permanent way of life, with a self-supporting network of friends, activities, doctors, and treatments'. She describes how they typically 'learn about diseases from the media, unconsciously develop the symptoms, and then attract media attention in an endless cycle. Culture forces people to deny the psychological and emotional sources of their symptoms, and to insist that they must be biological and beyond their control, for them to view themselves as legitimately ill.' Showalter quotes Norman Cohn in *The Pursuit of the Millennium* (Secker and Warburg, 1957), writing about the currents churning around the turn of the first millennium: 'Those who are first attracted will mostly be people who seek a sanction for the emotional needs generated by their own unconscious conflicts. It is as though units of paranoia hitherto diffused through the population suddenly coalesce to form a new entity: a collective paranoiac fanaticism. But these first followers, precisely because they are true believers, can endow their new movement with such confidence, energy and ruthlessness that it will attract into its wake vast multitudes of people who are not at all paranoid but simply harassed, hungry or frightened.' (And, Cohn noted, when 'a paranoiac mass movement captures political power', disaster follows.)

Ad paragraphs 3-5: All this is admitted.

Ad paragraph 6: With respect, most of the earnest personal testimony of the complainant in this paragraph is medical and scientific nonsense.

The complainant commences: 'Before I began taking antiretrovirals, I had AIDS.'

Since the complaint makes a series of dramatic statements with an impressively authoritative, scientific-sounding patina, it might be helpful, by way of introduction, to recall Charles Rosenburg's observation in *The Cholera Years* (University of Chicago Press, 1987) that 'A disease is no absolute physical entity but a complex intellectual construct, an amalgam of biological state and social definition.'

The Acquired Immune Deficiency Syndrome, AIDS, as invented and defined by the US Centers for Disease Control, as an ever-changing novel public health construct just two decades old – as a 'surveillance tool' only – is profoundly problematic.

In a memorandum addressed to the then recently appointed director of the CDC, David Satcher, the distinguished American mathematician Professor Serge Lang of Yale, pointed out some of its fundamental inconsistencies that offend simple logic and common sense; see annexure 'F'.

The problem of understanding 'what is AIDS?' is compounded by the fact that 'AIDS' in African countries is defined by the World Health Organization completely and incomparably differently from 'AIDS' in any other country of the developed or developing world.

Under the 'Bangui Definition' agreed at a meeting of the WHO in 1985 in Bangui, Central African Republic, an adult African is considered by the WHO to have 'AIDS' if – without any regard to antibody reactivity – he or she has two major symptoms and one minor symptom. Major symptoms include weight loss, chronic diarrhoea and prolonged fever; minor symptoms include coughing and generalized itching. Of course any number of ordinary, widely prevalent primordial diseases, such as malaria and TB, can give rise to these symptoms, but not to worry.

Having regard to Professor Lang's observations, and the applicability of the WHO definition of 'AIDS' in Africa, the complainant's declamation 'I had AIDS', actually means very little, notwithstanding its tremendous emotional and political resonance.

Especially since the complainant might have 'AIDS' if in South Africa according to the WHO, but not if he hops on a plane and lands in America or anywhere else. Then maybe he doesn't.

And if he thinks he's got AIDS because he's HIV-positive and has a low CD4 cell count, all he has to do is go to Canada, and he won't have AIDS any more. This is because the American CDC's fancy that a person with an abnormally low CD4 cell count on the unlucky day he got tested means he has 'AIDS', even if he is in perfect clinical health, is not one shared by the Canadian counterpart of that organization, the Canadian CDC.

None of the tragic health maladies enumerated by the complainant – 'opportunistic infections ... weight-loss, diarrhea [sic] and memory-loss' – are specific to 'AIDS'; indeed, Professor Luc Montagnier (whose claim to have 'isolated' HIV, then called LAV, in 1983 is meticulously analysed and debunked in Papadopulos-Eleopulos's et al. latest paper cited above) is on record conceding – correctly – that 'AIDS has no particular symptoms'. This is because, as mentioned a moment ago, AIDS is not a distinct disease, as the newspapers paint it, but is merely a 'surveillance tool' conceived by epidemiologists in the US CDC.

And far from preventing the development of 'opportunistic infections', AIDS drugs have repeatedly been found to cause them to develop, as Collazos et al. mentioned in the course of their report in *AIDS* on 14 June 2002 of **Lymphoma developing shortly after the onset of highly active antiretroviral therapy in HIV-infected patients** (16(9):1304-6).

Apart from developing B cell lymphomas, patients experienced 'paradoxical flares of diverse opportunistic conditions shortly after the onset of HAART' – so reported six studies cited by the researchers. Dozens of other similar studies have been published on this peculiar phenomenon. They've even given it a special name, 'immune reconstitution syndrome', as if this resolves the paradox for them, namely that as laboratory markers for drug success go up, gee, the health of the patient strangely seems to go down. Some studies are listed in annexure 'G'. See also those mentioned in numbered paragraph [14] of *Debating AZT: Mbeki and the AIDS drug controversy*, annexure [1].

Why these opportunistic infections are described as 'paradoxical' is because AIDS doctors have trouble understanding why toxic chemicals marketed as medicines to make you better should make you sick.

If they took a look at the pharmacology of nucleoside analogue drugs generally, the puzzle would instantly be solved for them. They wouldn't have to read any further than the very first page of the preface of Cheeson, Keating and Plunkett's authoritative *Nucleoside Analogs in Cancer Therapy* (Marcel Dekker, 1997), which kicks off talking about the 'profound immunosuppression that often accompanies therapy with nucleoside analog drugs', their 'potent immunosuppressive properties'. Also their 'neurotoxicity', but we're still getting to that.

Lest there be any doubt about AZT's membership of the cytotoxic family of cell-poisons known as nucleoside analogues, see the writer's essay *Inventing AZT*, annexed hereto marked 'H', in which the inventor of the drug, Professor Richard Beltz, makes plain in his account privately related to the writer how his original purpose in synthesizing AZT in 1961 was to kill human cells: cancerous ones in tumours.

In the particular experiments he did, AZT wasn't good at that; but it did slaughter E. coli – the bacteria in the human gut critically essential to digestion, hence the high prevalence of diarrhoea and vomiting as toxic effects of AZT ingestion, and the wasting that goes with it on account of the victim's inability to digest the food he eats; see AZT's toxic effects listed by GlaxoSmithKline below. Which in its practical effect means that AZT is starving you as it poisons you.

See also the several studies discussed at pages 23 and 24 of annexure 'P7', in which AZT, this time tried out as an experimental blood cell poison, was found to be a splendid killer of blood cells – precisely in accordance with the hazard warning on the Sigma AZT bottle label published in our article, which the complainant found objectionable: 'Target organs: Blood Bone marrow'.

