

In the matter between:

TREATMENT ACTION CAMPAIGN (TAC) First Complainant

GEORGE STACEY Second Complainant

and

TREATMENT INFORMATION GROUP Second Respondent

EXPERT VERIFICATION

I, SAMUEL WYSTAN POSHELA MHLONGO, declare:

1. I am a Professor, Chief Specialist and Head of Department of Family Medicine and Primary Health Care at Medical University of South Africa (MEDUNSA), Pretoria.
2. I am 64 years of age, and I reside in Johannesburg.
3. My professional qualifications and experience are as follows:
 - I hold a Bachelor of Medicine, Bachelor of Surgery degree (MBBS) awarded by the University of London;
 - I hold a Licence of the Royal College of Physicians, London (LRCP);
 - I am a member of the Royal College of Surgeons, England (MRCS);

- I hold a Master of Science degree in Internal Medicine, specialising in cardiology (MSc Med) University of London;
- I am a Member of the Royal College of General Practitioners, United Kingdom (MRCGP), signifying that I am trained to professorial level in advanced primary health care and family medicine;
- Having passed the US Visa Qualifying Examination (VQE), I am licensed to teach and practise medicine in the United States of America.
- After my medical training at Charing Cross Hospital, London, I practised medicine in London and taught at several hospitals attached to the University of London for 25 years – in addition to a two-year teaching tour between 1974 and 1976, in which I provided instruction to residents in Advanced Internal Medicine at the University of Pennsylvania in the US, and did a refresher course in cardiology.
- I was President of the African-Caribbean Medical Association in London from 1992 until 1998, when I returned to South Africa to take up my current post as Head of Department, Family Medicine and Primary Health Care, MEDUNSA, having been specially recruited by the Department of Health, Gauteng Province.
- I am chief supervisor all medical doctors training in Primary Health Care and Family Medicine in the public service in

Limpompo, Mpumalanga, North West Province and in about a third of Gauteng.

- I have published numerous articles and letters in the world's leading peer-reviewed medical and scientific journals, both as a principal author and as a co-author, and these professional scientific contributions to the understanding of AIDS are all catalogued in the US National Library of Medicine.
4. My special expertise in the subject of AIDS science is widely recognised, as evidenced by the following:
- I was appointed by the National Department of Health as an expert member of the Presidential AIDS Advisory Panel, and participated in both of its international meetings in May and July 2000.
 - I have been invited to attend and address numerous other professional meetings concerning AIDS in South Africa, including a meeting of the South African Association of Professionals in Health Care on 7 February 2002, at which I presented a PowerPoint slide show, *A Critical Analysis Of The Evidence Considered Proof That Nevirapine Prevents Mother-To-Child Transmission Of HIV*, of which I am co-author.
 - By special invitation of the European Parliament, I addressed it in Brussels on 8 December 2003 on the subject: 'AIDS in Africa'.

- I am co-author of an extensive literature review and analysis, *Mother to Child Transmission of HIV and its prevention with AZT and Nevirapine: A Critical Analysis of the Evidence* by Papadopulos-Eleopulos et al. At 137,000 words, the monograph was far too voluminous for publication in any medical journal, and it was consequently published as monograph on 1 October 2001, as a contribution to the international scientific debate about AIDS, its aetiology, and its treatment, opened by President Thabo Mbeki in 2000. Lead author of the monograph, Eleni Papadopulos-Eleopulos, is a senior bio-physicist in the Department of Medical Physics at the Royal Perth Hospital in Perth, Western Australia, and is also a member of the Presidential AIDS Advisory Panel.
 - On 6 August 2002 I submitted a 100-point memorandum to the Medicines Control Council concerning the perinatal use of nevirapine. Two days later I was telephoned by Dr Rajen Misra, Director of Clinical Trials, who thanked me for the submission and remarked, 'Clearly you know more about this drug than anyone on this Council', after which he said that he intended proposing to his colleagues that I be invited to join it.
5. I have never accepted any direct or indirect funding from the pharmaceutical industry, or from any other quarter likely to prejudice my impartiality and professional integrity. The professional expert opinions that I express in this statement are accordingly entirely my own, and have been arrived at quite

independently based upon my clinical observations and experience and my research of the published medical and scientific literature.

