

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

Case no 12156/05

In the matter between

**TREATMENT ACTION CAMPAIGN
SOUTH AFRICAN MEDICAL ASSOCIATION**

**First Applicant
Second Applicant**

and

**MATTHIAS RATH
DR RATH HEALTH FOUNDATION AFRICA
SAM MHLONGO
DAVID RASNICK
ALEXANDRA NIEDWIECKI
ANTHONY BRINK
TREATMENT INFORMATION GROUP
GOVERNMENT OF THE REPUBLIC OF
SOUTH AFRICA
DIRECTOR GENERAL, DEPARTMENT
OF HEALTH
CHAIRPERSON MEDICINES CONTROL
COUNCIL
REGISTRAR OF MEDICINES
MEMBER OF THE EXECUTIVE COUNCIL
FOR HEALTH WESTERN CAPE PROVINCE**

**First Respondent
Second Respondent
Third Respondent
Fourth Respondent
Fifth Respondent
Sixth Respondent
Seventh Respondent

Eighth Respondent

Ninth Respondent

Tenth Respondent
Eleventh Respondent

Twelfth Respondent**

APPLICANTS' HEADS OF ARGUMENT

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THE ISSUES

1. This application arises from the activities in South Africa of the first respondent, a German citizen, and various individuals and entities associated with him. Those individuals and entities are the second to seventh respondents.¹ We refer to the first to seventh respondents as “*the Rath respondents*”.
2. The first respondent (“*Dr Rath*”) is the proprietor of certain pharmaceutical products.
3. The applicants are the following:
 - 3.1 The first applicant is the Treatment Action Campaign, a non-governmental organisation which campaigns for the rights and health of people with HIV in South Africa. Its national office is in Cape Town. It has six provincial offices, five district offices, and 250 branches across the country.² A number of organisations and individuals in South Africa are associated with the first applicant. The organisations include the Congress of South Africa Trade Unions (COSATU), the Federation of Unions of South Africa (FEDUSA), the South African Catholic Bishops’ Conference, the

¹ The third respondent has passed away since these proceedings were instituted.

² Geffen para 31 – 32 page 17.

South African Council of Churches, Habonim Dror, Positive Muslims, the Children's Rights Centre, Medecins Sans Frontieres, and the AIDS Consortium. The first applicant and its chairperson have received a number of prestigious awards and commendations from various parts of the world.³

- 3.2 The second applicant is the South African Medical Association. It is a voluntary medical association of medical doctors in South Africa. It has approximately 16000 members. It is a member of the World Medical Association, which is a global federation of national medical associations representing doctors worldwide.⁴
4. The principal complaint of the applicants is that in carrying out their activities, the Rath respondents have been and are systematically contravening various provisions of the Medicines and Related Substances Act 101 of 1965 (*"the Medicines Act"*). These activities include the following:
- 4.1 distributing and/or selling medicines in contravention of the Medicines Act;

³ Geffen para 39 page 19.

⁴ Otto para 6 page 732

- 4.2 conducting unauthorised clinical trials in contravention of the Medicines Act; and
- 4.3 publishing false and misleading advertisements, and making unauthorised claims, concerning vitamins, multi-vitamins, and certain products produced by Dr Rath and the entities associated with him.
5. The applicants seek an interdict preventing the various Rath respondents from carrying out these activities.⁵
6. If these activities are indeed unlawful, the Government is under a duty to take reasonable measures to prevent them. The applicants allege that the eighth and ninth respondents (*“the Government respondents”*) have failed in their duties to investigate the matter properly, and to take reasonable measures to prevent these unlawful activities.⁶
7. The applicants accordingly seek an order:

⁵ Notice of Motion paras 1, 2, 3 and 4 pages 2-3.

⁶ The tenth respondent is the Chairperson of the Medicines Control Council (MCC), the statutory regulatory body. The eleventh respondent is the Registrar of Medicines, who is the chief officer of the MCC. The twelfth respondent is the MEC for Health in the Western Cape. These respondents are cited only for such interest as they may have in this matter. No order is sought against any of them, save for an order for costs in the event of their opposing this application: Geffen paras 19-21 pages 13-14.

- 7.1 declaring that the eighth and ninth respondents are under a duty to take reasonable measures in this regard;⁷
- 7.2 declaring that the eighth and ninth respondents have failed to carry out this duty, in that they have failed properly to investigate the alleged unlawful conduct of the Rath respondents;⁸
- 7.3 ordering the eighth to ninth respondents to take reasonable measures to investigate these matters and, in the light of the facts revealed by such investigation, to take further reasonable action in accordance with their duties;⁹
- 7.4 ordering the eighth and ninth respondents to take reasonable measures to prevent the Rath respondents from carrying out the activities in question;¹⁰ and
- 7.5 a structural interdict requiring the eighth and ninth respondents to report to this Court on what they have done and will do to give effect to the orders; an opportunity for the applicants to respond to this report and for the respondents to answer that response; and for the applicants, if so advised, then to enrol the matter for hearing for

⁷ Notice of Motion para 5 page 3.

⁸ Notice of Motion para 6 page 3.

⁹ Notice of Motion para 7 page 4.

¹⁰ Notice of Motion para 8 page 4.

a determination as to whether there has been compliance with the mandatory order.¹¹

8. The structure of these heads of argument is as follows:
 - 8.1. in Part 1, we analyse the relevant provisions of the Medicines Act;
 - 8.2. in Part 2, we analyse the relevant regulations issued under the Medicines Act in relation to the registration of medicines;
 - 8.3. in Part 3, we describe the conduct of the Rath respondents;
 - 8.4. in Part 4, we deal with the answering affidavits filed by the sixth respondent, Mr Brink;
 - 8.5. in Part 5, we deal with the answering affidavits filed on behalf of the first to fifth respondents.
 - 8.6. in Part 6, we analyse the legal obligations which rest on the government in this regard;

¹¹ Notice of Motion para 9 – 12 pages 4-5.

- 8.7. in Part 7, we analyse whether the government has carried out its legal obligations.
- 8.8. In Part 8, we address the question of an appropriate remedy.
9. The affidavits by Dr Rath (the first respondent) and Mr Brink (the sixth respondent) and are for the most part:
- 9.1. inadmissible, as they consist in large measure of opinion evidence by persons unqualified to give that evidence. They are accordingly inadmissible hearsay.
- 9.2. irrelevant, as they consist (also in large measure) of wide-ranging and irrelevant attacks on persons with whom the deponents disagree, and polemics about historical and political matters which are irrelevant to the matters which this Court is required to decide.
10. They are a gross abuse of the process of court.
11. On the basis of the decision of the Constitutional Court in the SARFU case,¹² the applicants have not brought an application to strike out the

¹² President of the Republic of South Africa and others v South African Rugby Football Union and others 2000 (1) SA 1 (CC) at [106]

huge volume of irrelevant and inadmissible material, and have simply not responded to it. However, the applicants will submit that a punitive costs order ought to be made against the first, second and sixth respondents as a result of their gross abuse of the process of court.

PART 1:

THE MEDICINES ACT

12. The key to an understanding of the provisions of the Medicines Act is the definition of “*medicine*” in section 1, which is as follows:

“‘medicine’ means 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.”

13. The following aspects of this definition are of particular importance in this application:

- 13.1. There is no power vested in any body (other than a court) to make a determination whether a substance is a medicine. It is also not registration which determines whether a substance is a

“medicine”. If the substance as a matter of objective fact falls within the scope of the definition, then it is a medicine.

13.2. Three different sorts of circumstances will result in a substance being a medicine. These are if the substance:

13.2.1. is used for the defined purposes; or

13.2.2. purports to be suitable for use for those purposes; or

13.2.3. is manufactured or sold for use for those purposes.

14. The defined purposes are wide. They include the treatment or mitigation or prevention of disease, or its symptoms; and they also include restoring or correcting or modifying any somatic (i.e. physical) or psychic or organic function.

15. It follows from this that if (for example) a substance is entirely inert and in fact has no effect on human beings, it will nevertheless be a medicine if it is used for one of these broad medicinal purposes, or if it purports to be suitable for use for one of these purposes, or if it is manufactured or sold for one of these purposes.

16. The definition in the Act of “sell” is also of significance. It includes to import, to offer, to advertise, and to dispose of, whether for a consideration or otherwise.
17. The consequence is that a person who offers or advertises a medicine, or who distributes it to other persons even without charge, “sells” it within the meaning of the Act.
18. In order to appreciate the structure of control of medicines which is created by the Act, it is necessary first to appreciate the purpose of the Act. This was described by Kriegler AJA (as he then was) as follows.
The object of the Act is

“to protect the population of the country against the evils of the uncontrolled dissemination of potentially harmful medicinal substances”¹³

“Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensible to most. The man in the street - and indeed many medical practitioners - could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines. Moreover, the marvels of advertising,

¹³ Administrator, Cape v Raats Röntgen & Vermeulen (Pty) Ltd 1992 (1) SA 245 (A) at 262

marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.”¹⁴

19. In order to achieve this purpose, the legislature has adopted a wide definition of “*medicine*”. This includes not only substances which actually have a particular physical effect on the body, but also substances which are promoted or distributed or used to achieve that effect, whether or not it is successful.¹⁵ In other words, it protects the public against “*quackery*”.¹⁶

20. The Act creates three principal mechanisms to protect members of the public. These are:

¹⁴ at 254B-E.

¹⁵ Reitzer Pharmaceuticals (Pty) Ltd v Medicines Control Council and Another TPD case no 8516/95, judgment at page 11.

¹⁶ Reitzer Pharmaceuticals at page 11.

- 20.1. a requirement that certain medicines must be registered before they may be “*sold*”;
 - 20.2. a prohibition of the “*sale*” (as broadly defined) of certain scheduled substances, except by qualified persons and under controlled conditions; and
 - 20.3. a prohibition on publishing false or misleading advertisements concerning medicines, or making unauthorised claims with regard to medicines.
21. We deal with each of those in turn.

The registration of medicines

22. As we have pointed out, the term “*medicine*” is of very wide import. The control measure which has been introduced by the legislature is to require that only certain medicines be registered by the MCC; and to prohibit the “*sale*” of such medicines unless they have been so registered.
23. Section 14 of the Act thus provides as follows:

- “(1) Save as provided in this section or sections 21 and 22A,¹⁷ 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 Council¹⁸ 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 resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.”*

24. From this, it follows that this mechanism of control operates as follows:

¹⁷ Which are not relevant here.

¹⁸ The Medicines Control Council.

- 24.1. the Medicines Control Council, by resolution approved by the Minister, determines that a medicine or class or category of medicines shall be subject to registration in terms of the Act;
 - 24.2. the resolution is published in the Gazette;
 - 24.3. thereafter, it is an offence to sell that medicine, unless it has been registered by the Medicines Control Council.
25. The issuing of a section 14(2)(a) notice is known as “*calling up*” a medicine for registration.¹⁹
26. Section 15 creates an extensive process which has to be followed in order to have a medicine registered.
27. From this it follows that:
- 27.1. the fact that a substance is a medicine does not, without more, make it an offence to sell that substance without having it registered;

¹⁹ Ingelheim Pharmaceuticals (Pty) Ltd v Novartis South Africa (Pty) Ltd WLD case no 2003/11880, judgment delivered April 2005, para 14.

27.2. if however the Council has determined that the medicine is subject to registration, and has published a notice to this effect, then it is an offence to sell that medicine unless it has been duly registered.

28. Section 21 provides that the Council may authorise the sale of an unregistered medicine for certain purposes and during a specified period. Section 36 authorises the Minister, on the unanimous recommendation of the members present at a meeting of the Council, to exclude a medicine from the operation of the Act. Subject to that, however, the requirements of the Act are peremptory. It does not fall within the power of any official either:

28.1. to make a determination that a substance is or is not a medicine;

or

28.2. to grant permission for the sale of a medicine which in terms of a resolution of the Council is required to be registered, without it having been registered.

The Foodstuffs, Cosmetics and Disinfectants Act

29. The Government respondents refer, in the affidavits filed on their behalf, to the provisions of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (*“the Foodstuffs Act”*). We therefore deal briefly with the relationship between the Foodstuffs Act and the Medicines Act.

30. Section 1 of the Foodstuffs Act defines a *“foodstuff”*. It means:

“any article or substance (except a drug as defined in the Drugs Control Act, 1965) (Act 101 of 1965) ordinarily eaten or drunk by man or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance...” [emphasis added]

31. The Medicines Act was originally promulgated as the Drugs Control Act in 1965. Section 1(1) of the Drugs Control Amendment Act 65 of 1974 substituted the definition section (section 1) of the Drugs Control Act. Section 1(2) of that amendment Act provided as follows:

“Any reference, in any law or elsewhere, to a drug as defined in section 1 of the principal act prior to the substitution thereof by subsection (1) of this section, shall be deemed to be a reference to a medicine as defined in the said section (1) as so substituted.”

32. It follows that the reference in the Foodstuffs Act to a drug as defined in what was then known as the Drugs Control Act, is in today's nomenclature a reference to a medicine in terms of the Medicines Act.
33. The purpose of the Foodstuffs Act is to control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants.²⁰ As we have seen, the definition of "*foodstuff*" in the Foodstuffs Act excludes a medicine under the Medicines Act.
34. It follows that the Foodstuffs Act does not regulate or control the sale, manufacture or importation of substances which are medicines under the Medicines Act. A substance which is a medicine under the Medicines Act is by definition not governed by the Foodstuffs Act.
35. From this it follows that officials exercising powers under the Foodstuffs Act have no power to deal with the requirements for lawful sale of a substance which is a medicine. This is so regardless of whether or not that substance is required to be registered in terms of a resolution of the MCC. If a substance is a medicine as defined in the Medicines Act, then whether or not it is required to be registered, it falls outside the purview of the Foodstuffs Act and of the officials who exercise powers in terms of that Act.

²⁰ See the long title of the Foodstuffs Act.

36. It follows, too, that no official may make a legally valid determination that a substance is a foodstuff, and not a medicine. Whether it is a foodstuff depends on whether it falls within the definition of “*medicine*” in the Medicines Act. As we have pointed out above, that is a question of fact which is to be determined objectively, and in respect of which there is no administrative discretion.

Scheduled substances

37. A second method by which the Act seeks to achieve its purpose is through the control of substances which are listed in schedules published in terms of the Act.

38. Section 22A(1) provides:

“Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine or Scheduled substance, except in accordance with the prescribed conditions.”

39. Although the subsection is not altogether happily worded, it seems that the prohibition is intended to apply not to all medicines, but only to a medicine which either consists of or contains a scheduled substance.

