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

Case No.

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 REPUBLIC OF SOUTH AFRICA	Eighth Respondent
DIRECTOR-GENERAL OF HEALTH	Ninth Respondent
CHAIRPERSON, MEDICINES CONTROL COUNCIL	Tenth Respondent
REGISTRAR OF MEDICINES	Eleventh Respondent
MEMBER OF EXECUTIVE COUNCIL FOR HEALTH WESTERN CAPE	Twelfth Respondent

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FOUNDING AFFIDAVIT

I the undersigned

hereby affirm and state as follows:

1. I am an adult male. I am employed by the Treatment Action Campaign (TAC) at 34 Main Road Muizenberg.

2. My position at the TAC is Co-ordinator of Policy, Research and Communications. I hold an M.Sc. in computer science from the University of Cape Town (UCT).

3. During 2000 and 2001 I was a lecturer in computer science at UCT. In this period I also volunteered for the TAC. This included serving as the organisation's treasurer. From 2002 to the beginning of 2005 I was employed by the TAC as its national manager.

4. I am duly authorized by a resolution of the TAC National Executive Committee (NEC) to make this application and depose to this affidavit on its behalf. A copy of the resolution of the NEC on 4 October 2005 is attached (**NG1**).

5. The facts contained herein are true and correct and are within my personal knowledge unless the context indicates otherwise.

THE PARTIES

6. The First Applicant is the Treatment Action Campaign (TAC). The TAC is a company incorporated in terms of section 21 of the Companies Act. It has legal

capacity to sue and be sued in its own name. Its head office is at 34 Main Road, Muizenberg, Cape Town. I attach a copy of the Constitution of the TAC (**NG2**).

7. The TAC campaigns for the rights and health of people with HIV in South Africa. It brings this application to further its own aims as set out in its Constitution, and on behalf of the many HIV-positive people who cannot do so in their own name through lack of knowledge or lack of access to legal representation, and in the public interest. I submit that it has standing to do so.

8. The Second Applicant is the South African Medical Association (SAMA). SAMA is the representative body for medical doctors in South Africa. It is a company incorporated in terms of section 21 of the Companies Act of South Africa (Act 61 of 1975 as amended). In this regard I refer to the affidavit of Marius Nico Otto which is filed together with this affidavit.

9. The First Respondent is Matthias Willfried Rath ("Rath") an adult male, a foreign national and a pharmaceutical product proprietor of 15th Floor, The Terraces, Bree Street, Cape Town. He apparently has medical qualifications, but is not registered with the Health Professions Council of South Africa.

10. The Second Respondent is the Dr. Rath Health Foundation Africa ("the Foundation") of 15th Floor, The Terraces, Bree Street, Cape Town. This entity is headed by Rath. The First Applicant is not aware of its further particulars.

11. The Third Respondent is Sam Mhlongo an adult male employed as a professor at the Medical University of South Africa (MEDUNSA), care of Dept of Family Medicine, Dr. George Mukhuri Hospital, MEDUNSA, Molotlegi Street, Pretoria 0204. His full names are not known to the First Applicant. He is identified in

advertisements published by the Foundation as a participant in its activities described below.

12. The Fourth Respondent is David Rasnick, an adult male and a foreign national, of 15th Floor The Terraces, Bree Street Cape Town. His full names are not known to the First Applicant. He is identified in advertisements published by the Foundation as a participant in its activities described below.

13. The Fifth Respondent is Alexandra Niedzwiecki, an adult female and a foreign national, employed by the First Respondent, of 15th Floor The Terraces, Bree Steet, Cape Town. Her full names are not known to the First Applicant. She is identified in advertisements published by the Foundation as a participant in its activities and also as a member of a US organisation, Rath Health Foundation USA, headed by the First Respondent.

14. The Sixth Respondent is Anthony Brink, an adult male of 15th Floor The Terraces, Bree Street, Cape Town. He is employed by the Foundation, and heads the Seventh Respondent.

15. The Seventh Respondent is the Treatment Information Group ("TIG") of 15th Floor, The Terraces, Bree Street, Cape Town. TIG is described in advertisements on its website, www.tig.org.za, as being in "a strategic alliance with the Dr. Rath Health Foundation Africa". It has the same address as the Foundation.

16. In this affidavit I refer to the First to Seventh Respondents collectively as "the Rath respondents".

17. The Eighth Respondent is the Government of the Republic of South Africa, represented herein by Dr Mantombazana Edmie Tshabalala-Msimang in her capacity as the Minister of Health in the national government ("the Minister"), care of the State Attorney, 22 Long Street, Cape Town.

18. The Ninth Respondent is the Director-General of the national Department of Health, care of the State Attorney, 22 Long Street, Cape Town. The present holder of that post is Thamsanqa Dennis Mseleku.

19. The Tenth Respondent is the Chairperson of the Medicines Control Council (MCC) care of 226 Vermeulen Street, Hallmark Building, Pretoria. The present holder of that post is Professor Peter Eagles. He is cited for such interest as he may have in this matter. No order is sought against him, save for an order for costs in the event of his opposing this application.

20. The Eleventh Respondent is the Registrar of Medicines 226 Vermeulen Street, Hallmark Building, Pretoria. He or she is cited for such interest as he or she may have in this matter. No order is sought against him or her, save for an order for costs in the event of his or her opposing this application.

21. The Twelfth Respondent is the Member of the Executive Council for Health of the Western Cape Province, care of the State Attorney, 22 Long Street, Cape Town. The present holder of that post is Pierre Uys. He is cited for such interest as he may have in this matter. No order is sought against him, save for an order for costs in the event of his opposing this application.

22. In this affidavit I refer to the Eighth to Twelfth Respondents collectively as "the government authorities".

THE ISSUES

23. The HIV/AIDS pandemic is a major public health crisis in South Africa.

24. AIDS can be effectively treated with medicines which are known generically as antiretrovirals ('ARVs"). These medicines have been registered for this purpose by the regulatory body, the Medicines Control Council. ARVs are not the only means of dealing with HIV, but they are an essential element of any effective treatment programme.

25. The Rath respondents carry on the following activities which are unlawful, and which place at risk the health and lives of people with AIDS:

25.1. They sell and distribute medicines which are not registered;

25.2. They sell products containing scheduled substances;

25.3. They make false and unauthorised statements that their medicines are effective in treating or preventing AIDS;

25.4. They conduct unauthorised and unethical clinical trials on people with AIDS;

25.5. They make false statements that ARVs are ineffective in treating AIDS, and are poisonous. They discourage people with AIDS from

taking medicines which are an essential element of an effective treatment programme.

26. The Rath respondents have acted contrary to statutes enacted to protect members of the public, including the members of the TAC and those whose interests the TAC seeks to promote. They have also violated the constitutional and common law rights of HIV-positive people, including their right to have their dignity respected and protected; their right to life; their right to bodily and psychological integrity; their right to make decisions concerning reproduction; their right to security in and control over their body; their right not to be subjected to medical or scientific experiments without their informed consent; their right of access to health care including reproductive health; and their right not to be subjected to medical treatment without informed consent.

27. The government authorities are under a duty to take reasonable and effective steps to stop the unlawful activities of the Rath respondents, and to respect, protect, promote and fulfil the constitutional rights to which I have referred. They have failed to take such steps.

28. The TAC has on a number of occasions given the government authorities evidence of the unlawful activities of the Rath respondents, and attempted to persuade them to take action to stop these activities. The TAC has through its attorneys written to the government authorities requiring them to take steps in this regard. The government authorities have failed either to take such steps or to state that they will do so. Generally, they have failed to reply to the letters at all.

THE WORK OF THE FIRST APPLICANT

29. In the words of the Constitutional Court in the case of Minister of Health and others v Treatment Action Campaign and others 2002 (5) SA 721:

"The HIV/AIDS pandemic in South Africa has been described as 'an incomprehensible calamity' and 'the most important challenge facing South Africa since the birth of our new democracy' and government's fight against 'this scourge' as 'a top priority'. It 'has claimed millions of lives, inflicting pain and grief, causing fear and uncertainty, and threatening the economy'. These are not the words of alarmists but are taken from a Department of Health publication in 2000 and a ministerial foreword to an earlier departmental publication."

30. In this environment, the principal objectives of the TAC as described in section 4 of its Constitution are to:

"4.1 Campaign for equitable access to affordable treatment for all people with HIV/AIDS;

4.2 Campaign for and support the prevention and elimination of all new HIV infections;

4.3 Promote and sponsor legislation to ensure equal access to social services for and equal treatment of all people with HIV/AIDS;

4.4 Challenge by means of litigation, lobbying, advocacy and all forms of legitimate social mobilisation, any barrier or obstacle, including unfair discrimination, that limits access to treatment for HIV/AIDS in the private;

4.5 Educate, promote and develop an understanding and commitment within all communities of developments in HIV/AIDS treatment;

4.6 Campaign for access to affordable and quality health care for all people in South Africa;

4.7 Train and develop a representative and effective leadership of people living with HIV/AIDS on the basis of equality and non-discrimination irrespective of race, gender, sexual orientation, disability, religion, sex, socio-economic status, nationality, marital status or any other ground;

4.8 Campaign for an effective regional and global network comprising of organisations with similar aims and objectives."

31. In addition to its national office in Cape Town, the TAC has provincial offices in the Western Cape, Gauteng, Eastern Cape, KwaZulu-Natal, Limpopo and Mpumalanga. The TAC also has district offices in Lusikisiki, Pietermaritzburg, Khayelitsha, Johannesburg and Queenstown.

