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

In the matter between:

TREATMENT ACTION CAMPAIGN First Applicant

SOUTH AFRICAN MEDICAL ASSOCIATION Second Applicant

and

MATTHIAS RATH First Respondent

DR RATH HEALTH FOUNDATION AFRICA Second Respondent

SAM MHLONGO Third Respondent

**DAVID RASNICK** Fourth Respondent

ALEXANDRA NIEDWIECKI Fifth Respondent

ANTHONY BRINK Sixth Respondent

TREATMENT INFORMATION GROUP Seventh Respondent

GOVERNMENT OF THE RSA Eighth Respondent

**DIRECTOR-GENERAL OF HEALTH**Ninth Respondent

CHAIRPERSON, MEDICINES CONTROL COUNCIL Tenth Respondent

Eleventh Respondent

MEC FOR HEALTH WESTERN CAPE

Twelfth Respondent

## **AFFIDAVIT**

I, the undersigned,

### **ANDREW LOFTS GRAY**

do hereby make oath and say:

**REGISTRAR OF MEDICINES** 

- I am a senior lecturer in the Department of Therapeutics and Medicines

  Management at the Nelson R Mandela School of Medicine ("the Mandela

  School of Medicine") at the University of KwaZulu-Natal. I have held this

  position since 2002. I was previously a lecturer in the School of Pharmacy,

  University of Durban-Westville.
- I am a pharmacist, registered with the South African Pharmacy Council. I have published extensively on issues of pharmacology and on the use and regulation of medicines in public health.
- Given my expertise and the nature of my work, I believe that I am suitably qualified to make this affidavit concerning the proper regulatory characterisation of the products distributed by the Dr Rath clinic in Khayelitsha Site C, as described in affidavits of Peter Saranchuk, Zondani Magwebu, Zukile Ngqase, Nandipha Ntsholo, Xolisa Mqambeli, Thembeka Ngubo, Nandipha Sigebenga and Zukile Ngqase, which I have read (hereafter referred to as 'the Khayelitsha affidavits').
- 4 Except where otherwise indicated, the facts stated in this affidavit are within my personal knowledge and belief and are true and correct.
- Accordingly to the Khayelitsha affidavits, patients attending the Dr Rath clinic in Khayelitsha Site C are in my view being issued with products which are presented as medicines, in that:

- 5.1 Mention is made of the need for photographic evidence of the efficacy of this treatment.
- 5.2 The circumstances in which they are issued are those consistent with a medical examination, history-taking and provision of treatment.
- 5.3 A blood test is requested.
- 5.4 A follow-up appointment is arranged.
- I received two containers of VitaCell™ from Nathan Geffen by courier on 4

  October 2005. According to Geffen these products were obtained from the

  Dr Rath Health Foundation Africa clinics in Khayelitsha. The appearance of the two bottles varies slightly.
  - 6.1 One container is labelled as "VitaCell Food Supplement 90 Tablets". The main body of the label is headed by the words "DR. RATH HEALTH FOUNDATION AFRICA". The bottom of the label contains banner "Donated by the Dr. Rath Health Foundation the "Responsibility for a health world"". The portion of the label that lists the ingredients states "VitaCell is a food supplement containing vitamins and other essential nutrients". It then states that each tablet contains: Vitamins: Vitamin C 200mg, Vitamin B3 (Nicotinate) 20mg, Vitamin B5 (Pantothenate) 10mg, Vitamin B1 (Thiamine) 3mg, Vitamin B2 (Riboflavin) 3mg, Vitamin B6 (Pyridoxine) 3mg, Folic acid 0.150mg, Biotin 0.020mg, Vitamin B12 (Cyanocobalamin) 0.0066mg, Beta-acrotene 382 IU, Vitamin D3 40 IU, Vitamin E (d-alpha-Tocopherol) 20 IU. Minerals: Magnesium 60mg, Calcium 29mg, Potassium 10mg, Phosphate 5mg. Trace elements: Zinc 5mg,

