CURRENT DEVELOPMENTS

PREVENTING MOTHER-TO-CHILD HIV TRANSMISSION IN SOUTH AFRICA: BACKGROUND, STRATEGIES AND OUTCOMES OF THE TREATMENT ACTION CAMPAIGN CASE AGAINST THE MINISTER OF HEALTH

I INTRODUCTION

In July 2002, the Constitutional Court gave judgement in the Treatment Action Campaign (TAC)'s constitutional challenge to government's policy of limiting the provision of Nevirapine for the purpose of preventing mother to child transmission (PMTCT) of HIV to a limited number of 'pilot sites'. In finding this policy to be unconstitutional, the Court found that

[t]he policy of confining nevirapine to research and training sites fails to address the needs of mothers and their newborn children who do not have access to these sites. It fails to distinguish between the evaluation of programmes for reducing mother-to-child transmission and the need to provide access to health care services required by those who do not have access to the sites.²

The Minister of Health and the nine Health Members of the provincial Executive Committees (MECs) were ordered 'without delay' to lift restrictions on the availability of Nevirapine. Thus ended the legal contest – one year and approximately 100 000 infant HIV infections after the start of the case.³ The Health Ministry tried to put the best slant on the judgment and continued as if it were business as usual: no apology was offered, no admission made that it had been wrong. On the contrary, a statement issued by the Minister on 5 July 2002 went as far as to suggest that the judgment 'confirmed' the approach of the cabinet and welcomed the fact that it 'has set aside the most restrictive aspects of the Pretoria High Court order'.⁴

This paper contextualises the litigation that challenged the South African government's PMTCT policy and documents its causes and effects. It examines the resort to constitutional litigation by civil society organisations, after being frustrated by what Cameron JA described in

¹ Ministwer of Health v Treatment Action Campaign (No 2) 2002 (5) SA 721 (CC).

² Ibid para 67.

³ On 5 April 2002, the front-page headline of *The Sowetan* was 'How Many More Babies Must Die?' It added: 'Had government implemented the High Court ruling handed down in December last year, and expanded its nevirapine programme to reach only one in every four HIV-positive mothers, it would have saved more than 900 babies from being infected with HIV'

⁴ Government Communication and Information Service 'Statement by Government on the Constitutional Court Judgment regarding PMTCT' (5 July 2002).

another context as 'a pitiable saga of correspondence, meetings, calls, appeals, entreaties, demands and pleas by public interest organisations'. More practically, it describes a 'contempt of people and process that does not befit an organ of government under our constitutional dispensation'.6 The TAC case is an interesting one, both inside and outside of the legal proceedings. It raises important issues about the functional independence of the public service from the Executive on matters where there is political sensitivity and pressure. It suggests how human rights disputes might increasingly revolve around socio-economic rights and it demonstrates that skilful litigation can take advantage of constitutional promises. Finally, the outcome of the case validates the Constitution, and should confirm to those who still suffer marginalisation and deprivation that the Constitution can materially impact on and better their lives. It need not be, as former Justice Minister Omar once suggested, 'a wonderful document' but one which 'because of the imbalances we have inherited ... will be the sole preserve of the rich and powerful'.

II THE SCIENTIFIC BACKGROUND

One of the earliest and most enduring breakthroughs in the AIDS epidemic was the discovery in 1994 that mono-therapy with the antiretroviral drug AZT dramatically reduced the risk of mother-to-child HIV transmission (MTCT).⁸ However, it was realised that the drug would be of limited efficacy outside of industrialised countries because of the need to begin administering it relatively early in pregnancy and the infra-structural requirements for its delivery. Consequently, research soon began for shorter and simpler anti-retroviral regimens that would also benefit parents in poorer countries. The most important break-through in this regard came in 1998 when a clinical trial in Thailand demonstrated that a short course of AZT given to mother and child (starting at 36 weeks of pregnancy) still brought about significant reductions in MTCT. This has become known as the Thai/Bangkok study. Since then various other regimens have been tested with the aims of further simplifying regimens, testing the durability of the benefit of

⁵ Permanent Secretary, Department of Welfare, Eastern Cape Provincial Government v Ngxuza 2001 (4) SA 1184 (SCA) para 5.

⁶ Ibid para 19.

⁷ A Omar 'Speech at the Opening of the SA Human Rights Conference' in SAHRC Conference Update (22 May 1997).

