

IN THE HIGH COURT OF SOUTH AFRICA
(CAPE OF GOOD HOPE PROVINCIAL DIVISION)

In the matter between:

TREATMENT ACTION CAMPAIGN	First Applicant
SOUTH AFRICAN MEDICAL ASSOCIATION	Second Applicant

and

MATTHIAS RATH	First Respondent
DR RATH HEALTH FOUNDATION AFRICA	Second Respondent
SAM MHLONGO	Third Respondent
DAVID RASNICK	Fourth Respondent
ALEXANDRA NIEDWIECKI	Fifth Respondent
ANTHONY BRINK	Sixth Respondent
TREATMENT INFORMATION GROUP	Seventh Respondent
GOVERNMENT OF THE RSA	Eighth Respondent
DIRECTOR-GENERAL OF HEALTH	Ninth Respondent
CHAIRPERSON, MEDICINES CONTROL COUNCIL	Tenth Respondent

REGISTRAR OF MEDICINES

Eleventh Respondent

MEC FOR HEALTH WESTERN CAPE

Twelfth Respondent

AFFIDAVIT

I, the undersigned

WILLEM DANIEL FRANCOIS VENTER

hereby make oath and say:

1. The facts deposed to in this affidavit are within my personal knowledge and are true and correct.

2. I am the President of the Southern African HIV Clinicians Society (“The Society”). This is the largest of the South African Medical Association’s Special Interest Groups. It has over 9,300 members. The Society is a public benefit organisation run by an executive of clinicians who are locally and internationally recognised HIV experts. The Society’s major objective is to inform doctors regarding state-of-the-art treatment and care for people infected and affected with HIV/AIDS. The Society has been very active in the last six years producing and providing:
 - a quarterly medical journal *Southern African Journal of HIV Medicine* (printed and distributed by *South African Medical Journal*);
 - a quarterly newsletter, Transcript;

- 11 sets of guidelines for the treatment and care of people infected and affected by HIV/AIDS, which are written by The Society's specialist sub-groups and are locally peer-reviewed and internationally approved;
 - 23 branches in South Africa and other SADC countries for local Continuing Medical Education meetings and discussion of difficult cases;
 - ongoing national HIV management courses run with the Foundation for Professional Development;
 - an alumni programme for successful graduates of the above and other courses;
 - curriculum, examination papers and marking for the *Diploma on HIV Management (SA)* of the College of Medicine of South Africa;
 - expert opinion and advocacy for legitimate organisations;
 - an office hours specialist consultancy for members with complicated cases.
3. In 1993 I registered with the then South African Medical and Dental Council (now the Health Professions Council of South Africa) as a medical practitioner. I was registered during 2000 as a Specialist of Internal Medicine. I am a Fellow of the College of Physicians (SA).
4. Since 2000 I have obtained the following degrees and diplomas:
- 4.1. Diploma in Tropical Medicine & Hygiene, University of the Witwatersrand;

- 4.2. Diploma in HIV Management; Colleges of Medicine, South Africa;
5. I spent two years (2001-2002) working for the Clinical HIV Research Unit, University of the Witwatersrand.
 6. I now hold the position of Clinical Director of the Reproductive Health and HIV Research Unit at the University of the Witwatersrand.
 7. I am a senior consultant in the Johannesburg Hospital antiretroviral clinic and the Hillbrow HIV clinic.
 8. Since 1997, I have developed extensive and specialist HIV/AIDS-related clinical experience in South Africa.
 9. I have been involved as an investigator for several HIV-related studies. I have researched and co-authored more than 20 peer-reviewed articles and I have presented at national and international science conferences on HIV/AIDS.
 10. I have supervised and evaluated the treatment of thousands of patients with HIV/AIDS, including over 2000 in Johannesburg Hospital, and over 300 in Hillbrow. Furthermore, I run support programmes to several of the largest clinics in the country, in North-West Province.
 11. I have served and continue to serve on local, provincial, and national committees on treatment for HIV/AIDS and other infectious diseases. I am a

reviewer for national and international scientific journals for HIV/AIDS related scientific manuscripts. I attach my curriculum vitae (**FV1**).

12. I have been asked to address the following issues which fall within my area of expertise:

12.1. The current status of the science of HIV treatment with particular reference to antiretroviral medicines (ARVs) and micronutrients.

12.2. The claims made in advertisements distributed by Dr Matthias Rath and his agents (“the Rath respondents”) with regard to

12.2.1. treatment of HIV and AIDS using micronutrients,

12.2.2. treatment of HIV and AIDS, and prevention of mother-to-child transmission, using ARVs

12.2.3. the comparison of ARVs to micronutrients.