6. I record that I have been approached by Advocate Anthony Brink, Convener and National Chairperson of the second respondent, to comment on its submission to the ASA ('the TIG submission') as well as on the separately filed submission of the first respondent (the 'Dr. Rath Health Foundation submission'). I am informed that these submissions were filed in response to complaints made to the ASA about the article 'Why should South Africans continue to be poisoned with AZT? There is a natural answer to AIDS' ('the article'), which was co-authored and jointly published by the Treatment Information Group and the Dr. Rath Health Foundation in the *Mail&Guardian* on 26 November 2004.
7. Adv Brink has emphasized to me that his request is made in his capacity just-mentioned, and not on behalf of the Dr. Rath Health Foundation. However as co-author of the claims in the article concerning the benefits of micronutrient therapy in AIDS, the Treatment Information Group wishes me to comment on these claims as well.
8. In view of my relevant expertise and my independence I am eminently qualified to express a credible, unbiased expert opinion in regard to the matters that the complainants have place in contention.
9. I wish to note my surprise that the ASA should require an additional independent, credible expert such as myself to

pronounce on and verify the reams of research reports set out and reviewed in the TIG submission. As is apparent from the hundreds of citations canvassed in the submission, all the findings reported therein have been published by research scientists and clinicians in the world's leading medical and scientific journals, after peer-review and editorial approval of their scientific integrity, so the credentials of their authors as independent, credible experts is beyond question.

10. I am equally surprised that a further independent, credible expert such as myself should need to satisfy the ASA concerning the fact that AZT is an extremely toxic, dangerous and immuno-suppressive chemical that is poisonous to all human cells. There is a vast amount of documented evidence in this regard in the scientific and medical literature. AZT patent-holder and manufacturer GlaxoSmithKline packages AZT with an insert warning physicians and patients about some of the potentially lethal severe toxic ill effects that it is known to cause. The dangerous toxicity of AZT has been a matter of general knowledge since President Mbeki brought it to the attention of the South African public more than five years ago in his statement in Parliament on 28 October 1999:

There ... exists a large volume of scientific literature alleging that, among other things, the toxicity of this drug is such that it is in fact a danger to health. These are matters of great concern to the Government as it would

be irresponsible for us not to heed the dire warnings which medical researchers have been making.

11. Although Glaxo Wellcome (now GlaxoSmithKline) responded by issuing a false public statement that President Mbeki had been 'gravely misinformed' about this, I can confirm that in truth President Mbeki's statement was correct in all respects, and it is consistent with the second respondent's statements about AZT in the article.

12. Nevertheless, to the extent that the ASA deems it necessary that a further independent, credible expert such as myself should verify all the published research reports by the hundreds of independent, credible experts cited by the second respondent, I record:

- The hundreds of research papers canvassed in the main body of the TIG submission and Annexure 'A' thereto are precisely cited and/or their purport is accurately recorded.
- I agree with the independent, credible expert assessment of Dr Etienne de Harven MD, Emeritus Professor of Pathology, University of Toronto, that Adv Brink's extensive survey of the literature on the toxicity of AZT, *Debating AZT: Mbeki and the AIDS drug controversy* that it is 'excellent ... the best most comprehensive review on AZT currently available'.
- I share the independent, credible expert opinion of Dr Peter Duesberg PhD, Professor of Cell and Molecular Biology, University of California at Berkeley, that Adv Brink's said work is

superb, extremely well researched, analyzed, written ... I could not have done a better job ... Are you a scientist or do you collaborate with one? How could you survey so many scientific publications as an attorney? ... Could you publish your article or a variant of it in a medical/scientific journal? It would strengthen our case no end, if scientific papers of that quality would come from several sources, not only from Berkeley and Perth ... I still can't believe he wrote that. He's really a molecular biologist pretending to be a lawyer.