⁸ EM O'Connor et al 'Reduction of Maternal Infant Transmission of Human Immuno Deficiency Virus Type 1 with Zidovudine Treatment' (1994) 331 *New England J of Medicine* 1173.

⁹ NA Wade et al 'Abbreviated Regimens of Zidovudine Prophylaxis and Perinatal Transmission of the Human Immuno Deficiency Virus' (1998) 339 New England J of Medicine 1409-44; INITIAL?? Shaffer et al 'Short Course Zidovudine for Peri-natal HIV-1 Transmission in Bangkok, Thailand: a Randomised Controlled Trial' (1999) 353 The Lancet 733-80.

reducing in intra-partum HIV transmission in breastfeeding populations and limiting drug resistance.¹⁰

The practical implementation of this knowledge about how to reduce MTCT is extremely important in developing countries, including South Africa. For pregnant women with HIV there is a 30 per cent risk that the child will be infected with HIV, mostly during the birth and breastfeeding period. In South Africa, by 1998, it was estimated that up to 70 000 children were being born every year with HIV and there were already signs that rising infant mortality was being caused by MTCT. Most of these children live short painful lives, with HIV infection carrying a terrible toll for both parents and children. This pain is described by Busiswe Maqungo in one of the personal affidavits that was filed in the *TAC* case:

My baby was always sick. I had to borrow money from her father's parents, to take her to hospital. She normally had to go to Red Cross or Conradie Hospital and she was once admitted in Tygerberg Hospital. Sometimes my baby would be out of hospital for a week and then she would be sick again. I never had enough time with her.

Doctors always told me that my baby will die and that there was nothing they could do for her. I knew my baby would die, but I didn't want to hear it, especially not from the doctors all the time. My baby received no special medicines after she was diagnosed, she got the same medicines normally given to HIV negative children.

I gave birth to an HIV positive baby who should have been saved. That was my experience, the sad one, and I will live with it until my last day. 12

It was with the aim of securing the benefits of these breakthroughs in medical science for parents like Busiswe Maqungo that, as early as 1997, organisations such as the AIDS Law Project (ALP) at the Centre for Applied Legal Studies, the AIDS Consortium and the Perinatal HIV Research Unit at the University of the Witwatersrand began a period of sustained lobbying of the Minister and the Department of Health to develop a policy and programme to prevent MTCT. The objective was to pressure the government to implement the 'steps to be taken to prevent peri-natal transmission of HIV' listed in the 1994 National AIDS Plan. These included offering HIV testing at ante-natal clinics on a voluntary basis and conducting research into methods of preventing perinatal transmission such as 'short course AZT' and 'non-nucleoside reverse transcriptase inhibitors'. ¹³ This campaign received renewed impetus in December 1998 when TAC was founded and set as one of its primary

¹⁰ UNAIDS/WHO (1999) HIV in Pregnancy: A Review Occasional Paper 2 prepared by J McIntyre; TAC Mother to Child Transmission of HIV, A Guide for Health Workers and HIV/ AIDS Trainers (2001).

¹¹ Ministry of Health SA Demographic and Health Survey (1998).

¹² Founding Affidavit TAC v Minister of Health TPD 21182/2001 (available at http://www.tac.org.za) (hereafter 'Founding Affidavit') Annexure BB, 472-76. See also M Heywood 'Something Missing in the Debate about Mother to Child Transmission' (2000) 9(4) AIDS Bulletin 10-11.

¹³ National AIDS Convention of South Africa A National AIDS Plan for South Africa (1994) 66, 120-24. See also Founding Affidavit (note 12 above) 184.

objectives a demand that government implement a programme to prevent MTCT.

TAC's activities around MTCT are too voluminous to describe in detail here. Between 1999 and 2001 there were meetings with the first and second Ministers of Health, demonstrations, the drafting of memoranda, a 50 000 person petition to the President and a campaign that targeted pharmaceutical companies to reduce the prices of essential anti-retroviral medicines ¹⁴ and particularly GlaxoWellcome's drug, Zidovudine (AZT). ¹⁵

Initially demands for a policy and plan on PMTCT received a relatively sympathetic ear from the government. In 1998, for example, the Gauteng Health Department responded timeously to the results of the Bangkok-Thai study¹⁶ by announcing the establishment of five pilot sites where programmes to reduce MTCT would be introduced. On 30 April 1999, a meeting between TAC and Dr Nkosazana Zuma led to a joint statement that the price of AZT was the major barrier to an MTCT programme and a promise that:

government would name an affordable price for the implementation of AZT to pregnant mothers and report within six weeks on the price and other issues pertaining to the prevention of mother-to-child transmission.¹⁷

At this point it looked as if TAC's MTCT campaign would be one primarily targeting the manufacturers of anti-retroviral medicines to reduce their prices. However, an unanticipated and unfortunate diversion revealed itself in late 1999.