40. As will appear below, for the purposes of this application it is the control of substances listed in Schedule 2 to the Act which is relevant.
41. Section 22A sets out stringent conditions with regard to the sale of scheduled substances, particularly those of Schedule 2 or higher. It is a criminal offence for any person to sell a Schedule 2 substance if he or she does not fall within one of the categories of specially qualified persons (broadly, qualified pharmacists or persons acting under their supervision, qualified medical practitioners, and manufacturers for sale to other persons who may lawfully possess the substance).
42. Section 22A(6) provides that the sale of a Schedule 2 substance may only take place on condition that all of the prescribed particulars of the sale are recorded in the prescribed manner in a prescription book or other permanent record, and also creates certain other controls.

False or misleading advertisements

43. In accordance with the purpose of the Act to prevent “*quackery*”, section 20 of the Act prohibits the publication or distribution of false or misleading advertisements or unauthorised claims concerning any medicine in the following terms:

“(1) 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 22 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) of paragraph (a) of that section.”

44. The word “advertisement” is broadly defined in section 1. It includes:

“Any written, pictorial, visual or other descriptive matter or verbal statement or reference –

(a) appearing in any newspaper, magazine, pamphlet or other publication; or

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine or Scheduled substance.”

45. Again, we draw attention to the fact that sale includes the supply of a medicine to a person, whether or not for a consideration. The definition of “*advertisement*” therefore includes material intended to promote the free distribution of the medicine or scheduled substance in question.
46. It will be observed that the prohibition takes two forms.
47. In the first instance, it is an offence to public or distribute a false or misleading advertisement concerning a medicine. It is a matter for objective determination whether:
- 47.1. the substance concerned is a medicine; and
- 47.2. the advertisement concerned was false or misleading.
48. In relation to the second form of the offence, the question is not whether the advertisement is false or misleading. It is whether the person concerned has:

- 48.1. made a claim that the therapeutic efficacy and effect of a medicine is other than what is stated by the Council in terms of section 22(a)(ii); or
- 48.2. suggested that a medicine should be used for a purpose or under circumstances or in a manner other than that stated by the Council in terms of section 22(a)(iii) of the Act.
49. If the Council has not approved registration of a medicine and determined its therapeutic efficacy and effect, or the purpose for which the medicine should be used, then it follows that any claim or suggestion in that regard is a claim or suggestion other than that stated by the Council.
50. The net effect of this is that unless the Council has made a finding and statement as to therapeutic efficacy and effect of a medicine, or has stated the purpose for which a medicine should be used, it is an offence for any person to make such a claim or suggest such a use.

Clinical trials

51. The Minister has made General Regulations under the Act. They are contained in Government Notice R510 in Government Gazette 24727 of 10 April 2003, as amended.

52. Regulation 1 defines “*clinical trial*” as follows:

“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 effects, study the absorption, distribution, metabolism and excretion of the medicine or ascertain its safety or efficacy.”

53. Regulation 34 regulates the conduct of clinical trials for humans. Regulation 34(1) provides as follows:

“A 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, shall apply to a Council on a form determine by the Council for authority to conduct such a clinical trial.”

54. Regulation 34(2) to (4) deals with the content of the application, the trial protocol, and the information which is required to be provided. Clinical

trials must be conducted in accordance with guidelines for good clinical practice as determined from time to time by the Council. Regulation 34(6) requires the person conducting the trial to submit regular progress reports to the Council. Regulation 34(7) empowers the Council to request information, inspect a clinical trial, or withdraw the authorisation.

55. Regulation 34(5) contains a prohibition:

“No person shall conduct clinical trials referred to in subregulation (1) without the authorisation of the Council.”

56. There do not appear to be any decided South African cases on this regulation. However, in Health Professions Council v Turner²¹ the Supreme Court of Zimbabwe interpreted the very similar provisions of section 15A of the Zimbabwe Drugs and Allied Substances Control Act. There, a clinical trial was defined as *“a systematic study... in order to establish the efficacy of, or to discover or verify the effects or adverse reactions of drugs.”*

57. The court pointed out that the definition in the Act is largely a subjective one. A series of experimental treatments with the drug becomes a *“clinical trial”* when the person conducting them does so *“in order to establish the efficacy of ... or to discover or verify the effects or adverse*

²¹ [2002] JOL 9499 (ZS).

reactions of ... drugs.” The court found that the doctor in that matter had two objectives in mind when he carried out the experimental treatments in question: primarily he was concerned with helping his patients, but *“inevitably, given that he was and is a man with an enquiring mind, he was equally intent on ‘establishing the efficacy of or discovering the effects or adverse reactions of’ the medicine in question. To that extent, he was carrying out a clinical trial.”*²²

58. Because of the subjective element of the definition – namely the purpose for which the activity is carried out – the court placed considerable reliance on the fact that Turner himself appeared to have used the phrase *“clinical trial”*. The words which the person concerned has used, and his or her conduct, go to establishing the subjective purpose of the activity.
59. A similar approach should be followed in determining whether an activity constitutes a clinical trial under the General Regulations. The actor’s own explanation of his or her conduct is an important element in establishing the purpose of the activity. The existence of an intention to *“treat”* the *“patients”* concerned does not negate the conclusion that a clinical trial was in fact conducted.

²² Page 12

PART 2:**THE REGULATIONS DEALING WITH REGISTRATION OF MEDICINES**

60. As we pointed out in Part 1, in terms of section 14(1) it is an offence to sell any medicine which is subject to registration by virtue of a resolution published in terms of section 14(2), unless it is registered.

61. Section 14(2)(a) provides that the Council may by resolution approved by the Minister determine that a medicine or class or category of medicines shall be subject to registration in terms of the Act.

62. On 15 December 1967, Government Notice R2025 was published. This notice described the categories of medicine.²³ The purpose of this regulation was to facilitate the “*calling up*” of medicines for registration by the Council in terms of section 14(2)(a) of the Act.²⁴

63. As appears from that notice,²⁵ “*vitamins*” are category 22 of the medicines so categorised. Subcategory 22.1 is “*multivitamins and multivitamins with minerals*”.

64. On 15 March 1985, in Government Notice 559 in Government Gazette 9620, the Medicines Control Council (with the approval of the Minister of

²³ AL Gray (Annexure NG13) para 10 page 338.

²⁴ Ingelheim Pharmaceuticals (Pty) Ltd v Novartis South Africa (Pty) Ltd (*supra*) at para 15.

²⁵ The relevant parts of the notice are reproduced in the judgment of Goldblatt J in Ingelheim Pharmaceuticals at pages 7 and 8

Health and Welfare) determined that all oral preparations containing a vitamin or vitamins, and which contain or exceed certain recommended total daily doses which were stated in that notice, were subject to registration.²⁶

65. From this it follows that from that date, no person was entitled to sell a medicine containing a vitamin which exceeded per recommended total dose the doses stated in Notice 559, unless the medicine was registered.
66. On 22 February 2002, the Council published a further call-up notice in Government Notice R204 in Government Gazette 20128.²⁷
67. As appears from the Notice that it is described as a “*call-up*” notice for medicines frequently referred to as “*complementary medicines*”. The categories of medicines to which it applies include, as paragraph 7, “*Nutritional substances that purport to have therapeutic or medicinal effects*”. The Notice states:

“Any person who contravenes this call-up notice shall be subjected to the provisions of section 14 read with section 29(b) and (h) and section 30 of Act 101, 1965.”

²⁶ The text of the notice is Annexure ALG1 to the affidavit of AL Gray (which is itself annexure NG14 to the affidavit of Geffen) pages 347-348.

²⁷ That Notice is annexure TDM1 to the affidavit of Mseleku on behalf of the eighth and ninth respondents pages 802-804.

68. The Notice states further that the Council has determined that:

“All preparations or mixtures or substances that fall under the definition of a medicine, including all dilutions, mixtures or derivations of any substances that are ... nutritional substances that purport to have therapeutic or medicinal effects ... shall be subject to a call-up process instituted as a primary step towards registration of such medicines and shall be submitted to the MCC within 6 (six) months of the date of publication of this notice.

It is further notified that under section 14(2)(b) of Act 101 of 1965, the abovementioned resolution shall relate to medicines available for sale or distribution in the Republic on the date on which it comes into operation and shall relate also to medicines that become available after the said date.”

69. The notice exempts the medicines called-up for registration from complying with certain provisions of the application form which is generally used in applications for registration.

70. The following appears clearly from this Notice:

70.1. it is described as a “*call-up*” notice, referring to section 14 of the Act. The only “*call-up*” power which the Council has in terms of section 14 of the Act is to determine that a medicine or class or

category of medicines shall henceforth be subject to registration in terms of the Act;

70.2. the notice specifically draws attention to the fact that any person who contravenes the call-up notice shall be subject to the provisions of section 14 read with sections 29(b) and (h) and 30 of the Act. Section 14 creates the offence of selling a medicine which is subject to registration, unless it is registered. Section 29 constitutes the offence and section 30 provides the penalty;

70.3. the notice determines that in terms of section 14(2)(b) of the Act, the resolution is of immediate effect on publication. The only resolution contemplated by section 14(2)(b) is a resolution by the Council, approved by the Minister, determining that a medicine or class or category of medicines shall be subject to registration under the Act.

71. It follows inexorably that the Notice of 2002 can only be a notice in terms of section 14(2), stipulating that “*nutritional substances that purport to have therapeutic or medicinal effects*” are subject to registration in terms of the Act; and that accordingly, it is an offence to sell any such medicine unless it is so registered.

72. The Notice states further that “*this call-up notice supersedes all previous call-up notice for preparations of this nature.*” In relation to vitamins, that must mean that the call-up notice supersedes Notice 559 of 15 March 1985, which required the registration of vitamins and multivitamins only where the recommended total daily dose exceeded the doses stipulated in that notice.
73. It follows that where a medicine consists of vitamins or multivitamins, it is required to be registered under the Act, regardless of the recommended daily dose of the medicine in question.
74. In the context of that legal framework, we now turn to deal with the conduct which has been alleged and proved against the Rath respondents. We shall submit in the sections which follow that in responding (or failing to respond) to the conduct of the Rath respondents, the government respondents have fundamentally misunderstood:
- 74.1. the meaning of a “*medicine*” in terms of the Medicines Act;
- 74.2. the structure and requirements of the Act; and

74.3. the meaning of the 2002 Government Notice dealing with registration of medicines; and

74.4. the relationship between the Foodstuffs Act and the Medicines Act.

75. We will submit that it is clear that on Mr Mseleku's own version, the government respondents have fundamentally misunderstood the structure of the regulatory framework which has been created by Parliament. They have accordingly failed to exercise their powers, and to carry out their functions and duties.

PART 3:**THE CONDUCT OF THE RATH RESPONDENTS****Selling unregistered medicines which are required to be registered**

76. We have submitted above that:
- 76.1. it is an offence to sell an unregistered medicine which is required to be registered;
 - 76.2. to “sell” includes to offer, advertise, or keep for sale, which includes to supply whether for a consideration or otherwise;
 - 76.3. a medicine is any substance used or purporting to be suitable for use or sold for use in the treatment, mitigation, modification or prevention of disease or its symptoms;
 - 76.4. vitamin and multivitamin medicines have been “*called up*” for registration by notice in terms of section 14 of the Medicines Act. They are therefore required by law to be registered.
77. The record shows that the Rath respondents have systematically offered, advertised, kept, and disposed of their vitamin and multivitamin products

for the purpose of treating or mitigating or preventing HIV/AIDS, or restoring or correcting the illness caused by HIV/AIDS. These products are not registered as medicines.²⁸

78. Examples of this are the following:

78.1. Nandipha Ntsholo went with two other people to the “*clinic*” conducted by the first and second respondents. Blood was drawn from her arm; she was told to strip naked, except for her panties, for a photograph; and photographs were taken of abnormalities on her skin. She was given the following medicines produced by the first and second respondents: Lysin C-Drink Mix, Vitacore Plus tablets, Epican tablets. She was told by the person in charge that these medicines help the immune system, and that any illness will be helped by these medicines because they boost the immune system.²⁹

78.2. Zukile Ngqase went with Nandipha Ntsholo to the “*Rath Clinic*”. He confirms what is stated by Ms Ntsholo. He was given the same medicines as Ms Ntsholo. A white man who appeared to be in charge told him that if he took these multivitamins it would boost his immune system.³⁰

²⁸ Geffen para 25.1 page 14, para 55 page 28, para 32, page 62. Mseleku para 30 page 772, paras 28.4 & 28.5 page 771.

²⁹ Annexure NG5 pages 285-287.

³⁰ Annexure NG6 pages 293-294.

- 78.3. Thembeke Ngubo went to the Rath Clinic at Mandela Park in Hout Bay. She was medically examined, and blood was drawn from him. She was required to undress to his underwear, and was then photographed. She was given medicines by a white woman working at the clinic.³¹
- 78.4. Xoliswa Velem went to the Hout Bay clinic with Ms Ngubo. She confirms the events described by Ms Ngubo.³²
- 78.5. Xolisa Mqambeli went to the Rath Foundation Clinic in Khayelitsha. She was questioned about her medical condition. She was told that "*Rath Foundation vitamins*" boost the immune system. She was given two bottles of VitaCell, and told to take two of these tablets three times a day after breakfast, lunch and dinner.³³
- 78.6. Nandipha Sigebenga cared for her sister Ntombekhaye Kruthani, until she died of AIDS. Representatives of the first and second respondents came to the house at least three times to pick up her sister and take her to the Rath Clinic. On the first occasion, she came back with food parcels and lots of vitamins. These

³¹ Annexure NG7 pages 300-301.

³² Annexure NG8 page 302.

³³ Annexure NG9 pages 304-306.

people told her that her sister would get better if she used the treatment from Dr Rath for at least two months. Her sister subsequently died.³⁴

78.7. Zondani Magwebu states that his wife Noluthando Magwebu was diagnosed with HIV in 2002. A neighbour took her to the Rath Clinic. When his wife came back, she had been given VitaCell tablets. She had been told to take ten tablets in the morning and ten at night. On a subsequent occasion she returned to the Rath Clinic and came back with three more bottles of VitaCell and other medicines. She continued taking these medicines, and died about a month later.³⁵

79. These accounts are confirmed by the evidence of Dr Peter Saranchuk.³⁶ He is a registered medical doctor who works at a comprehensive provincial HIV clinic administered by the provincial administration of the Western Cape in Site C, Khayelitsha. He reports on his experience in his practice:

79.1. Patient 1 had a lung infection, possibly tuberculosis. She was taking multivitamins prescribed by the second respondent. She believed that the vitamins would make her immune to infections.

³⁴ Annexure NG10 pages 311-312.

³⁵ Annexure NG11 pages 315-317.