- Professors de Harven and Duesberg are both scientists of the highest rank and achievement, as appears from their *Curricula Vitae* appended hereto; and their special expertise in the subject of AIDS medicine is acknowledged by the Department of Health in that both are members of the Presidential AIDS Advisory Panel.
13. I confirm that indeed 'hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system', as the article correctly stated.
14. I confirm that the published, peer-reviewed medical and scientific research findings canvassed by Adv Brink in the second respondent's ten unanswered letters to the Medicines Control Council, concerning the pre-, peri- and post-natal use of AZT and nevirapine, unequivocally support the second respondent's statements that 'numerous studies have found

that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death', as the article correctly stated.

15. I accordingly agree with the independent, credible expert views expressed by the inventor of AZT, Dr Richard Beltz, Professor of Biochemistry at Loma Linda Medical School in California, when remarking on Adv Brink's work in collating the reported toxicity data on AZT and bringing them to the attention of the South African government:

[Y]ou are justified in sounding a warning against the long-term therapeutic use of AZT, or its use in pregnant women, because of its demonstrated toxicity and side effects. Unfortunately, the devastating effects of AZT emerged only after the final level of experiments were well underway, that is, the experiments which consisted of giving AZT to large numbers of human patients over a long period of time. Your effort is a worthy one ... I hope you succeed in convincing your government not to make AZT available.

16. Concerning Adv Brink's comprehensive history of the licensing and use of nevirapine in the US, Canada and South Africa, and his detailed critique of this chemotherapeutic substance as an AIDS drug and perinatal antiretroviral prophylactic, *The trouble with nevirapine*, I agree with the independent, credible expert

opinion expressed by Dr Jonathan Fishbein, former Director of the Office for Policy in Clinical Research Operations, Division of AIDS in the National Institute of Allergies and Infectious Diseases (NIAID), a wing of the National Institutes of Health (NIH) in the US Department of Health and Human Services, that it is 'an expertly written piece about this very dangerous drug'. Dr Fishbein's CV and credentials are appended hereto.

17. I confirm that nevirapine is indeed a 'very dangerous drug', whose toxicity is so severe and so acute that it has reportedly killed people following just a couple of weeks use. It was for this reason that it was contraindicated on 5 January 2001 by the US Centers for Disease Control on the advice of the US FDA for even short term prophylactic use by health professionals. No drug regulatory authority in any country of the First World has licensed the administration of nevirapine to women in labour and their newborn babies.
18. As mentioned above, in his capacity as National Chairperson of the Treatment Information Group, Adv Brink has also asked me to peruse and evaluate the Dr. Rath Health Foundation's submission in regard to the clinical benefits of micronutrient therapy in AIDS and the many peer-reviewed studies published in the medical and scientific literature included in the Foundation's submission, and I have accordingly done so.
19. I confirm that the statement originating from Associated Press that the Harvard University study (Fawzi et al. *NEJM* 2004 Jul 1; 351(1):23-32) found that multivitamins 'slow down the disease and cut the risk of developing AIDS in half', reproduced

by other reputable major international news services, and in turn reproduced in the article, is an accurate synopsis of the findings of the Harvard study.

20. Apropos of the Harvard researchers' reported statements about the alleged therapeutic value of AIDS drugs, both in the report of the study and recently in the mass media, it is important to note that no drugs were tested in their trial, so these statements were opinion only.
21. The Harvard researchers have not disputed the accuracy of the article's summation of their clinical findings, as synopsized by AP and other major reputable international news media.
22. I confirm that indeed no similar large-scale, long-term, double-blind, placebo-controlled study of any ARV drug has ever yielded clinical benefits equivalent to those reported in the Harvard multivitamin study.
23. In fact GlaxoSmithKline explicitly concedes in its package insert for AZT that: 'RETROVIR is not a cure for HIV infection and patients remain at risk of developing illnesses which are associated with immune depression, including opportunistic diseases and neoplasms.' Similarly, Boehringer Ingelheim concedes in its package insert for nevirapine: 'At present there are no results from controlled clinical trials evaluating the effect of VIRAMUNE in combination with other antiretroviral agents on the clinical progression of HIV-1 infection, such as the incidence of opportunistic infections or survival.'
24. I disagree with the first complainant's opinion, asserted as an allegation of fact, that it was 'premature to project' the findings

of the Harvard study, and I disagree with the complainant's implication that the clinical benefits reported cannot reasonably be expected for other HIV-positive Africans generally. On the contrary, in my expert opinion, the impressive positive clinical findings of the Harvard study support such an expectation.