13. I respectfully submit that I am, by training and experience, duly qualified to express the views and opinions set out in this affidavit.

CURRENT STATUS OF THE SCIENCE OF HIV TREATMENT

ARVs

14. There is scientific consensus that HIV is the cause of AIDS. Without medical intervention the vast majority of people with HIV will progress to AIDS and consequently die. No reputable scientific body disputes this.
15. There is scientific consensus that the benefits of ARVs, when used as a chronic lifelong treatment for people with advanced HIV-disease, outweigh the risks, and that currently ARVs are the only medicines that specifically treat HIV and reverse the course of AIDS.
16. There is scientific consensus that ARVs, including AZT (Zidovudine) and nevirapine, are effective at reducing the risk of transmission of HIV from pregnant women to their unborn babies.
17. ARVs, including AZT, are recommended in government policy for post-exposure prophylaxis following occupational exposure and sexual assault.
18. In contrast to mother-to-child transmission prevention and the treatment of people with HIV, no controlled clinical trials have examined ARVs for post-exposure prophylaxis of HIV. Conducting such a study would pose insurmountable practical and ethical problems. However the balance of evidence of comparisons of people exposed to HIV with access to this intervention against those without, indicates that ARVs are effective for post-exposure prophylaxis.
19. It is official South African government policy to provide ARV treatment to people through the public health system for the treatment of HIV and the

reduction of mother-to-child transmission. AZT and nevirapine are both used in this programme. The government's policy is described in the Department of Health's Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, published on 19 November 2003.

20. Guidelines for using ARV treatment are published by the Southern African HIV Clinicians Society and the Department of Health. I attach (**FV2**) a copy of the former.
21. According to a statement by the Director-General of Health, in September 2005 about 61,000 people were being treated with ARVs in the public health sector. According to government over 1,500 public health facilities provide ARVs for the purpose of mother-to-child transmission prevention.
22. AZT, nevirapine and other ARVs are approved by the Medicines Control Council (MCC) for the treatment of HIV/AIDS. Other ARVs registered by the MCC for the treatment of HIV/AIDS include lamivudine, efavirenz, stavudine, didanosine, saquinavir, lopinavir, ritonavir, nelfinavir, abacavir, and indinavir.
23. Registration of a medicine for a specific purpose with the MCC means that the medicine has been found to be acceptably safe and effective for this purpose by South Africa's regulatory body charged by statute with the responsibility of determining such matters.

24. AZT, nevirapine and other ARVs are approved by the statutory regulatory bodies of (amongst other nations) the European Union, USA and Canada as safe and effective for the treatment of HIV.

25. ARV treatment (including AZT and nevirapine) is an integral component of the global treatment response to HIV of the World Health Organisation (WHO). The WHO is the world's leading public health organization. Its recommendation was endorsed by the Joint United Nations Programme on HIV/AIDS ("UNAIDS"). The entire WHO "3 by 5" programme (to treat 3 million HIV-infected individuals by the year 2005) is premised on the efficacy of these medicines. The WHO treatment guidelines may be found at www.who.int/3by5/publications/documents/antiretroviral_guidelines/en. This document describes the centrality of ARVs to the global public health response to HIV/AIDS.

26. About 5,000 scientists from around the world (including 11 Nobel Prize winners) signed the Durban Declaration of July 2000, affirming that HIV is the cause of AIDS, and affirming the life-saving nature of ARV treatments. The list of signatories includes directors of leading research institutes and presidents of academies and medical societies, including the US National Academy of Sciences, the Royal Society of London, the UK Academy of Medical Sciences, the Pasteur Institute, the Max Planck Institutes, the US Institute of Medicine, the European Molecular Biology Organization, the AIDS Society of India, and the National Institute for Virology in South Africa.

Scientists working for pharmaceutical companies were not asked to sign the Declaration. I attach (“**FV3**”), a copy of this Declaration.

27. The Revised Guideline 6 of the International Guidelines on access to prevention, treatment, care and support promulgated jointly by the United Nations High Commissioner for Human Rights and UNAIDS (2003) calls on all states to “ensure for all persons...the availability of...antiretroviral and other safe and effective medicines...for care of HIV/AIDS...”. This guideline (**FV4**) is available at www.unaids.org/html/pub/Publications/IRC-pub02/JC905-Guideline6_en_pdf.pdf.
28. On 22 May 2004 the World Health Assembly at its 57th session issued a statement “acknowledging that antiretroviral therapy has reduced mortality and prolonged healthy lives”. It welcomed the WHO HIV/AIDS programmes in securing access to ARV treatment. The statement (**FV5**) also lists other international developments acknowledging the significance of ARV treatment, including the United Nations General Assembly adoption on 27 June 2001 of its Declaration of Commitment on HIV/AIDS at a special session, in which it specifically called for comprehensive strategies including for access to antiretroviral drugs.