³⁶ Annexure NG13 pages 321-330

- 79.2. Patient 2 was ill with abdominal pains and vomiting. The diagnosis was pelvic inflammatory disease. She could not understand how she could have an infection, as she was taking multivitamins which had been prescribed to her by the Rath Foundation.
- 79.3. Patient 3 was very sick, in the final stage of HIV infection. She improved as a result of treatment. She reported to Dr Saranchuk that she had been referred by a homecare worker to the Rath Foundation Clinic, and understood that the Rath treatments would fight HIV. The result had been that she had stopped taking the antiretrovirals for a period of two weeks.
- 79.4. Patient 4 was extremely ill with HIV and related diseases. Dr Saranchuk established that for a period of two months before he came to hospital for treatment, he had been a patient at one of the Rath clinics.
80. These accounts show that the first and second respondents have been supplying or disposing of the Rath vitamin products to persons who are ill, claiming that they are suitable for use in the treatment or mitigation or modification of the diseases suffered by the persons concerned. This is

directly in breach of the prohibition on the sale of unregistered medicines which are required to be registered.

81. The Rath respondents consistently advertise these medicines as suitable for use in the treatment, mitigation, modification or prevention of HIV/AIDS. Examples of this are the following.

82. Annexure FV14³⁷ is a newsletter published by the second respondent. It states that “*dozens of young men and women*” from Khayelitsha with AIDS have achieved the reversal of the course of AIDS, and improved their health, by using “*micronutrients*”. It is stated that the first respondent, the founder of the second respondent, has donated a vitamin program to HIV positive people of Khayelitsha and Gugulethu “*to improve their health*”. It refers to “*the vitamins donated by the Dr Rath Health Foundation*”. Page 3 of that document consists of testimonials by persons who state that as a result of taking vitamins, they have been cured of HIV/AIDS.

83. Annexure NG16³⁸ describes what is referred to as a “*vitamin community programme*”. It describes the activities of the Rath Clinic in Khayelitsha, and states that “*a combination of vitamins and other micronutrients can improve immune system function and quality of life for AIDS patients.*” It

³⁷ Pages 270-281.

³⁸ Pages 356 - 365.

states that AIDS-related symptoms have been reversed through the use of these vitamins.

84. Annexures FV8 – FV14,³⁹ NG16 – 17,⁴⁰ and NG22 – NG32⁴¹ are advertisements and pamphlets published by the first and second respondents in which they make the explicit and repeated claim that vitamins, multivitamins and micronutrients can reverse the course of AIDS.
85. This is illustrated by the transcript of an interview conducted on the radio between P4 Radio and the first respondent, the fifth respondent and a Marietta Tanziba on P4 Radio on 27 April 2005. The core of it is a claim that Ms Tanziba *“is currently on vitamins for, who is HIV positive and these are vitamins, vitamins as prescribed or noted by the Foundation.”*⁴² Ms Tanziba describes her treatment with the vitamins, which she says has improved her life.⁴³
86. This conduct of the first and second respondents is further illustrated by the transcript of an interview between the first respondent and Radio 786 on 19 April 2005. There, the first respondent says the following:

³⁹ Pages 243 - 281.

⁴⁰ Pages 356 - 367.

⁴¹ Pages 392 - 415.

⁴² Annexure NG48 pages 504 (lines 25-26) – 505 (line 1)

⁴³ Pages 515, line 20 – page 516, line 11.

“All we are doing is, we are helping the 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 how they are after that. And we found dramatic, dramatic improvements which we actually published last Thursday in the ... Durban (indistinct) on a centre spread.”⁴⁴

87. The products concerned are advertised on the website of the first and second respondents. The advertisements appear in Annexure ALG3 to the affidavit of Mr Gray.⁴⁵

The sale of scheduled substances

88. The products advertised on the first respondent’s website, and supplied to certain of the persons who visited the Rath Clinic, include Epican Forte and VitaCell.
89. The contents of Epican Forte are described on the first respondent’s website.⁴⁶ They include 200mg of N-acetylcysteine. According to its packaging, the second respondent’s product VitaCell also contains N-acetylcysteine.⁴⁷ Dr Rath acknowledges that VitaCell contains N-acetylcysteine.⁴⁸

⁴⁴ Annexure NG47, page 486 lines 16 – 21.

⁴⁵ Pages 353-354.

⁴⁶ Annexure ALG3 page 354.

⁴⁷ Gray para 26 page 344.

⁴⁸ Rath para 313 pages 2 930-2 932.

90. N-acetylcysteine is a Schedule 2 substance under the Act. It may therefore only be sold by a pharmacist or other person listed in section 22A(5) of the Medicines Act, and under the conditions listed in section 22A(6) of the Medicines Act.⁴⁹
91. We submit that it is, to put it at its lowest, highly probable that VitaCell and Epican Forte are being sold by the first and second respondents under circumstances which constitute multiple breaches of section 22A of the Medicines Act, in particular sections 22A(5) and (6).⁵⁰

Vitamins containing an excess of the permitted amount in the prescribed dose

92. We submit that the call-up Notice 204 of 22 February 2002 governs all “*nutritional substances that purport to have therapeutic or medicinal effects*”, and that accordingly the vitamin, multivitamin and micronutrient products distributed by the first and second respondents are required to be registered under the Act.
93. If however it is for some reason held that Notice 204 of 2002 is not a notice in terms of section 14(2) of the Act – as the government

⁴⁹ Gray para 27 page 344.

⁵⁰ Gray para 28 page 345.

respondents apparently assert – then the prior Notice 559 of 15 March 1985 is applicable. Notice 559 requires the registration of all preparations containing a vitamin or vitamins which contain or exceed per the recommended daily dose, the amount stipulated in the Schedule.

94. Mr Gray has conducted an analysis of the stated contents and recommended dosages of four Rath products, namely VitaCell, Lysin C-drink, Epican Forte and Vitacore Plus. He obtained the contents and recommended dosages of these products from the website of the first and second respondents.⁵¹ He prepared a detailed analysis in which he compared the recommended daily dosages of these four Rath products with the dosages which in terms of Government Notice 559 trigger the registration requirement.

95. That analysis is annexure ALG2 to his affidavit⁵². As appears from that analysis:

95.1. Epican Forte and Lysin C exceed the registerable limit for vitamin C on the basis of the website dosage alone;

⁵¹ Gray para 7 page 336.

⁵² Pages 350-352.

- 95.2. Vitacore Plus exceeds the limits for Vitamins B1, B2, B6, B12, C, E and Pantothenic Acid on the basis of the website dosage alone.
- 95.3. The dosage recommended to Nandipha Ntsholo was three times the labelled dose of that medicine, and the verbally recommended dose of Epican Forte was 1.5 higher than the labelled dose.⁵³
96. It follows that all four of these products are liable to registration under Government Notice 559 of 1985, whether the “*recommended daily dosage*” is taken as that published on the labels and the Rath website, or that actually recommended to the persons who were given these products at the health facilities ran by the first and second respondents.⁵⁴

Unauthorised clinical trials

97. No person may conduct a clinical trial without prior authorisation of the Medicines Control Council.

⁵³ Gray para 14 page 339.

⁵⁴ Gray para 15 page 340.

98. Various of the Rath respondents have conducted clinical trials for humans in South Africa without authority from the MCC. This appears both from the “*Khayelitsha affidavits*”, and from the statements of the Rath respondents in their various publications and in interviews. Examples of the latter are the following.

99. The advertisement in the *Natal Mercury*⁵⁵ 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 cause 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 program. The nutrient program 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 program. 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.”

100. We submit that in the light of the definition of “*clinical trial*” in the Regulations, it is difficult to find a clearer statement that a clinical trial was conducted. This study was “*an investigation in respect of a*

⁵⁵ Annexure FV13 pages 262-269.

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... or ascertain its safety or efficacy.” The advertisement includes alleged before and after information about 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.

101. The advertisement states that *“the scientific responsibility of these results is shared by Alexandra Niedzwiecki Ph.D. (Dr Rath Health Foundation USA) [fifth respondent], David Rasnick, Ph.D. (Dr Rath Health Foundation, South Africa) [fourth respondent], Sam Mhlongo M.D. (Medical University of Southern Africa, South Africa) [third respondent] and Matthias Rath, M.D. [first respondent].”*

102. The first and second respondents have repeatedly published statements that they have conducted a *“clinical pilot study”* in Khayelitsha, Cape Town, and that the goal of the study was *“to show that a combination of micronutrients can reverse the course of Aids, even in its advanced stage.”* The scientific responsibility is generally attributed as in the Mercury advertisement to which we have referred. Examples of this are the following:

- 102.1. an advertisement in the New York Times;⁵⁶
- 102.2. a pamphlet distributed for Freedom Day;⁵⁷
- 102.3. an entry on the website of the second respondent.⁵⁸
103. The first respondent personally made these statements during the course of the radio interviews to which we have referred above.⁵⁹ The same claim is made in an interview in *Die Burger*.⁶⁰ The interviewer asks Dr Rath “*Het die Medisyne Beheerraad sy goedkeuring vir die studie gegee?*”. To this Dr Rath is quoted not as denying that he carried out a study, but as answering “*Nee, die Raad beheer medisyne. Dit is nie medisyne nie.*”
104. Dr Rath now seeks to suggest that these were the activities of SANCO, and not of the Rath respondents:

“The nutritional supplements were distributed to community members by the South African National Civic Organisation (SANCO) at its own locations or through community physicians.”⁶¹

⁵⁶ Annexure NG23 pages 394-395.

⁵⁷ Annexure NG27 pages 399-406.

⁵⁸ Geffen para 100 page 46.

⁵⁹ The Radio 786 interview NG47, page 486 lines 16-19; the P4 Radio interview NG48, page 506 lines 9 – 13.

⁶⁰ Annexure NG49 pages 527-528.

⁶¹ Rath answering affidavit, paragraph 11.

*“Fact is that we have never conducted any clinical trials in South Africa. The distribution of vitamin programmes is organised by SANCO or community physicians with the informed consent of the participants in these programmes”.*⁶²

105. That denial, however, is (in the well-known formulation in Plascon-Evans) so clearly far-fetched that it can be rejected. It is entirely inconsistent with the Rath respondents’ own repeated statements, none of which they have denied making. It is a desperate attempt to escape liability for their widely-proclaimed conduct, now that its legality has been challenged.

False and unauthorised claims that the Rath medicines are effective in treating or preventing Aids

106. As we have pointed out above, section 20(1) of the Act creates two sorts of offence:

106.1. publishing any false or misleading advertisement concerning any medicine; and

106.2. making a claim as to therapeutic efficacy and effect other than that which has been stated by the Council, or suggesting that a medicine should be used for a purpose or under circumstances other than that stated by the Council.

⁶² Rath answering affidavit, paragraph 12.

107. We submit that the Rath respondents have demonstrably committed this offence in both of its forms.

False or misleading statements

108. As we have pointed out above, the various Rath respondents have made numerous claims that vitamins and micronutrients in general, and their products in particular, can reverse the course of Aids, even in its advanced stage. The clearest statements to that effect are those to which we have referred in the section of these heads of argument dealing with unauthorised clinical trials. Similar statements were made to the persons who made the Khayelitsha affidavits. The statements are repeated frequently in the radio interviews and the interview in *Die Burger*, and also in the various advertisements and pamphlets published by the Rath respondents. These include the following: NG17,⁶³ NG25,⁶⁴ NG26,⁶⁵ and NG31.⁶⁶
109. The applicants have placed before the Court the evidence of Dr Francois Venter, who is an expert in the science of HIV/AIDS.⁶⁷ He is a specialist physician, and is the clinical director of the Reproductive Health and HIV

⁶³ Pages 366-367

⁶⁴ Page 397

⁶⁵ Page 398

⁶⁶ Pages 410-413

⁶⁷ NG4 pages 135-172.

Research Unit at the University of the Witwatersrand. He is the president of the Southern African HIV Clinicians Society, which has over 9300 members. He is a senior consultant at 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 20 peer-reviewed articles on HIV/AIDS.⁶⁸ We submit that he is plainly an expert, and what is more a very eminent expert, on the current status of the science of HIV treatment with particular reference to antiretroviral medicines and micronutrients.

110. Dr Venter states that there is some evidence that a specific combination of multivitamin supplements in specific doses slows down the progression of HIV to AIDS. There is however no evidence that vitamins or micronutrients reverse the course of AIDS. The available evidence shows only that a particular combination in a particular dose delays the onset of AIDS in a specific group of patients.⁶⁹
111. He states further that the MCC has not registered any micronutrients for the treatment of HIV, and to the best of his knowledge no other regulatory authority has done so.⁷⁰

⁶⁸ NG4 paras 1 – 10 pages 137-139.

⁶⁹ Paras 29, 32 pages 145-146.

⁷⁰ Para 35, page 146.

112. Dr Venter refers to the conference statement of the World Health Organisation consultation on nutrition and HIV/AIDS in Africa, which was held in Durban from 10 – 13 April 2005. The conference included the world's experts on nutrition and HIV. The Statement by the Participants (annexure FV6)⁷¹ represents the current international scientific consensus on nutrition, micronutrients and HIV. That Statement makes, *inter alia*, the following points:

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

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

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

112.4. micronutrient supplements are not an alternative to comprehensive HIV treatment including ARV therapy.⁷²

⁷¹ Pages 223-226

⁷² Venter para 35 page 147.

113. From a detailed analysis of the claims made by the Rath respondents about micronutrients, Dr Venter concludes that they are false and misleading.⁷³
114. None of the respondents has produced any acceptable expert evidence to rebut this evidence of Dr Venter, who is highly qualified in this regard. The evidence of Dr Venter is confirmed by that of Professor Rollins, who is internationally recognised as an expert in the field.⁷⁴
115. Under the circumstances, we submit that it has been proved that the first to seventh respondents have made false claims regarding medicines, namely vitamins, multivitamins, micronutrients, and the products distributed by the first and second respondents.
116. Similarly, the claims made in respect of the medicines promoted by the Rath respondents are claims to therapeutic efficacy other than those which have been stated by the Council, and suggestions that the medicines concerned should be used for a purpose or under circumstances other than those stated by the Council.

⁷³ Venter paras 62 – 70 pages 156-163.

⁷⁴ Pages 5757-5826.

117. We submit that it follows that it has been proved that the various Rath respondents have contravened both legs of the prohibition contained in section 20 of the Act.

118. The respondents have also made demonstrably false or misleading statements concerning the nature and effect of antiretroviral medicines. However, these statements are not made in order to promote the sale of such (antiretroviral) medicines. It follows that they do not fall within the scope of the definition of "*advertisement*".

PART 4:**THE ANSWER OF THE SIXTH AND SEVENTH RESPONDENTS**

119. The sixth respondent, Mr Brink, is a non-practising advocate. He is the “*convenor and national chairman*” of the seventh respondent, the Treatment Information Group. At the time when this application was launched he worked for the second respondent, but he no longer does so, although he and the Treatment Information Group “*remain strategically allied with it*”.⁷⁵

120. Mr Brink has filed a 165-page affidavit together with 106 annexures which run to 1289 pages.

121. As we pointed out in the introduction to these heads of argument (“The Issues”), this application concerns the following questions:

121.1. whether the Rath respondents are distributing medicines in contravention of the Medicines Act;

121.2. whether the Rath respondents are conducting unauthorised clinical trials in contravention of the Medicines Act;

⁷⁵ Brink para 2-5, page 1068.