25. Scientific truth is not determined by head count, and it has nothing to do with majorities and minorities. It should be remembered that scientific advances throughout history have always been the product of dissenting individuals or minority groups, always strenuously opposed initially by the professional and commercial interests invested in the dominant orthodoxy. I would like to illustrate the malignant consequences of consensus in medical science with a few famous examples.

26. Between 1910 and about 1950, the universal settled medical consensus was that arsenic-based Salvarsan and its derivatives were clinically indicated for repeated injection into patients with syphilis, malaria, relapsing fever, yaws, angina, anaemia and other conditions – as reflected in a standard reference handbook carried by doctors on their clinical rounds, *Hale-White's Materia Medica: Pharmacy, Pharmacology and Therapeutics*, 24th ed. by AH Douthwaite, published in 1939:

Usually six to eight arsenical doses are given at intervals of a week; some give weekly intramuscular injections of mercury or bismuth [both extremely toxic as well] at the same time; others do not begin the mercury till the completion of the first arsenical course, which is, after a

rest, repeated more than once for a shorter time, and arsenic and mercury are thus given for a year or even two or three years.

According to the medical consensus conveyed by *Hale-White's Materia Medica* arsenic also 'often improves the metabolism, the appetite, and the weight in those whose general health is feeble'.

27. As late as 1944, Gelfland's *The Sick African* (Cape Town: Stewart Printing Co) was still recommending:

Syphilis is a subject of paramount importance. The incidence is difficult to gauge, but it seems to be present in 20 per cent. or more of all Natives. Its recognition is important, not because the treatment given to the Native is in any way inadequate, but largely in order to prevent his spreading the infection by contact with the Europeans or his own people. This is accomplished by giving the syphilitic a short course of arsenical injections, to render him non-infectious. ... Of course, if ... the Native can be persuaded to attend for a longer course, better results will be obtained. ... Perhaps the solution to the problem may be found in the administration of arsenic in massive doses by intravenous injection continued over a few days. Reports from the Union of South Africa ... appear to be promising. This is certainly a form of therapy that should draw the attention of the public authorities. ... I am

confident that the solution to syphilis in the Native lies in this form of treatment, but its potential danger must not be overlooked.

28. Today, any doctor injecting his patient with arsenic, mercury and/or bismuth as formerly clinically indicated, would be struck off the roll immediately and prosecuted for attempted murder in short order. Weighted for risk of exposure, arsenic is currently ranked the deadliest poison known to man by the Agency for Toxic Substances and Disease Registry, US Department of Health and Human Services – and mercury the third most toxic.
29. For many decades until the nineteen-thirties, the established, settled consensus of all medical experts in the US and in Europe was that pellagra (similar to kwashiorkor) was a contagious condition caused by infectious germs, which could be contained by quarantining patients in the isolation wards of specially built pellagrins hospitals, and for which exceptionally toxic drugs were clinically indicated. Dr Joseph Goldberger's proposal in the second decade of last century that pellagra is caused by a micronutrient-deficient diet was fiercely resisted: Dr Townsend of the National Medical Association's Pellagra Commission derided it, remarking 'that pellagra is a communicable, and therefore, preventable disease, is abundantly evident to anyone open to conviction'; only insect carriers such as blackbirds could explain the spread of the disease 'like a prairie fire,' he said. 'How gladly would we if we could say that this disease was due to some particular form of

diet alone. Then our task as a Board of Health would be comparatively easy,' scoffed Dr Hayne, South Carolina's Health Director in response to Goldberger's proposal that pellagrins eat more beans; it was 'an absurdity,' he thought. Goldberger's dietary model for explaining and preventing pellagra was 'pernicious,' damned Dr Leroy from Memphis. Goldberger's famous prison diet experiment, proving his malnutrition hypothesis, was slammed as 'silly' by Dr Perdue of Kansas City; in fact it called for 'the execration and scathing denunciation of reasonable men'.