Multivitamins and other micronutrients

29. There is some evidence that a specific combination of multivitamin supplements in specific doses slows down the progression of HIV to AIDS.

Multivitamin supplements are available to people with HIV/AIDS through public sector health facilities.

30. I have been shown a bottle of VitaCell, a medicine allegedly sold by the Rath respondents. I have been informed that some of their patients have been prescribed 30 such pills per day. There is no evidence published in credible peer-reviewed journals demonstrating that this combination of vitamins in those doses has any beneficial effect on people with HIV.
31. On the contrary, the prescription of such high dosages is likely to be dangerous for people with advanced HIV-disease. For example, assuming that the package label of VitaCell accurately reflects its contents, 30 pills per day would imply that a patient takes 2400mg of Vitamin C per day. This can cause diarrhea, with a consequent risk of increased illness and death in people with advanced HIV-disease.
32. There is no evidence that vitamins or micronutrients reverse the course of AIDS. The available evidence shows only that a particular combination in a particular dose delays the onset of AIDS in a specific group of patients.
33. The MCC has not registered any micronutrients for the treatment of HIV. To the best of my knowledge no other regulatory authority has done so.
34. There is consensus among all credible scientific institutions dealing with the HIV epidemic that malnutrition and undernutrition adversely impact on the health of people with HIV/AIDS.

35. From 10 to 13 April 2005, a World Health Organisation Consultation on Nutrition and HIV/AIDS in Africa was held in Durban. The conference included the world's experts on nutrition and HIV. The Participants' Statement (**FV6**) represents the current international scientific consensus on nutrition, micronutrients and HIV. It makes the following points:

“The participants of the consultation reviewed the scientific evidence and discussed the programmatic experience on nutrition and HIV/AIDS.

- Adequate nutrition cannot cure HIV infection but it is essential to maintain the immune system and physical activity, and to achieve optimal quality of life.

- Adequate nutrition is required to optimize the benefits of antiretroviral drugs (ARVs), which are essential to prolong the lives of HIV-infected people and prevent HIV transmission from mother-to-child.

- There is a proliferation in the marketplace of untested diets and dietary therapies, which exploit fears, raise false hopes and further impoverish those infected and affected by HIV and AIDS.

- There is no evidence for an increased need for protein intake of people infected by HIV/AIDS over and above that required in a

balanced diet to satisfy energy needs (12 to 15% of total energy intake).

- Micronutrient intakes at daily recommended levels need to be assured in HIV-infected adults and children through consumption of diversified diets, fortified foods, and micronutrient supplementation as needed.

- Studies have shown that some micronutrient supplements may prevent HIV disease progression and adverse pregnancy outcomes. Additional research is urgently required.

- Micronutrient supplements are not an alternative to comprehensive HIV treatment including ARV therapy.

- The value of ARV therapy far outweighs the risks.

- The effects of traditional remedies and dietary supplements on the safety and efficacy of ARV drugs need to be evaluated.

[Good dietary practices were considered important because:]

- HIV-infected adults and children have increased energy needs compared with uninfected adults and children.

- Optimal nutrition of HIV-infected mothers during pregnancy and

lactation increases weight gain, and improves pregnancy and birth outcomes.

- Improved dietary intake is essential to enable children to regain lost weight after opportunistic infection.” (comment in square brackets added)

AIDS Denialism

36. There is a fringe group of people collectively referred to in the media and in debate as “AIDS dissidents”, “AIDS denialists” or “HIV denialists”. They argue that HIV is not the cause of AIDS and/or that the risks of ARVs outweigh their benefits. I will refer to this group as “AIDS denialists”.
37. There is no consensus amongst this group regarding their theories. For example, some do not believe HIV exists; some believe it is a harmless passenger virus; some do not believe that ARVs are effective; and some even believe that ARVs cause AIDS.
38. There is no credible scientific institution that shares or reflects the AIDS denialist views. Scientific evidence refutes the views of the AIDS denialists.
39. I attach a detailed rebuttal of the AIDS denialist viewpoint written for the layperson (**FV7**). It is published by the National Institutes of Health, an

authoritative public research institution in the United States. I endorse its contents.