121.3. whether the Rath respondents are publishing unauthorised, false and misleading advertisements concerning vitamins, multivitamins, and certain products produced by Dr Rath and the entities associated with him;

121.4. whether the Government has taken reasonable measures to investigate and put an end to such activities.

122. Mr Brink's affidavit and the annexures do not address these questions. He acknowledges at the outset that he claims no expertise on the subject of nutrition. He says that while he was working for the second respondent he was not involved in its "*micronutrient supplementation programme*" which, as he acknowledges, "*lies at the core of this case*". He is accordingly "*not placed to give useful direct evidence about it, and so shall not address the applicants' case in this regard.*"⁷⁶

123. It follows that Mr Brink's extensive affidavit and annexures are irrelevant to the case which the applicants make and the relief which they seek.

124. The affidavit and annexures consist almost entirely of the following:

124.1. Mr Brink's views with regard to scientific matters relating to HIV/AIDS and antiretroviral medicines;

⁷⁶ Brink para 13, page 1071.

- 124.2. attacks on the first applicant and its leading figures, particularly Mr Achmat;
 - 124.3. attacks on the medical profession;
 - 124.4. attacks on the Medicines Control Council; and
 - 124.5. attacks on the judiciary.
125. In essence, Mr Brink's affidavit is a polemical attack on those with whom he disagrees, and a statement of his opinions with regard to scientific matters. Although it is irrelevant to the issues before the court, for the sake of completeness we deal with it briefly in these heads.
126. We wish to point out at the outset that the affidavit is replete with hearsay of the most egregious kind. Mr Brink, who has practised law, ought to know better. It is not clear whether the reason his affidavits are filled with hearsay is that in fact he does not know better, or that in fact he does know better, but does not care.

Attacks on those with whom he disagrees

127. The nature of Mr Brink's approach, and the weight which should be attached to it, is illustrated by his gratuitous, polemical and insulting attacks on those persons with whom he disagrees. Examples of this are the following.

128. In relation to the South African judiciary, he refers to its "*ardour*" for "*this ridiculous bogey*" of what he refers to as "*the contemporary Aids scare*".⁷⁷ He then proceeds to make successive gratuitous attacks on "*51 judges of this Division*";⁷⁸ Desai J, Louw J and Moosa J;⁷⁹ "*the entire Supreme Court of Appeal Bench*" which "*labours under the same fantastic apprehensions*";⁸⁰ Langa CJ;⁸¹ Bertelsman J.;⁸² Sachs J.;⁸³ Chaskalson CJ.;⁸⁴ and Van der Merwe J.⁸⁵

129. His attacks on the Medicines Control Council involve comparing them with the Broederbond, accusing the persons concerned of being "*disgracefully ignorant, indolent, incompetent and demonstrably*

⁷⁷ Brink para 16, page 1072.

⁷⁸ Brink para 46, page 1083.

⁷⁹ Brink para 57, page 1088; AB7, pages 1395 – 1397.

⁸⁰ Brink para 58, page 1088.

⁸¹ Brink para 59, page 1089.

⁸² Brink para 60, page 1089.

⁸³ Brink para 61; page 1090.

⁸⁴ Brink para 61; page 1090.

⁸⁵ Brink para 62, page 1090 – 1091.

incapable of discharging their statutory responsibility”⁸⁶ and “rank professional indolence and incompetence”⁸⁷.

130. An analysis of the personal and gratuitous attacks on the TAC and the people in its leadership would have to be so extensive that it would unnecessarily lengthen these heads of argument. It is sufficient to say that they are personal, insulting and polemical, and also demonstrably inaccurate where they consist of allegations of fact as opposed to mere abuse.

131. We submit that Mr Brink’s claim to objective scientific expertise ought to be viewed through the prism of his conduct in this litigation.

Scientific expertise

132. The essence of Mr Brink’s position is captured in the following statement which he makes:

“I deny that the expressions ‘exposed to HIV’ and ‘contracting HIV’ have any more empirical content than possession by the Devil even if they are just as exciting.”⁸⁸

⁸⁶ Brink para 266, page 1160 – 1161.

⁸⁷ Brink para 423, page 1207.

⁸⁸ Brink para 423, page 1218.

133. Mr Brink has no formal training in the subject of medicine or ARV pharmacology. He is, on his own version, “*a self-trained expert*”.⁸⁹ He has received no scientific or medical training, and has no university degree in this area. He has taught himself.
134. He says that his expertise was recognised by his being honoured with a co-authorship credit of a “*major scientific monograph*” on mother to child transmission of HIV.⁹⁰ That monograph is AB38 to his affidavit.⁹¹ It is a typescript document, not published in any journal or by any recognised publisher. It is “*published*” by “*the Perth Group*” in Australia.⁹²
135. Mr Brink also refers to other materials which he has published. As far as we have been able to establish, they are all self-published. It does not appear that any one of them, including AB38, has been subjected to any process of scientific peer review.
136. Annexure NG83 to the applicants’ replying affidavit is an affidavit by Prof George Ellis.⁹³ Prof Ellis was until his recent retirement Professor of Applied Mathematics at the University of Cape Town. His qualifications are set out in some detail in paragraph 2 of his affidavit.⁹⁴ We do not repeat them here. It is sufficient to say that he holds a doctorate from

⁸⁹ Brink para 10, page 1070.

⁹⁰ Brink para 10, page 1070.

⁹¹ Page 1575 – 1777.

⁹² Page 1576.

⁹³ Pages 2600 – 2635.

⁹⁴ Pages 2601 – 2604.

Cambridge University, and honorary doctorates from Haverford College (Pennsylvania), the University of Natal, and Queen Mary College (London University). He has been a visiting professor at various universities in other parts of the world; has lectured and given seminars at eminent academic institutions throughout the world; was awarded a comprehensive CSIR (Foundation for Research Development) support grant in the “A” category; was awarded the South African medal (Gold) by the South African Society for the Advancement of Science; was awarded the Star of South Africa Medal by President Mandela; and was awarded the Order of Mapungubwe by President Mbeki. He holds numerous fellowships and positions of leadership in learned societies.

137. It is fair to say that Prof Ellis is one of South Africa’s most distinguished scientists.

138. Prof Ellis states that where a scientific claim is made, it needs to be examined with the following questions in mind:⁹⁵

138.1. has the person, who is making the claim, been trained and tested in scientific method and in the particular field of study, by persons who are recognised as knowledgeable and expert in the field?

⁹⁵ Pages 2604-2605.

- 138.2. has this training been recognised by an institution of recognised scientific standing, such as a university, through the award of a degree or other qualification?
- 138.3. what is the source of the claimed knowledge in terms of its theoretical basis, and how satisfactory is this linked to the proposed theory? When it is based to some degree on quotation from other sources, how reliable are those resources?
- 138.4. has the claimed knowledge been tested, and if so how? In what way do experiments or observations support the claims made?
- 138.5. can the person claiming the knowledge, persuade honest scientist with expertise in the field that he or she is correct?
- 138.6. has the claimed knowledge been published in peer review to journals or other publications, where it has to stand rigorous scrutiny by people with expertise in the relevant field?
- 138.7. have other who have knowledge and expertise in this area invited the person making the claim to make presentations at conferences, in order to enlighten them.⁹⁶

⁹⁶ Ellis para 6, page 2604-2605.

139. Prof Ellis then concludes as follows:

“If the person making the claim is not able to answer these questions satisfactorily, then the claim can safely be discounted, at least on a provisional basis, until more substance has been provided to the claim. Those not properly trained in scientific method, and without a proven record of accomplishment in some scientific domain, are not reliable arbiters on what is and is not established as scientific truth. The fact that the person who is making the claim may intensely and sincerely believe that he or she is right, does not show that he or she is indeed right.”⁹⁷

140. Prof Ellis further states as follows:

“A person who purports to be a scientist, and who makes extravagant claims that those who disagree with him or her are dishonest or fraudulent, immediately raises questions about his or her own scientific integrity.”⁹⁸

141. The “*scientific evidence*” which is submitted by Mr Brink is in any event irrelevant to any of the questions which this Court has to determine. However, to the extent that it might conceivably be considered to have some tangential relevance, Mr Brink on his own showing is not a scientific expert. His “*evidence*” in this regard is simply the statement of

⁹⁷ Ellis para 7, page 2605 – 2606.

⁹⁸ Ellis para 13, page 2607 – 2608.

his opinion, which some may find interesting, but which does not constitute evidence as to the truth of its contents, because it is the expression of opinions which he is not competent as an expert to express. It can and simply should be disregarded.

142. In truth, Mr Brink's abusive, polemical, and irrelevant answering affidavit and annexures constitute an abuse of the process of Court.

PART 5:**THE ANSWER OF THE FIRST TO FIFTH RESPONDENTS**

143. The first to fifth respondents rely principally on an affidavit by Dr Rath, the first respondent. His affidavit runs to 320 pages, and includes an additional seven files of annexures. It can be divided into three parts:

143.1. A wide-ranging polemical attack on the pharmaceutical industry and “*pharmaceutical colonialism*”. This is irrelevant to the matters which this court is required to decide. Most of it is also inadmissible. We shall not address it.

143.2. Specific responses to factual allegations made by the applicants. We address those matters, where they are relevant, at the appropriate point in our analysis of the facts of the case. In this section of these heads of argument we make submissions as to the general approach to his truthfulness as a witness.

143.3. Assertions in respect of scientific matters on which Dr Rath apparently claims to be an expert witness in this matter. We address this in this section of these heads of argument.

THE APPROACH TO THE EVIDENCE OF DR RATH

144. We submit that the evidence shows that Dr Rath:

144.1. is not an honest person on whom a Court can place reliance as to facts; and

144.2. is not a witness on whom a Court can rely as an expert with regard to scientific matters.

HONESTY AS TO FACT

145. There are three incidents which demonstrate that when it suits him, Dr Rath simply does not tell the truth. These are matters which are not incidental to this case: they go close to the heart of it. They are the following:

145.1. the response to the interim interdict granted by this Court on 3 March 2006;

145.2. the response to the complaint that the Rath respondents have conducted unapproved clinical trials; and

145.3. the attempt to justify and explain the belated filing of answering affidavits.

146. We deal with each of those in turn.

The response of the Rath respondents to the interim interdict⁹⁹

147. During 2005, the TAC brought an application against Dr Rath and the foundation for an order interdicting them from publishing defamatory statements about the TAC, pending the determination of an action for damages. On 3 March 2006, the Court delivered judgment.¹⁰⁰

148. The Court interdicted the respondents from publishing any statement that the TAC:

148.1. is a front for pharmaceutical companies or the pharmaceutical industry, or the *“Trojan horse”* of that industry, or the *“running dog”* of that industry;

148.2. is funded by pharmaceutical companies or the pharmaceutical industry;

148.3. receives funds from pharmaceutical front organisations in return for promoting anti-retroviral drugs;

148.4. targets poor communities as a market for the drug industry in order to promote the interests of pharmaceutical industries.

⁹⁹ This is dealt with by Geffen: replying affidavit, paragraphs 12 to 27.

¹⁰⁰ Annexure NG89, pages 2673 to 2688.

149. The Court found that the evidence showed that as a matter of deliberate policy, the TAC had not received money from drug companies either directly or indirectly, and had implemented mechanisms to preclude such an eventuality. The Court found that save for speculation and conjecture, the respondents had produced no factual material to advance a sustainable defence in respect of those defamatory allegations.
150. The TAC also sought an order interdicting the respondents from publishing statements that the TAC organises rented crowds for the drug industry; that it pays people to participate in demonstrations; that it encourages people to take toxic medicine which is harmful to them and will kill them; that it forces the government to spend millions of rand on toxic drugs and to spread disease and death among the people of South Africa; and that it destabilises democracy in South Africa.
151. The Court was not persuaded that these statements were defamatory or that the TAC had established a *prima facie* right to the relief sought in respect of those statements. Having regard to the importance of free expression, the Court accordingly declined to grant an interdict in respect of these statements. The Court made no finding on whether the statements were true, except to say

“the suggestion that the TAC destabilises democracy is incapable of fair-minded support ... The tactics employed by the TAC may be somewhat boisterous and, at least in one instance, abusive towards the Minister of

Health. Their conduct, however, does not threaten the security of the state and few, if any, right-thinking South Africans would see it in that light".¹⁰¹

152. Immediately after that judgment had been given, the second respondent (which is the first respondent's alter ego) published a pamphlet entitled "*High Court ruling exposes TAC!*"¹⁰² It states, *inter alia*:

"The Cape High Court found that the reason why the Treatment Action Campaign (TAC) has been fighting against the Dr Rath Health Foundation and its allies, the South African National Civics Organisation (SANCO), is because they want to spread disease and death amongst the people of Khayelitsha and South Africa as a whole.

"In the ruling of March 3 2006, the judges have affirmed that: "The TAC forces the government to spread disease and death among the people of South Africa ..."

"Even the Court exposed the TAC for what it is. The High Court looked behind its 'Mother Theresa' cover and identified its true business as an organisation that, among other things – is spreading disease and death among the people".

153. In a further pamphlet¹⁰³ the second respondent said the following under the heading "*High Court ruling exposes TAC!*":

¹⁰¹ Page 2682.

¹⁰² NG94 page 5966.

¹⁰³ NG95 page 5967

“Judges affirm: ‘TAC forces the government to spread disease and death among the people of South Africa’.

“... After 8 months of careful deliberations the High Court ruled that the majority of exposures about the TAC’s business are correct, and they will not be interdicted ... After this thorough deliberation, the judges now affirmed the most devastating exposures of the TAC, including that it helps promote disease and death among the people of South Africa ...”

“For the first time in the history of democratic South Africa, the High Court found the following to be truthful statements about any organisation in South Africa:

“The TAC organises rented crowds for the drug industry”...

“The TAC pays people to participate in its demonstrations”...

“The TAC encourages people to take medicine which is harmful to them and will kill them”

“The TAC forces the government to spend millions of rand on toxic drugs” ...

“The TAC forces the government to spread disease and death among the people of South Africa” ...

“The applicant destabilises democracy in South Africa””

154. The judgment makes it absolutely clear that the reason why the Court did not grant an interdict in respect of these statements was not because it found them to be true, but because it was not persuaded that they were defamatory. The only one of those statements on which the Court made a finding of fact was: *“The applicant destabilises democracy in South Africa”*. The Court found that this statement was *“incapable of fair-minded support”*.

155. Dr Rath personally associated himself with the statements in these pamphlets. He stated the following:¹⁰⁴

“By unmasking yet another organisation which helps to spread disease and death across the country we have made an important contribution to the people of Africa and to the liberation of Africa from debilitating economic dependency. The courageous and historic verdict of the High Court of Cape Town encourages the people and government of South Africa to take the necessary action and rid the country of this and other undue burdens”.