III THE ADVENT OF AIDS DENIAL IN SOUTH AFRICA AND ITS IMPACT ON PMTCT

Since the mid 1990s there has been a small group of scientists who have developed a thesis that HIV has not been properly isolated as a virus, and that the real causes of AIDS were initially the recreational drugs taken by many gay men in the USA in the late 1970s and early 1980s, and thereafter anti-retroviral medicines. This group (often referred to as 'AIDS dissidents') has argued that, rather than helping to restore the immune system, anti-retroviral drugs destroy it by destroying cell

¹⁴ The details of this campaign were set out in a 'Memorandum Calling for Commitment, Action and Implementation of a Prevention and Treatment Plan' handed to the Minister of Health on 11 June 2001 (available at http://www.tac.org.za).

¹⁵ Zidovudine or AZT was the first anti-retroviral drug to receive FDA approval as a treatment for HIV/AIDS. Its benefits in reducing MTCT were discovered later.

¹⁶ See note 9 above

¹⁷ Joint Statement of the Minister of Health and TAC (30 April 1999).

replication and causing a range of life-threatening side-effects. ¹⁸ Although their arguments vary, the basic contention is that AIDS in Africa is caused by poverty and that a range of poverty related illnesses (such as Tuberculosis) are being misdescribed as HIV-related in order to create markets for first world drugs, particularly anti-retrovirals.

When TAC launched legal action to demand broader access to Nevirapine in 2001, none of the affidavits filed by government officials made reference to these 'dissident' views on anti-retroviral medicines, or whether HIV is the cause of AIDS, as reasons to justify the failure to develop or implement a programme. However, a sometimes hidden, sometimes open, relationship that has become apparent between the President and AIDS denialists would seem to be the primary reason for the delays.

For reasons that are not yet fully documented, the fact that such a relationship existed was first signalled in October 1999 in a speech by President Mbeki to the second chamber of South Africa's Parliament, the National Council of Provinces (NCOP). At the end of this speech he unexpectedly questioned the safety of AZT and warned that the 'toxicity of this drug is such that it is, in fact, a danger to health'. Mbeki informed the NCOP that he had instructed the Minister of Health to launch a probe into the safety of AZT and that, until this was complete, it would not be used in South Africa. October 1999 in a speech by President South Africa.

From this point onwards, progress with implementation of a national programme to prevent mother to child HIV transmission was derailed. Two weeks later, on 16 November 1999, the Minister of Health announced to the National Assembly that, although she was aware of the positive results of AZT, 'there are other scientists who say that not enough is yet known about the effects of the toxic profile of the drug, that the risks might well outweigh the benefits, and that the drug should not be used'. ²¹ As a result, she had instructed the Medicines Control Council (MCC) to review the use of AZT.

¹⁸ The most well-know proponent of this thesis is Dr Peter Deusberg (see http://www.virusmyth.net). In 2000 President Mbeki became a cause celebre for the AIDS denialists, who did not hide that they had found a new champion. The Virus Myth web-site has a 'Petition to Support President Mbeki' on its opening page, which seeks support for Mbeki's call for an 'open, scientific debate on the definition, causation, treatment and prevention of AIDS'. The web-site also documents (and celebrates) the SA government's decision not to give in on AZT. A scientific refutation of the contentions of the AIDS denialists, by the US National Institutes for Health, is available at http://www.niaid.nih.gov/factsheets/evidhiv.html.

¹⁹ T Mbeki 'Address to the National Council of the Provinces' (28 October 2001) (available at http://www.anc.org.za/ancdocs/history/mbeki/1999).

²⁰ Ibid. During the first session of the Presidential AIDS panel in April 2000, a senior official working for the Minister of Health informed the author that the Minister had not been informed in advance of the comments on AIDS that would be made in this speech.

²¹ Debates of the National Assembly Hansard (16 November 1999) 1835-62. Own emphasis.