In one study discussed there it was found good at killing cells in tumours too – even though GlaxoSmithKline pretends in its AZT package insert under the heading 'PHARMACOLOGICAL ACTION' that 'Competition by zidovudine-TP for HIV reverse transcriptase is approximately 100-fold greater than for cellular DNA polymerase alpha.' Implying that AZT goes for 'HIV' and pretty much leaves our cells alone.

In a press release about AZT, released on 5 March 1990, the US FDA perfectly explained the 'paradox' of opportunistic infections setting in after commencing treatment with AZT (and/or similar drugs), but sadly no one seems to have been listening: 'The drug can inhibit the production of red blood cells and may reduce white blood cell counts to the point where the drug has to be discontinued to avoid infections.'

Which is to say AZT is toxic, destroys the immune system and opens the way for the onset of opportunistic infections. Causes AIDS in other words. Which AIDS doctors think is 'paradoxical'.

That AZT destroys all types of white blood cells (causing leucopenia, granulocytopenia) is warned against in GlaxoSmithKline's AZT Product Information advisory in capital letters emphasized in bold typeface: 'WARNING: RETROVIR (ZIDOVUDINE) MAY BE ASSOCIATED WITH HEMATOLOGIC TOXICITY INCLUDING GRANULOCYTOPENIA AND SEVERE ANEMIA.'

Neutropenia is the suppression of a class of white blood cells called neutrophils, essential for overcoming bacterial infections. *Harrison's Principles of Internal Medicine* explains: 'Leukopenia, and particularly neutropenia, increases the risk of infections complications in patients receiving chemotherapy. Fever is the hallmark of infection. Any patient with neutropenia..and fever requires a prompt medical evaluation and subsequent administration of empirical, broad spectrum parenteral [injected] antibiotics.'

To the extent that the complainant means to imply that his immune system has been restored by his strong medicine, this claim is again inconsistent with research findings; see the several reports in this regard discussed in numbered paragraph [14] of *Debating AZT: Mbeki and the AIDS drug controversy*, annexure <u>'I'</u>.

The complainant's statement that his 'CD4 count [is] a measure of the strength of my immune system' is an evergreen canard of contemporary AIDS dogma, but unfortunately it is completely fallacious.

More than ten years ago, having employed CD4 cell counts, in line with conventional wisdom at the time, as a surrogate marker for drug efficacy in the largest, best conducted AZT clinical trial yet conducted (the Concorde trial, which found AZT a total flop; see paragraphs [16] to [19] of *Debating AZT*, annexure '1'), the researchers pointed up the irrelevance of this laboratory measure, and its lack of a correlation to clinical health, noting that the results of the study 'call into question the uncritical use of CD4 cell counts as a surrogate endpoint for assessment of benefit from long-term antiretroviral therapy'.

In their review **Surrogate End Points in Clinical Trials: Are We Being Misled?** published on 1 October 1996 in *Annals of Internal Medicine* (125; 7:605-13) Fleming and DeMets pointed out that CD4 cell counts are 'as uninformative as a toss of a coin ... Effects on surrogate end points often do not predict the true clinical effects of interventions. ... Three..trials, including the Concorde Trial showed an inverse relation between survival and improved CD4 cell counts.'

Which is to say, the better you got on AZT according to the tests, the faster you died.

In the abstract of his latest paper, published this month in *Health Affairs* (24;1:67-78) under the title **Surrogate Endpoints And FDA's Accelerated Approval Process**, Fleming makes the point that 'To use surrogate endpoints and the accelerated-approval process, challenging issues must be addressed to avoid compromising what is truly in the best interest of public health: the reliable as well as timely evaluation of an intervention's safety and efficacy.'

The 'challenging issue' concerning AIDS drug researchers' reliance on CD4 cell counts as a marker for AIDS drug efficacy instead of looking at whether the drugs actually make ill people better is that, as Fleming himself had noted nine years earlier, the practice is 'as uninformative as a toss of a coin'.

Certainly there is no evidence whatsoever for the popular myth that 'HIV' attacks and kills off CD4 cells in the blood. This enduring fable was taken to pieces ten years ago already; see annexure 'J': A critical analysis of the HIV-T4-cell-AIDS-hypothesis. Papadopulos-Eleopulos et al. *Genetica* 1995. 95:25-50.

Read with his other statements in this paragraph, the complainant implies that his AIDS drugs have cured his 'AIDS', or at least that, on these drugs, he no longer has

any AIDS-defining diseases or non-clinical conditions such as an unusually low CD4 count.

But no manufacturer of any AIDS drug claims, as the complainant suggests, that their drugs cure 'AIDS', or that for as long as one is swallowing them one no longer has 'AIDS', or one's 'viral load' stays low and one's CD4 cell count stays up.

If it is truthful, which we doubt, the complainant's sunny testimony in this regard is accordingly anomalous and not in accordance with the findings and claims of the manufacturers of the antiretroviral medicines he claims to be taking.

The effect of the drugs vaunted by the complainant consequently appears to be psychological in origin. We don't mean this facetiously; both the nocebo effect (belief in deadly HIV infection diagnosis) and placebo effect (belief in life-saving cure) on clinical health are basic in psychoneuroimmunology.

To illustrate the point: tonics containing the heavy metal arsenic, one of the most toxic substances known to man, were enthusiastically consumed in the Victorian Era, and beyond it into the 20<sup>th</sup> century, in the belief, sold by their manufacturers, and bought by gulled doctors and credulous patients, that swallowing them fortified the blood. (In fact arsenic is particularly lethal to blood cells, and results in severe anaemia). The same medical fraud saw arsenical drugs survive as the standard medical treatment for people diagnosed with syphilis until well into the first half of that century. It took an official enquiry in England in 1922 to end the drug manufacturers' game with this stuff.

The complainant's statement that his 'viral load was 11 million, indicating that I was in the advanced stages of HIV-disease', is scientifically vacant.

Could he make up his mind: 'AIDS' or 'HIV disease'? Because 'HIV disease' and 'AIDS' are not the same. No matter how magnificent the numbers, high 'viral load' is not considered evidence of 'AIDS' by anyone's definition.

The complainant evidently labours under the misconception that his 'viral load' reading indicates the extent of his HIV infection, the severity of his viraemia, the number of viruses swilling around in his blood, how sick he is. It doesn't.

'Viral load' testing as a modern medical gimmick is closely analysed and exposed as completely useless at pages 8 to 10 of annexure 'C'.