Manganese 0.4mg, Copper 0.1mg, Selenium 0,010mg, Chromium 0.010mg, Molybdenum 0.0010mg. Other important nutrients: Green Tea Leaf Extract (Polyphenols) 100mg, Taurine 100mg, L-lysine 30mg, L-proline 30mg, Bioflavonoids 30mg, N-acetylcysteine 30mg, L-arginine 16mg, L-carnitine 10mg, L-cysteine 10mg, Inositol 10mg, Coenzyme Q-10 5mg. This is followed by a statement that: "This nutrient combination is labelled as a food supplement according to the "Foodstuff" Act No 54 of 1972. It does not contain any artificial colours, flavourings, starch, wheat or milk derivatives or components form genetically modified plants." The dosage instruction is as follows: "Suggested use as food supplement: 1-3 tablets daily." There follows a statement about the source of the product and contact details: "The Dr. Rath Health Foundation Africa is a non-profit organization dedicated to research and education in natural health. Dr. Rath Health Foundation Africa, 34 Bree Street, Cape Town 8001. For more information call us at 0861112656 or visit our website www.Dr-Rath-Foundation.org.za." The last line of the label reads: "Expiration date: See bottom of bottle". The base is printed with the following: "LOT #403197 EXP. 03/06". The label has been applied over an existing label, the left-hand edge of which resembles the label described below. The lid has a sticker proclaiming "Health Now<sup>®</sup>". The tablets in the container are unscored, oval, biconvex and yellow in colour.

6.2 The second container differs from the first in a number of aspects.

The product is labelled as "Dr. Raths Vitacell™ Nutrient Supplement for Daily Use 90 Tablets" The main body of the label contains this

statement: "Improves and maintains well being by strengthening the immune system, tissue stability and energy metabolism of millions of body cells". This is accompanied by a photograph of Dr Rath. The banner on the bottom is similar, with the addition of the word "Africa" after "Foundation". The listed ingredients are the same, in the same order, but the claimed quantities per tablet are generally half that stated on the label described above: Vitamins: Vitamin C 80mg, Vitamin B3 (Nicotinate) 10mg, Vitamin B5 (Pantothenate) 5mg, Vitamin B1 (Thiamine) 1.5mg, Vitamin B2 (Riboflavin) 1.5mg, Vitamin B6 (Pyridoxine) 1.5mg, Folic acid 0.075mg, Biotin 0.010mg, Vitamin B12 (Cyanocobalamin) 0.003mg, Beta-carotene 190 IU, Vitamin D3 20 IU, Vitamin E (d-alpha-Tocopherol) 10 IU. Minerals: Magnesium 30mg, Calcium 15mg, Potassium 5mg, Phosphate 2.5mg, Trace elements: Zinc 2.5mg, Manganese 0.2mg, Copper 0.05mg, Selenium 0,005mg, Chromium 0.005mg, Molybdenum 0.0005mg. Other important nutrients: Green Tea Leaf Extract (Polyphenols) 50mg, Taurine 50mg, L-lysine 25mg, L-proline 15mg, Bioflavonoids 15mg, N-acetylcysteine 15mg, L-arginine 8mg, L-carnitine 5mg, L-cysteine 5mg, Inositol 5mg, Coenzyme Q-10 2.5mg. No statement about the labelling being in compliance with Act 54 of 1972 is included, and the contact details are slightly different, the distributor is identified as "Dr. Rath's Health Programs Africa (Pty) Ltd" and no telephone number is provided. The recommended use is the same (1-3 tablets daily). The lot and expiry dates, however, appear to be the same as those on the container described above. The lid has a sticker stating that: "For almost two decades, Dr. Rath has been fighting to improve the health

of millions of people worldwide. By buying this product you will not only contribute to the improvement of your own well being, but also to the promotion of natural health research in the fight against heart disease, cancer, immune deficiencies and other diseases. RSAP11024". The tablets contained are, to the naked eye, indistinguishable from those in the container described above.