Experiences such as the Thalidomide crisis²² mean that there is now universal acceptance of the need for governments and regulatory authorities constantly to monitor the safety and efficacy of all registered medicines, including anti-retrovirals.²³ However, the AIDS crisis in South Africa has been compounded by the readiness of senior politicians to cite Thalidomide as cause for caution regarding the use of antiretrovirals, but then to ignore the advice of the scientists they have called upon to review safety profiles. So, in early 2000 when the MCC issued the report of its careful, internationally supported review of AZT, which concluded again that benefits of its use outweighed risks, the report was at first rejected and sent back to the MCC for further work, and later ignored.²⁴ Indeed, in spite of the views of the MCC, the World Health Organisation (WHO) and a multitude of other scientists, political opposition to the use of AZT continued. In January 2000 for example, President Mbeki responded personally to the author of an article in s Day²⁵ advising that he 'contact the Perth scientists and Dr Rasnick directly' and stating that '[t]he question we must all answer, including the scientists, is whether we should continue to harm the health of the women in our country, to avoid "causing public confusion".²⁶

- 22 Thalidomide was initially developed in the 1950s as a sedative. It was prescribed to pregnant women to reduce morning sickness and other pregnancy related discomfort and was registered for this purpose in a number of countries, including Germany, Canada and Britain. However, in 1961 a link was established between Thalidomide and serious birth defects (eventually affecting nearly 12 000 babies) and it was rapidly withdrawn from use. The Thalidomide experience led to greater caution in the registration of medicines but also to awareness of the need for ongoing monitoring of registered medicines. See L Hanna 'Drug Watch: Thalidomide's Long and Winding Road' (April 1998) Bulletin of Experimental Treatments for AIDS
- 23 See the affidavit of Peter Ian Folb in Replying Affidavit *TAC v Minister of Health* TPD 21182/2001 (available at http://www.tac.org.za) (hereafter 'Replying Affidavit') Annexure A 1849-56: 'It is in the nature of science that knowledge is always subject to review, revision and correction in the light of new information and evidence which emerges. In this sense, any scientific conclusion is provisional. Registration of a drug by the Council amounts to an unequivocal determination that availability of the drug as specified is in the public interest, which means that the Council has determined that the drug is safe, of acceptable quality, and therapeutically efficacious. This determination, like any other scientific determination, can be revised or annulled in the light of new scientific evidence which emerges' (ibid para 16).
- 24 Because of the potential damage to public health and HIV prevention efforts of the highprofile questioning of AZT's safety by the South African government, the World Health
 Organisation conducted its own extensive review of the literature and concluded: 'WHO
 considers Zidovudine to have an acceptable clinical safety profile. For the specific indication
 of the prevention of MTCT, WHO considers Zidovudine to be an essential drug that should be
 made available at all times, in adequate amounts and in the appropriate dosage formulations.
 Zidovudine should be used under careful medical supervision, paying due attention to the
 relative clinical contraindications and monitoring for potential toxicities'. WHO Safety and
 Tolerability of Zidovudine: A Review of Literature (2000) 5.
- 25 M Cherry 'Mbeki's Claims on AZT are Problematic' Business Day (18 January 2000).
- 26 Personal letter from President T Mbeki to M Cherry (19 January 2000). The scientists referred to by Mbeki are leading figures associated with AIDS denial. Later in 2000, David Rasnick, Peter Deusberg and other AIDS denialists were invited by Mbeki to become members of the Presidential AIDS panel, to debate the causes of AIDS with 'orthodox' scientists and to advise the President on how best to respond to the epidemic.

Unfortunately, Mbeki's endorsement of denialist views gained currency in the ANC and the government, and increasingly determined health policy. These views prevented the government from fulfilling its constitutional duties progressively to realise access to health care services, specifically for women and children with HIV. Thus on 5 April 2000 the Minister of Health, Dr Tshabalala-Msimang, made a speech to Parliament that had all the hallmarks of 'dissidentese'. Raising reasonable concerns about a number of deaths of adults on therapeutic drug trials that appeared to be associated with daily Nevirapine use as part of a combination of anti-retroviral drugs, she confused these deaths with use of the same medicine for preventing intra-partum HIV transmission – despite the knowledge that it requires only one dose to mother and child and the fact that there were no reported adverse safety events concerning its use in MTCT.²⁷

Tshabalala-Msimang remained steadfast in opposition to AZT. At the end of 2000, at a meeting in New York to launch the International Partnership Against HIV/AIDS in Africa (IPAA), she told this author that the government would 'never use AZT' in the prevention of MTCT. Three years later this position prevails.