40. I am familiar with the principal argument of some AIDS denialists, particularly Anthony Brink and David Rasnick, who I understand are respondents in this case.
41. Mr Brink produced AIDS denialist arguments about the toxicity of AZT in paragraphs 6 to 22 of an affidavit in the Petermaritzburg High Court in 2002. His claims were refuted in detailed affidavits by Professor Robin Wood (University of Cape Town), Professor Brian Gazzard (President of the British HIV Association) and Professor David Back (Head of the Pharmacology Department of Liverpool University, UK). The plaintiff, represented by Brink, did not proceed with that case.
42. The AIDS denialist arguments are characterised by poor logic, misleading statements, and outright falsehoods. I give here one illustrative example.
43. A commonly made argument, and one made by David Rasnick, is that ARVs have not been shown to be clinically effective in controlled clinical trials. In this regard:
 - 43.1. It is true that most clinical trials examining ARVs have examined surrogate endpoints of clinical outcomes as opposed to clinical outcomes themselves.

- 43.2. However, some trials, including the trial upon which the US registration of AZT was based, have shown dramatic clinical benefit.
- 43.3. There is sufficient evidence that the surrogate endpoints for clinical trials, namely CD4 and viral load measurements, are predictors of clinical outcome.
- 43.4. A clinical trial meta-analysis is an accepted scientific technique for evaluating the results of a health intervention by grouping together all clinical trials to determine whether a statistically significant effect occurs. The AIDS denialist argument is refuted by a meta-analysis of antiretroviral clinical trials:
- 43.4.1. An analysis by Rachel Jordan and colleagues in the British Medical Journal in 2002 examined studies comparing one ARV drug against placebo. It found that that AIDS or death with AZT was 70% of placebo. (BMJ 2002;324:757)
- 43.4.2. It examined studies comparing two ARVs against one and found that death or AIDS for patients using two ARV was 60% of those using one ARV.

43.4.3. It examined studies comparing three ARVs against two and found that death or AIDS for patients using three ARVs was 60% of those using two ARVs.

43.4.4. This alone constitutes convincing evidence that the benefits of ARV treatment extend life and reduce illness.

44. In summary, ARVs have been sufficiently tested in clinical trials to demonstrate that they reduce mortality and morbidity in people with advanced HIV disease and that they prevent transmission from mother-to-child. Clinical trial findings have been supported from cohort data published in many countries and in numerous communities. My colleagues and I have published such cohort study findings.

Side effects of antiretrovirals

45. As with most effective scientifically proven and approved medicines, ARVs (including AZT and nevirapine), can cause serious side-effects.

46. However, the benefits of ARV treatment far outweigh the risks. Without ARV treatment, nearly all patients with HIV progress to death from AIDS. Once patients have developed AIDS, approximately 50% will die within 12 months in the absence of ARV therapy. ARV treatment decreases progression to AIDS and reduces mortality of AIDS patients by approximately 90%.

47. The point is perhaps most easily illustrated by the use of chemotherapy treatment for cancer. Chemotherapy is much more likely than ARV therapy to result in serious toxicity, and the survival benefits are frequently modest. It is however well established in medical science that the benefits of chemotherapy outweigh its risks.
48. There is not a single recorded incident of a serious adverse event associated with the single-dose nevirapine regimen, which is used in most South African hospitals to prevent transmission of HIV from mother to child.
49. Side-effects are more common with multiple dosing and ARV combination therapies. These more complex regimens (frequently including AZT and/or nevirapine) are more effective for mother-to-child transmission prevention than single dose nevirapine. Recommended regimens are chosen for their tolerability and safety.
50. Side effects of ARVs commonly include short term effects, such as rash, hepatitis, headache, gastrointestinal disturbances, fatigue, sleep disturbances, and dizziness. Longer term effects can include anaemia, lipodystrophy, peripheral neuropathy, and metabolic disturbances. There are a large number of rarer side effects, including life-threatening conditions such as pancreatitis and lactic acidosis.
51. My colleagues and I published the results of one of our cohorts of patients in 2004 (S Afr J Epidemiol Infect 2004; 19: 48-51). Out of 352 patients

receiving ARV treatment followed up from 2 April 2004 to 11 June 2004, seven were lost to follow-up and five died. In other words a maximum of 12 died (3.5%). All 352 patients presented with AIDS. Nearly all would likely have been dead by the end of the period if they had not received ARV treatment.

52. Side-effects were recorded in 44% of patients. However, only 10 patients (2.8%) required a change in ARV regimen by week 10 of the programme.
53. Sixteen (4.5%) patients were hospitalized, 11 (3.1%) experienced immune reconstitution syndrome, 7 (2%) were lost to follow up and 5 (1.4%) died.
54. From this we can conclude that ARV treatment, despite its side-effects, is beneficial to patients in a large-scale hospital setting in South Africa.
55. We are following up these data with a study of the first 1900 patients. The preliminary data are similarly reassuring regarding side effects.
56. Successful cohort results have also been reported from ARV sites in other South African settings, including Somerset Hospital in Cape Town, Khayelitsha and Lusikisiki.
57. Regardless of the side effects of ARVs, if patients with advanced HIV disease did not take them, they would likely die prematurely of AIDS.