I have undertaken a similar analysis of the stated contents and recommended dosages of three other Rath products, namely Lysin C drink, Epican forte and Vitacor Plus. I obtained the contents and recommended dosages of these products from the Rath website <a href="http://store.dr-rath-vitamins-com">http://store.dr-rath-vitamins-com</a>.

#### The registration of medicines

- 8 The Medicines and Related Substances Act 101 of 1965 (the Medicines Act) defines medicine as "any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine".
- 9 Section 14 of the Medicines Act states that no medicine which is subject to registration may be sold unless it is so registered. The relevant provisions are:

- Prohibition on the sale of medicines which are subject to registration and are not registered
  - (1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.
  - (2) (a) The Council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.
  - (b) Any such resolution may also relate only to medicines which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.
  - (c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.
- 10 Government Notice R2025 of 15 December 1967 sets out the categories of medicines. "Vitamins" are category 22. Sub-category 22.1 is "multivitamins and multivitamins with minerals".
- All categories of medicine have been "called up" for registration under section 14 of the Medicines Act by resolutions of the Medicines Control Council (the MCC). It follows that in terms of sec 14(1) of the Act, no

medicine may be sold unless it is registered, except in those cases where the "call-up" notice limits the registration requirements.

- The "call-up" notice in respect of oral preparations which contain a vitamin or multivitamin is contained in Government Notice 559 of 15 March 1985. I attach a copy of that notice (**ALG1**). The essence of it is that an oral preparation shall be subject to registration as a medicine if it
  - (1) contain a vitamin or vitamins [including food supplements which contain a vitamin or vitamins, but excluding foodstuffs as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), which contain a vitamin or vitamins] either as such or in combination with any other pharmacologically active ingredient or ingredients (including trace elements), whether medicinal claims are made or not; and
  - (2) contain or exceed per recommended total daily dose any of the respective doses stated in this notice or, in the absence of a dosage schedule, contain or exceed per oral dosage unit of any particular dosage form any of the respective doses stated in this notice;
- I have prepared a detailed analysis in which I have compared the recommended daily dosages of the four Rath products which I have listed above, with the dosages which in terms of Government Notice 559 trigger the registration requirement. I attach a copy of that analysis (ALG2).
- 14 As appears from that analysis

- 14.1 Both Epican forte and Lysin C exceed the registrable limit for vitaminC, on the basis of the website dosage alone.
- 14.2 Vitacor Plus exceeds the limits for Vitamin B1 (thiamine), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Vitamin E and Pantothenic acid, on the basis of the website dosage alone.
- 14.3 Two examples of VitaCell have been recovered from patients. The labelled contents of one version exceed the limits for Vitamin B1 (thiamine), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Vitamin E, Niacin and Pantothenic acid, if taken as labelled as a maximum of 3 tablets daily. The labelled contents of the other version, taken on the same basis, exceed the limits for Vitamin B12 and Pantothenic acid.
- 14.4 According to the affidavit of Nandipha Ntsholo, the verbally recommended doses of Vitacor Plus was 3 times the labelled dose (3 tablets 3 times a day), while the verbally recommended dose of Epican forte was 1.5 times higher than the labelled dose (3 capsules 3 times a day, rather than 6 capsules per "serving").
- 15 As appears from that analysis, all four of these products are therefore liable to registration, 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 run by the first and second respondents.
- According to the affidavit of Ntsholo and the advertisements published by the Rath respondents, medicinal claims are made for these products.
- 17 None of the aforementioned products is registered with the MCC for the purpose of treating HIV or at all.
- The doses prescribed to the patients who attended the Dr. Rath clinics were considerably higher. Zondani Magwebu states that he was told to take 10 tablets of VitaCell twice a day (1600 or 4000mg of vitamin C, depending on which label is used). Xolisa Mqambeli states that she was told to take 2 tablets of VitaCell three times a day (480 or 1200mg of vitamin C). Nandipha Ntsholo and Thembeka Ngubo both attest to being given large quantities of tablets to take.
- Doses of vitamin C in excess of 1000mg per day may predispose the patient to developing kidney stones. Excessive doses commonly cause diarrhoea.
- 20 Nandipha Ntsholo states that she was told that the only side effect associated with the Dr. Rath vitamins was diarrhoea, and that she was advised to reduce the dose of a powder called Lysin C-Drink Mix and eat bananas if this problem was encountered.