32. There are more than 250 TAC branches across the country, including in the poorest communities in the Eastern Cape (such as Lusikisiki) and at institutions such as the University of Cape Town. Most of our volunteers and staff live in the communities in which they work. In Khayelitsha in the Western Cape, the TAC has more than 1,500 active members at community level in several branches. Our database lists approximately 12,000 members.

33. A number of organisations and individuals in South Africa are associated with the TAC. They include the Congress of South African Trade Unions (COSATU), the Federation of Unions of South Africa (FEDUSA), the Southern African Catholic Bishops Conference (SACBC), the South African Council of Churches (SACC), Habonim Dror, Positive Muslims, the Children's Rights Centre, Médecins Sans

Frontières (MSF), the AIDS Consortium, and a range of other organisations of people with HIV/AIDS and individuals with HIV/AIDS.

34. Internationally, the TAC is associated with the Pan African Treatment Access Movement (PATAM), itself a coalition of various HIV/AIDS treatment access organisations and individuals across Africa. It is also associated with the International Treatment Preparedness Coalition.

35. The TAC interacts regularly with the Joint United Nations Programme on HIV/AIDS ("UNAIDS"), the World Health Organisation ("WHO"), and the Global Fund to Fight AIDS, TB and Malaria ("GFATM") on HIV/AIDS treatment strategy and policy. The TAC's chairperson, Zackie Achmat, was appointed to the World Health Organization's HIV Strategic and Technical Committee in November 2004. The World Health Organisation is the world's leading authority on public health matters.

36. The TAC has consistently campaigned for access to affordable and quality treatment for all people with HIV/AIDS in South Africa. In this work the TAC has challenged both government and the private sector, including pharmaceutical corporations, to take action to make information about treatment more widely available, and to increase the availability and affordability of treatment.

37. The TAC has also initiated a Treatment Project which has raised funds to provide treatment for TAC members, and others, with advanced HIV-disease.

38. TAC and its chairperson, Zackie Achmat, have received a number of awards and commendations from prestigious organisations for their work. These include:

38.1. Katlego Award for Excellence in Advocacy, third prize (1999)

38.2. The first Desmond Tutu Leadership Award (2002)

38.3. Nelson Mandela Health and Human Rights Award (2003)

38.4. Jonathan Mann Award for Global Health and Human Rights (2003)

38.5. Silver Rose Award for Social Justice (2003)

39. In addition the American Friends Service Committee (better known as the Quakers) nominated the organisation and its chairperson, Zackie Achmat, for the 2004 Nobel Peace Prize.

HIV, AIDS, AND THE EPIDEMIC IN SOUTH AFRICA

40. I attach marked **NG3** an affidavit by Professor Robert Dorrington of the Centre for Actuarial Research at the University of Cape Town. It states the following:

40.1. There are between 4.5 and over 6 million people in South Africa living with HIV, the virus that causes AIDS.

40.2. The Actuarial Society of South Africa estimates that over half a million of the people in South Africa with HIV have AIDS.

40.3. Mortality due to the HIV/AIDS epidemic has risen dramatically. A report released earlier this year by Statistics South Africa showed a 57% increase in mortality between 1997 and 2002. This study was based on a full count of all available death certificates. There is scientific consensus that the increase in mortality in South Africa is due to the HIV epidemic.

40.4. The Actuarial Society of South Africa estimates that over 300,000 South Africans died of AIDS last year. It estimates that an even greater number will die of AIDS this year and in years to come.

41. On 19 November 2003 the Department of Health released a Cabinet-approved Operational Plan for Comprehensive HIV and AIDS Care Management and Treatment for South Africa on 19 November 2003 ("the Operational Plan"). The Operational Plan includes, among other important interventions, the provision of nutritional support for people with HIV, and antiretroviral treatment for people with HIV whose disease has progressed to AIDS.

42. The TAC's view is that the Operational Plan, although flawed, is a critical plan necessary for reducing mortality and morbidity due to the HIV epidemic. We support its implementation through various activities including campaigns to bring down medicine prices, public information campaigns on nutrition, prevention and treatment with respect to HIV, and a community education programme that operates in six provinces.

43. I attach marked **NG4** an affidavit by Dr. Francois Venter, who is an expert on the science of HIV/AIDS. He is a specialist physician who is the Clinical Director of the Reproductive Health and HIV Research Unit at the University of the

Witwatersrand. He is the President of the Southern African HIV Clinicians Society. He is also a senior consultant in the Johannesburg Hospital antiretroviral clinic and the Hillbrow HIV clinic. He has supervised and evaluated the treatment of thousands of patients with HIV/AIDS. He has researched and co-authored more than twenty peer-reviewed articles on HIV/AIDS.

44. Dr Venter explains:

44.1. There is consensus among all generally recognised scientific institutions dealing with the HIV epidemic that ARV treatment is the only current specific treatment for HIV, and the only current health intervention that reverses the course of AIDS. It is a lifelong treatment.

44.2. There is scientific consensus that malnutrition and undernutrition adversely impact on the health of people with HIV/AIDS.

44.3. There is no scientific 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.

45. Dr Venter's affidavit also explains the following:

45.1. 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.

45.2. Currently ARVs are the only medicines that specifically treat HIV and reverse the course of AIDS.

45.3. ARVs, when appropriately prescribed and used, reduce morbidity and mortality in the vast majority of patients.

45.4. There is scientific consensus that antiretroviral treatment can have side-effects. These are described in Dr Venter's affidavit. In some cases these side-effects are fatal. However, the vast majority of patients who take ARVs benefit from them. Without taking them, they would in all likelihood die prematurely of AIDS.

45.5. There is scientific consensus that the benefits of ARVs, when used as a chronic lifelong treatment for people with advanced HIV-disease, far outweigh the risks associated with ARVs.

45.6. There is scientific consensus that ARVs, including zidovudine (AZT) and nevirapine, are effective in reducing the risk of transmission of HIV from pregnant women to their unborn babies.

45.7. ARVs, including AZT, are recommended in government policy for post-exposure prophylaxis following occupational exposure and sexual assault.

45.8. It is official South African government policy to provide ARVs through the public health system for the treatment of HIV and the reduction of mother-to-child transmission prevention. AZT and nevirapine are both part of this programme. The mother-to-child transmission prevention

programme is being implemented following an order of the Constitutional Court.

45.9. According to government 61,000 people are being treated with ARVs in the public health sector. (I am aware, from a statement by the Ministry of Health on 25 October 2005, that this has increased to 78,000 people initiated on ARVs as of the end of August 2005.)

45.10. According to government over 1,500 public health facilities provide ARVs to prevent mother-to-child transmission of HIV.

45.11. A number of ARVs, including AZT, nevirapine, lamivudine, efavirenz, stavudine, didanosine, saquinavir, lopinavir, ritonavir, nelfinavir, abacavir, indinavir and others, are registered with the MCC for the treatment of HIV.

45.12. Registration of a medicine for a specific purpose with the MCC means that the medicine is considered sufficiently safe and effective for this purpose by South Africa's regulatory body charged with the responsibility of determining such matters.

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

45.14. It is government policy to distribute multivitamin supplements to people with HIV through public sector health facilities.

45.15. The MCC has not registered any micronutrients for the treatment of HIV, and neither to the best of Venter's knowledge has any other regulatory authority done so.

THE MEDICINES ACT

46. The main statutory instrument for the regulation of medicines in South Africa is the Medicines and Related Substances Act 101 of 1965 (“the Medicines Act”).

47. Section 1 of the Medicines Act defines “medicine” as

any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine;

48. Section 1 of the Medicines Act defines “sell” as

sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings.

49. Section 14 of the Medicines Act deals with the registration of medicines. It provides as follows:

(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.

(2) (a) The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.

(b) Any such resolution may also relate only to medicines which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.

(c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.

50. Section 20(1) of the Medicines Act provides that no person shall-

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine; or

(b) in any advertisement make any claim to the effect that the

therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of subparagraph (ii) of paragraph (a) of section twenty-two or state or suggest that any medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of subparagraph (iii) or paragraph (a) of that section.

SELLING MEDICINES IN BREACH OF THE MEDICINES ACT

51. I annex affidavits by the following persons:

51.1. Nandipha “Nancy” Ntsholo (**NG5**),

51.2. Zukile Ngqase (**NG6**),

51.3. Thembeka Ngubo (**NG7**),

51.4. Xolisa Velem (**NG8**),

51.5. Xolisa Cyntheria Mqambeli (**NG9**),

51.6. Nandipha Violet Sigebenga (**NG10**),

51.7. Zondani Magwebu (**NG11**) together with an affidavit by Noluthando Ntlokwana (**NG12**) stating that Magwebu, who does not read or write English, understood the affidavit and took the oath in the prescribed manner,

51.8. Dr. Peter Saranchuk (**NG13**).

52. These affidavits record that the deponents or their patients or family members visited health facilities run by the first and second respondents. At these health facilities they were given medicines. Photographs of the packaging of these medicines appear in the affidavits of Ntsholo, Ngqase and Mqambeli.