THE RATH ADVERTISEMENTS

58. I have been asked to comment on claims in a number of advertisements.

These advertisements are:

58.1. Mail & Guardian 26 November to 2 December 2004 (**FV8**)

58.2. Sowetan, 28 January 2005 (**FV9**)

58.3. Business Day 18 February 2005 (**FV10**)

58.4. Sowetan 4 March 2005 (**FV11**)

58.5. Sowetan 11 March 2005 (**FV12**)

58.6. Mercury 15 April 2005 (**FV13**)

58.7. Dr Rath Health Foundation newsletter, *You Can!*, dated
September 2005 (**FV14**)

59. I analyse these advertisements below. My conclusions from this analysis
are:

59.1. The advertisements are based on pseudo-science, not science.

59.2. A person with advanced HIV disease who reads these
advertisements, or is influenced by someone who has read them,

and who chooses to follow their advice, will be placed at unnecessary risk of becoming ill or dying.

59.3. The advertisements endanger public health.

60. I do not present here every false, unsubstantiated or misleading claim.

There is much repetition across the advertisements. Materially identical claims are often made using different wording.

61. I have read an ASASA ruling of 9 March (Dr Rath Health Foundation / TAC & Another / 1861) which relates to certain of these advertisements. I understand that a copy is attached to the affidavit of Nathan Geffen.

Claims about micronutrients

62. The advertisements claim *“On 1 July 2004, a landmark study by Harvard University was published in one of the world’s leading medical journals, the New England Journal of Medicine [NEJM], summed up the same day by the world’s most influential and respected newspaper, the New York Times: ‘The study found that daily doses of multivitamins slow down the disease and cut the risk of developing AIDS in half.’ FV8, FV10*

- 62.1. According to the ASASA ruling, the Respondents did not submit to it the New York Times article to which reference is made. In any case the New York Times, while it is a prestigious newspaper, is not a peer-reviewed credible scientific journal. No medical advice should be given on the basis of a New York Times article or any newspaper article for that matter.
- 62.2. The article in the NEJM makes no such claim, and the advertisement misrepresents this research. The NEJM study found that, “Multivitamin supplements delay the progression of HIV disease and provide an effective, low-cost means of delaying the initiation of antiretroviral therapy in HIV-infected women.” (NEJM 2004 Jul 1; 351(1)23-32; p. 23) This is not the same as “daily doses of multivitamins slow down the disease and cut the risk of developing AIDS in half.” There is no evidence that the study cut the risk of developing AIDS. The study showed that multivitamin supplements slightly slowed progression to AIDS.
- 62.3. The scientists who conducted the NEJM study have issued a statement (**FV15**) condemning Rath’s misuse of their study.
63. The advertisements claim *“More than a decade ago, a study co-authored by two-time Nobel Prize winner Linus Pauling, published in another leading scientific journal, found that an optimal dose of vitamin C alone can block*

the replication of HIV by 99%.” FV8, FV10 (and materially identical in FV12)

63.1. This study was conducted *in vitro* only and is therefore not relevant to clinical treatment of individuals infected with HIV. No clinical trials published in any peer reviewed scientific journal substantiate this claim in respect of individuals. The claim is therefore misleading as it is based solely on an *in vitro* study.

64. The advertisements claim *“Every textbook of biochemistry recognises that vitamins and other micronutrients are the most decisive factor determining the optimum function of the immune system.” FV8, FV10, FV12*

64.1. Vitamins and micronutrients are important to the overall functioning of the immune system, but the above statement is misleading as that is not the most salient concern for the vast majority of patients with HIV. HIV specifically targets and destroys a subset of the white blood cells (CD4) responsible for the immunological defence of the body. Although vitamins and micronutrients support the overall immunologic functioning of the body, they do not solve the problem of patients with advanced HIV-disease, whose CD4 cells have been destroyed by the HI virus. The statement is therefore misleading in this context.

65. **FV13** claims *“My scientific discoveries contributed to these advances in science-based natural health. In the fight against HIV/AIDS, the finding that the amino acid lysine in combination with certain other micronutrients can block the spread of viruses through the connective tissue of our body paves the way for the control of this disease by natural means.”*

65.1. Although this claim is unclear, a reasonable interpretation of it, in its context, is that “lysine in combination with other micronutrients” reduces the spread of HIV through the body.

65.2. There is no published controlled trial on humans in any credible peer reviewed scientific journal to substantiate this claim.