Most sensible people, without hysterical and/or hypochondriacal afflictions, consider the best indication of whether of not they are free of disease, whether they are sick or not, to be their clinical health, namely how well they feel, rather than what doctors tell them on the basis of some or other laboratory test result.

So it will come as an awful surprise to the complainant, no doubt, to learn that his 'viral load' test is so non-specific that its use is prohibited even for blood screening, let alone for making 'HIV infection' diagnoses or for confirming antibody test results.

Oddly enough, his 'viral load' sure doesn't tell him whether he's got the virus in him or not. Whatever the numbers given to him by the doctor with the long face. The manual for the FDA-licensed 'viral load' Roche Amplicor HIV-1 Monitor test explicitly cautions near the top of its front page: 'The Amplicor HIV-1 Monitor test is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection.'

Several years ago Julianne Sacher, a German doctor alive to this scam, told the writer how she sent a sample of her own (HIV-antibody-negative) blood under a pseudonym to a path lab for a 'viral load' reading, and got back a report telling her that she was full of HIV. (She's perfectly healthy.)

The complainant claims that 'Since taking antiretrovirals, my viral load has become undetectable and my CD4 count at last check was 375.'

In view of the fact that the complaint concerns our statements about AZT and nevirapine only, we will confine our comments to the effect that those drugs have on 'viral load' – none.

#### Effect of AZT on 'viral load':

- 1. According to leading American HIV experts Saag, Shaw and Coombs and their associates: 'A three-fold or greater sustained reduction (>0.5 log) of the plasma HIV RNA levels is the minimal response indicative of an antiviral effect... [R]eturn of HIV RNA levels to pre-treatment values (or to within 0.3 0.5 log of the pre-treatment value), confirmed by at least two measurements, is indicative of drug failure.' (*Nature Medicine* 1996; 2 (6): 625-9)
- 2. According to the 1997 British HIV Association guidelines for antiretroviral treatment: 'If the viral load has not fallen by about 1 log 8-12 weeks after treatment initiation, consideration should be given to modify therapy.' (*Lancet* 1997; 349:1086-1092)
- 3. All studies reported in the scientific literature in which the effect of AZT on HIV viral load in patients has been investigated have consistently established that AZT taken alone or in combination with other reverse transcriptase inhibitors is not able to induce a sustained decrease in the plasma HIV RNA level of >0.5 log (the American criterion for anti-HIV drug efficacy), much less 1 log (the British criterion).
- 4. By both the American and British criteria mentioned above, AZT fails to achieve 'the minimal response indicative of an antiviral effect' and is therefore a 'drug failure' i.e. ineffective as an antiviral medicine against HIV.

See the findings of all reported studies to date graphically charted at page 157 of annexure 'C'.

#### Effect of nevirapine on 'viral load':

Nevirapine has no or no significant enduring effect on 'viral load'. The drug was provisionally licensed under special fast-track procedures in the US, Canada and Europe solely on the strength of a finding that combined with two nucleoside analogue drugs, it positively modulated CD4 cell counts. That was it. (Combined with AZT alone, the drug caused a decreased CD4 count.)

No clinical benefits for nevirapine have ever been reported in any study conforming to the basic requirements of a clinical trial. The drug is so useless that it is not licensed for use on its own in any Western country, but only in combination with two nucleoside analogues as a treatment option of last resort. When all else has failed.

All this is canvassed in detail in *The trouble with nevirapine*, Parts One and Two, annexed hereto marked 'K'.

Apropos of the statements that 'My memory has returned and I have had no opportunistic infections', none of the manufacturers of any drug that the complainant claims to be taking, nor the manufacturers of AZT and nevirapine, make the claim in their product information advisories or package inserts that ingesting their drugs will keep the patient healthy, much less restore lost cerebral function. This is because no studies have ever found and reported these miracles.

On the contrary, both AZT and nevirapine are neurotoxic, and the brain damage they cause has been found to cause clinically evident mental degeneration.

The neurotoxicity of nevirapine, causing serious neuropsychiatric deterioration, was reported in the *British Medical Journal* by Wise et al. and is discussed at page 25 of *The trouble with nevirapine*, annexure 'K'.

Reporting his virgin encounter on 4 September 2003 with a cocktail of AIDS drugs including nevirapine, among friends and family assembled around him for the trip, Zackie Achmat told journalists that the experience left him with a severe headache and feeling 'high'. Which might be expected from the *Physicians' Desk Reference*'s note that 'Animal studies have shown that nevirapine is widely distributed to nearly all tissues and readily crosses the blood-brain barrier.'

Within a few months of commencing treatment – with Triomune, a combination of nevirapine, d4T and 3TC (the latter two being nucleoside analogues very similar to AZT) – the neurotoxicity of the drugs had turned him into a physical and psychiatric wreck, as recounted above.

Concerning the neurotoxicity of AZT, see the research reports discussed in numbered paragraphs [56] and [57] of the writer's review, *Debating AZT: Mbeki and the AIDS drug controversy*, annexure '1' hereto, and further the nucleoside analogue neurotoxicity findings for human foetuses and neonates discussed in depth in the writer's sixth, seventh and tenth letters to the Medicines Control Council, annexures 'P6', 'P7' and 'P10'.

Some observers find it noteworthy that after nearly a decade of 'AIDS', 'ARC' (AIDS Related Complex – now abandoned as a disease construct) and their predecessor GRID (Gay Related Immunodeficiency Complex) 'dementia' and 'wasting' were only conceived by the US CDC as AIDS defining diseases in 1987 – the same year that AZT hit the market.

Regarding the complainant's claims that 'My weight has risen to 65kg from 55kg. My skin has also improved', no antiretroviral drug manufacturer claims that the ingestion of their drugs by HIV-positive people results in weight gain and a beautiful new complexion.

On the contrary, instead of fixing unsightly dermatological conditions from liver spots to weeping poxes and worse, AZT and nevirapine both cause them.

Among some of AZT's ill effects admitted by its manufacturer –

Body as a Whole: abdominal pain, back pain, body odor, chest pain, chills, edema of the lip, fever, flu syndrome, hyperalgesia;

Cardiovascular: syncope, vasodilation;

Gastrointestinal: bleeding gums, constipation, diarrhea, dysphagia, edema of the tongue, eructation, flatulence, mouth ulcer, rectal hemorrhage;

Haemic and Lymphatic: lymphadenopathy;

Musculoskeletal: arthralgia, muscle spasm, tremor, twitch;

Nervous: anxiety, confusion, depression, dizziness, emotional lability, loss of mental acuity, nervousness, paresthesia, somnolence, vertigo;

Respiratory: cough, dyspnea, epistaxis, hoarseness, pharyngitis, rhinitis, sinusitis;

Skin: acne, changes in skin and nail pigmentation, pruritus, rash, sweat, urticaria;

Special senses: amblyopia, hearing loss, photophobia, taste perversion;

Urogenital: dysuria, polyuria, urinary frequency, urinary hesitancy

- we read in the 'Skin' section: 'acne, changes in skin and nail pigmentation, pruritus, rash, sweat, urticaria' among the other the pleasantries. Just the thing for the complainant's Saturday night date.