- 21 Both acute and chronic diarrhoea complicate the management of many AIDS patients. Recommending high doses of a vitamin product known to cause diarrhoea to such patients is thus unacceptable, as the anticipated benefit does not justify the anticipated risk.
- On the basis of the affidavits of Ntsholo, Ngqase, Ngubo, Velem, Mqambeli and Magwebu, the amount of vitamin C prescribed by the first and second respondents is high enough to cause diarrhoea and kidney stones.
- 23 It appears that the first and second respondents are selling the four products which I have mentioned, within the meaning of "sell" in the Medicines Act. In this context, selling does not necessarily imply receiving remuneration in exchange for the product.
- General Regulation 8(1)(a) under the Medicines Act requires the following:

  "Save as provided in sub-regulations (2), (3) and (4), the immediate
  container of every medicine in which a medicine intended for administration
  to humans is sold shall have a label attached to it on which only the
  following particulars shall appear in clearly legible indelible letters in English
  and at least one other official language: (a) in the case of a medicine listed
  in any Schedule made in terms of the Act, the letter 'S' followed by the
  number of the relevant Schedule, in a prominent type size and face and
  surrounded by a square border, immediately preceding the proprietary
  name of such medicine". Neither of the labels described above complies
  with this requirement. They are thus in contravention of sec 18(1) of the
  Medicines Act, which reads: "No person shall sell any medicine or

Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars."

#### Sale of scheduled substance

Section 22A of the Medicines Act deals with the control of medicines and Scheduled substances. The relevant portions are as follows:

#### 22A Control of medicines and Scheduled substances

- (1) 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.
- (2) The Minister may, on the recommendation of the Council, prescribe the Scheduled substances referred to in this section.
- (3) Any Schedule 0 substance may be sold in an open shop.
- (4) Any Schedule 1 substance shall not be sold-
  - (a) by any person other than .....
- (5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than-
- a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;
- (b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;

- (c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
  - (d) a medical practitioner or dentist, who may-
- (i) prescribe such substance;
- (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
- (e) a veterinarian who may prescribe, compound or dispense such substance;
- (f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-
- (i) prescribe only the Scheduled substances identified in the Schedule for that purpose;
- (ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a).
  - (6) Any sale under subsection (5) shall only take place on condition that-
- (a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;
- (b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;
- (c) in the case of verbal instructions the treatment period shall not exceed seven days;
- if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;
- (e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 14 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 14 years;

- (f) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
- An advertisement for Epican Forte from the internet (attached as **ALG3** and available online at http://store-dr-rath-vitamins.com) states that Epican Forte contains N-acetylcysteine. According to its packaging, VitaCell also contains N-acetylcysteine.
- Schedule 2 to the Act contains "acetylcysteine". Acetylcysteine is the N-acetyl derivative of the naturally occurring amino acid, L-cysteine. The label states that the tablets contain "N-acetylcysteine", either 30 or 15mg per tablet. N-acetylcysteine is a schedule 2 substance in terms of the Medicines Act. It can therefore only be only be sold by a pharmacist or other person listed in sec 22A(5) of the Medicines Act, and under the conditions listed in sec 22A(6) of the Medicines Act.
- 28 It appears from the affidavits to which I have referred, that VitaCell and Epican Forte are being sold by the first and second respondents under circumstances which constitute multiple breaches of sec 22A of the Medicines Act, in particular 22A(5) and (6).

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