53. In March 2005, Ngqase and Ntsholo handed to me the medicines they had so obtained. These were:

53.1. a bottle, branded as “Dr Rath’s” Vitacor Plus,

53.2. a bottle, branded as “Dr Rath’s“ Epican Forte,

53.3. a bottle, branded as “Dr Rath’s” Lysin C Drink Mix,

53.4. a bottle of VitaCell. The bottle bears a photograph of the first respondent.

54. These products are all medicines by virtue of:

54.1. their contents;

54.2. the claims which are made by the second respondent and other Rath respondents, which are set out in the affidavits of the people referred to in the previous paragraph; and

54.3. the advertisements which are published by various Rath respondents, which I set out below.

55. None of these products is registered with the Medicines Control Council.

56. The first three products were placed in police-sealed bags at a police station. On 3 May 2005 I handed them to Lionel Snyman, a law enforcement investigator of the Department of Health.

57. Ms Mqambeli handed over her bottle of VitaCell to volunteers of the TAC who are assisting in this matter. I sent the bottle by courier to Andrew Gray of the University of KwaZulu-Natal, and asked him for his expert opinion on it.

58. At some point the branding of bottles of VitaCell changed. For example, the previous branding of VitaCell contains a photo of Rath while the new branding contains the logo of the Rath Health Foundation Africa. On the newer bottles, the new label is pasted over the older label. I also obtained and sent a bottle with the new branding to Andrew Gray.

59. I annex (**NG14)** an affidavit by Andrew Gray, who is a senior lecturer in the Department of Therapeutics and Medicines Management at the Nelson R Mandela School of Medicine at the University of KwaZulu-Natal. He states:

59.1. The categories of medicine are set out in Government Notice R2025 of 15 December 1967. “Vitamins” constitute category 22. Sub-category 22.1 is “multivitamins and multivitamins with minerals”.

59.2. All categories of medicine have been "called up" for registration under section 14 of the Medicines Act by resolutions of the MCC. It follows that in terms of sec 14(1) of the Medicines Act, no medicine may be sold unless it is registered, except in those cases where the "call-up" notice limits the registration requirements.

59.3. The "call-up" notice in respect of oral preparations which contain a vitamin or multivitamin is contained in Government Notice 559 of 15 March 1985. A copy of that notice is attached to the affidavit of Gray marked "**ALG1**". The essence of it is that oral preparations shall be subject to registration as a medicine if they

(1) contain a vitamin or vitamins [including food supplements which contain a vitamin or vitamins, but excluding foodstuffs as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), which contain a vitamin or vitamins] either as such or in combination with any other pharmacologically active ingredient or ingredients (including trace elements), whether medicinal claims are made or not; and

(2) contain or exceed per recommended total daily dose any of the respective doses stated in this notice or, in the absence of a dosage schedule, contain or exceed per oral dosage unit of any particular dosage form any of the respective doses stated in this notice;

59.4. Gray has prepared a detailed analysis in which he has compared the recommended daily dosages of the Rath products which I have listed above, with the dosages which in terms of Government Notice 559 trigger the registration requirement. As appears from that analysis, all four of these products are liable to registration, whether the "recommended daily dosage" is taken as that published on the labels and the Rath internet advertisement, or that actually recommended to the persons who were given these products at the health facilities run by the first and second respondents.

59.5. On the basis of the affidavit of Ntsholo and the advertisements published by the Rath respondents, medicinal claims are made for these products.

59.6. According to the definition of "sell" in the Medicines Act, the first and second respondents are selling these products. In this context, selling does not necessarily imply receiving remuneration in exchange for the product.

59.7. On the basis of the affidavits of Ntsholo, Ngqase, Ngubo, Velem, Mqambeli and Magwebu, the amount of vitamin C prescribed by the first and second respondents is high enough to cause diarrhoea and kidney stones.

59.8. An advertisement for Epican Forte from the internet (attached marked **NG15** and available online at http://store-dr-rath-vitamins.com) states that Epican Forte contains N-acetylcysteine.

59.9. According to its packaging, VitaCell also contains N-acetylcysteine.

59.10. N-acetylcysteine is a schedule 2 substance in terms of the Medicines Act. It can therefore only be only be sold by a pharmacist or other person listed in sec 22A(5) of the Medicines Act, and under the conditions listed in sec 22A(6) of the Medicines Act.

59.11. It appears from the affidavits to which Gray refers, that Vitacell and Epican Forte are being sold by the Rath respondents under circumstances which constitute multiple breaches of sec 22A of the Medicines Act.

59.12. None of the aforementioned products is registered with the MCC for the purpose of treating HIV or at all.

60. The Rath respondents have at times claimed they are distributing foodstuffs, not medicines. For example in their publication *Silondoloze You can! Unako!* (**NG16**), they state “[T]his vitamin programme is a food supplement and not a medication.” (p. 8)

61. However, the advertisements claim that micronutrients reverse the course of AIDS, and provide alleged results of a clinical trial using these products. And in the above-mentioned affidavits, the patients state that they were led to believe they were receiving medicines. I have been advised that under such circumstances, it is not legally possible to avoid the requirements of the Medicines Act by asserting that the product in question is a foodstuff.

62. I accordingly submit that the first and second respondents have violated the Medicines Act by selling unregistered medicines that are subject to registration, and by selling medicines in breach of sec 22A(5) and (6) of the Medicines Act..

PUBLICATION AND DISTRIBUTION OF FALSE ADVERTISEMENTS CONCERNING MEDICINES

63. The Rath respondents have placed advertisements in newspapers and distributed advertisements as pamphlets and posters throughout the country. I deal below with the content of these advertisements.

64. The advertisements are in breach of the Medicines Act, in that in breach of sec 20(1)(a) of the Act, they make false claims about the treatment of AIDS using multivitamins and micronutrients. These claims, besides being false as a matter of fact, are in any event illegal because multivitamins and micronutrients are not registered with the MCC for that purpose.

65. The advertisements also claim that ARVs (and particularly zidovudine (AZT) and nevirapine) are not a treatment for AIDS and make people with AIDS sicker, even though ARVs are registered by the MCC for the purpose of treating HIV.

66. Typical of the advertisements is one which Rath, the Foundation, Brink and TIG published in the *Mail & Guardian* of 26 November to 2 December 2004 (**NG17)**.

67. The logos of the Dr Rath Health Foundation Africa and TIG appear at the foot of the advertisement. In essence, the advertisement claims that multivitamins and

micronutrients are an appropriate treatment for HIV/AIDS, and that antiretrovirals are not an appropriate treatment for HIV/AIDS, and do more harm than good.

68. The TAC and a member of the public, one George Stacey, both lodged complaints with the Advertising Standards Authority of South Africa (ASASA) about this advertisement. Both complainants asserted that the advertisement contained unsubstantiated claims.

69. ASASA ruled in favour of the complainants on 9 March 2005. ASASA ruled that the Dr Rath Health Foundation Africa did not substantiate the claim that multivitamins and micronutrients were a treatment for HIV/AIDS, or the claim that antiretrovirals were not an appropriate treatment for HIV/AIDS. ASASA accordingly ordered the withdrawal of the advertisement. The ASASA ruling is attached (**NG18**).

70. I have previously referred to the affidavit of Dr Venter (**NG4**). In that affidavit he has assessed various advertisements published by various Rath respondents. In order to avoid unnecessarily burdening the papers, I do not repeat here the details of his analysis. The advertisements analysed by Dr Venter, and attached to his affidavit, were published in the following newspapers:

70.1. The Mail & Guardian of 26 November 2005.

70.2. The *Sowetan* of 28 January 2005. It contains a photograph of Matthias Rath and directs readers to the websites of the Dr Rath Health Foundation Africa and the TIG.

70.3. *Business Day* of 18 February 2005

70.4. The *Sowetan* of 4 March 2005

70.5. The *Sowetan* of 11 March 2005.

70.6. The *Mercury* of 15 April 2005

70.7. A newsletter of the Dr Rath Health Foundation dated September 2005 and titled *You Can!*.

71. Dr Venter divides the claims in the advertisements into three categories: claims about multivitamins, claims about antiretrovirals, and claims comparing multivitamins to antiretrovirals. He concludes that the advertisements make false and/or misleading claims in each of these categories. These include (but are not limited to) the following:

71.1. “Micronutrients Reverse the Course of AIDS!”

71.2. “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.”

71.3. “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.”

71.4. “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.”

71.5. “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.”

71.6. “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.”

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

71.8. “The ... study showed that inexpensive multivitamin treatment is more effective in staving off disease among HIV-positive women than any toxic AIDS drugs.”

71.9. “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?”

72. Venter also states that:

72.1. Harvard University researchers published an article in the New England Journal of Medicine on a trial using multivitamin supplements. They concluded *"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."*

72.2. The results of the trial, while positive, demonstrated that the effect of multivitamins used in the trial on HIV progression was to slow it down marginally in women.

72.3. The best that can currently be said about multivitamin supplements is that a particular combination in a particular dose delays the time when ARV treatment becomes necessary. Their effect on mortality and morbidity relative to antiretroviral treatment is small.

72.4. There is no evidence that vitamins or micronutrients reverse the course of AIDS. The available evidence shows only that they delay the onset of AIDS.