The intricacies and ongoing evidence of what emerged as President Mbeki's sympathies with the AIDS-denialist cause have been partially reported elsewhere. They were admitted to by the late Peter Mokaba and put on public display in a document that was given wide circulation in the ANC titled Castro Hlongwane, Caravans, Cats, Geese, Foot and Mouth and Statistics: HIV/AIDS and the Struggle for the Humanisation of the African. This anonymous document, which Mokaba admitted was penned by a collective in the ANC, has lengthy chapters on AZT, Nevirapine and MTCT. Its main argument is that an unholy combination of scientists, AIDS activists and pharmaceutical companies are engaged in a campaign of 'scare-mongering that is condemning millions of our own people to ill-health, disability and death.... [t]o sustain a massive

²⁷ Statement by the Minister of Health on 'Nevirapine Drug' in Debates of the National Assembly Hansard (5 April 2000) 2022-26.

²⁸ C McGreal 'Thabo Mbeki's Catastrophe' (2002) Prospect PAGE??; D Forrest 'Behind the Smokescreen' Mail and Guardian (26 October 2001). Although in late 2002 the relationship between Mbeki and the dissidents is denied, there remains a paper trail of speeches and comments that point to a lengthy period during which it can be said that Mbeki was preoccupied with the main theses of the denialists. These include his 'Letter to World Leaders' (3 April 2000) http://www.virusmyth.net/aids/news/lettermbeki.htm; 'Opening Speech to the Presidential Advisory Panel on AIDS' (6 May 2000) http://www.virusmyth.net/aids/news/tmspeech.htm and various interviews, including a live television interview with South African journalist Debra Patta (E-TV 'On the Record' (24 April 2001)), where Mbeki said that he would not take an HIV test on the grounds that it would be a 'publicity stunt', adding 'when you do an HIV test what is the test testing? . . . what is it measuring? So I go and do a test I'm confirming a particular paradigm. It doesn't help in addressing this health need'. (Accessed from http://www.virusmyth.net/aids/news/etvmbeki.htm).

²⁹ Anonymous, January 2002.

political-commercial campaign to promote anti-retroviral drugs'.³⁰ Poverty is artificially counterpoised to HIV/AIDS as the real challenge to the health of African people, ignoring the actual link between vulnerability to HIV infection and poverty, and the consequences of HIV infection on household income.³¹

IV THE GOVERNMENT'S CHOICE OF NEVIRAPINE

In July 1999 the first results of a trial known as HIVNET 012, testing the efficacy of a single dose of Nevirapine in reducing MTCT, were released by the National Institutes for Health (NIH).³² The results showed similar efficacy to AZT but were achieved with a much less complex regimen. In the face of Presidential opposition to AZT the Minister of Health and others latched onto Nevirapine as an alternative – and quickly arranged a study-tour to Uganda, which included the objective of hearing more of the trial of this drug.

In answer to the growing pressure from TAC, Nevirapine was now offered as the government's probable medicine of choice and TAC was persuaded to still its demands pending the outcome of a local trial known as the South African Intra-partum Nevirapine Trial (SAINT). TAC accepted the bona fides of the Minister and for a period of nine months pressure on government policy on MTCT was reduced and TAC engaged in a number of other successful campaigns that aimed to bring down the price of essential anti-HIV medicines and targeted patent abuse and drug pricing. This was not well received by clinicians working on MTCT who felt that TAC had 'let the government off the hook' over MTCT. As the preliminary results of SAINT supported the use of Nevirapine and started to leak out in mid-2000, a new catalogue of excuses emerged from the Minister It seemed as if the clinicians' concern was correct.

Fear of further delays and political interference in public health policy appeared to be confirmed at the International AIDS Conference held in Durban in July 2000. The conference opened in controversy as President Mbeki spoke eloquently about poverty, but refused to name HIV as a specific challenge for Africa. At the same time the government declined an offer from Boehringer Ingelheim, the manufacturer of Nevirapine, for a 'free' supply of the drug for 5 years and reacted coolly to the

³⁰ Ibid.

³¹ For an in-depth analysis of the links between TB, HIV and poverty see P Farmer *Infections and Inequalities, The Modern Plagues* (2001).