156. This patent dishonesty is carried through into Dr Rath’s answering affidavit in this case. He says¹⁰⁵ that this Court *“stated we could not – yet – conclusively prove that the ‘TAC’ operates as a front for the pharmaceutical industry”*. What the Court in fact stated was: *“The evidence shows that as a matter of deliberate policy the Applicant has*

¹⁰⁴ NG95 pages 5967-5970.

¹⁰⁵ Para 42 page 2749.

*not received monies from drug companies either directly or indirectly and it has implemented mechanisms to preclude any such eventuality.*¹⁰⁶

157. No honest person could possibly make the statements which are made by the first and second respondents in the pamphlets which they distributed, and in the answering affidavit in this matter.

The clinical trials in Khayelitsha¹⁰⁷

158. In a series of publications, advertisements and statements, the first and second respondents refer to *“a clinical study conducted by the Rath Foundation; we conducted a clinical pilot study in HIV patients with advanced AIDS”*.¹⁰⁸
159. They state: *“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.”*¹⁰⁹
160. Dr Rath stated in interviews: *“We are helping the 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”*,¹¹⁰ and *“we have just completed a clinical pilot study with the nutritional programme, so we are not treating patients but we are giving*

¹⁰⁶ Page 2686.

¹⁰⁷ This is dealt with in the replying affidavit of Geffen paras 43 to 63, pages 5718-5724.

¹⁰⁸ See annexures FV13, NG22, NG23 and NG27, pages 262, 392, 394 and 399.

¹⁰⁹ Page 266.

¹¹⁰ NG47 page 486.

them nutrients, micronutrients, vitamins and other essential nutrients. And we have showed results ...".¹¹¹

161. He refers further to: *"The encouraging results of a pilot nutrient programme with AIDS patients we conducted in Khayelitsha, Cape Town"*.¹¹²
162. Further examples of this are given in the affidavit of Mr Geffen in the passages we have cited, and in these heads of argument.
163. Quite remarkably, in these proceedings - now that the legality of these activities is in issue - Dr Rath seeks to pass these activities off as those of SANCO, and to deny that he and the second respondent have conducted clinical trials:

"The nutritional supplements were distributed to community members by the South African National Civic Organisation (SANCO) at its own locations or through community physicians".¹¹³

"Fact is that we have never conducted any clinical trials in South Africa. The distribution of vitamin programmes is organised by SANCO or community physicians with the informed consent of the participants in these programmes".¹¹⁴

¹¹¹ Page 506.

¹¹² NG102 page 6500.

¹¹³ Rath para 11 pages 2734-2735.

¹¹⁴ Rath para 12 page 2735.

164. This is further evidence of dishonesty. Dr Rath has made widespread and repeated statements, both locally and internationally, that he and the foundation have distributed these products and conducted a clinical pilot study. He does not deny having made those statements. The truth of these statements is confirmed by the people who have received these products.¹¹⁵ Now that the legality of these activities is in issue, Dr Rath states under oath that they were not his activities at all, they were the activities of SANCO. This is patently false.

The condonation application

165. Dr Rath's dishonesty, including under oath, was further demonstrated in the condonation application in this matter.

166. In that application, Dr Rath made an affidavit which purported to explain why he had delayed for more than a year in filing his answering affidavit. That explanation was patently dishonest. It was inconsistent with the statements previously made by his attorney, and it was simply not credible on its own terms. The honesty of the explanation was placed in issue. In his judgment,¹¹⁶ Fourie J found that the explanation "*does not bear scrutiny*".

¹¹⁵ NG5 page 285; NG6 page 293; NG9 page 304; NG10 page 311 and NG11 page 315. See also paras 94, 98, 99, 100, 101, 104, 106 and 107 of the founding affidavit of Geffen pages 45-48.

¹¹⁶ NG97 page 5980.

167. We submit that these three examples alone show that Dr Rath is not a person who can be relied upon to speak the truth. When it suits his case, he is dishonest.

DR RATH AS AN EXPERT WITNESS

168. The evidence of Dr Rath shows that with regard to scientific matters, he is not a person on whom the Court can place any reliance as an expert witness. This is so for multiple reasons. We mention three:

168.1. He does not meet the standards of independence and objectivity required of an expert.

168.2. His extravagant and hyperbolic claims about his own expertise are sufficient reason to reject his evidence.

168.3. The quality of his evidence disqualifies him as an expert on scientific matters:

168.3.1. He is unable or unwilling to consider in an open-minded fashion the views of those who disagree with him, simply dismissing them on the basis of those persons' alleged associations or connections with the pharmaceutical industry.

168.3.2.He misrepresents or misunderstands the evidence on which he relies in support of his claims.

168.3.3.He ignores or suppresses evidence which is contrary to the position which he is advocating.

169. We deal with each of these in turn.

Independence and objectivity

170. The requirements of an expert witness are well known. The fundamental starting point is the following:

*“Expert witnesses should be impartial”.*¹¹⁷

171. This does not mean that an expert may not have an opinion on the matter in question. On the contrary, the very purpose of an expert witness is to express an expert opinion. What is required is that:

*“An expert must assist the Court by providing objective, unbiased opinion on matters within his expertise, and should not assume the role of an advocate. He must consider all material facts, including those which might detract from his opinion ...”*¹¹⁸

172. This gives rise to the need for independence:

¹¹⁷ *Doyle v Sentraoer (Cooperative) Ltd* 1993 (3) SA 176 (SE) at 181B.

¹¹⁸ Halsbury’s Laws of England (4th ed) Vol 17(1) paragraph 764.

*“It is essential that an expert be independent, that is to say that although he may have been identified, retained and remunerated by one of the parties, the Court must be satisfied that he will give his objection in an objective and balanced manner appropriate to scientific discourse, and that he will place his duty to assist the Court above any duty of loyalty to the party who has retained him... There are many ... circumstances in which the independence of an expert witness may be called into question, for example where he is related to a party, or is an employee of a corporate party, or even perhaps where he has given evidence for the same party or for other claimants or defendants in similar cases on previous occasions”.*¹¹⁹

173. The importance of objectivity and a lack of bias has repeatedly been emphasised:

*“The testimony of an expert is likely to carry more weight, and more readily relate to an ultimate issue than that of an ordinary witness. It is thus understandable that higher standards of accuracy and objectivity should be required. The obligations of an expert witness in these respects were helpfully summarised by Cresswell J in The Ikarian Reefer, in the course of which he remarked that “An expert witness should provide independent assistance to the Court by way of objective, unbiased opinion in relation to matters within his expertise ... An expert witness in the High Court should never assume the role of an advocate”.*¹²⁰

¹¹⁹ Murphy On Evidence (8th ed) 371 to 372.

¹²⁰ Cross and Tupper on Evidence (9th ed) 522 to 523.

174. This raises a flaw which goes to the heart of the evidence of Dr Rath, to the extent that he purports to give expert evidence. He is not simply related to or employed by a party: he is the party. We submit that on a fair reading of his evidence, no-one could suggest that he is independent, objective, impartial or balanced in his approach to the scientific issues. He is an advocate for the cause which he propagates. He cannot be criticised for that. That is his right. But it can hardly be doubted that it disqualifies him as an expert witness. It is difficult to think of a case in which a person is less able to give expert evidence on which a Court can rely.

175. It is striking, and we submit in fact decisive of the scientific questions, that the only persons whom Dr Rath has been able to produce to support his theories, are:

175.1. Dr Alexandra Niedzwiecki: she is herself a respondent, and who is CEO and Director of Research at the Dr Rath Research Institute in the USA and has "*other administrative functions in the Executive Board of Dr Rath's group of companies*".¹²¹ It is again difficult to conceive of a person less qualified to give independent expert evidence.

175.2. Dr Raxit Jariwalla: He is strikingly silent as to the person or institution by whom he is employed, and does not provide a

¹²¹ Niedzwiecki para 3 page 5688.

curriculum vitae. However, Dr Rath discloses that he heads virology research at the Dr Rath institution which is headed by Dr Niedzwiecki.¹²² This makes him, too, unsuitable as an independent expert. In any event, he does not address any question which has to be decided in this case.

Extravagant and hyperbolic claims about his own expertise

176. Dr Rath's extravagant and hyperbolic claims about his own work throw doubt upon his reliability as a scientist, and as a person capable of giving reliable evidence about these matters. For example:¹²³

176.1. on the outside cover of his book *"Why Animals Don't Get Heart Attacks – But People Do!"*, Dr Rath states:

"This book documents one of the most significant medical breakthroughs ever made in human health".

176.2. in that same book, he states the following of a lecture which he once gave at Stanford University:

"My lecture at Stanford University was a historic event because it broke the stranglehold of the pharmaceutical cartel on established

¹²² Rath para 96 page 2780.

¹²³ Geffen paras 31-34 pages 5715.

*medical institutions ... Twenty minutes of my lecture felt like an earthquake to the house of cards that is pharmaceutical cardiology.*¹²⁴

176.3. In that same book, he quotes himself as saying of his own research:

*“...The greatest study every conducted on Planet Earth has revealed that in billions of animals, cardiovascular disease is essentially unknown because they produce their own vitamin C.”*¹²⁵

177. As Mr Geffen states, if it is true as Dr Rath claims that his work is “*the greatest study ever conducted on Planet Earth*”, it is quite remarkable that he has been unable to produce a single independent scientist to say so. He has to say it himself.

178. Dr Rath’s extravagant and hyperbolic claims about his own research plainly show that he is not an objective person of the kind on whom a court can rely as an expert witness.

The quality of his evidence shows that he is not a reliable expert on scientific matters

179. We have referred above, in the section dealing with the evidence of Mr Brink, to the explanation by Prof Ellis of what constitutes reliable

¹²⁴ Page 5985.

¹²⁵ Page 5989.

scientific evidence. We will not repeat that here. We submit, however, that by any standard, Dr Rath fails miserably to meet what is required of experts on scientific matters.

180. Professor Solomon Benatar is one of South Africa's most distinguished medical scientists. He was Professor and Chairman of the Department of Medicine at the University of Cape Town from 1980 to 1999, and Head of the Department of Medicine at Groote Schuur Hospital from 1980 to 1999. He has had numerous awards and visitorships from some of the most distinguished institutions in the world.¹²⁶
181. Professor Benatar explains in his affidavit¹²⁷ that the Cochrane Collaboration is an international not-for-profit and independent organisation, dedicated to making up-to-date, accurate information about the affects of healthcare readily available worldwide. It produces and disseminates systematic views of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions.
182. Cochrane Reviews are undertaken by Cochrane Review Groups which concentrate on specific healthcare areas. They are based on the best available information about healthcare interventions. They explore the evidence for and against the effectiveness and appropriateness of

¹²⁶ Benatar paras 1-3 pages 6054-6055; and pages 6057-6066.

¹²⁷ Benatar paras 5-10 pages 6055-6056.

treatments in specific circumstances. Each review and the methodology for conducting it are peer reviewed by experts in the field.

183. The authors of Cochrane Reviews are experts in their fields.
184. Cochrane Reviews are a highly authoritative and reliable source of information on the best available evidence-based research on healthcare interventions, and on the effectiveness and appropriateness of specific treatments in specific circumstances. Medical scientists frequently rely on Cochrane Reviews as a comprehensive and reliable source of establishing and assessing the evidence which is available in respect of particular treatments.
185. The Cochrane Collaboration has published a Review titled "*Micro Nutrient Supplementation in Children and Adults with HIV*". A copy of this Review is attached to the First Applicant's replying affidavit to the answering affidavits of the First, Second and Fifth Respondents.¹²⁸
186. One of the co-authors of that Review is Professor Nigel Rollins, Professor of Paediatrics and Child Health, and Head of the Centre for Maternal Child Health Research at the Nelson R Mandela School of Medicine at the University of Kwa-Zulu Natal. He has made an affidavit in this application.¹²⁹

¹²⁸ Annexure NR3, pages 5850 - 5916.

¹²⁹ Pages 5757 to 5826. His *Curriculum Vitae* is at pages 5827 to 5843.

187. The evidence of Professor Rollins is important in two respects:
- 187.1. He confirms the evidence of Professor Venter that the claim made that micronutrients (whether acting alone or with other substances) reverse the course of AIDS is false; and
- 187.2. He demonstrates that the evidence of Dr Rath with regard to scientific matters cannot be relied upon.
188. We have dealt elsewhere in these heads of argument with the falseness of the claim made by the Rath respondents with regard to micronutrients and HIV. In this section we focus primarily on the analysis by Professor Rollins of the evidence of Dr Rath with regard to scientific matters. With regard to the falseness of the Rath claims, we refer here only to the Conclusion of the Cochrane Review:

*“There is no conclusive evidence at present that micro nutrient supplementation effectively reduces or increases morbidity and mortality in HIV-infected adults. It is reasonable to support the current WHO recommendations to promote and support adequate dietary intake of micronutrients at RDA [recommended daily allowance] levels wherever possible. There is evidence of benefit of vitamin A supplementation in children. The long-term clinical benefits, adverse effects and optimal formulation of micro nutrient supplements require further investigation”.*¹³⁰

¹³⁰ Rollins para 38 page 5777; NR3, pages 5850-5916.

189. Dr Rath's apparent claim to be able to give reliable expert evidence founders completely when his use of evidence is analysed. Examples of this are the following:

189.1. Not a single scientific report referred to in his affidavit, even if read uncritically, proves that the claim that micronutrients reverse the course of HIV/AIDS is correct;¹³¹

189.2. He overstates and misrepresents the results of the Fawzi Study on which he relies;¹³²

189.3. He similarly overstates and misrepresents the Jiamton Study;¹³³ he makes no mention of the caution which the authors themselves expressed with regard to their findings;

189.4. He fails to refer to the studies that do not show HIV-specific benefits of micro nutrient supplementation. A failure to address all of the evidence demonstrates scientific incompetence or bias, or both;¹³⁴

189.5. He incorrectly interprets data, indicating either an inability to understand research design and medical statistics or an

¹³¹ Rollins para 59 page 5789.

¹³² Rollins para 61.1 pages 5792 to 5795.

¹³³ Rollins para 61.2 pages 5795 to 57979.

¹³⁴ Rollins para 63, page 5797.

alternative reason for interpreting the data as included in his affidavit.¹³⁵

189.6. He makes a claim from “MWR39” (a WHO document) which is not explained, but merely asserted;¹³⁶

189.7. He makes a claim based on “MWR40” and “MWR41” which is both arithmetically incorrect, and in any event, false: the studies concerned provide evidence that contradict his assertions about antiretrovirals;¹³⁷

189.8. He fails also to mention that the paper in question demonstrated that antiretroviral treatment in operational settings substantially prolongs and improves the lives of people with HIV. He however fails to refer to this, because it does not support his case;

189.9. He fails to appreciate that the Palella Study (“MWR40”) in fact says the opposite of what he claims it says, namely it concludes that *“the recent declines in morbidity and mortality due to AIDS are attributable to the use of more intensive antiretroviral therapies”*.¹³⁸ Again, he fails to refer to the evidence which contradicts his case;

¹³⁵ Rollins para 62, page 5798.