72.5. This is in contrast to ARVs, which have been shown through numerous clinical trials and cohort studies, published in credible peer-reviewed scientific journals, to reverse the course of AIDS.

72.6. The medicines sold by the first and second respondents are not the same micronutrient combination used in this trial, nor are they prescribed in the same dose.

72.7. There is currently no published scientific literature to support the use of the multivitamin and micronutrient regimen prescribed by the Rath respondents, nor for the high doses that they prescribe.

73. The advertisement in the *Sowetan* of 11 March 2005 followed the ASASA ruling of 9 March. It was clearly placed with knowledge of the ASASA ruling because it specifically refers to this ruling, stating "The ASA[SA] ruling is not in the interest of the people of South Africa, but is solely in the interests of the drug cartel."

74. TAC complained to ASASA about this and an advertisement in the *City Vision* of 17 March 2005, on the basis that they breached ASASA's ruling. On 12 May 2005 ASASA upheld this complaint, ruling that the advertisements were in breach of its 9 March ruling. The ASASA ruling is attached (**NG19**).

75. I also attach (**NG20)** an ASASA sanctions ruling of 24 August 2005 against the Dr Rath Health Foundation Africa. This ruling ordered that an adverse publicity statement "must appear once in each South African publication in which the respondent has, to the knowledge of the Committee, placed an advertisement in breach of the original ruling, being The Sowetan, The City Vision and The Mercury."

76. All of the Second Respondent's correspondence with ASASA in relation to these advertisements which I have seen, was written in the name of Anthony Brink.

77. The Dr Rath Health Foundation has published an advertisement in Business Day (**NG21**) which contains a photograph of Matthias Rath, describing himself as a "world renowned scientist". It also states that "Dr Alexandra Niedwiecki, a world-renowned biologist now heads the Dr. Rath Research Institute." Neither Matthias

Rath nor Alexandra Niedwiecki is world-renowned for their scientific endeavours, but I include this advertisement to demonstrate that they are both associated personally with this advertising campaign.

78. Various Rath agents have distributed numerous other publications which are either identical or similar to the advertisements to which I have referred. I list a few:

78.1. A pamphlet (**NG22**) that is in many respects materially identical to the advertisement that appeared in the Mercury. It was distributed in the Western Cape.

78.2. An advertisement published in the New York Times (**NG23**), and also in the International Herald Tribune, a newspaper distributed widely around the world, and in The Namibian.

78.3. A pamphlet distributed in the Western Cape which is a replica of the New York Times advertisement, stating on the side-margin that it appeared in the New York Times.

78.4. A Xhosa version of the above pamphlet (**NG24**).

78.5. A pamphlet materially identical to the 4 March Sowetan advertisement (**NG25**).

78.6. A materially identical large black and red poster version of the above pamphlet, widely distributed throughout the Cape Town area. This poster is too large to attach.

78.7. A Xhosa version of the above pamphlet (**NG26**).

78.8. A pamphlet distributed at Freedom Day 2005 celebrations in Cape Town, containing the contents of the Mercury advertisement pertaining to the "clinical pilot study in HIV-positive patients" (**NG27**).

79. The Dr Rath Health Foundation Africa's South African website, www.dr-rath-foundation.org.za, contains the following advertisements (all downloaded on 30 September 2005):

79.1. "Stop AIDS Genocide by the Drug Cartel" (**NG28**), containing much content that is materially identical to the Mercury advertisement.

79.2. "The End of the AIDS Epidemic is in sight" (**NG29**), which states "Thus, with micronutrients alone, the AIDS patients could reverse the symptoms of AIDS and lead almost normal lives again."

79.3. "Why should South Africans continue to be poisoned with AZT?" (**NG30**), materially identical to the Mail & Guardian advertisement.

79.4. "No Censorship of Life-Saving Natural Health Information!" (**NG31**), containing materially very similar to the Sowetan advertisement of 11 March 2005.

80. The front page of the Foundation's website (an extract of which is attached marked **NG32**) gives details of a press conference held on 15 June 2005. It contains a photograph purporting to show patients on a trial run by the Rath respondents.

81. The front page of the TIG website, www.tig.org.za (**NG33**) is itself an advertisement. I accessed this on 5 October 2005.

82. I attended a public meeting convened by Rath in Athlone in November 2004. Both he and Brink delivered speeches. Rath claimed that micronutrients treat AIDS. Brink claimed that ARVs are toxic.

83. Meetings organised by the first and second respondents continue to be held on a regular basis in many cities. Their paid agents, who include members of the South African National Civics Organisation, assist with these events and try to persuade people with HIV to take vitamins instead of ARVs.

84. I submit that the above evidence demonstrates that the Rath respondents have consistently breached sections 14 and 20 of the Medicines Act.

85. These repeated false claims and misrepresentation are part of a pattern of conduct by Matthias Rath and his agencies.

86. A number of rulings, findings, statements, investigations and warnings have been issued about or against him or institutions for which he is responsible. These have emanated from regulatory authorities, as well as from recognised medical experts and religious organisations. For example:

86.1. On 8 March 2000 the British Advertising Standards Authority ruled that Rath had to desist from advertising what he refers to as 'treatment', as the advertisements and claims made therein were unsupported by evidence and therefore deliberately misled the public. A copy of the ruling is attached (**NG34**). It is available online at

http://www.asa.org.uk/asa/adjudications/Adjudication+Details.htm?adjudication_id=30238. Rath applied to the High Court (Queen's Bench Division), under case number CO/4041/2000, for judicial permission to review the decision to the ASA to publish its adjudication, and for an interdict restraining the publication pending the review. The application was dismissed.

86.2. On 28 August 2002, the Food and Drug Administration of the United States cautioned Rath for advertising some of his vitamin and so-called treatment products in contravention of US law. A copy of the caution is attached (**NG35**). It is available online at http://www.fda.gov/cder/warn/cyber/2002/CFSANvitacor.htm.

86.3. The Swiss Study Group for Complementary and Alternative Methods in Cancer found, contrary to his claims, no proof that any of Rath's products have any impact upon human cancer. A copy of this finding is attached (**NG36**). It is available online at http://www.swisscancer.ch/dt_fr/content/orange/pdf/skak/04_rath_e.pdf.

86.4. A British Medical Journal article dated 17 October 1998 examined the claims made by Rath about one of his products and found no evidence to support them. A copy is attached (**NG37**). It is available online at http://bmj.bmjjournals.com/cgi/content/full/317/7165/1069.

86.5. On 2 March 2005 the South African Medical Association (SAMA) condemned Rath's activities. A copy of its statement is attached (**NG38**).

86.6. The Southern African HIV Clinicians Society (SAHCS) has also condemned Rath's activities, as appears from its statement **NG39**.

86.7. On 23 March 2005 the Western Cape Provincial Government issued a statement condemning the claims of people that effectively undermine the implementation of the HIV/AIDS Operational Plan. Given the circumstances under which it was issued, I believe that the statement was directed at the activities of Rath, although it is somewhat obscure in that it does not mention him by name. If I am incorrect in this regard, the twelfth respondent will no doubt explain at whose activities the statement was directed. A copy is attached (**NG40**).

86.8. On 30 March 2005 UNAIDS, WHO and UNICEF condemned Rath's misrepresentations. A copy of their statement is attached (**NG41**).

86.9. On 18 April 2005 the South African Council of Churches condemned Rath's activities. A copy of their statement is attached (**NG42**). It is available online at http://www.sacc.org.za/news05/rathads.html.

86.10. The Harvard School of Public Health Researchers, whom Rath has incorrectly cited in his advertisements, have issued a statement (**NG43**) explaining that Rath has misrepresented them in his advertisements. It is available online at http://www.hsph.harvard.edu/press/releases/press05062005.html.

86.11. In October 2003 a German lower court ordered Rath to stop his advertising campaign. Rath was fined 45,000 Euros. Rath had

claimed he was selling food supplements and not medicines, but the court found that he was presenting his products as medicines. A copy of the judgment, with a sworn translation, is annexed (**NG44**).

86.12. In December 2003 the Berlin High Court found that Rath had no basis for claiming he was a “renowned scientist” or a “renowned doctor”. He was fined 28,000 Euros. A copy of the judgment, with a sworn translation, is annexed (**NG45**).

87. I do not know whether there are other instances in which Rath and his institutions have been found to have made false or unsubstantiated claims. I invite him to disclose whether there are any other such instances.

UNAUTHORISED CLINICAL TRIALS

88. I attach (**NG46**) an extract from the General Regulations made under the Medicines Act. As these regulations are lengthy, I do not attach a copy of the full regulations. I shall make a copy available to any respondent who requests same. I shall have a copy available at the court at the hearing of this matter.

89. Regulation 34(1) states that any person desiring to initiate or conduct a clinical trial in respect of an unregistered medicine, a new indication or a new dosage regimen of a registered medicine or substance must apply to the MCC for authority to conduct the trial.

90. Regulation 1 defines a clinical trial as

"an investigation in respect of a medicine for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy"

91. Regulations 34(2) and 34(3) set out detailed information which must be provided to the MCC in respect of a proposed clinical trial.

92. Regulation 34 (5) states that no person may conduct a clinical trial referred to in regulation 34(1) without the authorisation of the MCC.