66. **FV13** claims “The HIV/AIDS epidemic can be controlled naturally.”

66.1. This statement in the context of the advertisement implies that micronutrients treat or control HIV and/or AIDS. This is false.
There is no scientifically acceptable evidence to support it.

67. In **FV13** the results of a “clinical pilot study” are presented. It appears that the people conducting this study gave micronutrients to patients with HIV. The advertisement makes the following statements:

“Micronutrients Reverse the Course of AIDS!”

“this new scientific approach has now been confirmed in a clinical pilot study conducted by the Rath Foundation.”

They then present results of this clinical pilot study after what they claim is one month. The results show some surrogate markers for HIV-disease progression improving remarkably.

“Evidence from a pilot study that micronutrients alone can dramatically improve clinical conditions and immune function of HIV/AIDS patients, increasing white blood cells, lymphocytes, monocytes, T-cells and CD4 counts.”

This is unethical, misleading and implausible:

- 67.1. The study has not been peer-reviewed or published in an independent credible journal. It has not, to the best of my knowledge, been presented at any scientific conference.
- 67.2. As a reviewer for peer-reviewed journals and abstracts at major conferences, I would not consider this data strong enough to be presented in its current form in any significant scientific forum. The mode of presentation of data, the parameters measured, and interpretation of the statistics are poor.
- 67.3. No credible scientist publishes the results of a clinical pilot study for the first time as a newspaper advertisement. Most credible

journals would not accept a study once it has been published as an advertisement in this form.

- 67.4. I have been informed that the clinical pilot study has not been approved by the Medicines Control Council, and that its design has not been approved by a recognised South African ethics committee.
- 67.5. There appears to be no independent oversight of the study, rendering its results untrustworthy.
- 67.6. The design of this “clinical study” is not indicated. A study of this nature needs a randomized control group before any conclusions can be drawn. It does not appear that this was the case with this study.
- 67.7. The advertisement mentions that this “clinical study” had a four-week duration. Given the complexity of the pathogenesis of HIV in the human body, any clinical study of only four weeks’ duration is inadequate from which to draw any meaningful conclusions.
- 67.8. Only very insubstantial data are presented to support these claims that would never meet the criteria for publication in any peer reviewed scientific journal.

- 67.9. The advertisement does not indicate the authors' definition of "advanced stages of AIDS."
- 67.10. Only anecdotal statements claiming that "the clinical condition of all patients significantly improved" are presented. The authors then proceed to list all the symptoms that improved. They give no details of the patients' conditions prior to commencing the study. This is unscientific.
- 67.11. The authors claim that these clinical improvements were "paralleled by dramatic improvements in the production of the immune system-related white blood cells." However, only sketchy data and rudimentary statistics are presented to substantiate and illustrate these claims. There is also no way of verifying these claims as the raw data is not presented.
- 67.12. The size of the sample of patients was only 15, an extremely small cohort by any scientific standards – especially when making these extraordinary claims.
- 67.13. Conducting trials with unscientifically proven vitamins, amino acids and other micronutrients on individuals with "advanced AIDS" while discouraging them from taking scientifically proven antiretrovirals is unethical and dangerous.

- 67.14. Even in the remote case that the results of the trial were true, the findings could not be accepted as part of medical practice because of the failures mentioned above.
68. In **FV13**, clinical case vignettes are presented. In one, before and after photographs are presented of a wound on a patient's neck. The advertisement alleges that the infected wound began to heal after she started "the nutrient programme" (no details of which are provided), and after one month had almost completely disappeared. In this regard:
- 68.1. Many skin lesions heal spontaneously without medical intervention. There is no evidence here that the lesion improved because of multivitamins.
- 68.2. Neither the veracity of the clinical vignette nor the authenticity of the photographs can be verified, as they form part of a paid advertisement and are not published in a credible scientific or medical journal.
- 68.3. The vignette is misleading because it implies that the patient improved due to the authors' medical intervention. There is no scientific evidence to support this.
69. A second case vignette in **FV13** describes a dramatic improvement in CD4 cell count. The CD4 cell count is a measure of immune response that is particularly important for monitoring HIV disease progression.

- 69.1. As with the above vignette, the anecdote is unverifiable.
- 69.2. Unlike the above vignette, the claim is extraordinary, a 150% improvement in CD4 count in 3 months. For extraordinary claims, extraordinary evidence should be presented. Such evidence should first be presented for peer-review to a credible scientific journal, not published in a newspaper advertisement.
70. In the newsletter **FV14** many of the claims made in **FV13** are repeated, with different wording. For example “... *a combination of vitamins and other micronutrients are food supplements and as Mokaba said before: ‘Our people need food.’ And the nutritional programme conducted by the South African National Civics Organisation (Sanco) in Khayelitsha and Gugulethu has proved that with micronutrients alone – you can reverse the course of AIDS.*” (p. 2) The claims are materially equivalent to those already considered above and are false and misleading. I draw particular attention to the claim that “with micronutrients alone – you can reverse the course of AIDS”. This is false.