³² L Guay et al 'Intra-partum and Neonatal Single Dose Nevirapine Compared with Zidovudine for Prevention of Mother-to-child Transmission on HIV-1 in Kampala, Uganda: HIVNET 012 Randomised Trial' (2000) 354 *The Lancet* 795; Affidavit of Robin Wood in Founding Affidavit (note 12 above) Annexure F 135-51; Affidavit of Robin Wood in Replying Affidavit (note 23 above) Annexure B 1857-75; Affidavit of Laura Guay in Replying Affidavit (note 23 above) Annexure V 2055-69.

³³ See Founding Affidavit (note 12 above) paras 234-35.

³⁴ Dr G Gray, personal communication with author (July 2000).

preliminary announcement of the SAINT results. It took the intervention of former President Mandela to quell the storm. In his closing speech at the Conference, he called for widespread interventions to prevent MTCT.

In response to these developments, TAC publicly reinstated its threat of litigation. This threat of legal action in July 2000 raises important issues about the timing and objectives of litigation. By this time TAC's campaigns had already made government policy on MTCT a matter of national concern and had achieved wide support. At the International AIDS Conference, TAC seriously considered bringing an urgent High Court application for access to Nevirapine on behalf of several women in the late stages of pregnancy. However, despite scientific consensus on its safety and efficacy, the medicine was not yet registered in South Africa for the prevention of MTCT. AZT was registered, but it was felt that the greater cost of this medicine, together with a more complicated drug regimen (AZT must be taken daily from 36 weeks of pregnancy) made successful litigation more difficult. TAC's legal counsel cautioned against commencing litigation before Nevirapine was registered.

When medicines are registered by the MCC, the registration is for specific 'indications' that are described in the mandatory package insert that accompanies all medicines. 'Off-label' use of a medicine refers to its use for indications that have not been formally approved. This happens frequently, particularly in the use of medicines to treat children. ³⁵ But although TAC could point to precedents for 'off-label' use of medicines, and even instances where government policy endorsed this, a court would have stuck to the strict letter of the law. ³⁶ For a court formally to condone 'off label' use of medicines was inviting compromise in the system of medicine registration. There was no option for TAC but to continue the campaign, but delay the litigation. Pressure was now turned to the MCC to speed up registration of the drug and on government to clarify its programme.

On 12 and 13 August 2000 the Department of Health convened a meeting with South African scientists to assess the new knowledge gleaned from the Durban conference. After this meeting, MinMEC (a committee of the Minister of Health and the nine Provincial MECs for Health) decided that the current policy of not using AZT would continue and that the use of Nevirapine, once registered, would first be tested for two years at two 'pilot sites' in every province. The reason for this was:

to determine whether or not the exercise would be feasible, taking into account all the operational issues. Should the pilot sites be successful, the next step would be phased implementation; should this not be possible the exercise would be terminated.³⁷

³⁵ Many medicines are used off-label for children because there have not been full clinical studies, but their efficacy and safety is assumed based on evidence from adult use.

³⁶ Medicines and Related Substances Control Act 101 of 1965.

³⁷ Health MinMEC Minutes (18 August 2000).

What exactly MinMEC decided in August 2000 later became a major subject of dispute in the legal proceedings. Although the government's affidavits were peppered with repeated references to MinMEC minute, the actual document was never officially disclosed to the Court. Repeated requests by TAC's attorney were stonewalled and then refused.³⁸ On 12 November 2001 TAC brought an application to compel the government to produce the minute. Shortly afterwards, the MinMEC minute was given in confidence to TAC chairperson Zackie Achmat and, on 20 November, TAC filed a supplementary affidavit that annexed the document. However, this was opposed by the government in an affidavit which was served minutes before the start of the main proceedings on 26 November.³⁹ In this affidavit the Director General of the Health Department, Dr Ntsaluba, claimed that 'for the sake of good governance' the minutes were 'confidential and protected against disclosure'. 40 He also claimed that they were 'irrelevant' and that disclosure of such confidential documents 'could reasonably be expected to frustrate the success of that policy'.41

Ntsaluba's affidavit refused to admit the authenticity of the minutes, claiming that he had not had time to study them. A strange situation then arose when adv Moerane, senior counsel for the government, claimed in the first hour of the first day of the court hearing, that the Director General (who was seated behind him) had not had time to authenticate the document. The state then attempted to argue that the case could not proceed until the question of the admissibility of the MinMEC minute had been determined. At this point, in order to prevent the issue of the MinMEC minute becoming cause for a delay in the main proceedings, TAC withdrew its application to compel – and the case proceeded.