(And predicting that there's not going to be much action after it, Collazos et al. reported on 1 November 2002 in the *Journal of Acquired Immune Deficiciency Syndromes* (31(3):322-6): **Sexual dysfunction in HIV-infected patients treated with highly active antiretroviral therapy**.)

Boehringer Ingelheim cautions in special black box warnings in its package insert for nevirapine that 'Severe and life-threatening skin reactions have occurred in patients treated with VIRAMUNE, including Stevens-Johnson syndrome and toxic epidermal necrolysis. Fatal cases of toxic epidermal necrolysis have been reported.' This and other toxic manifestations of nevirapine is discussed in depth in Parts One and Three of *The trouble with nevirapine*, annexure 'K'.

Stevens Johnson Syndrome characteristically involves blistering ulcerations of the cornea, mouth, rectum, genitalia, skin, and urethra, usually accompanied by a high fever and generalized weakness.

Toxic Epidermal Necrosis involves the entire skin and all mucous membranes, with the skin literally sloughing off the victim's body.

The incidence of 'rash', a milder form of these exceedingly dangerous conditions, is high – twenty per cent among youngsters in a study reported by Verweel et al., **Nevirapine use in HIV-1-infected children**. *AIDS*. 2003 Jul 25;17(11):1639-47.

That AZT is a cell poison causing mitochondrial myopathy, clinically apparent from marked weight loss, also called 'wasting', – rather than weight gain – is borne out by scores of studies, and is openly conceded by GlaxoSmithKline in its AZT package insert: 'The following events have been reported in patients treated with RETROVIR ... myopathy'.

A few of these studies, those already published by 2000, are surveyed in numbered paragraphs [3] to [8] of *Debating AZT: Mbeki and the AIDS drug controversy*, annexure '1'. See also paragraphs [109] and [110].

Certainly wasting was virtually unknown among 'AIDS' patients before the introduction of AZT. Poznansky et al. reporting in the *British Medical Journal* in 1995, **HIV positive patients first presenting with an AIDS defining illness:** characteristics and survival, noted that 'wasting syndrome [occurs] almost exclusively' among AZT-treated patients – confirming what Coker et al. had reported

in Exacerbation of HIV-associated myopathy by zidovudine in AIDS (5(2):229-31) in 1991: 'A clinically significant myopathy that precedes the development of zidovudine associated mitochondrial myopathy has been a rarity in our experience.' And Dalakas et al. the year before that in Mitochondrial myopathy caused by long-term zidovudine therapy, published in the New England Journal of Medicine (1990 Apr 19;322(16):1098-105): 'Before 1986, when zidovudine (formerly called azidothymidine) was introduced [actually 1987], the number of patients with HIV-associated myopathy was small, and myopathy was considered a rare complication of HIV infection.'

The reason you lose weight on AZT is because it poisons off your cells wholesale.

If the complainant understands that 'I still have HIV', because his blood is still reactive upon repeated antibody testing, whether based on either ELISA or Western blot technology, he is regrettably mistaken.

Contrary to popular opinion and widespread medical misconception, no 'HIV' antibody test-kit manufacturer of either kind makes the claim that a reactive result to their antibody test means 'HIV infected'.

This is because such tests are manufactured for blood screening, and not for diagnosis, precisely because they are non-specific, and react to innumerable common diseases and other conditions, from a flu vaccination to past pregnancy. (The reason is that it's elementary in immunology that all antibodies are polyclonal (non-specific).) See the light introductory overview of some basic trouble with 'HIV' antibody testing in the essay **Why the 'AIDS' test is useless and pathologists agree** in the appendixes to *Debating AZT: Mbeki and the AIDS drug controversy*, annexure 'I', page 127.

Scores of disparate conditions have been described in reports in the medical literature causing 'HIV' antibody tests to register positive for 'HIV' antibodies. A list of citations is annexed hereto marked 'M'. In short, as will be obvious from a glance, just about anything can cause these tests to light up.

The complainant's understanding that he 'will have to take ARVs everyday for life' is a medical wisdom briefly extant, but now in the trash – as discussed above. In making this foolish statement, he is simply behind the times. Maybe he should wake up and get with it.

The complainant's claim that on chemotherapeutic, cytotoxic AIDS drugs 'my quality of life and fitness has improved substantially' appears to have been lifted from a drug advertisement of the kind outlawed by the US FDA: on 12 May 2001 the *British Medical Journal* reported an **FDA warning to manufacturers of AIDS drugs**: 'The US Food and Drug Administration (FDA) has issued a warning letter to manufacturers of AIDS drugs cautioning them to tone down the optimistic tenor of their antiretroviral..billboard and magazine..drug advertisements. Thomas Abrams, director of the FDA's division of drug marketing, advertising, and communications said that current antiretroviral advertisements directed at consumers are misleading as they fail to depict the limitations of AIDS drugs and also feature healthy looking people ... sexy and athletic models in the prime of health who were climbing mountains, sailing boats, and riding bikes. These are pursuits which are quite difficult for people with HIV infection, who have to take drugs several times a day that have debilitating side effects ... The advertisements therefore violate the Federal Food and Drug Act.'

Numerous published studies and anecdotal accounts have reported a serious decline in quality of life of people on antiretroviral drugs – and predictably so, given their well-established potent cellular toxicity; see some reports and accounts discussed in numbered paragraphs [22] to [26] of *Debating AZT: Mbeki and the AIDS drug controversy*, annexure 1.

The complainant's assertion that swallowing toxic AIDS drugs like AZT imparts a marvellous new vigour and sense of wellbeing originates, of course, with their lying manufacturers.

A couple of days after President Mbeki ordered that the safety of AZT be investigated in Parliament on 28 October 1999, GlaxoSmithKline's South African medical director Peter Moore responded by claiming that 'For more than a decade, AZT has extended and improved the quality of life of millions of people living with HIV/AIDS around the globe.'