¹³⁶ Rollins para 62.1, page 5799.

¹³⁷ Rollins para 62.2, page 5799.

¹³⁸ Rollins para 62.5, page 5800.

- 189.10. His comparison of the patients in the Palella Study, all of whom had at least one CD count below 100, which means that their HIV infection had already progressed to AIDS, with the general population, suggests either incompetence or dishonesty;¹³⁹
- 189.11. The article by Hogg and others (“MWR41”), records that triple-drug combination antiretroviral therapy has been shown to dramatically decrease morbidity and mortality in symptomatic and asymptomatic HIV infected individuals. This fundamentally contradicts the conclusion which Dr Rath suggests is to be drawn from it.¹⁴⁰
- 189.12. He seriously misrepresents the data in the Hogg study. He deals with the information in a manner which either incompetent or dishonest;¹⁴¹
- 189.13. The finding of the Morgan Study (“NR8”) directly contradicts Dr Rath’s assertion that less than 20% of people with HIV develop AIDS after 13 years since infection. Dr Rath’s assertion is therefore not only unsupported by the report which he claims provides the evidence, it is also false;¹⁴²
- 189.14. He incorrectly represents the findings of the study “MWR48”.¹⁴³

¹³⁹ Rollins para 62.6 and 62.7, page 5800.

¹⁴⁰ Rollins para 62.8, page 5801.

¹⁴¹ Rollins para 62.10 and 62.11, pages 5801 to 5802.

¹⁴² Rollins paras 63 to 65, pages 5802 to 5803.

¹⁴³ Rollins para 67, pages 5803 to 5804.

189.15. He fails to acknowledge the limitations of laboratory experiments as opposed to randomised clinical controlled trials.¹⁴⁴

190. Professor Rollins states that most (if not all) credible scientists in the field of micronutrient science would not regard Dr Rath as a serious or significant researcher in the field. Any credibility he might have is undermined by the extravagant claims, apparently linked to the marketing of his products.¹⁴⁵

¹⁴⁴ Rollins para 69.2, pages 5804 to 5805.

¹⁴⁵ Rollins paras 76 and 77, page 5808.

PART 6:**THE LEGAL OBLIGATIONS OF GOVERNMENT**

191. As pointed out above, the applicants do not seek any relief against the tenth to twelfth respondents, save for an order of costs in the event of their opposing this application.¹⁴⁶ It is for this reason that we refer in these heads to the eighth and ninth respondents, namely the Government of the Republic of South Africa and the Director-General of the Department of Health, as “*the government respondents*”.

The functions and duties of the government respondents*The Constitutional context*

192. Section 12(2) of the Constitution entrenches the right to psychological and bodily integrity. Section 27(1) entrenches the right of access to health care services.

193. The constitutional entrenchment of the right to bodily and psychological integrity is strongly indicative of a legal duty upon the state to take reasonable steps to protect persons from violence perpetrated by third parties.¹⁴⁷ We submit that it is also indicative of a duty on the state to

¹⁴⁶ Notice of Motion para 11 page 5, Geffen para 19-21 pages 13-14.

¹⁴⁷ Van Eeden v Minister of Safety and Security 2003 (1) SA 389 (SCA) at para 18.

take reasonable steps to protect persons from conduct by others which may endanger their health. This is all the more so where the conduct in question is contrary to a statute which, as we show below, places enforcement in the hands of the government. The state has, at a minimum, an obligation to protect the right from improper invasion.¹⁴⁸

The statutes

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

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

194.2. determine the policies and measures necessary to protect, promote, improve and maintain the health and wellbeing of the population.¹⁴⁹

195. The Minister of Health is assisted by the Director-General (“DG”) who in terms of the Health Act is responsible for (amongst other things): insuring the implementation of the National Health Policy.¹⁵⁰

¹⁴⁸ Ex parte Chairperson of the Constitutional Assembly: in re Certification of the Constitution of the Republic of South Africa 1996 (First Certification judgment) 1996 (4) SA 744 (CC) para 78.

¹⁴⁹ Geffen para 153 page 60.

¹⁵⁰ Geffen para 154 page 66.

196. The Medicines Act envisages tight control of the quality, manufacture and dissemination of medicines. The state is the watch-dog which exercises such control.¹⁵¹
197. The Act therefore creates a specialist body (the MCC) to scrutinise all medicinal substances. It clothes the titular head of the appropriate department of the central government (the DG) with a number of powers and duties. His department is to provide *“the requisite administrative, policing and enforcement agencies”*. The legislature has appointed the executive as the general overseeing authority with regard to the working and enforcement of the Act.¹⁵²
198. The DG has the power to authorise as inspectors, such persons as he may consider necessary *“for the proper enforcement”* of the Act. An inspector has wide powers of search and seizure, including powers to enter upon places or premises; to inspect medicines or scheduled substances or books or records or documents; and to seize books, records, documents, medicines or scheduled substances.¹⁵³
199. The Department of Health has a law enforcement unit to which the inspectors are attached.¹⁵⁴ Where the inspectors find evidence of unlawful activities, they supply this to the South African Police Services.

¹⁵¹ Administrator, Cape v Raats Röntgen & Vermeulen (Pty) Ltd 1992 (1) SA 245 (A) at 263

¹⁵² Raats Röntgen at 263.

¹⁵³ Section 26(1) and 28(1).

¹⁵⁴ Geffen para 156 page 61; Mseleku paras 59 – 62 pages 786-787.

Where required by the South African Police Services, the inspectorate assists them with their work, and on request provides the pharmacological expertise the SAPS may require.¹⁵⁵

200. The government has both the legal responsibility to prevent breaches of the Medicines Act, and the mechanisms to achieve this.

¹⁵⁵ Mseleku para 62 page 787.

PART 7:**HAS THE GOVERNMENT CARRIED OUT ITS LEGAL OBLIGATIONS?**

201. The applicants and other concerned parties have, since February 2005, repeatedly brought the unlawful conduct of the Rath respondents to the attention of the government. They have provided the government respondents and the MCC with the information at their disposal, and have attempted to persuade them to take some reasonable and effective action in this regard. We do not set out the full details of those efforts here. In summary, they include the following:

201.1. a telephonic discussion between the chairperson of the first applicant and the chairperson of the MCC in February 2005;¹⁵⁶

201.2. numerous approaches in February and March 2005 by Ms Martha Darder, the co-ordinator of Medecins Sans Frontieres, to the chairperson of the MCC, to Mr Du Toit of the Department's Law Enforcement Unit, to Dr Cloete of the provincial Department of Health, and to Dr Abdullah of the provincial Department of Health;¹⁵⁷

¹⁵⁶ Geffen para 142 page 55.

¹⁵⁷ Darder para 10-20 pages 703-706.

- 201.3. a letter dated 11 March 2005 from the Aids Law Project to the chairperson of the MCC;¹⁵⁸
- 201.4. a letter dated 17 March 2005 from the Legal Resources Centre to the chairperson of the MCC;¹⁵⁹
- 201.5. a letter dated 22 April 2005 from Mr Geffen to the Registrar of Medicines, with copies to the Minister of Health, the DG and the chairperson of the MCC;¹⁶⁰
- 201.6. a letter dated April 2005 from the Legal Resources Centre to the Registrar of Medicines, with copies to the Minister of Health, the DG and the chairperson of the MCC;¹⁶¹
- 201.7. a discussion between Mr Geffen and Mr Lionel Snyman, an inspector employed by the Department of Health;¹⁶²
- 201.8. a radio discussion in which Mr Geffen and the Registrar of Medicines participated on 5 September 2005, in which this matter was raised, and in which the Registrar acknowledged being aware of the Rath vitamins, acknowledged that they were

¹⁵⁸ Geffen para 143 page 55, annexure NG54 pages 614-616.

¹⁵⁹ Geffen para 144 page 57, annexure NG55 pages 617-619.

¹⁶⁰ Geffen para 147 page 58, annexure NG57 pages 622-623.

¹⁶¹ Geffen para 149 page 58, annexure NG58 pages 624-626.

¹⁶² Geffen para 150 page 59.

not registered, and stated that if they were making claims that the vitamins cured Aids, then the MCC would find that “*problematic*”. The Registrar also acknowledged that if the dosages were too high they needed to be registered with the MCC. He appeared to acknowledge being aware that the Rath products contained N-acetylcysteine, which would render them subject to the controls in the Medicines Act;¹⁶³

201.9. a letter dated 12 August 2005 from the Legal Resources Centre to the chairperson of the MCC;¹⁶⁴

201.10. an open letter signed by 199 Western Cape health-care workers, including eminent physicians and public health experts.¹⁶⁵

The response of the government respondents

202. As appears from the affidavit of Mr Geffen, most of the letters to which we have referred, went unanswered.

203. The sum total of the response of the Government respondents to these serious allegations of unlawful conduct was the following:

¹⁶³ Geffen para 151 pages 59-60; annexure NG59 627-659.

¹⁶⁴ Geffen para 152 page 60; annexure NG60 page 660.

¹⁶⁵ Geffen para 131 page 52-53; NG52 page 603

- 203.1. Mr Snyman, an inspector, had a discussion with Mr Geffen, and handed over his information to Mr Du Toit, the head of the law enforcement unit of the Department of Health;
- 203.2. In about September 2005 Mr Du Toit “*visited the offices of the second respondent and also interviewed the former employee of the second respondent, Dr Anthony Reese.*”¹⁶⁶
- 203.3. On 31 October 2005 the Registrar of Medicines wrote a letter to the second respondent asking some questions with regard to the clinical trials.¹⁶⁷ When the sixth respondent replied on behalf of the second respondent by a letter denying that it was carrying out clinical trials,¹⁶⁸ the matter was taken no further.
204. The applicants allege in terms that “*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.*”¹⁶⁹

¹⁶⁶ Mseleku para 63 page 787.

¹⁶⁷ TDM3 page 807

¹⁶⁸ TDM4 page 808-810

¹⁶⁹ Geffen para 27 page 15.

205. The response of the Government respondents to this allegation¹⁷⁰ is the following:

“When complaints about the activities of some of the first to seventh respondents were made, the Minister and I asked the Law Enforcement Unit to investigate the allegations, with the outcomes mentioned above.”¹⁷¹

206. The sole investigation which is disclosed is that which we have cited above, namely interviewing Mr Brink (the sixth respondent) and a former employee of the Rath Foundation, Dr Reese.

207. We will submit that this is a wholly inadequate response to a complaint about a serious and sustained course of unlawful conduct, which is dangerous to the health of members of the public. As Kriegler AJA held in Raats Röntgen, in the passages we have cited above, the Medicines Act envisages tight control of the quality, manufacture and dissemination of medicines. The state is the watch-dog which is to exercise such control. The DG is given powers and duties, and the Department of Health is to provide *“the requisite administrative, policing and enforcement agencies”*.¹⁷²

¹⁷⁰ Save for a reference to the South African Police Services and the prosecuting authorities, to which we refer below.

¹⁷¹ Mseleku para 18 page 766.

¹⁷² Administrator, Cape v Raats Röntgen & Vermeulen (Pty) Ltd 1992 (1) SA 245 (A) at 263

208. We submit that in a matter of this nature, a token response of the kind described by Mr Mseleku cannot conceivably be regarded as the taking of reasonable measures in fulfilment of the constitutional and statutory duties of the government respondents.

“It is not our responsibility”

209. Mr Mseleku repeatedly asserts that it is not the responsibility of the Minister of Health to deal with this matter: it is a matter, he says, for the South African Police Services and/or the prosecuting authorities.¹⁷³

210. With due respect, Mr Mseleku misconceives the nature of this application. The eighth respondent is the Government of the Republic of South Africa. There is only one national government in South Africa. It bears constitutional and statutory duties. It acts through a large number of Ministers, officials, and agencies. Where a party sues the government as respondent, for its failure to carry out its constitutional and statutory duties, it is not necessary for the applicant to identify each Minister, each official and each agency which has failed to carry out his, her or its share of the constitutional and statutory duties of the government. It is the government which bears the duties, and the government which must answer.

¹⁷³ This is a recurring theme of his affidavit. Examples of this are paras 18 page 766 and 41.1 page 779-780.

211. It is therefore no answer, in a case brought against the government, for one arm of government to say that a particular job should be performed by another arm of government. The question in an application such as this is whether the government has carried out its constitutional and statutory duties. It does not avail a particular deponent to attempt to pass the buck to other persons, who then do not answer the complaint.
212. Mr Mseleku places much reliance on the fact that paragraph 10 of the founding affidavit states that 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 identification of the Minister as the person with primary responsibility in this area¹⁷⁴ does not detract from the fact that it is not she who is the eighth respondent. The eighth respondent is named and described as the Government. She is simply its representative. If she finds it more appropriate that another person in government should represent the interest of the government, or requires information or evidence from other persons in government, she is entitled to act accordingly. None of that, however, makes her the respondent. The respondent is the Government.

¹⁷⁴ Which in terms of the judgment of Kriegler AJA is correct.

Failure to exercise powers and carry out functions

213. We submit that the papers show that the Government has failed completely in its constitutional and statutory duties to protect the health of members of the public. All it has done is that Mr Du Toit spoke to Mr Brink and Dr Reese, and the Registrar of Medicines wrote a letter.

214. We submit that on the government respondents' own showing, they have failed to take reasonable and effective measures to enforce the law and to protect the constitutional and statutory rights of members of the public.¹⁷⁵

215. Even if we are incorrect in this, and it is only the conduct of the Minister of Health and her officials which is in issue in this matter, we submit that the evidence shows clearly that they have failed to carry out their duties. This is so because:

215.1. as held by Kriegler AJA, they are the persons appointed by the Legislature as the watchdog of enforcement of the Act, and are given the powers to carry out this function;

¹⁷⁵ We address the content of reasonableness below.

- 215.2. evidence has been placed before them of a sustained and continuing course of unlawful conduct by the Rath respondents, which is damaging to the health of members of the public;
- 215.3. the only response of the Minister's staff has been to interview Mr Brink and Dr Reese. No other investigation has been carried out.
216. Mr Mseleku thus misconceives the situation. Parliament has, in sections 26 and 28 of the Medicines Act, given the Minister the power to appoint inspectors, and has given those inspectors wide powers of entry, search and seizure, in order to achieve "*the proper enforcement of the Act*".¹⁷⁶
217. Mr Mseleku in effect asserts that the department and the Government should only act if there is "*convincing proof*" from "*independent sources*", "*which can be relied upon in a court of law*" and which is "*beyond reasonable doubt*", that an offence has been committed.¹⁷⁷ This completely misconceives the functions and powers of the department.
218. Section 28 (1)(a)(ii) of the Medicines Act empowers an inspector to carry out a search

¹⁷⁶ Section 26(1).