Claims about antiretrovirals

71. The advertisements claim:
- “Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system.”*

FV8

“Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death.” FV8, FV10

- 71.1. Hyperbole is used in the statement “AZT is profoundly toxic to all cells of the human body”. It will mislead people who do not have access to or the background to understand the scientific data pertaining to zidovudine (AZT).
- 71.2. While AZT has side effects, some of which can be serious in some individuals, there is no scientific evidence that it is “profoundly toxic to all cells of the human body”.
- 71.3. Presenting the fact that AZT is toxic, without informing readers that scientific studies have found its benefits to outweigh its risks, is misleading.
- 71.4. AZT has been shown in clinical studies to reduce transmission of HIV from mother to child. There is scientific consensus that for such infants exposed to AZT, the benefit of not contracting HIV outweighs the risks that AZT may present to them.
- 71.5. I am unaware of studies that show that AZT is definitely teratogenic in doses used to prevent transmission of HIV from mother-to-child.

72. In **FV8**, **FV12** and **FV14** a picture of an AZT bottle is shown, accompanied by statements denigrating AZT. For example, **FV8** states *“This is a 25mg bottle of AZT supplied by Sigma-Aldrich for use in research laboratories. The label speaks for itself. GlaxoSmithKline recommends between 500 and 1500mg of AZT daily – twenty and sixty times the quantity that Sigma-Aldrich warns research workers could kill or severely injure them – alleging that ‘AZT has extended and improved the quality of life of millions of people living with HIV/AIDS around the globe.’ Also that ‘Glaxo Welcome (now GSK) are a reputable company. We do not lie to people.’”*
- 72.1. The Sigma-Aldrich bottle of AZT shown in the picture is not formulated for oral intake, and is meant solely for experimental work in the laboratory. It is therefore misleading to compare this product with that formulated for oral intake and ingested by thousands of individuals daily worldwide for the treatment of HIV.
- 72.2. AZT is recommended at doses of 600mg or less daily. The doses quoted above are probably from the era of monotherapy in the late 1980s and early 1990s.
73. **FV12** claims *“Pharma-Fraud with HIV/AIDS: The TAC promotes AIDS drugs such as AZT that are extremely toxic and kill people. They damage the immune system, thereby worsening immune deficiency. This is why many people taking AZT get sick with tuberculosis and other infectious diseases.”*

- 73.1. The above statements are false or misleading.
- 73.2. As explained above, the benefits of AZT outweigh its risks. While in rare cases patients on ARVs die as a result of the medicines, many more would die if they did not take ARVs.
- 73.3. Local research has demonstrated that ARV, using regimens that include AZT, reduce the risk of tuberculosis.
- 73.4. ARVs improve immune reconstitution. They do not worsen immune deficiency.
74. **FV8** refers readers to an article called "*Poisoning our Children: AZT and nevirapine in pregnancy*" on the Treatment Information Group website.
- 74.1. That article claims that nevirapine used for mother-to-child transmission prevention in South Africa is poisonous. Referring people to this article in the above manner appears to support the claim of this article. But the claim is false. There has not been a single life-threatening side-effect associated with the use of single-dose nevirapine used for mother-to-child transmission prevention in public health facilities in South Africa.
- 74.2. Tens of thousands of women and infants around the world have used this regimen. There have been no reports of life-threatening events associated with it.

74.3. While nevirapine does have serious side-effects when used as a chronic treatment, this is not the case for mother-to-child transmission prevention.

75. **FV11** claims *“The TAC demands that the South African government buy AIDS drugs that do not cure but actually make people even more sick.”*

75.1. It is true that “AIDS drugs” do not cure HIV/AIDS. Currently, antiretrovirals are a lifelong chronic treatment for HIV/AIDS. Because they do not clarify this point, the Respondents' assertion that they “do not cure” is misleading. To the best of my knowledge, neither TAC nor any reputable scientific body claims that antiretrovirals can currently cure AIDS.