This black lie was exposed in March 2001: reporting **The use of highly active** antiretroviral therapy (HAART) in patients with advanced HIV infection: Impact on medical, palliative care, and quality of life outcomes in the *Journal of Pain Symptom Management* Bechtl et al. confirmed (per *AIDS Weekly* synopsis) that 'HAART treatment does not appear to have significant benefits for the mental health of HIV patients; patients did not report a quality of life improvement after HAART; this was true even when the treatment regimen was clinically successful'. Not surprisingly, since 'treatment failure, either intolerance or death, occurred in up to 40% of the patients studied'.

Wu et al. reported in Volume Six of the *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* in 1993 (p452-8) that 'patients on AZT had an inferior quality of life compared to those on a placebo in terms of overall health, wellbeing, energy, mental health and pain' (summarized by Joan Shenton in *Positively False* (I B Tauris, 1998)).

And obviously, as might be expected from a nucleoside analogue drug that was designed to kill human cells, there is no credible evidence that AZT extends life at all.

As Lemp et al. reported on 1 November 1997 in the *Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology* (16(3):182-90), HAART 'confers no long-term survival advantages'.

Instead, AZT shortens life; see the findings cited at page 21 of annexure 'P2'.

Apropos of the complainant's statement that 'All of this is in accordance with current medical science', it must be obvious from the foregoing discussion and research citations that the complainant is completely ignorant of 'current medical science'. His statement is, on the other hand, entirely 'in accordance' with his employer Zackie Achmat's public boast in *Rapport* on 20 February 2002: 'We are scientifically illiterate.' We'd noticed.

Ad paragraphs 7-9: This is admitted.

Ad paragraph 10: We dispute that our article constitutes commercial advertising, but we admit that the Code applies to our article.

Ad paragraph 11.1: We deny that 'The advert ... exaggerates the efficacy of multivitamins in "treating" AIDS' and refer to the submission of the Dr. Rath Health Foundation in this regard.

Ad paragraph 11.2: This is denied. The fact that AZT is currently approved by the MCC does not imply that our contentions about the potentially deadly toxicity of this substance are misleading.

Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development, a non-profit research group affiliated with Tufts University in Boston, has just made the point succinctly in an article in the *Christian Science Monitor* on 6 January 2005, **Drug tests: too speedy – or safe enough?**: 'It's a common misperception that the FDA approves drugs that are safe and effective. The FDA actually approves drugs where the expected benefits outweigh the expected risks of that drug. It's always a risk-benefit analysis.'

The dozens of FDA-approved drugs that have been withdrawn in the US in recent years after proving deadly poisonous make this plain. Vioxx and Celebrex in the past few months are cases in point.

Ad paragraph 11.3: We repeat the main point above. In the case of nevirapine used to prevent 'mother to child transmission of HIV', Part Nine of *The trouble with nevirapine* (annexure 'K') details the fraudulent suppression by the Director of the Division of AIDS, US NIH, of information concerning 'thousands' of unrecorded adverse events (Principal Investigator Professor Laura Guay's own word) and many unreported fatalities in the HIVNET 012 trial – on the basis of which the Medicines Control Council trustingly granted Boehringer Ingelheim a special conditional licence to market nevirapine in South Africa for this special indication.

It seems that nevirapine's number is just about up as a perinatal antiretroviral prophylactic used on Africans. (But not on whites anywhere in the world.)

That the toxicity of nevirapine may be lethal is well-recognised among informed doctors. Yesterday Reuters reported *U.S.Warns of Safety Risks of Boehringer AIDS Drug*: 'An important AIDS drug can cause sometimes deadly liver damage..U.S. health officials warned on Wednesday. The Food and Drug Administration said doctors should weigh benefits and risks before prescribing the drug, Boehringer Ingelheim's Viramune, also known by the generic name nevirapine.'

The Los Angeles Times quoted Sally Satel, a physician and resident scholar at the American Enterprise Institute on 1 July 2004 warning that 'a calculable percentage of patients will become very sick or even die from the nevirapine component of this three-in-one drug'. She was referring to the Indian-produced generic combo Triomune, which had poisoned and crippled Achmat earlier in the year.

In fact, both d4T and 3TC, nucleoside analogues like AZT, which are packaged in Triomune along with nevirapine, are also potentially lethal general metabolic poisons, but nevirapine appears to be the most acutely toxic, in terms of the rapid onset of serious life-threatening adverse reactions.

This is why nevirapine is contraindicated by the US Centers for Disease Control for even a couple of weeks use by American doctors and nurses suffering needle-stick

injuries; see annexure 'N'. It is too poisonous for doctors and nurses to use themselves, but fine for patients.

US attorney Gregory Johnson described the effects of this 'safe and effective' drug on his client in a recent email, annexure 'O'.

Ad paragraph 11.4: This is denied. Events have overtaken this allegation: on 17 January 2005 the Minister of Health announced her decision to reject the draft new regulations, against which the Dr. Rath Health Foundation had vigorously campaigned.

It had indeed been the foundation's case that the new regulations proposed by the MCC represent the threat complained of. The regulations were accordingly opposed by nearly all organized proponents of health care systems outside allopathic medicine, a currently hegemonic system of commercial medicine in the industrialized world organised around the sale and consumption of patented synthetic patented chemicals, marketed as pharmaceutical drugs.

The foundation's case against the proposed new regulations, on precisely the grounds stated in our article, was made in formal written submissions, and was argued viva voce at an oral hearing conducted by the MCC in Pretoria last year. The campaign against the proposed new regulations on the grounds stated was legitimate and was Constitutionally protected. The statement in this connection in the article was not misleading.

Since the TAC promotes the sale and use of antiretroviral drugs on behalf of pharmaceutical corporations – be they manufactured in first or developing world countries – and the new regulations would have served the industry's commercial interests perfectly, it is unsurprising that the TAC should have come out in strong support of the proposed new regulations and should have denounced our campaign against them as 'misleading'.

Explaining her decision to reject the draft regulations, the Minister said her department 'would like to avoid the pitfall of putting such products in the same regulatory environment as pharmaceutical drugs, whose testing and control is very different' – thereby restricting their free availability, and the right to make statements about their benefits, as we warned in our article.

A report in the *Cape Times* on 17 December nicely described the problem: 'If this draft became law, alternative medicines would have to undergo trials designed for Western medicines and a pharmacist would have to oversee their manufacture. Experts say the producers of complementary medicines cannot afford these expensive, large-scale trials as alternative medicines are not patented.'

At an international conference on natural products and molecular therapy, held at UCT Medical School the week before the announcement of her decision, the Minister alluded to one of the principal planks of the foundation's campaign against the draft regulations, namely that they were driven by pharmaceutical interests under the guise of consumer protection (a line the TAC has uncritically swallowed; see below): the conflict between natural and pharmaceutical medicine that had arisen over the draft regulations was 'a division fostered by the need to make money from patented drugs through discrediting the use of natural products,' she said. Exactly.