93. Various Rath respondents have been conducting clinical trials for humans in South Africa without authority from the MCC. They admit to this in numerous advertisements. I give some examples below.

94. The Mercury advertisement (attached to **NG4** as **FV13**) states

"We conducted a clinical pilot study in HIV-positive patients with advanced AIDS. The goal of the study was to show that vitamins and other micronutrients alone reverse the course of AIDS, even in its advanced stage. ... Thus, it was essential that none of the patients had received any ARV [antiretroviral] drugs before or during this nutritional programme. The nutrient programme consisted of vitamins, minerals, amino acids and certain other essential nutrients. Blood tests and clinical evaluations were performed at the start and after four weeks on the nutrient programme. The results of this pilot study were so profound after only one month that

we decided to publish the data of the first 15 patients without delay. After the completion of the study a comprehensive report will follow."

95. The advertisement also includes alleged before and after information of 15 patients in the clinical pilot study, including graphs of total t-cells, CD4 counts, CD8 counts, red blood cells, white blood cells, neutrophils, lymphocytes and monocytes.

96. It further states that the "scientific responsibility of these results [the clinical pilot study] is shared by Alexandra Niedzwieki, Ph.D. (Dr. Rath Health Foundation, USA), David Rasnick, Ph.D. (Dr. Rath Health Foundation, South Africa), Sam Mhlongo, M.D. (Medical University of Southern Africa, South Africa) and Matthias Rath, M.D."

97. These trials are widely advertised by the Rath respondents, as appears below.

98. The New York Times advertisement (**NG23**) states "In Khayelitsha, a township of Cape Town, South Africa, we conducted a clinical pilot study in HIV-positive patients with advanced AIDS who had never taken any ARV drugs. The goal of the study was to show that a combination of micronutrients can reverse the course of AIDS, even in its advanced stage." Similar graphs are shown to those published in the Mercury.

99. The Freedom Day pamphlet (**NG27**) states "We conducted a clinical pilot study in HIV-positive patients with advanced AIDS. The goal of the study was to show that vitamins and other micronutrients *alone* reverse the course of AIDS, even in its advanced stage. Thus it was essential that none of the patients had received any ARV drugs before or during this nutritional programme. ... The nutrient programme

consisted of vitamins, minerals, amino acids and certain other essential nutrients. Blood tests and clinical evaluations were performed at the start and after 4 weeks on the nutrient programme. The results of this pilot study were so profound after only one month that we decided to publish the data of the first 15 patients without delay."

100. On the Foundation's website: http://www.dr-rathfoundation.org.za/open_letters/open_letter_2005_05_06.htm, the Foundation has published an open letter which states:
"In Khayelitsha, a township of Cape Town, South Africa, we conducted a clinical pilot study in HIV-positive patients with advanced AIDS who had never taken any ARV drugs. The goal of the study was to show that a combination of micronutrients can reverse the course of AIDS, even in its advanced stage."

101. In most of these advertisements, the following text, or similar text, appears:
"The scientific responsibility of these results is shared by Alexandra Niedzwiecki, (Ph.D.) (Dr Rath Research Institute, USA), David Rasnick, Ph.D. (Dr. Rath Health Foundation Africa), Sam Mhlongo, M.D. (Medical University of Southern Africa, South Africa) and Matthias Rath, M.D."

102. Matthias Rath has admitted in interviews that he has conducted a clinical trial without MCC authorisation.

103. I attach (**NG47**) a Snellers transcription of an interview conducted between Radio 786 and Matthias Rath, which according to Rath's South African website took place on 19 April 2005.

104. At page 21, lines 16-19 of the transcript, Rath states “All we are doing is, we are helping people in the townships by distributing vitamins and we have been doing blood tests how the white blood cells are before they take the vitamins and then how they are after that.”

105. I attach (**NG48**) a Snellers transcription of an interview conducted between P4 Radio and Matthias Rath, which according to Rath's South African website took place on 27 April 2005.

106. On page 3, at lines 9-13 Rath states “And we have just completed a clinical pilot study with the nutritional programme, so we were not treating patients but we were giving them nutrients, micro-nutrients, vitamins and other essential nutrients. And we have showed results both in the blood defence cells' level, that is the white blood cells, lymphocyte, CD4 cells.”

107. I attach (**NG49**) an interview with Matthias Rath that appeared in Die Burger. In this interview, Rath is quoted as saying “Ons het mense met vigs genooi en aan hulle gese hulle sal 'n vraelys moet invul. ... Ons het hulle ook ingelig dat hul bloed voor en na die tyd getrek sal word om te sien hoe goed dit werk. En ons het foto's van hulle geneem om die studie te dokumenteer.”

108. The interviewer asks Rath “het die Medisynebeheerraad sy goedkeuring vir die studie gegee?” To this Rath is quoted as answering, “Nee, die raad beheer medisyne. Dit is nie medisyne nie.”

109. The first and second respondents operate health facilities in the Western Cape (“the Rath clinics”). One of these is in Khayelitsha. A photograph of this clinic is attached to the affidavit of Mqambeli (**NG9**).

110. According to the affidavits of Ntsholo, Mqambeli, Saranchuk, Magwebu and Sigebenga, the employees and agents of the Rath clinics purport to provide treatment for HIV. The affidavits of the deponents who visited the Rath clinics show that they perceived themselves to be in a context of receiving medicines from a medical service provider.

111. According to the affidavits of Ntsholo, Ngqase, Ngubo, and Velem, patients are subjected to medical examination, including blood-tests, which are conducted without proper informed consent from the patients.

112. According to the affidavit of Ntsholo, she attended the Rath clinic, received medicines and was subjected to a blood test. Photographs were taken of her while she was semi-naked. The affidavit of Ngqase confirms Ntsholo's affidavit and attests that the same occurred to him.

113. According to the affidavit of Ngubo, she attended the Rath clinic on 17 March 2005 and was subjected to a blood test. Photographs were taken of her while he was semi-naked. The affidavit of Velem confirms Ngubo's affidavit and attests that the same occurred to her.

114. Ntsholo, Velem, Ngubo and Ngqase describe the following common experience:

114.1. Each patient was asked to undress;

114.2. Each patient was photographed in their underwear;

114.3. Without seeking their permission, blood samples were taken from each patient;

114.4. Each patient was given medicines.

115. Professor Mhlongo applied for permission from a MEDUNSA ethics board to run this trial in August 2004. Permission was not granted.

116. As far as I have been able to establish, the MCC has not granted authority to any of the Rath respondents to conduct this clinical trial.

117. I attach (**NG50**) an affidavit by Professor Leslie London on the conduct of clinical trials and on the Rath trial in particular. Prof London explains

117.1. the process and ethics of conducting a clinical trial,

117.2. that the conduct set out in the affidavits describes a clinical trial,

117.3. that those conducting the trial have not done so in accordance with the required process or ethics.

118. I submit that this evidence demonstrates that various of the Rath respondents have been conducting clinical trials in breach of Regulation 34 of the General Regulations under the Medicines Act.

119. As I have stated, Rath himself is not registered as a medical practitioner in South Africa. His clinics, conducted under the style of “Dr” Rath, give members of the public the impression that they are conducted by a medically qualified person who is entitled to carry on the activities in question.

120. I do not know whether the persons who have been conducting this activity – advising patients, providing them with medicines, and drawing their blood – are in fact qualified and professionally authorised to do so. I invite the first and second respondents to state the names, qualifications and professional registrations of the persons who are carrying on these activities on their behalf.

CONSEQUENCES OF THE ILLEGAL ACTIVITIES OF RATH AND HIS ASSOCIATES

121. Rath's advertisements are intended to persuade people with AIDS not to take ARVs. In some instances they have that result.

122. The staff of the Rath health facilities advise people with AIDS not to take ARVs. They do so even though to the best of my knowledge those facilities are not run by or under the control of a person who is registered with the Health Profession Council and entitled to undertake that activity. Nevertheless, the staff of the Rath medical facilities give medical advice and prescribe treatment. In some instances they persuade people with AIDS not to take ARVs.

123. The consequence is that the advertisements and the Rath staff can and do dissuade patients from following accepted medical advice for a life-threatening illness.

124. I refer again to the affidavit of Dr. Peter Saranchuk (**NG13**). He is employed by Medecins Sans Frontieres to work in public clinics specialising in HIV care in Khayelitsha.

125. Dr. Saranchuk describes four patients whom he has seen, and who were persuaded to take the first and second respondents' medicines instead of ARV treatment. One patient was put at risk of becoming ill by following the advice of the Rath respondents. Two patients did become ill as a consequence of following the advice of the Rath respondents. The fourth patient died as a consequence of following the Rath respondents' advice.

126. The affidavit of Zondani Magwebu (**NG11**) describes how his wife fell gravely ill while on the Rath respondents' trial and subsequently died.

127. The affidavit of Nandipha Violet Sigebenga (**NG10**) describes how her sister died while on the Rath respondents' trial.

128. Another patient of the Rath respondents, Marietta Ndziba, who was also the leader of their support group in Gugulethu, died in early October 2005. Attached to Professor London's affidavit (**NG50)** is a report from the Cape Times reporting this (**LL6**). To the best of my knowledge, the Rath respondents have not denied the correctness of this report. However, her personal testimony of the efficacy of first and second respondents' medicines was still on the Foundation's website on 14 November 2005, when I last checked.