75.2. As I have explained, it is false that AIDS drugs “make people even more sick.”

Claims comparing antiretrovirals to micronutrients

76. The advertisements state *“The [NEJM] study showed that inexpensive multivitamin treatment is more effective in staving off disease among HIV-positive women than any toxic AIDS drugs.”* **FV8, FV10**

76.1. Nowhere in the NEJM article is any reference made to “toxic AIDS drugs.”

- 76.2. The researchers explicitly state “The benefits with respect to immunologic and virology outcomes in our study were small relative to the effects of triple antiretroviral therapy (p. 31).”
- 76.3. The study did not however claim to draw any definitive conclusions in relation to the relative efficacy of various treatments (including ARVs), and the study did not use any drug-treated control group.
- 76.4. On p. 31 the NEJM study states: “Our data suggest that multivitamins delay the onset of disease progression and thus the time to the initiation of antiretroviral therapy. Introducing these supplements would preserve the use of antiretroviral drugs for later stages of the disease, avert adverse events associated with them, and significantly reduce treatment costs.”
- 76.5. The study therefore does not suggest that ARV therapy is to be replaced by multivitamins but merely that their use delays “the onset of disease progression and thus the time to the initiation of antiretroviral therapy.” The study clearly indicates that ARV therapy can be reserved “for later stages of the disease” through the use of daily multivitamins in the earlier stages of the disease.

77. **FV8** states *“Do you want to continue being misled by the pharmaceutical industry and its front organizations to believe that exorbitantly expensive and highly toxic drugs like AZT and nevirapine are the answer to AIDS?”*
- 77.1. The characterisation of AZT as highly toxic is misleading, as I have explained above.
- 77.2. Nevirapine, like AZT, has been shown in numerous trials to be effective, and is accredited for the treatment of HIV/AIDS by both the MCC and the US Food and Drug Administration.
78. **FV13** states *“The goal of the study was to show that vitamins and other micronutrients alone reverse the course of AIDS, even in advanced stages. ... Thus, it was essential that none of the patients had received any ARV drugs before or during this nutritional programme.”*
- 78.1. Vitamins and micronutrients cannot reverse the course of AIDS at all.
- 78.2. As explained above, ARVs are the only specific treatment currently available for HIV.
79. **FV10** claims *“The people of South Africa now have an historic opportunity to liberate themselves from the yoke of HIV/AIDS and many other diseases. The solution to these health epidemics does not come from high-priced and toxic pharmaceutical drugs but from public education about the dramatic*

health benefits of vitamins and other natural therapies.” FV14 claims “As opposed to toxic ARV drugs, these nutrition programmes are safe because they are natural.” (p. 2)

- 79.1. I do not dispute the health benefits of vitamins and some natural therapies. But it is unsubstantiated, misleading and false to claim that vitamins and other natural remedies can “liberate” individuals “from the yoke of HIV/AIDS and many other diseases.”
- 79.2. It is also misleading for reasons already described to characterise ARVs as toxic without clarifying that their benefits outweigh their risks.
- 79.3. I have been informed that the Rath products are sold on the Internet from approximately R180 to R445 for a month's supply. While it is true that ARVs and other patented medicines are high-priced, the standard first-line ARV regimen used in the public sector is purchased by the state at approximately R100 per month. A standard first-line regimen in the South African private sector costs the consumer an amount comparable to the upper end of the Rath products.
80. **FV10** claims “In a series of official recommendations UNICEF, WHO, and other United Nations Organizations have encouraged people and their governments – especially in developing countries such as South Africa – to

help spread knowledge about the health value of vitamins and nutritional medicine. The dissemination of this information will save the lives of millions of people in South Africa, especially in the battle against HIV/AIDS and other infectious diseases caused by immune deficiencies. But we all must fight for this health freedom. Its biggest enemy is the pharmaceutical business with patented drugs – such as ARVs. This industry promotes disease as multi-billion dollar markets for their drugs, and these global markets are threatened by effective, natural, side-effect-free, non-patented therapies.”

- 80.1. This is misleading. WHO, UNICEF and UNAIDS have issued a condemnation of the Rath advertisements and the misuse of their names in his advertisements. The statement is attached (**FV15**).
- 80.2. The Rath Respondents themselves promote a pharmaceutical business, namely their own.
- 80.3. The claim implicit in the above statement that ARVs can be replaced by side-effect free natural treatment is materially identical to those I have already considered, and is false and misleading.

WILLEM DANIEL FRANCOIS VENTER

I CERTIFY THAT THE DEPONENT ACKNOWLEDGED TO ME THAT HE KNOWS AND UNDERSTANDS THE CONTENT OF THIS DECLARATION, AND THAT HE HAS TAKEN PRESCRIBED OATH IN THE PRESCRIBED MANNER. THUS SIGNED AND SWORN TO BEFORE ME AT CAPE TOWN ON THIS ____ DAY OF NOVEMBER 2005.

COMMISSIONER OF OATHS