Ad paragraph 11.5: This is denied. AZT certainly harms infants, and in precisely the appalling ways described in our article. The extensive reported literature in this regard is canvassed in our letters to the MCC between July 2004 and January 2005, a complete set of which is annexed marked 'P1-10'. The MCC's response to them is still outstanding.

Ad paragraph 12: This should be interesting.

Ad paragraph 13: The complainant's assertion of the popular dogma propounded in the newspapers that people diagnosed HIV-positive will develop 'AIDS' – unless, the complaint implies, they take AIDS drugs – 'even if they are using the most optimal nutrition and vitamin supplements' has no foundation in medical science or epidemiology.

On the contrary: numbered paragraph [40] of *Debating AZT: Mbeki and the AIDS drug controversy* (annexure 'I') looked at the one thing HIV-positive 'long-term survivors' all have in common: avoidance of AZT and similar chemotherapies, and it discussed a few studies.

The late Robert Johnston of the Canadian NGO HEAL Toronto found some more:

In AIDS Weekly, (News Report), 15 & 29 May 1995, Munoz reported in **Disease** progression of 15% of HIV-infected men will be long-time survivors that not one of the 'HIV-positive long-term survivors' in the MACSA study in question had used AZT. In a review, Five myths about AIDS that have misdirected research and treatment, in Genetica in 1995, Root-Bernstein documents that 'long-term survivors' have all avoided antiviral drugs. In their study of such guys reported in Strong cytotoxic T-cell and weak neutralizing antibody responses in a subset of persons with stable nonprogressing HIV type-1 infection in AIDS Research and Human Retroviruses 12: 585 (1996), Harrer et al. noted that of 'Ten HIV+ people; 11-15 years infected ... All showed the same risk factor (sexual exposure), and all had...virus...and none had been treated with antiretroviral agents.' Garbuglia's et al. report, In Vitro activation of HIV RNA expression in peripheral blood lymphocytes in AIDS 10:17 (1996), told that eleven HIV-positive long-term nonprogressors with normal CD4 cells counts, and well for at least 7 years, had taken no 'antiretroviral therapy'. And blowing another hole through the idea that a low CD4 cell count predicts doom, Hoover et al. wrote in Long-term survival without clinical AIDS after CD4+ cell counts fall below 200 in AIDS, 9:145 (1995) that of the 446 men in the MACS study with 200 T-cells, 26 per cent (118) were free of AIDS illnesses three years later: '45% of the group who were AIDS-free > three years after CD4+ cells fell below 200 had not used these [antiretroviral] treatments' and accordingly concluded: 'Significant numbers of individuals remain free of illnesses and AIDS symptoms > three years after CD4+ cell counts drop below 200. This occurs even in the absence of treatment.' Even AZT promoter Lawrence Altman on the New York Times has noticed. In his article on 24 January 1995, Long-term survivors may hold key clues to puzzle of AIDS – the bewildering puzzle that HIVpositive people weren't getting sick as expected – he profiled a San Franciscan man 'infected' for at least ten or 'maybe' fifteen years, who had 'never taken anti-HIV medication'.

The complainant's implication that the South African population faces literal decimation by 'AIDS' some time in the future (which AIDS experts and AIDS activists keep on postponing), on the basis, they say, that at least one in ten has the deadly sex virus in them (and they always mean black people), which inexorably kills all it touches, without the beneficence of the pharmaceutical industry's merchandise, is utterly absurd, other than to fools and hysterics.

Quoting the AIDS experts, Oprah Winfrey predicted just as foolishly on her TV show in 1985: 'Research studies now project that one in five heterosexuals [in the US] could be dead from AIDS at the end of the next three years. That's by 1990. One in five. It's no longer just a gay disease. Believe me.' Believe anything. The TAC does.

Ad paragraph 14: The complainant's statement that 'when a person develops AIDS ... ARV treatment is necessary to prolong life' sets out two myths, widely believed, but bereft of any empirical foundation. It's simple drug marketing propaganda that the TAC has swallowed whole without stopping to chew. And this is what makes the TAC such a treasured asset of the pharmaceutical cartel in South Africa. The childlike credulity of its leadership. Its uncritical, unquestioning deference to medical authority.

The idea that AZT extends life originated with the dazzling reported findings of the clinical trial that preceded the licensing of the drug in the US (and everywhere else).

Indeed it was precisely for the reason that AZT appeared to extend life that the drug was licensed. But the trial was an abject fraud, as detailed by the writer in *Licensing AZT*, annexure 'L', and its findings have never been duplicated, not by a long shot; see numbered paragraphs [19] to [21] of *Debating AZT: Mbeki and the AIDSA drug controversy*, annexure '1'.

There is no evidence whatsoever for the propositions that 'when a person develops AIDS' – as defined under either the special Bangui definition for Africans or the other one applicable everywhere else in the world – his condition is incurable, and will inexorably end in premature demise, and that it cannot be recovered from like any other disease; nor is there any evidence for the notion that people diagnosed with 'AIDS' are unable to recover their health without ARV drugs.

Although pure myth, these notions are widely and passionately subscribed to by the faithful in medicine, by newspaper journalists and by 'educated' people full of 'AIDS awareness'.

We have no comment to make on the averment that 'there is no evidence that multivitamins increase life expectancy once a patient commences ARV treatment' because we did not make it.

We agree that people on ARV drugs have a limited life expectancy, whether or not they take multivitamins – although a paper published on 19 November last year, **AZT** induces oxidative damage to cardiac mitochondria: Protective effect of vitamins C and E published in *Life Science* (76(1):47-56), reports experimental evidence from murine studies that intensive multivitamin supplementation mitigates the destruction of heart muscle tissue by AZT.

Ad paragraphs 15&16: With due respect to his office, the thoughts of the Public Protector in regard to a separate motion are irrelevant to the ASA's determination of

the complaint that our article breached the Code by mentioning the toxicity of AZT and nevirapine, and by reporting research findings and media reports concerning the health benefits of multivitamin therapy for HIV-positive persons.

We are still to treat with the Office of the Public Protector regarding the MCC's dereliction of its statutory responsibilities to protect unborn and newly born South African children from being harmed by AZT and nevirapine in the womb and after birth. We'll be there shortly.

Ad paragraph 17: We deny that our article was factually incorrect and dishonest in any respect.

Ad paragraph 18: We refer to the submissions of the Dr. Rath Health Foundation in this regard, and accord ourselves with them.