30. On account of the intense opposition that Goldberger ran into from what he described as 'an unthinking public and a half-educated commercialised medical profession' that preferred prescribing toxic drugs over giving corrective dietary advice, he bypassed the obstructive medical journals, and propounded his new model of understanding to the lay public in the newspapers instead. This led to the universal acceptance of his discovery that poor diet, and not infection, caused pellagra. (Per Elizabeth Etheridge's PhD dissertation on the history of pellagra in the US for the University of Georgia in 1966, published in expanded form as a book, *The Butterfly Caste* (Connecticut: Greenwood Press, 1972).)

31. The first complainant's allegation that there is 'no proven, safe and effective "natural health" answer to AIDS' is a matter of opinion, which, in my view, is incorrect. The allegation carries with it the implication that the only safe and effective treatment for immune deficiency in HIV-positive people is the

administration of exceptionally toxic synthetic chemicals, such as AZT and nevirapine, manufactured and sold by the pharmaceutical industry as medicinal drugs. The first respondent's second implication is that ARV drugs are 'proven, safe and effective'. In my expert opinion, based on a profusion of published research findings canvassed in the TIG submission, the first complainant's allegation and implications are wrong.

32. The Harvard study authors found that 'As compared with women in the placebo group, those in the multivitamin group were significantly less likely to progress to WHO stage 4 or die of AIDS-related causes.' I accordingly dispute the first complainant's unwarranted discounted interpretation of the study, namely, 'that it is possible that multivitamins (vitamins B, C and E to be precise) are slightly effective in delaying the onset of AIDS for the general population'.
33. The basis upon which the Pauling vitamin C study referred to in the article (*Proc. Natl. Acad. Sci. USA* Vol 87, pp 7245-7249, September 1990) is clinically relevant in AIDS is clearly set out in the Dr. Rath Health Foundation submission, and I agree with it.
34. The burden of the statement, 'Every textbook of biochemistry recognizes that vitamins and other micronutrients are the most decisive factors determining the optimum function of the immune system' is elementary to undergraduate medical students, and I confirm it.

35. I accordingly support and endorse both the Treatment Information Group and Dr. Rath Health Foundation submissions in response to the two complaints filed against the article, and record my view that the complaints are insupportable.
36. In conclusion, I wish to make the following comments about the attempt by the first complainant and the ASA to censor the information contained in the article and prevent the people of South Africa from learning about it.
37. The March 2003 issue of the *South African Medical Journal* announced in an editorial that the journal will no longer publish any articles that criticize the orthodox virus/chemotherapy model in AIDS and that propose novel causation/treatment hypotheses:

Medical journals have a responsibility to put all sides of important questions to readers. However, there comes a time when continuing to pander to tangential viewpoints serves no useful purpose and indeed may be harmful. ...
The SAMJ therefore does not accept such material.

- In short, by editorial fiat, physicians and medical academics in South Africa are barred from questioning the contagious hypothesis of AIDS and its management with highly toxic pharmaceutical agents in their principal professional journal.
38. In view of the closure of the *South African Medical Journal* to heterodox approaches to the management and treatment of AIDS, in favour of the patented synthetic drug approach

hegemonized by the multinational pharmaceutical industry, it is critically important to public health in South Africa that truthful health information be ventilated in the mass media and especially in the indigenous languages of communities most affected.