¹⁷⁷ Mseleku para 32 pages 773-774, para 33 page 774, paras 37 page 775, para 39.3 page 777, para 39.5 page 777-778, para 41.2 page 786.

“if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence. . .”.

219. This court has explained this power as follows:

“In dealing with the concept of reasonable suspicion, Cameron JA in Powell NO and Others v Van der Merwe NO and Others 2005 (5) SA 62 (SCA) ... at paras [36] - [37] endorsed the formulation adopted by Lord Devlin in Shaaban Bin Hussien and Others v Chong Fook Kam and Another [1970] AC 942 (PC) ([1969] 3 All ER 1626) at 948:

[36] This Court has endorsed and adopted Lord Devlin's formulation of the meaning of "suspicion".

"Suspicion, in its ordinary meaning is a state of conjecture or surmise where proof is lacking; 'I suspect but I cannot prove'. Suspicion arises at or near the starting point of an investigation of which the obtaining of prima facie proof is the end."

[37] To the passage already adopted, I would add the sentence that immediately follows, since it has bearing on the present: "When such proof has been obtained, the police case is complete; it is ready for trial and passes on to its next stage." Ferreira and Swanepoel were not ready to charge Powell or Nell. Prima facie proof was as yet lacking. Lord Devlin went on to point out "another distinction between reasonable suspicion and prima facie proof:

Prima facie proof consists of admissible evidence. Suspicion can take into account matters that could not be put in evidence at all. . . . Suspicion can take into account also matters which, although admissible, could not form part of a prima facie case".'

In the present case Snyman has set out a series of facts upon which he contended he could reasonably surmise that applicant had been or was committing an offence in terms of the Act. That the admissible evidence may not even have amounted to prima facie proof at the stage when he sought to act in terms of s 28, is no bar to the execution of a power in terms of s 28(1)(a)(ii) ...¹⁷⁸ [emphasis added].

220. It is difficult to avoid drawing the conclusion that there are other, unstated, reasons for the lack of enthusiasm for the investigation of the activities of the Rath respondents. But even if one takes the statements of Mr Mseleku at face value, they provide no justification for the sustained refusal of the Department to carry out its functions and exercise its powers. On the contrary, they show a fundamental misdirection and a failure to appreciate the nature of the government's powers and duties.

221. A Government department which has been given the power to ensure the proper enforcement of a statute, and which has been given the powers necessary to enable it to achieve this, fundamentally misconceives its powers, and fails to exercise them, if it takes the view

¹⁷⁸ B C C Pharmaceuticals (Pty) Ltd v Minister of Health and others 2007 (3) SA 72 (C) at 77

that it will only act where the complainant produces “*convincing proof*”, and what is more from “*independent sources*”, “*which can be relied upon in a court of law*”, that an offence has been committed. A person who lodges a complaint or lays a charge is not a litigant, and the department is not a court. The department is responsible for investigating (not adjudicating) alleged breaches of the law, and for taking the necessary and reasonable steps to ensure the proper enforcement of the Act.

222. We submit that it is patently clear from the evidence that even if only the conduct of the Department of Health is an issue, it has failed in its constitutional and statutory duties to take reasonable measures to enforce the law. Reasonableness is one of the touchstones for the evaluation of the lawfulness of conduct of the Government.

223. The Constitutional Court has explained the concept of “reasonable measures” as follows:

“[88] What constitutes reasonable measures will depend on the circumstances of each case. Factors that would ordinarily be relevant would include the nature of the duty, the social and economic context in which it arises, the range of factors that are relevant to the performance of the duty, the extent to which the duty is closely related to the core activities of the duty-bearer - the closer they are, the greater the obligation on the duty-bearer, and the extent of any threat to fundamental

rights should the duty not be met as well as the intensity of any harm that may result. The more grave is the threat to fundamental rights, the greater is the responsibility on the duty-bearer. Thus, an obligation to take measures to discourage pickpocketing may not be as intense as an obligation to take measures to provide protection against serious threats to life and limb. A final consideration will be the relevant human and financial resource constraints that may hamper the organ of State in meeting its obligation. This last criterion will require careful consideration when raised. In particular, an organ of State will not be held to have reasonably performed a duty simply on the basis of a bald assertion of resource constraints. Details of the precise character of the resource constraints, whether human or financial, in the context of the overall resourcing of the organ of State will need to be provided. The standard of reasonableness so understood conforms to the constitutional principles of accountability, on the one hand, in that it requires decision-makers to disclose their reasons for their conduct, and the principle of effectiveness on the other, for it does not unduly hamper the decision-maker's authority to determine what are reasonable and appropriate measures in the overall context of their activities.”¹⁷⁹ [emphasis added]

224. In this case, there is direct evidence of threat to life arising from the unlawful activities of the Rath respondents. It is not simply that the vitamins are “prescribed” in doses which are potentially damaging to health;¹⁸⁰ or that it is inherently dangerous to health for unqualified people

¹⁷⁹ Rail Commuters Action Group and others v Transnet Ltd t/a Metrorail and others 2005 (2) SA 359 (CC)

¹⁸⁰ Gray para 19 page 341

to distribute scheduled substances; or that unregulated clinical trials are by their nature potentially dangerous to health. The combined effect of the various unlawful acts – publishing false advertisements, making unauthorised claims, distributing unregistered medicines, and distributing scheduled substances – has actually led to people losing their lives to HIV/AIDS because they have been induced by the false and unauthorised claims to forsake the medicines approved by the MCC for this purpose, and instead to take the medicines proffered by the Rath respondents.¹⁸¹

225. Under these circumstances, in the words of O'Regan J the obligation to take reasonable measures, and the standard of what will be accepted as reasonable, is "*intense*"; and there is a "*grave*" responsibility on government.
226. The government respondents have however taken a supine attitude. In the face of compelling evidence of at least *prima facie* sustained and continuing breaches of the law, which are directly threatening to health and to life, the Department has failed to exercise its powers. It is not necessary to decide whether the cause of this was a misapprehension of the nature of the government respondents' powers and duties, or whether there was another motive, for example an inexplicable desire to

¹⁸¹ Affidavit of Nandipha Sigebenga NG10 page 311; affidavit of Zondani Magwebu NG11 page 315; and the affidavit of Dr Saranchuk NG13 para 8 page 322.

protect Dr Rath. On any basis, the government respondents have simply failed to take reasonable measures to ensure “*the proper enforcement*” of the Act.

227. This is not the only instance of Government misunderstanding of its legal obligations. We now turn to deal with the multiple misconceptions and misdirections disclosed by the affidavit of Mr Mseleku.

The relationship between the Medicines Act and the Foodstuffs Act

228. Mr Mseleku states that the Directorate of Food Control of the Department of Health “*had taken the view*” that VitaCell “*is a food supplement as contemplated in the Foodstuffs, Cosmetics and Disinfectants Act*”. He says that “*traditionally, vitamins, micronutrients and nutrients have not been classified as medicines, but as food supplements.*”¹⁸² And he asserts that the MCC “*does not have any power over anyone that manufactures or sells or distributes foodstuffs as defined in the Foodstuffs Act unless it resolves that a particular product, though considered a foodstuff, is a medicine and is registerable.*”¹⁸³

229. This is demonstrably wrong:

¹⁸² Mseleku para 39.5.2 page 779.

¹⁸³ Mseleku para 53 page 785.

- 229.1. the Medicines Control Council does not have the power to “*resolve*” that a particular product is a medicine;
- 229.2. whether a substance is a medicine is a factual question, and depends on whether it falls within the definition in the Medicines Act. The Medicines Control Council has no discretion in this regard;
- 229.3. by definition, a substance which is a medicine cannot be a foodstuff in terms of the Foodstuffs Act. It is specifically excluded from the definition of “*foodstuff*”. Mr Mseleku has it exactly wrong: it is not, as he thinks, that a foodstuff can not be a medicine; it is that a medicine can not be a foodstuff.
230. In addition, we may point out that the Foodstuffs Act does not contain any reference to “*food supplements*”.
231. It is clear that Mr Mseleku is not alone in his misconception. He places some reliance on annexure TDM2, a letter written on behalf of his Department, which states that it is the opinion of the Department that in terms of the Foodstuffs Act, VitaCell “*will be regarded as a nutritional supplement*”. The letter states further “*we declare the combination*

[VitaCell] as a Food Supplement for distribution and importation in South Africa in terms of the Foodstuffs, Cosmetics and Disinfectants Act.”¹⁸⁴

232. Mr Mseleku appears to endorse the view taken in his Department’s letter.

The letter is patently and fundamentally wrong, for the following reasons:

232.1. no official has the power to declare that a substance is a food supplement or a food. The “*declaration*” is meaningless and unlawful;

232.2. if a substance is a medicine, then by definition it is not a foodstuff;

232.3. the question whether a substance is a medicine is determined by reference to whether it falls within the definition in the Medicines Act. There is no power on the part of any official or agency to make a decision or declaration in that regard.

232.4. there appear to be no such entity as a nutritional supplement in the Foodstuffs Act.

¹⁸⁴ Page 806.

The call-up notice of 22 February 2002 (Government Notice R204)

233. Mr Mseleku takes the view, in relation to nutritional substances that purport to have therapeutic or medicinal effects, that

*“the MCC has not passed a resolution to the effect that the products referred to are medicines, and that they are subject to registration¹⁸⁵....
“multivitamins and micronutrients do not have to be registered by the MCC. They are foodstuffs and not medicines”¹⁸⁶ “I am not aware that the MCC has designated any of the products distributed by the second respondent to be a medicine or that the MCC regards this as registerable in terms of the law as it stands at present.”¹⁸⁷*

234. With due respect, Mr Mseleku again fundamentally misunderstands the Act which he is required to enforce (and in respect of which he has acted as Registrar of Medicines).¹⁸⁸ Again, this may explain his failure to act. His fundamental misconceptions arise from the following:

234.1. the MCC does not “*pass resolutions*” which determine what products are and are not medicines. Whether a substance is a medicine depends on whether it falls within the ambit of the definition of the Medicines Act;

¹⁸⁵ Mseleku para 28.4 page 771; see also 25.1 pages 768-769, 28.3 page 770, and 30 pages 772-773.

¹⁸⁶ Mseleku para 74 page 791.

¹⁸⁷ Mseleku para 77 page 792.

¹⁸⁸ Mseleku para 1 page 761.

- 234.2. the view of *the* Directorate of Food Control that a substance is a “*food supplement*” is irrelevant to the question whether it is a medicine;
- 234.3. the MCC does not have the power to “*designate*” substances as medicines;
- 234.4. the Directorate of Food Control does not have the power to “*designate*” substances as nutritional supplements under the Foodstuffs Act;
- 234.5. multivitamins and micronutrients are medicines, and therefore not foodstuffs, if they are used or purported to be suitable for use or sold for use in the treatment, mitigation, modification or prevention of disease or its symptoms.
235. We have already submitted that the clear effect of Government Notice R204 of 22 February 2002 is to require the registration of the substances referred to therein. This is so for the following reasons:
- 235.1. the notice is described as a “*call-up notice for medicines frequently referred to as complimentary medicines*”. As pointed

out by Goldblatt J in the Ingelheim case, the term “*call-up*” is used to denote the imposition of a requirement that a particular medicine be registered;

235.2. the notice specifically refers to contraventions of section 14 of the Act. The only action which the Council may take under section 14 is to resolve that a medicine will be subject to registration in terms of the Act;

235.3. the notice specifically states that the MCC has determined that the substances in question “*shall be subject to a call-up process instituted as a primary step towards registration of such as medicines*”;

235.4. the notice further refers to these as “*the medicines called up for registration in terms of the call-up notice*”.

236. This misconception is the most fundamental of all. Again, it may go to explain why the government respondents have failed to exercise their powers. On their own version, they thought that:

236.1. the Rath products are not medicines because the MCC has not declared them to be such;

236.2. the Rath products are not medicines because they have been declared to be foodstuffs or “*nutritional supplements*”;

236.3. the Rath products do not qualify as medicines in terms of the Medicines Act; and

236.4. substances such as the Rath products have not been called up for registration by the MCC.

237. The government respondents are simply wrong in each of these respects.

238. This may go to explain the failure to act in respect of the sale of medicines, and the making of false statements and unauthorised claims. It does not however explain the failure to act in respect of the distribution of scheduled substances and the conducting of unauthorised clinical trials. We now turn to these breaches of duty.

The unauthorised distribution of scheduled substances

239. As we have pointed out above:

- 239.1. the distribution of substances listed in Schedule 2 to the Act is strictly controlled. Such substances may only be distributed by the persons identified in the Act, and under the circumstances and with the keeping of records prescribed by the Act;
- 239.2. two of the Rath products contain N-acetylcysteine, which is a substance listed in Schedule 2 to the Act.
240. The affidavits of the persons who were “*treated*” and provided with medicine at the Rath Clinics suggest strongly that the products in question (VitaCell and Epican Forte) are being “*sold*” by the Rath respondents under circumstances which constitute multiple breaches of section 22A of the Act.
241. It hardly needs to be pointed out that the unauthorised distribution of scheduled substances is a serious offence.
242. Although this matter was brought to the attention of the Government respondents, there is no evidence that it has ever been investigated. Mr Du Toit, who describes the investigation which he carried out (consisting principally of a visit to the offices of the Rath Foundation), has plainly never been to the sites at which these substances are being distributed, to check whether they are in fact being distributed, and if so by whom

and under what circumstances. That is an elementary part of any reasonable investigation of a serious complaint such as this.

243. The reasons for this are difficult to fathom. Again, there are two possible reasons. One would be an inexplicable desire on the part of the government respondents to protect Dr Rath and his activities. Another would be a failure to understand the law which the Government is required to implement in order to protect members of the public.
244. Mr Andrew Gray 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 is a pharmacist registered with the South African Pharmacy Council. He has published extensively on issues of pharmacology and on the use and regulation of medicines in public health.¹⁸⁹ He is a member of one of the subcommittees of the MCC.¹⁹⁰
245. Mr Gray has read the affidavits which are attached to the affidavit of Mr Geffen, with regard to the distribution of products by the Rath clinics.¹⁹¹ He has also examined the advertisement for Epican Forte on the internet. He concludes that it appears from the affidavits to which he has referred (*“the Khayelitsha affidavits”*), that VitaCell and Epican Forte are

¹⁸⁹ Gray paras 1 and 2, page 332.

¹⁹⁰ Mseleku para 28.1, page 769 – 770.