Ad paragraph18.6: Although our article did not impeach AZT on efficacy grounds, and went to toxicity issues only, the complainant's statement that 'AZT [has] been shown to be effective in suppressing HIV' is false, and cannot pass.

Au contraire, the most thorough analytical review of the published literature on the molecular pharmacology of AZT yet conducted has found that AZT has no, or no significant, effect on any parameter conventionally considered an index of virustatic activity: 'viral load' and what have you.

A copy of the review, published in the prestigious academic medical journal, *Current Medical Research and Opinion* (and considered sufficiently important to have been flagged in *Nature*) is annexed marked 'Q'.

The critique remains unanswered; see paragraphs [115] to [125] of *Debating AZT: Mbeki and the AIDS drug controversy*, annexed marked <u>1</u>. (Please note an error here: for 'phosphor', read 'phosphate'. And the statement on page one of the book that AZT was initially called Suramin is off the mark; that's actually a different cell poison. Like AZT.)

An unpublished attack on the AZT paper in *CMRO* by *Nature*'s South African correspondent Dr Michael Cherry, a zoologist, taking instructions from Professor Peter Folb of the University of Cape Town – one of South Africa's most eminent pharmacologists, and past chairman of the Medicines Control Council for seventeen years, himself apparently instructed by GlaxoSmithKline – proved to be a disgraceful professional embarrassment for the two of them, with both of them ending up thrashed and limping home crying – see annexures 'R' and 'S'.

Ad paragraph 19.1: These drugs are indeed registered by the MCC, but the conditional registration of nevirapine for perinatal use remains provisional and appears to still be under review.

Our article did not impeach the efficacy of AZT and nevirapine 'for the reduction of mother-to-child transmission', but we record that contrary to conventional wisdom neither of these drugs has any such effect whatsoever.

In this regard we refer to three extensive analyses and debunks demonstrating this:

Papadopulos-Eleopulos's et al. 'mother to child' monograph, annexure 'C'; a slideshow presentation prepared by the same authors, including the writer, and presented by Professor Sam Mhlongo, Head of Department, Primary Health and Family Medicine, MEDUNSA, at a meeting of the South African Association of Professionals in Health Care on 7 February 2002, which refutes the claim that nevirapine has any use as a perinatal anti-HIV prophylactic, annexed marked 'T'; and Part Four onward of *The trouble with nevirapine*, annexure 'K', which does likewise.

Ad paragraph 19.2: All these allegations are irrelevant to our incontestable statements concerning the exceptionally dangerous toxicity of AZT and nevirapine, which both their manufacturers warn may be fatal.

We dispute that anyone 'needs' AZT or nevirapine in any circumstances, any more than they need their veins opened and a couple of pints of their blood let into a bowl. Which doctors said we needed for two and half thousand years. Sir William Osler's standard text *Principles and Practice of Medicine* continued to esteem bloodletting highly until as late as 1923. Indeed, the centrality of bleeding to scientific medicine until quite recently is reflected in the title to one of its leading journals: *Lancet* – a broad, two-edged, sharp-pointed surgical knife specifically designed for puncturing and opening veins.

Were the South African public to learn the facts about AZT and nevirapine, set out in this memorandum and annexures, the TAC's reputation would instantly collapse; its R18 million a year donor funding (swelling exponentially by the year) would immediately dry up; and all the TAC's leaders and employees would be out on the streets looking for new jobs, personally disgraced and totally discredited.

This is why they must suppress this information at all costs if they can. Their own survival is on the line.

Ad paragraph 19.3: We dispute that our publication of statements about the dangerous toxicity of AZT and nevirapine breaches the Code. The complaint's statements in this paragraph are otherwise completely irrelevant to the determination of the substance of the complaint and misconceive the ASA's function – which is not to serve the pharmaceutical industry's marketing programme, spun to the public as a white-knight operation. Coming to our rescue.

It is a pathetic display of gullibility (at best) that the TAC should contend that AZT and nevirapine will resolve South Africa's health problems. The notion that 'people need ARVs' is matter of medical orthodoxy which is constantly changing, and, as we have seen, consistently in a reverse direction. These drugs are certainly headed for the dump.

The reason why AZT and nevirapine are available in the public sector – although it would appear from supply figures they're not very popular – has nothing to do with their merits and everything to do with the coercion of the South African government by the TAC, acting in the interests of the pharmaceutical cartel.

Saturation propaganda to the contrary notwithstanding, there is no evidence whatsoever for the canard that unless HIV-positive people take ARV drugs they will

die of 'AIDS'. This is a marketing myth propounded by drug manufacturers and their agents in drug lobbying organizations.

It is medically incontestable that AZT and nevirapine are exceptionally toxic.

The headline of our article was accordingly a legitimate expression of our opposition to the continued inclusion of AZT in the allopathic material medica. And of nevirapine too.

Ad paragraphs 19.4-5: The relevance of Sigma-Aldrich's label is obviously a matter of opinion.

South Africans exposed only to the propaganda of the TAC and other pharmaceutical interest groups have a legitimate interest in learning that laboratory workers handling exactly the same toxic chemical as that packaged by GlaxoSmithKline as a medicine carries a warning, on miniscule amounts, that not only should they not swallow it by mistake, they should not inhale any of it or let it come anywhere near their skin – and that they should wear gloves, plastic overalls, protective headgear and a pair of eye-protecting goggles with a nose and mouth screen attached beneath them before opening the bottle and using it.

It's our opinion that only a mental defective would fail to get the point.

Ad paragraph 19.6.1: Far from being misleading, this is a statement of simple fact, known to anyone with even a cursory familiarity with the medical and scientific literature.

Ad paragraph 19.6.2: The medical and scientific papers that have made these findings are canvassed in our recent letters to the Medicines Control Council, annexures 'P1-10'.

Ad paragraph 19.6.3: We insist that the question posed in the headline of our article is a legitimate expression of opinion, having regard to the published toxicity data on AZT, from which any reasonable person will conclude that it is a completely useless and deadly drug, and that it is high time that it be abandoned, just as deadly and useless but once ever popular arsenic- and mercury-based drugs were dropped just a few decades before it.

It is common cause among informed people that AIDS drugs are highly toxic and very expensive.

On the cost of AIDS drugs, see Fauci's confirmation in our comments on the statements made in the complainant's first paragraph.

Ad paragraph 19.6.4: There can obviously be nothing objectionable in publishing an invitation to readers to read our memoranda to the Medicines Control Council.

Ad paragraph 19.7: We deny this.

Ad paragraph 19.8: This is correct.