39. Finally, I wish to make the following comment. Following centuries of colonial oppression and decades of racist dictatorship in South Africa, in which the manipulation and censorship of information and the silencing of dissent played a pivotal role in the maintenance of the old order, we have achieved our precious new democratic freedoms though great sacrifice. There is accordingly no room for censorship of any sort in our young democracy, especially in a matter directly affecting the health of our people, the poor black majority in particular.
40. Fifteen years ago, Albie Sachs, now a Justice of the Constitutional Court, wrote in *Protecting Human Rights in a New South Africa* (Oxford University Press, 1990): 'As Thabo Mbeki, member of the National Executive of the ANC, has pointed out, freedom of expression will have a special significance in a new South Africa.' The struggle against apartheid had as one its objectives the creation of an open society in which citizens had free access to all information to enable them to make informed decisions on all matters affecting their lives. This should be respected by everyone claiming a place in our country.

.....
S.W.P. MHLONGO

Cc:

Dr ME Tshabalala-Msimang MP, National Minister of Health ;

Mr J Ngculu MP, Acting Chairperson, Health Portfolio Committee,
Parliament;

Mr MT Goniwe MP, ANC Chief Whip, Parliament.

Etienne de Harven: CV

Physician Etienne de Harven graduated *prima cum laude* with his M.D. from the University of Brussels, Belgium in 1953. As a research fellow, first at the Institut Gustave Roussy, in Villejuif, France, and immediately afterwards at the Sloan Kettering Institute in New York, he rapidly made two contributions to viral research. In 1958, he and Sloan-Kettering's Charlotte Friend published the first electron micrographs (pictures taken with an electron microscope) of the Friend leukemia virus (FLV), a retrovirus just discovered by Friend in murine (mouse) leukemia cells. In 1960, he demonstrated with electron microscopy that the assembly of such retroviral particles occurs on the host cell's outer membrane. In describing the steps leading to the release of retroviruses from host cells, he coined the term "budding," which has become a staple in the vocabulary of freshmen microbiology students.

In 1962, he joined the staff of the Sloan-Kettering Institute as its chief of Ultrastructural Research Section, in a joint appointment as Professor of Biology at Cornell. His laboratory became an international center for ultrastructural studies of retroviruses. In 1981, he moved to Canada, to lead the Electron Microscope Laboratory at the University of Toronto Pathology Department, while serving as a staff pathologist at Toronto General Hospital. He retired from both posts in 1993, and transferred to southern France, where he continues his affiliation with the University of Toronto as emeritus professor of pathology.

Dr De Harven spent most of his research career characterizing and isolating murine retroviruses, using filters and ultracentrifuges to purify the particles, and electron microscopy to monitor the level of success of purification and to study viral morphology. His extensive publication record led him to serve as associate editor of *Virology* and *Cancer Research*, and as editorial board member of *Scanning Microscopy*, *Submicroscopic Cytology*, and the *Journal of Electron Microscopy Technique*.

Peter Duesberg: CV

Prof. of Molecular and Cell Biology, University of California, Berkeley, CA

Born: December 2nd, 1936 Birthplace: Germany

Education: University of Wurzburg, Germany, 1956-1958: Vordiplom (Chemistry) University of Basel, Switzerland, 1958-1959 University of Munich, Germany, 1959-1961: Diploma (Chemistry) University of Frankfurt, Germany, 1961-1963: Ph.D. (Chemistry) Research & Professional Experience: Max Planck Institute for Virus Research, Tubingen, Germany, 1963: Postdoctoral Fellow Department of Molecular Biology and Virus Laboratory; Dept. of Molecular & Cell Biology, University of California, Berkeley CA 1964: Assistant research Virologist and Postdoctoral Fellow 1968: Assistant Professor in Residence and Research Biochemist 1970: Assistant Professor 1971: Associate Professor 1973 to present: Professor