¹⁹¹ Gray para 3, page 332.

being sold by the first and second respondents under circumstances which constitute multiple breaches of section 22A of the Medicines Act, in particular 22A(5) and (6).¹⁹² His conclusions in this regard are summarised in paragraphs 59.8 to 59.11 of the affidavit of Mr Geffen.¹⁹³

246. The response of Mr Mseleku to paragraph 59 of Mr Geffen's affidavit, which summarises the conclusions of Mr Gray with regard to the distribution of medicines by the Rath respondents, is contained in paragraph 28.¹⁹⁴ In this paragraph, Mr Mseleku makes the following remarkable statements:

246.1. *"Since the MCC has not resolved that any of the products in question are medicines and that they are subject to registration and since the view is held in the Department that they are food supplements, there is apparently nothing objectionable to their distribution."*¹⁹⁵ and

246.2. *"The fact that the product contains a Schedule 2 substance does not necessarily make it a medicine. It is necessary for the MCC to resolve, and not for the Court to declare, that it is a medicine, as envisaged in the Medicines Act, especially if the product could also be regarded as a foodstuff or a food supplement."*

¹⁹² Gray para 28, page 345.

¹⁹³ Pages 42 – 43.

¹⁹⁴ Pages 769 – 772.

¹⁹⁵ Para 28.5, page 771.

Furthermore, it is for the MCC to resolve that any particular product requires to be registered and the MCC has to have in place a system for its registration and regulation. It has not been established, let alone beyond a reasonable doubt, that the products containing the Schedule 2 substance have been dispensed by persons not competent and qualified to do so and that there has accordingly been a transgression of section 22A(5) of the Medicines Act.”¹⁹⁶

247. This passage is riddled with misconceptions. The fact that a product contains a Schedule 2 substance automatically brings it under the controls in section 22A, whether or not it is a “*medicine*”. The MCC does not have the power to “*resolve*” that a substance is a medicine. And where a serious allegation of this kind of unlawful activity (including the distribution of scheduled substances via the internet) is brought to the attention of the Government, the Government misconstrues its duties if it takes the view that it has no obligation to do anything at all, unless the person reporting the apparent contravention produces proof (whether or not “*beyond a reasonable doubt*”), that the offence has been committed. The duty of the Government is to investigate the matter.

¹⁹⁶ Para 28.6, page 772.

248. The failure of the Government to take any action at all with regard to these serious allegations of the unauthorised distribution of a Schedule 2 substance is quite remarkable.

Unauthorised clinical trials

249. As we have pointed out above, the Rath respondents have made numerous statements in the print media, on radio and in their pamphlets, that they have carried out a *“clinical pilot study the goal of which was to show that a combination of micronutrients can reverse the course of Aids, even in its advanced stage.”* They state that the study was carried out in Khayelitsha, Cape Town.¹⁹⁷
250. All of this is set out in detail in the affidavit of Mr Geffen from paragraphs 93 to 118.¹⁹⁸ In those paragraphs, Mr Geffen describes the statements made by the Rath respondents; refers to annexures which show that they have made with those statements; and refers to the Khayelitsha affidavits which show that the people concerned were given medicine, had blood taken from them for testing, and were photographed in a state of undress.

¹⁹⁷ Annexures FV13 pages 262-269, NG23 pages 394-395, NG27 pages 399-400, Geffen para 100 page 46; Annexures NG47 pages 467-503, NG48 pages 504-526 and NG49 pages 527-528.

¹⁹⁸ Pages 57 – 61.

251. One might reasonably conclude from this evidence – the statements of the Rath respondents themselves, and the independent evidence corroborating what they say – that there is a very strong case that unauthorised clinical trials have indeed been carried out. At the very least, a serious investigation is called for.
252. The only response of the Government respondents to this serious allegation is that the previous Registrar of Medicines wrote to the Dr Rath Health Foundation asking whether it had been conducting clinical trials for humans. When the latter replied denying that it had been conducting a clinical trial, that was the end of the matter.¹⁹⁹
253. That is the sole response of the government respondents to allegations and evidence of this kind. It is simply not an adequate response by a government responsible for the enforcement of a law and the protection of the fundamental rights of its people.
254. In seeking to justify government inaction, Mr Mseleku says that the advertisement referred to *“does not say that the second respondent conducted clinical trials for humans in South Africa”*.²⁰⁰ This statement is simply incomprehensible in the light of the repeated assertions by Dr Rath that the trials were carried out on people in *“Khayelitsha, Cape*

¹⁹⁹ Annexures TDM3 page 807 and TDM4, pages 808-810.

²⁰⁰ Para 38, page 776.

Town, South Africa". Mr Mseleku states that the advertisements "*cannot on the advice I have received, be used on their own to establish conclusively or beyond reasonable doubt that a clinical study as envisaged in the Medicines Act was conducted. There has to be supporting independent evidence of substance*".²⁰¹ Again this shows a remarkable misconception:

254.1. on their own version, which they have published repeatedly, the Rath respondents have committed an offence;

254.2. their assertions in this regard are indeed backed up by independent evidence, in the form of the Khayelitsha affidavits; and

254.3. in any event, the question is not whether the evidence establishes "*conclusively or beyond reasonable doubt*" that a clinical study as envisaged in the Act was conducted. The question is whether there is sufficient evidence to justify a proper and reasonable enquiry. No such enquiry was conducted.

255. Finally, Mr Mseleku repeats (in response to the affidavit of Prof London) that Prof London is not able to say whether the trial took place or is

²⁰¹ Para 39.5, pages 775-776.

taking place “*in South Africa and if this trial was for humans*”.²⁰² With due respect, in the light of the claims by the Rath respondents themselves and the evidence in the Khayelitsha affidavits, this statement simply beggars belief.

²⁰² Para 91, page 797.

PART 8:**APPROPRIATE RELIEF**

256. Paragraphs 1 to 8 of the notice of motion provide for the remedies of declaration, interdict and mandamus. Paragraphs 9 to 12 provide for what is usually described as a structural interdict. In this section of these heads of argument, we address the need for a structural interdict.

257. An order containing a structural interdict usually includes declaratory and mandatory relief of the usual kind. What distinguishes the structural interdict is that it generally contains either or both of the following additional elements:

257.1. an order requiring the respondent to report on what it has done and will do in order to give effect to the mandatory order. We refer to this as the “reporting” element; and

257.2. an order that the parties may file papers in relation to that report, and then return to the court in order for the court to determine whether the respondent has complied with its obligations, and if not, to consider ordering further relief. We refer to this as the “supervisory” element.

Situations where structural relief is appropriate

258. Our courts have issued structural interdicts in an increasing number of cases.²⁰³ From those cases and from the experience in other parts of the world, one can establish the sorts of cases in which various forms of structural interdicts will provide appropriate relief.
259. In Treatment Action Campaign, the Constitutional Court emphasised that the decision to grant mandatory and structural interdicts would depend on the circumstances of each particular case. It concluded that structural interdicts constitute “appropriate relief” when they are “necessary to secure compliance with a court order”. This could be the case, for example, where there is a proven “failure to heed declaratory orders or other relief granted by a court in a particular case”.²⁰⁴
260. Subsequently, in Sibiya,²⁰⁵ the Constitutional Court ordered a structural interdict in order to enable it to exercise supervisory jurisdiction over the

²⁰³ They include August v Electoral Commission 1999 (3) SA 1 (CC); Strydom v Minister of Correctional Services 1999 (3) BCLR 342 (W); Ngxuza v Permanent Secretary, Dept of Welfare, Eastern Cape 2001 (2) SA 609 (E); 2000 (12) BCLR 1322; S v Z and 23 Similar Cases 2004 (1) SACR 400 (E); City of Cape Town v Rudolph 2004 (5) SA 39 (C); Sibiya and others v Director of Public Prosecutions, Johannesburg and Others 2005 (5) SA 315 (C); Minister of Education (Western Cape) v Mikro Primary School 2006 (1) SA 1 (SCA); Magidimisi v Premier of the Eastern Cape & others [2006] JOL 17274 (Ck); Kiliko and Others v Minister of Home Affairs and Others 2006 (4) SA 114 (C); Centre for Child Law and Others v MEC for Education and Others, Transvaal Provincial Division, Case No. 19559/2006, 30 June 2006 (unreported); EN and Others v Govt of the RSA and Others 2006 JOL 18038 (D); Ngxuza & others v Permanent Secretary, Department of Welfare, Eastern Cape Provincial Government & another [2006] JOL 18239 (E)

²⁰⁴ Minister of Health and Others v Treatment Action Campaign and Others (No 2) 2002 (5) SA 721 (CC) at [129]

²⁰⁵ Sibiya and Others v Director of Public Prosecutions, Johannesburg, and Others 2005 (5) SA 315 (CC); 2005 (8) BCLR 812 (CC)

process of converting the sentences of those who had been sentenced to death prior to the decision in S v Makwanyane. The court engaged in an extended process of receiving reports prepared by the government, considering them and giving further directions as to the steps required for compliance. The process was finally completed by a judgment given on 30 November 2006,²⁰⁶ in which the Court expressed its satisfaction at the effectiveness of the procedure which had been followed. The Court noted that it had ordered a structural interdict because

“[5] ... The mandamus was therefore principally aimed at ensuring compliance with the order of this Court in Makwanyane.

“[6] The Court felt that given the delay that had occurred since its order in Makwanyane coupled with the pressing need for the sentences to be replaced, it was an appropriate case for a supervisory order to be made in addition to the mandamus.”

261. A failure to comply with a previous order of court, and particularly a sustained failure to do so, is perhaps the paradigmatic case for a structural interdict. There are other indicators of where a structural interdict may be appropriate. These include the following.²⁰⁷

²⁰⁶ Sibiya and Others v Director of Public Prosecutions, Johannesburg, and Others CCT 45/04 judgment delivered 30 November 2006

²⁰⁷ In the analysis which follows we borrow liberally, without further attribution, from K Roach & G Budlender “Mandatory Relief and Supervisory Jurisdiction: When is it Appropriate Just and Equitable?” (2005) *SALJ* 325

262. First, proven past non-compliance is not a prerequisite for the court to take steps to ensure compliance. Where it is found, as it was in Sibiya (No 1), that it would be “inadvisable for the court to assume” that the order would be carried out promptly, that would justify the grant of a structural interdict.
263. Secondly, a structural interdict may be considered necessary where the consequences of even a good-faith failure to comply with a court order are so serious that the court should be at pains to ensure effective compliance.
264. Thirdly, a structural interdict may be necessary to ensure compliance with a court order where the order in question is so general that it is not possible to define with any precision what the government is required to do – either because of the general nature of the right it enforces, or because the court is anxious to leave the state with as much latitude as possible with regard to compliance.
265. Sibiya is an example of this: The Constitutional Court ordered the respondents to take “*all the necessary steps*”, without describing each step in specific terms, or stating when each step should be taken. As the Court noted, its use of the phrase “*as soon as possible*” also had a lack of specificity. This was plainly relevant to the decision to order a

structural interdict, as there would be debate, in any enforcement proceedings, as to whether the respondents had done everything in their power that was necessary.²⁰⁸

266. We do not suggest these as either rigid categories or as a *numerus clausus*: rather, they demonstrate types of instances in which it will be “appropriate” to order structural relief.

267. In such circumstances, a structural interdict may provide benefit to all, including government. The approval of a plan of action by the court can allow the government to move forward with implementation, secure in the knowledge that implementation will constitute compliance with its obligations. The court can make an order which is as non-intrusive as possible on the choices which the elected government makes, because it can be secure in the knowledge that this will not be an invitation to non-compliance, but rather an invitation to the government to formulate a plan in order to achieve compliance with the Constitution.

268. Structural interdicts granted in these circumstances do not undermine the separation of powers, but actually allow the state the space to fulfil its executive function.

269. In a recent judgment, Froneman J stated:

²⁰⁸ See the discussion in the judgment of 30 November 2006 at [6]

“in my personal experience [structural interdicts] have contributed to a better understanding on the part of public authorities of their constitutional legal obligations in particular areas, whilst it has also assisted the judiciary in gaining a valuable insight in the difficulties that these authorities encounter in their efforts to comply with their duties.”²⁰⁹

270. We submit that this matter presents a clear case for structural relief:

270.1. The breach has been continuing for a sustained period, despite numerous attempts to move the government respondents to appropriate action.

270.2. The consequences of non-compliance are such that it is not advisable to assume that there will now be compliance. There is a direct threat to health and to life.

270.3. The precise content of the government respondents’ obligations is difficult to define. The government respondents should be left with latitude to make the operational choices which are properly within the ambit of their functions; but they should be required to place its plans and their implementation before a court, to ensure that they are consistent with their obligations.

²⁰⁹ Magidimisi para 29 (referring to S v Z and Ngxuza (2001))

271. We submit that at the very least, the government respondents should be ordered to report on:

271.1. what they have done to comply with their obligations;

271.2. what further steps they will take in order to comply with their obligations; and

271.3. when they will take such steps.

272. We submit that this is necessary both because of the history of this case, and also because it is an appropriate element of accountability. Accountability is a founding value of our Constitution:

“[74] Accountability of those exercising public power is one of the founding values of our Constitution and its importance is repeatedly asserted in the Constitution. Section 1 of the Constitution provides as follows:

'The Republic of South Africa is one, sovereign, democratic State founded on the following values: ...

(d) *Universal adult suffrage, a national common voters roll, regular elections and a multi-party system of democratic government, to ensure accountability, responsiveness and openness.'*

Accountability is also to be found in ch 3 of the Constitution, in which s 41(1) provides:

'All spheres of government and all organs of State within each sphere must - ...

(c) provide effective, transparent, accountable and coherent government for the Republic as a whole.'

It is again recognised as one of the key values of public administration in s 195 of the Constitution which provides that:

'(1) Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:

(f) Public administration must be accountable.²¹⁰

273. Public reporting enables those who are affected by the exercise of public power to hold those in power accountable for what they do. It is a core element of the democratic process. The mere fact of having to report, requires the defaulting authority to apply its mind to the problem at hand and take reasonable measures.

²¹⁰ Rail Commuters Action Group and others v Transnet Ltd t/a Metrorail and others 2005 (2) SA 359 (CC) at [74]

274. We submit that this is a case which calls out for an order of this kind.

275. The applicants accordingly seek an order as prayed in the notice of motion. In addition, they seek and order that the first, second and sixth respondents be ordered to pay costs on the scale as between attorney and client.

GEOFF BUDLENDER

Counsel for Applicants

26 February 2008

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7. EN and Others v Govt of the RSA and Others 2006 JOL 18038 (D).
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17. President of the Republic of South Africa and others v South African Rugby Football Union and others 2000 (1) SA 1 (CC) at [106].
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19. Reitzer Pharmaceuticals (Pty) Ltd v Medicines Control Council and Another TPD case no 8516/95, judgment at page 11.
20. Sibiya and Others v Director of Public Prosecutions, Johannesburg, and Others 2005 (5) SA 315 (CC); 2005 (8) BCLR 812 (CC).
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23. Strydom v Minister of Correctional Services 1999 (3) BCLR 342 (W)
24. Van Eeden v Minister of Safety and Security 2003 (1) SA 389 (SCA).