Ad paragraph 19.9: The leading studies relied upon by advocates of AZT and/or nevirapine in pregnancy, labour and for neonatal administration are meticulously analysed and completely debunked in annexures 'C', 'K' and 'T'.

There is no foundation at all for the complainant's eager assertion that 'the MCC has been extremely cautious in its registration of AZT and nevirapine for mother-to-child prevention'. Since he doesn't work there he wouldn't know.

On the contrary, the gravamen of our correspondence to the MCC is that in the light of the published medical research literature it has been reckless, or at best disgracefully indolent. Either way, it has demonstrated itself to be utterly incompetent. The whole lot of them should be sacked.

Ad paragraph 19.10: Nothing in our article supports the inference that there is 'a conspiratorial state cover-up against the use of vitamins', so we have no comment on this silly statement.

Ad paragraph 19.11: The complaint's breathtakingly naïve defence of the proposed new regulations is not supported by most natural medicine practitioners in South Africa, who have rallied to oppose them – in the result successfully.

Ad paragraph 20: All this is denied. None of our claims are false, all are quite true.

Ad paragraph 21: The use of ARV drugs in 'AIDS' has been a resounding failure. They have not saved a single life, and have wreaked a holocaust of deadly ill effects on people diagnosed 'HIV-positive' and 'having AIDS'.

Clearly medicine has been barking up the wrong tree, and the time for a radically new approach to bolstering immunity and restoring health has arrived.

This is our position, and we are completely within our rights to assert it.

Ad paragraph 22: All this is denied.

Ad paragraph 23: All this is denied.

Ad paragraph 24: This is denied.

Ad paragraph 25: This is denied

Ad paragraph 26: This is denied.

Ad paragraph 27: This is a legitimate expression of opinion, based on the published data available.

Ad paragraph 28: All our allegations in regard to AZT and nevirapine are true, and are supported by abundant reported research data.

Ad paragraph 29: This is denied.

Ad paragraph 30: There is no evidence whatsoever that not taking ARV drugs will lead to early death, or that taking vitamins instead will cause this. Any more than there is for believing that unless you are saved you'll go to Hell when you die.

Ad paragraph 31: It will be obvious that the positions we assert in our article involve a fundamental conflict of competing health paradigms, in which we contend for the advantages of natural medicine, specifically non-toxic, side-effect-free, micronutrient therapy, as against the dangerously toxic synthetic drugs AZT and nevirapine, which, in terms of clinical outcomes, are both completely useless and deadly poisonous.

It is ridiculous to allege that because our position in this regard has not been blessed by the agency that we criticise, we have infringed the Code. We did not in any event make any product comparisons; we state some incontestable facts.

Ad paragraph 32: These allegations, to the extent that the Dr. Rath Health Foundation deems them relevant, will be addressed in the foundation's submission.

Ad paragraph 33: We dispute that in calling attention to the life-threatening toxicities of AZT and nevirapine, and to the reported literature on the health benefits of micronutrient therapy, we are endangering public health. The allegation is perfectly Carrollian.

What South Africa's most pressing health problem is a matter of opinion, about which there is a division.

For our part, we consider it to be the diseases that attend poverty, always did and always will. The top echelons of the African National Congress take the same view, as is well known.

The TAC and the Bush administration, whose biggest election donor was the pharmaceutical industry, see the problem instead as too much free sex among black people, which makes them all sick, for which they need the industry's antiretroviral drugs.

Ad paragraph 34: These arguments and allegation do not concern us.

Ad paragraph 35: We obviously oppose all this.

Ad paragraph 36: We deny that our article in any way jeopardised public health.

The rest may be addressed in the Dr. Rath Health Foundation submission.

The complainant has not made out any case why it has made no attempt to resolve this matter with the Treatment Information Group, and to the extent that this might be a jurisdictional requirement, we take the point and object.

Ad paragraph 37: We have no comment on the opinions expressed in the noisy letter filed by the Rural Doctors Association, which raises no new issues.

Ad paragraph 38: The letter from the South African Medical Association raises some novel issues.

A 'recent study in the journal *AIDS*' is mentioned without providing the citation. We are consequently unable to comment on the design or conclusions drawn in that study. CD4 cell counting is a waste of time anyway, as mentioned earlier.

We reiterate that no AIDS drug study anywhere has ever returned findings of clinical health benefits akin to those of the Harvard study.

The Harvard researchers' finding that the effect of multivitamins on 'immunologic and virologic outcomes were small relative to the benefits of triple antiretroviral therapy' is an interpretation proceeding from their understanding that these surrogate markers demonstrate treatment success. They don't, as discussed above.

Our interest is less in the Harvard researchers opinions, than in their concrete findings concerning clinical health outcomes among the women treated with micronutrient therapy – and these are unequalled by any AIDS drug, as might be expected considering how extremely poisonous these chemicals are.

The South African Medical Association's statement that the 'data [concerning] the toxicity of AZT..comes from work in rats. The doses given to these rats equate to a human being given 10 to 12 times the ordinary effective dose' is a phenomenally stupid, ignorant and arrogant statement, as the hundreds of studies cited in this memorandum show. It is pure invention calculated to mislead the ASA and pervert the outcome of its enquiry into the legitimacy of our article in terms of the provisions of the Code.

We consider the false statements by the doctors concerned disgraceful, and should the ASA share this view, we propose a referral of the matter for the institution of disciplinary proceedings against them.

If the ASA does not share our view that the false statements are professionally reprehensible, we would appreciate its reasons.

Apropos the foetal toxicity of AZT, the shortcomings of the all-clear study to which the doctors allude were expressly identified and discussed by the French Paediatric AIDS Study Group, which found very differently; see annexure 'P6'.

As they do all over the world, the poor in South Africa undoubtedly suffer a much higher incidence of disease than the rich. Whether our census and other hard clinical

epidemiological data establish that South Africa is in the grip of a deadly new sexplague as alleged by the TAC, doctors and deeply concerned American experts and politicians, in reality and on the ground, rather than in the medical and popular mind as the latest delusional enthusiasm of the sort that cyclically seizes the Western imagination over the centuries, is a controversy not relevant to enter into in this submission.

## ADV ANTHONY BRINK CONVENER AND NATIONAL CHAIRMAN TREATMENT INFORMATION GROUP

CC: The South African Government

The African National Congress

The Freedom of Expression Institute

The Press Ombudsman

The South African National Editors Forum

The CEO, the Mail&Guardian: Trevor Ncube

The COO, the *Mail&Guardian*: Hoosain Karjeiker The editor, the *Mail&Guardian*: Ferrial Haffejee

'The Ombud', the Mail&Guardian: Frans Kruger

Local and foreign media Other interested parties