Honors: 1969: Merck Award 1971: California Scientist of the Year Award 1981: First Annual American Medical Centre Oncology Award 1986: Outstanding Investigator Award, National Institutes of Health 1986: Elected National Academy of Sciences 1986-1987: Fogarty Scholar-in-Residence at the National Institutes of Health, Bethesda, MD 1988: Wissenschaftspreis, Hannover, Germany 1988: Lichtfield Lecturer, Oxford, England 1990: C. J. Watson Lecturer, Abbott Northwestern Hospital, Minneapolis, 1992: Fisher Distinguished Professor, University of North Texas, Denton, TX 1992: Shaffer Alumni Lecturer, Tulane University, New Orleans, LA 1996: Distinguished Speaker, Department of Biology, Univ. Louisville, KY 1997: January-July: Guest professor of the University of Heidelberg at the Medical School in Mannheim (III Med. Klinik, director Prof. R. Hehlmann) 1998: August-December: Guest professor of the University of Heidelberg at the Medical School in Mannheim (III Med. Klinik, director Prof. R. Hehlmann) 2000-03: Recipient of a Mildred Scheel Guestprofessorship at the University of Heidelberg at Mannheim from the Deutsche Krebshilfe.

Jonathan Fishbein: CV

Jonathan M. Fishbein, M.D. was appointed Director of the newly created Office for Policy in Clinical Research Operations (OPCRO), Division of AIDS, National Institute for Allergy and Infectious Diseases in July, 2003. OPCRO's purpose was to develop, standardize, implement and execute policies, procedures and standards of conduct for clinical research in support of the DAIDS scientific agenda. The goal of these activities would be the protection of volunteer's rights and the enforcement of accountability, in order to achieve the highest standard of scientific integrity in the Division's sponsored research.

Previously, Dr. Fishbein had served as Vice President of North American Medical Services at PAREXEL International Corporation (Waltham, MA) from 1999 to 2003. Since 1997, Dr. Fishbein's responsibilities included the financial, strategic, and operational oversight for the North American medical safety and consulting arm of one of the world's largest contract research organizations (CRO).

At PAREXEL, Dr. Fishbein's accomplishments included the expansion of his professional staff four-fold to eighty employees, who he placed in five offices throughout the U.S. He recruited established clinical researchers with a wide variety of therapeutic area expertise from industry and academia to increase the staff of physician clinical trial specialists from five to fourteen. He was responsible for improving safety monitoring capabilities and establishing new services such as DSMB creation and oversight, pharmacovigilance, and medical telecommunications center support for phase IV studies. He maintained corporate relationships with academic institutions, most notably McGill University/Montreal General Hospital. Under Dr. Fishbein's leadership, North American Medical Services grew its revenues substantially and was a leader in corporate profitability. As a Department Head, Dr. Fishbein continued to maintain medical and safety oversight on a number of trials, including a phase III study of Riquent for La Jolla Pharmaceuticals.

Dr. Fishbein joined PAREXEL as an Associate Medical Director in 1993. By 1997, Dr. Fishbein was promoted to Senior Medical Director where his responsibilities included providing scientific and strategic guidance on medical issues, clinical drug development, protocol development, regulatory submissions, manuscript development, safety monitoring and evaluation of new technologies. Dr. Fishbein's business development activities focused primarily on securing awards in the transplantation field. As a result, PAREXEL became a leading contractor for clinical trials in this therapeutic area.

Dr. Fishbein was appointed a Medical Staff Fellow at the Immunology Branch of the National Cancer Institute in 1990. Under the mentorship of David H. Sachs, M.D., Dr. Fishbein studied mechanisms of transplantation tolerance using inbred miniature swine. After a year, Dr. Fishbein accompanied Dr. Sachs to Boston to continue his work as a Research Fellow in Surgery at the Harvard Medical School and the Transplantation Biology Research Center (TBRC) at the Massachusetts General Hospital. In his research, Dr. Fishbein studied the mechanism of tolerance using a renal transplantation model in miniature swine. He co-authored 14 publications relating to this research in such journals as Transplantation, Journal of Immunology, and Immunologic Reviews.

Dr. Fishbein trained in general surgery for 2 years at Vanderbilt University Medical Center and one year at the Michael Reese Hospital and Medical Center in Chicago prior to his fellowship. He is a 1987 graduate of The Johns Hopkins University School of Medicine and received his Bachelor's degree from Lafayette College in 1983.