129. I attach (**NG51**), an affidavit by Dr. Kevin Rebe of GF Jooste Hospital, a public health facility. He describes how he and his facility had to intervene to assist two patients with HIV who were confused by the Rath respondents' activities.

130. I have browsed some of the Rath websites. Rath claims on those websites that his "natural" medicines also cure cancer, and treat diabetes and heart disease. He also claims his medicines are able to treat asthma, arthritis and other diseases.

131. I attach (**NG52**) an open letter signed by 199 Western Cape health-care workers, including eminent physicians and public health experts. The letter states

> *"Call by concerned health workers demanding action against the Dr Rath Foundation ... We are health professionals involved in the Provincial antiretroviral programme. This is probably one of the largest challenges our health services have ever been confronted with. We hereby voice our outrage at the unhindered activities of the Dr Rath Health Foundation. In the name of this Foundation, our patients are being inundated with propaganda encouraging them to stop life-saving medicine. Many of us have had experiences with HIV-infected patients who have had their health compromised by stopping their antiretrovirals due to the activities of this Foundation. ... the Foundation is in breach of many of the ethical principles we, in our professions, adhere to in order to protect our patients. They have conducted unregistered clinical experiments on patients, and distribute unregistered medicines with potentially harmful effects."*

FAILURE OF GOVERNMENT AUTHORITIES TO ENFORCE THE MEDICINES ACT

132. I submit that the government is under an obligation to ensure that the Constitution and the Medicines Act are effectively enforced. Particular duties rest on the National Department of Health, MCC and provincial departments of health. I have

been advised that the Registrar of Medicines has a dual role, being the Minister of Health's representative on the MCC.

133. I demonstrate below that the government authorities have had repeated notice of the illegal activities of the Rath respondents, but have failed to take any effective action in this regard.

134. I have been further advised that the Minister of Health has ultimate responsibility for matters related to public health, and that she has special responsibility for the failure of the government authorities to act against the Rath respondents.

135. To the best of my knowledge, the Minister of Health has never taken any action to discourage the Rath respondents from continuing in their unlawful activities. On the contrary, as I will set out below, her conduct has actually encouraged them to persist in these unlawful activities.

136. The TAC has attempted since February 2005 to persuade the government authorities to act against the Rath respondents. Other parties have also attempted to get the relevant authorities to act. These efforts are described in this affidavit.

137. Only on two occasions did the authorities initiate action that questioned the activities of the Rath respondents. This was not on either occasion followed up with a systematic effort to stop those activities. For the rest, the government authorities have either ignored complaints made to them, or acted in a manner which could only have emboldened the Rath respondents to continue their activities. In the case of the Minister of Health, in my view the Rath respondents had a reasonable basis for interpreting her behaviour as supportive of their activities. I set out below the evidence which has led me to this conclusion.

CHAIRPERSON OF MCC AND REGISTRAR OF MEDICINES

138. The MCC is established under sec 2 of the Medicines Act. The main purpose of the MCC is to safeguard and protect the public by ensuring that all medicines that are sold and used in South Africa are safe and therapeutically effective, and meet acceptable standards of quality.

139. The MCC determines what medicines are registered, and the conditions under which they may be used. It has powers of investigation with regard to medicine. It may require any person who manufactures or sells or administers or prescribes any medicine, or on whose direction any medicine is administered, to furnish it with any information which such person has in his possession or which such person is in a position to obtain regarding such medicine.

140. A major responsibility of the MCC is the registration and classification of medicines. Section 14(2) of the Medicines Act empowers the MCC to determine that a medicine or class or category of medicines or part thereof shall be subject to registration in terms of the Act. The MCC has a responsibility to take reasonable steps to ensure that unregistered medicines are not sold or distributed, except with its authority.

141. In terms of Regulation 34 of the General Regulations made under the Medicines Act, the MCC has the power to authorise a clinical trial in respect of an unregistered medicine. The MCC has a responsibility to take reasonable steps to ensure that unauthorised clinical trials do not take place.

142. TAC first alerted the MCC to the activities of Rath, the Foundation and his associates in February 2005 when TAC's chairperson Zackie Achmat discussed telephonically the activities of Rath with the chairperson of the MCC, Professor Eagles and urged him to take action. I attach (**NG53**) Achmat's affidavit in this regard.

143. When no action was taken, TAC instructed the AIDS Law Project (ALP) to write to Professor Eagles on its behalf. I attach a copy of this letter (**NG54**), dated 11 March 2005. I draw attention specifically to the following aspects of the letter:

143.1. It alerts the MCC to the first and second respondents' activities.

143.2. It states *"the MCC has a legal obligation to take action aimed at minimising the negative impact of the campaign of misinformation [of Rath]. This may include (but would not be limited to) the public release of a clear and unequivocal public statement that dismisses the assertions made by the Rath Foundation by reaffirming that the ARV [antiretroviral] medicines already registered by the MCC satisfy the requirements of safety, quality and efficacy. Such a press release ... would go some way towards ensuring that public confusion is minimised.*"

143.3. It requests the MCC to ask the Minister of Health to ask the MCC to provide a report *"in which public health concerns relating to the publication of false and misleading information about ARV medicines are highlighted and solutions to the problem identified."*

143.4. It asks *"What steps, if any, has the MCC taken to address the Rath Foundation's campaign of misinformation?"* and *"If the MCC has not taken any such steps, why has it failed to act?"* and *"If the MCC is of the opinion that the Medicines Act does not empower it to take decisive action – ... what steps if any, has it taken to draw such alleged deficiencies in the Medicines Act to the attention of the Minister and the Department of Health"* and *"What amendments should be made to the Medicines Act and the General Regulations issued in terms thereof"*

143.5. It requests a written response from the MCC by 24 March 2005.

144. On 17 March 2005 the Legal Resources Centre ("LRC"), on the instructions of the TAC, sent a further letter (**NG55**) to Professor Eagles.

145. In summary, this letter contains the following information:

145.1. Affidavits intended to assist the MCC with its investigation are attached to it.

145.2. It states that the first and second respondents have been dispensing medicines for the treatment of HIV, which are not registered for this purpose.

145.3. It states that the first two respondents have been making false claims.

145.4. It states that there are strong suggestions that the first two respondents have been conducting an unapproved clinical trial on human subjects.

145.5. It sets out under which sections of the Medicines Act these activities are illegal.

145.6. It urges the MCC to take immediate and urgent steps to enforce compliance with the Medicines Act.

145.7. It requests a written response by 23 March 2005.

146. The MCC has never responded to the letter from the ALP. On 18 April it replied to the letter from the LRC. I draw attention to the following aspects of its reply (**NG56**):

146.1. The letter is signed by Dr Humphrey Zokufa, the Registrar of Medicines.

146.2. It commits to investigating the activities of the first two respondents in relation to carrying out unauthorised clinical trials and distributing unregistered medicines.

147. On 22 April 2005 I sent a letter to Dr. Zokufa (**NG57**). I sent copies to the Minister of Health, the Director-General of Health and the chairperson of the MCC. I draw attention to the following aspects of this letter:

147.1. It notes that the MCC has committed to investigating our allegations.

147.2. It brings to the attention of the MCC the Mercury advertisement.

147.3. It requests the MCC to alert "the public to the fact that Rath 'medicines' are not registered as safe and effective in the treatment of HIV/AIDS".

148. The MCC has never replied to this letter.

149. On 4 May 2005, the LRC wrote a further letter (**NG58**) on behalf of TAC. It was sent to Dr Zokufa and Mr Terence Shoba of the Health Professions Council of South Africa (HPCSA). Copies were sent to the Minister of Health, the Director-General of Health and the chairperson of the MCC. It describes the three key allegations against the Second Respondent – making false claims, selling unregistered medicines, and conducting unauthorised trials - and sets out why these are breaches of the Medicines Act. It requests that appropriate action be taken by the MCC within seven days of receipt of the letter.

150. Following this letter I was contacted by Lionel Snyman, whom I understand to be a law enforcement agent employed by the Department of Health. I describe my interactions with Snyman and this unit in the later section of this affidavit dealing with the Department of Health.

151. I participated in a radio debate on the Vuyo Mbuli show on SAFM on 5 September 2005. Dr. Zokufa and others participated in this debate too. I attach a Snellers transcript of the debate (**NG59**). I draw attention to the following:

151.1. It begins with a radio documentary conducted by Health-e, a news agency specialising in health matters. That documentary refers to deaths that occurred on the Rath respondents' trial.

151.2. Dr. Zokufa acknowledges being aware of Rath's vitamins. He acknowledges that they are not registered. He also states that if they are making claims that they cure AIDS, then the MCC would find that "problematic" (pages 27, 28, 53 and 54).

151.3. He acknowledges that if the dosages are too high they need to be registered with the MCC (pages 55 and 56).

151.4. He appears unable to describe coherently what progress, if any, has been made in investigating Rath and Associates (pages 42 to 45).

151.5. He appears to acknowledge being aware that Rath's products contain N-acetylcysteine (page 59), which would render them subject to the controls in the Medicines Act.

152. On 12 August 2005 the LRC sent a final letter of demand to the MCC (**NG60)** requesting an adequate response within two weeks. The MCC has not responded in any way.

MINISTER OF HEALTH AND DIRECTOR-GENERAL OF HEALTH

153. In terms of the National Health Act, the key responsibility for health rests with the Minister of Health who must

153.1. endeavour to protect, promote, improve and maintain the health of the population; and

153.2. determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population.

154. The Minister of Health is assisted by the Director-General ("DG") who, in terms of the National Health Act, is responsible for (amongst other things) ensuring the implementation of the national health policy.

155. The DG has the power to authorize persons as inspectors in terms of the Medicines Act. The inspectors have wide powers, including powers of search and seizure, which are set out in sec 28 of the Act.

156. The Department of Heath has a Law Enforcement Unit, to which inspectors are attached. I now describe my meetings with Lionel Snyman and other members of the Law Enforcement Unit of the Department of Health.

157. Snyman and a colleague of his met members of the AIDS Law Project and me at 6 Spin Street Cape Town on 10 May 2005. At this meeting:

157.1. I explained to Snyman the details of Rath's activities.

157.2. I handed over to Snyman medicines distributed by the first two respondents.

157.3. Snyman asked me to write a detailed affidavit explaining all relevant aspects of the Rath case.

157.4. Snyman informed me that he would visit Rath's offices. He also said he would speak to a former employee of Rath's, Anthony Reese.

158. In accordance with Snyman's request I completed a detailed affidavit describing all the evidence I had of Rath's wrong-doings. I signed it on 17 May 2005 and sent it by courier to Snyman. I attach a copy of this affidavit without its attachments (**NG61**).

159. I subsequently had a number of telephone conversations with Lionel Snyman. He confirmed that his office had received my affidavit. It appeared to me that Snyman was willing to act against Rath with some urgency. However, it also appeared that he had been removed from the case. It is my belief that he was removed from the case because of his willingness to act against Rath.

160. The LRC wrote to Snyman requesting confirmation of receipt of my affidavit. Snyman faxed a reply dated 3 June 2005, which indicated:

160.1. that my affidavit was received by him on 20 May 2005 and subsequently handed over to a Mr. Du Toit, manager of the Law Enforcement Unit,

160.2. that he was no longer assigned to the case and that Mr. Du Toit should be contacted for further details.

161. Thereafter, on 17 June, the LRC sent a letter to Du Toit requesting a status update. Du Toit sent a reply on 3 July 2005 (**NG62**). I draw attention to the following aspects of this response:

161.1. It provides no useful update on the status of the investigation, other than to say that it was continuing.

161.2. It states that the Law Enforcement Unit is the responsibility of the Department of Health, and not the MCC.

162. We have not received any report from the MCC or Department of Health on the status of the investigation.

163. In a last attempt to avoid the necessity for this litigation, on 27 October 2005 the LRC wrote to Du Toit (**NG63**) stating "Despite this matter being inherently urgent, we will again delay launching the application provided you inform us within ten days of the date of this letter when the investigation will be complete and its outcome made known and that you confirm the date for the investigation and the outcome thereof will be within a reasonable time".

164. Du Toit responded on 31 October 2005. His letter (**NG64**) speaks for itself. It discloses an inability to appreciate the obligations of the Department of Health, and fails to respond in any way to the LRC's enquiry with regard to the investigation. Du Toit sent a copy of his letter to the Director-General.

165. The Minister of Health has never, to the best of my knowledge, made a statement criticising the activities of Matthias Rath, despite having numerous opportunities to do so. On the contrary:

165.1. In an answer (**NG65**) to a question in Parliament on 15 June 2005, the Minister admitted to having had a meeting alone with Rath on 16 April, and said that they *"discussed his concern for people infected with HIV and suffering from the impact of AIDS"*. She said she would *"only distance myself from Dr Rath if it can be demonstrated that the Vitamin supplements that he is prescribing are poisonous for people infected with HIV."*

165.2. On 16 April 2005 I attended an Imbizo in Khayelitsha addressed by the Minister of Health. Matthias Rath was at this meeting. During question-time, numerous members of the Khayelitsha community asked the Minister, in one way or another, to condemn the activities of Rath. She refused to do so.

165.3. The Rath publication *You Can!* states on page 2

"The Dr. Rath Health Foundation Africa has the support of our Minister of Health and our Government. The vitamin programmes used are qualified as food and nutrition. As opposed to toxic ARV drugs, these programmes are safe because they are natural. Don't fall for the dirty tricks of the Drug Cartel: trust our Government and those who support it."

To the best of my knowledge the Minister of Health has not distanced herself from this statement.

165.4. According to the affidavit of Achmat (**NG53**), David Rasnick and Professor Mhlongo presented the findings of their unapproved clinical trial at the National Health Council in Midrand on 23 September 2005, at the invitation of the Minister of Health.

166. In about March 2003 I attended a meeting of the Parliamentary Portfolio Committee of Health, where the Minister portrayed nutrition as a treatment for HIV. She named specific foods in this regard including garlic and African potato. The Minister has since been repeatedly reported in newspapers as promoting particular foodstuffs as treatment for HIV.

167. The TAC views nutrition as a critical component of the care of people with HIV. Good nutrition appears to help people with HIV live longer, healthier lives. However, as explained in the affidavit of Venter, good nutrition cannot reverse the course of AIDS.

168. I attach (**NG66**) a response by the Minister to a question in Parliament on 14 September 2005. She states

"Firstly, I have never said that traditional medicines and vitamins should be offered as alternatives, which means instead of ART. What I have emphasized is that our people must be given a choice."

She further states

"Certain traditional medicines may help to treat numerous symptoms of opportunistic infections that are part of AIDS. They represent alternatives to formal general medicine and for many people will be the only options they have."

169. I submit that the Minister's obligation is to provide public information based on the best available scientific evidence and current policy. Individuals may then make choices as to whether or not to follow these recommendations. The Minister should not be providing choices between an approach that the scientific consensus recommends and one that has no scientific basis at all.

170. I attach (**NG67**) a transcript of a Health-e interview with Director-General Mseleku. In this interview, he states:

170.1. *"The message of the Minister is clear. The message of the Minister says 'we will give you information about what works and about what is on the table. Let's talk about ARVs. You've got this treatment. You can actually take it at a certain point, but it does have side-effects. Full stop."*

and

"That can be managed if you say so. I'll add another word – 'in some instances' – because in others it's not manageable. We cannot deceive our people. We must be very clear about what we are saying to our people. You yourself saying 'that can be managed' is not actually completely true. It's partly true. So, let's not try and get to the Minister to say you must say it this way. She says nutrition and I'll stand by nutrition and no one can challenge the Minister on nutrition… There's nothing wrong with that. I don't understand where the mixed

message is."

and

"No, we are saying to people the government provides you the possibility, if you need to take ARVs, take them. But those people that are actually working in the forefront will tell you about the side-effects that they have. That's all we're saying. We have never said don't take ARVs. The Minister has never said so, otherwise this Plan wouldn't be rolling out. So, I don't know what the issue is about. Just because she says I will not stop to say ARVs have side-effects? That's what you'll hear also when you go to any site. They'll tell you that we must observe you this way, that way, that way because these things have side-effects. But that doesn't mean I'm saying don't take them… If you have to take ARVs, here, they are available, but you have got other alternatives, too. So, I don't know what the confusion is, where this mixed message is. We're just imagining a mixed message. There's nothing mixed about that. Where is the mix?"

171. In this, Mseleku misleads the public in the following respects, as appears from the explanation of the science of HIV in Venter's affidavit:

171.1. He does not mention the fact that the benefits of ARVs outweigh their risks.

171.2. He does not mention that ARV side-effects are only unmanageable in rare circumstances, where death from AIDS would probably occur anyway.

171.3. He states, “If you have to take ARVs, here, they are available, but you have got other alternatives, too.” This statement is false. There is no scientifically accepted alternative treatment to ARV treatment for people who have developed AIDS.

172. The Minister and the Director-General frequently issue warnings about ARVs, which are the MCC-registered treatments for HIV. I am not aware of any instance in which the Minister and Director-General have warned that multivitamins and micronutrients are not a treatment for AIDS or able to reverse the course of AIDS, even though multivitamins and micronutrients are not registered by the MCC to treat HIV/AIDS.

173. I attach an edited transcript (**NG68**) of a further interview between Health-e and the Director-General of Health. The Director-General makes the following references to Rath's products:

> “*From our point of view Dr Rath is actually providing vitamins, which are immune boosters just like many vitamins that are there.”*
>
> *“If Dr Rath came into South Africa and had this particular product there would have to be a determination as to whether this product is supposed to be a complementary product, or is supposed to be a medicinal product which then, would actually have to be registered in terms of the Medicines Regulatory Act, whereas a complementary product does not have to go through all those processes.”*
>
> *“There have been allegations that Dr Rath was actually using medicine*

that was not registered in South Africa. And the law enforcement agency says, in accordance with what was pronounced by the Department of Health before about the complementarity of Dr Rath's vitamins, there hasn't been anything that was done wrong with regard to that."

174. On 21 June 2005 I participated in a radio debate with Anthony Brink on Cape Talk. During this debate Brink admitted that the Rath products contain N-acetylcysteine. But he also claimed that they had received a letter from the Department of Health allowing them to use this product.

175. In terms of sec 21 of the Medicines Act it is only the MCC which may authorise the sale of an unregistered medicine. The power to do so is circumscribed. The authorisation has to be in writing. I invite the Rath respondents to produce such writing, if it exists.

176. On 24 August 2005, in the hope of avoiding this litigation, the LRC sent a letter (**NG69**) on behalf of TAC to the Minister of Health, requesting an adequate response within two weeks. The Minister has not replied at all.

177. On 13 September 2005, I had a telephonic discussion with Charity Bhengu, who I understand is a communications officer in the Department of Health. She telephoned me after Cape Talk Radio Station had contacted her about our threat of litigation against the Minister of Health had been reported in the media.

177.1. She said that she did not know we had sent a letter giving the Minister of Health two weeks to act. I therefore summarised matters for her.

177.2. She wanted to know what could be done to avert litigation. I told her that it was late and that we were preparing papers. I said if we had not received a response by the time our papers were ready, we would proceed.

177.3. I said though that if the Department of Health took action against Rath, we would not proceed with litigation. I told her if we got a letter from them saying they needed three weeks to act before we filed, we would give that to them. To which Bhengu replied "three months?" and I said "No, three weeks."

177.4. She then asked what our attitude would be if they sent us a letter saying that the investigation was still continuing. I said that would be unacceptable because we had heard the same excuse for six months.

177.5. I pleaded with her to make sure that action was taken. I said that we suspected Rath had the support of the Minister of Health.

177.6. I immediately discussed my conversation with Zackie Achmat, the TAC chairperson. He was dissatisfied that I had told Bhengu that the Department had three weeks to act before we filed papers, but said that we had to keep our word. I therefore telephoned Bhengu and told her that there was dissatisfaction from the TAC secretariat about my agreeing to an additional three weeks. But I said we would stick to this on condition we received a written commitment the next day stating that three weeks were needed to act against Rath and Associates.

177.7. I have not heard further from Bhengu.

178. On 21 September 2005 I was asked by Andrew Gray (who has made an affidavit in this matter) to contact Russell Coote, a member of the Department of Health's Law Enforcement Unit in KwaZulu-Natal.

179. I telephoned Mr Coote. This is what transpired:

179.1. He asked me to provide him with evidence that Rath had acted in KwaZulu-Natal. I found this strange, because we had not specifically complained about Rath's activities in KwaZulu-Natal. In any event, I informed him of the Mercury advert.

179.2. He told me he had not seen the Mercury advert, and was unaware of the affidavit I had submitted to the MCC. I promised to send him both my affidavit and the Mercury advertisement.

179.3. He told me there were worse violators of the law than Rath. He said that the TAC should institute a private prosecution against the Rath respondents. I said I would discuss this with our lawyers. He said he would speak about Rath to the “one honest policeman” he knew.

180. It was my impression that there was not much prospect of his acting, but we sent him a copy of the affidavit we had originally sent to Lionel Snyman. I also sent him an email, which amongst other things asked him for an update by Monday 26 September. I have not heard from him since.

181. I have met Coote once before this. This was at the time when the TAC conducted a civil disobedience campaign that involved importing generic fluconazole from Thailand. Coote oversaw a raid on Zackie Achmat's home when this occurred.

182. Coote subsequently also conducted an investigation, which included a "visit", into the activities of the Brooklyn Medical Centre, which distributed generic fluconazole under authorisation from the MCC.

183. Coote also conducted an investigation of Medecins Sans Frontieres with regard to the importation of generic ARVs. Again, he visited their premises to determine whether they were acting legally.

184. The speedy and zealous actions of the Department with regard to these matters contrasts sharply with the virtual inaction with regard to the Rath respondents. It certainly does not suggest that they are unable to act.

185. In March 2005 the TAC also lodged a complaint with the Health Professions Council of South Africa (HPCSA) in March regarding Rath apparently practising as a doctor without a licence.

186. The HPCSA subsequently laid a complaint against Rath, primarily on the basis of the evidence TAC had provided, with the Khayelitsha Site B police.

187. My colleague Mandla Majola and I provided extensive assistance to the police, including providing them with affidavits and facilitating communication with the HPCSA.

188. On 6 June 2005 the TAC met with the police and a senior prosecutor at Khayelitsha Magistrate's Court. At this meeting we were asked to assist the police in setting up a “sting” operation against Rath. I found this quite strange, because the HPCSA had told me that they had explained to the inspector working on the case who was present at this meeting that there was sufficient evidence to act immediately without any ”sting” operation. Nevertheless, we said we would be willing to assist in this regard.

189. Despite efforts by Mandla Majola to get the police to act, nothing further has happened in this regard.

WESTERN CAPE MEC FOR HEALTH

190. As is confirmed by Zackie Achmat (**NG53**), a TAC delegation had a meeting with MEC Uys on 10 March 2005. Mr Uys was accompanied by Professor Craig Household (his head of department), Dr. Keith Cloete and Mr. Pierre Grobbelaar.

191. The TAC delegation raised the issue of the distribution of the Rath pamphlets to patients and HIV support groups. They said that this was impinging on service delivery at public health clinics, and they asked that the Provincial Government intervene and issue a statement condemning Rath’s misleading publicity.

192. I have followed this up with telephonic conversations with officials of the Provincial Department in which I requested them to take action against Rath.

193. I attach (**NG70**) answers by MEC Uys on 23 September 2005 to questions by ANC MPL, Yusuf Gabru, in the Western Cape Provincial Legislature regarding the investigation of Rath and his associates. In these answers the MEC denies that the Foundation's experiment in Khayelitsha has been brought to his attention. He also denies "possession of any information on the nature and composition of the substances used by the foundation."

194. In my view that response is not plausible, in the light of the following:

195. First, I have already mentioned the letter by Western Cape health-care workers urging MEC Uys to take action against Rath (**NG52**).

196. Secondly, I attach a letter (**NG71**) which six health-care workers - Andrew Boulle, Greg Hussey, Rodney Ehrlich, Peter Saranchuk and Mpumi Matangana – sent to MEC Uys on 6 October 2005. That letter sets out possible actions which the MEC could take against Rath. It includes descriptions by doctors of patient confusion caused by Rath. It states

> *"Finally, to put on record the concerns raised previously by health workers with officials, we attach extracts of minutes from meetings on 18/02, 11/03, 18/03, 20/05 and 17/06 where this matter was discussed in meeting where clinicians were present. These are in addition to the media reports that have brought some of the activities of the DRHF to all of our attention, and many informal discussions with officials."*

197. Thirdly, that letter also contains extracts of minutes going back to February in which senior provincial government Department of Health officials were warned of

Rath's activities. In a meeting of 18 May 2005, a senior official, Keith Cloete, was tasked with taking the Rath issue up with MEC Uys.

198. Apart from the Western Cape Department of Health statement referred to earlier, which does not mention Rath by name, and a statement by an official in the Western Cape Department of Health, Dr Fareed Abdullah, no action, that I am aware of, has been taken by the Western Cape Department of Health.

199. On 5 September 2005, the LRC sent a letter (**NG72**) to MEC Uys requesting information on the response of the Western Cape Provincial Department of Health with regard to the Rath respondents' unlawful activities. Apart from acknowledging receipt of the letter, the MEC has not responded to it at all.

EFFORTS BY OTHER MEMBERS OF THE PUBLIC

200. I am aware that some other interested parties have attempted without success to stir the government authorities to action in this regard.

201. I attach (**NG73**) an affidavit by Marta Darder of Medecins Sans Frontieres, describing her efforts to get the MCC and Department of Health to act.

202. I attach (**NG74**) an affidavit by a journalist, Terry Bell, describing his efforts to get the MCC to act.

URGENCY

203. The activities of Rath and his associates, and the misinformation which they disseminate, have a devastating impact on HIV positive people and deny them opportunities for adequate health care. In some cases, death is the result.

204. There is evidence that the activities of the Rath respondents have resulted in deaths of their patients by causing them to delay seeking treatment from the public health system. The Rath respondents' continued activity will potentially result in more such deaths.

205. The continued inaction of the government authorities contributes directly to the suffering and death of HIV positive people.

206. This matter is therefore inherently urgent, because so long as the activities of the Rath respondents continue, people are likely to suffer and die. The TAC has since February worked consistently to bring this matter to resolution without going to court. However, the government authorities have failed to act.

207. We appreciate that the respondents require a proper opportunity to respond to this application, and we therefore do not request that the time periods prescribed in Rule 6 be shortened. We will however, because of the inherent urgency of the matter, not agree to any extension of time, and will hold the respondents to the time limits set out in the Rules of Court. We will in due course ask that an early date be allotted for the hearing of the matter, because of its inherent urgency.

208. The first applicant accordingly asks for an order as set out in the notice of motion.

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NATHAN GEFFEN

I CERTIFY THAT THE DEPONENT ACKNOWLEDGED TO ME THAT HE KNOWS AND UNDERSTANDS THE CONTENT OF THIS DECLARATION, THAT HE HAS CONSCIENTIOUS OBJECTIONS TO TAKING THE PRESCRIBED OATH AND CONSIDERS THIS AFFIRMATION BINDING ON HIS CONSCIENCE. SIGNED AND AFFIRMED TO BEFORE ME AT CAPE TOWN ON THIS ___ DAY OF NOVEMBER 2005.

_____

COMMISSIONER OF OATHS