However, the reasons for government's desire to keep this critical decision out of the court's eye seem clear. The minute showed that in August 2000 Dr Nono Simelela, the Chief Director for HIV/AIDS and STDS, had recommended a revision to the existing policy and had spoken unambiguously of a range of benefits that would flow from expanding the programme. ⁴² She proposed that a specially formed task

³⁸ See correspondence between G Budlender and the State Attorney (October 2001) in Replying Affidavit (note 23 above) Annexures N-Q. See also State Attorney to G Budlender (8 November 2001) in Respondents Further Affidavit *TAC v Minister of Health*. In this letter the request was finally denied on the grounds that access to documents, such as the MinMEC Minutes, is 'subject to limitations, such as privilege' and that disclosure 'could reasonably be expected to frustrate the success of that policy'.

³⁹ See Supplementary Affidavits of G Budlender & Z Achmat in TAC v Minister of Health Application to Compel and the Answering Affidavit of Dr Ntsaluba in the same application. Because TAC withdrew its application to compel, these documents are not part of the official court record.

⁴⁰ Ibid para 12.

⁴¹ Ibid para 23.3.

⁴² Note 37 above 9: 'The benefits of a preventing mother to child transmission programme will be wider than those for positive women and their children Several studies have demonstrated the powerful prevention benefits of knowing about a negative HIV serostatus'.

team or the Research Monitoring and Evaluation Task Team of the SA National AIDS Council (SANAC) 'be charged with developing a specific plan for implementation'. In addition she had made the Minister and MECs aware of the ethical problems arising from denying access to a life-saving medicine to women who already knew their HIV status and arrived at health facilities seeking means to reduce the risk of HIV transmission to their children. A discussion document she had prepared for the MinMEC advised:

The provision of a package of intervention for the prevention of MTCT requires strengthening health services to offer VCT in order to identify HIV positive women. However, some consideration should be given to the case of pregnant women who already know that they are HIV infected. *Ethically, it is important to provide NVP to these women while strengthening existing health services* (my emphasis).

This recommendation was ignored by MinMEC. The adverse consequences of this for doctors were profound. Dr Haroon Saloojee, a paediatrician working at a hospital in Johannesburg, complained that

as doctors who place the health of our patients first, we would act against our constitutional right to freedom of conscience and against our ethical duty of clinical independence, if we were to deny women the right to use anti-retroviral therapy to prevent mother to child transmission of HIV. The current policy . . . denies women this right and undermines the doctor-patient relationship. 44

The policy's effect on mothers is described in two affidavits obtained by TAC. In one case a pregnant woman with HIV, Sarah Hlalele, described how she had obtained a Nevirapine tablet from Chris Hani Baragwanath Hospital, sixty kilometres away from her home in Sebokeng. Unfortunately, she went into premature labour and left the tablet at home. Sebokeng hospital, where she gave birth to K, her son, had neither Nevirapine tablets nor syrup. ⁴⁵ In another case, 'DEN', a young woman from Welkom, had to receive a Nevirapine tablet and syrup by courier, sent to her by staff at the ALP, after a nurse at Virginia hospital 'told me that I could not get Nevirapine because I was not a resident of Virginia and I could not be a part of the project. I asked her how I could get into the project. She said she didn't know'. ⁴⁶

After the August MinMEC meeting, local clinicians tried to make the best of a bad decision by investing energy and time in setting up the pilot sites which were due to start in March 2001. Once again however, there were allegations of political interference. In April the start of the pilot sites was delayed because Nevirapine was still not registered for

⁴³ Department of Health Chief Directorate HIV/AIDS Preventing Mother to Child HIV Transmission in SA Discussion Document (18 August 2000).

⁴⁴ Affidavit of second applicant Dr H Saloojee in Founding Affidavit (note 12 above) 523-34.

⁴⁵ Founding Affidavit (note 12 above) Annexure CC 476-81.

⁴⁶ Affidavit of DEN sworn under oath (1 November 2001). This affidavit was not used in the

prevention of intra-partum transmission. This led to one newspaper publishing allegations by members of the MCC that the delays were deliberate 'kowtowing to government antagonism towards a life-saving anti-retroviral drug' by some members of the MCC.⁴⁷ Activists were also told that the protocol for the pilot sites would have to be submitted to Cabinet for approval.

The role of the MCC at this point requires further scrutiny. In the context of an epidemic where children were being infected daily, the delays and obfuscations surrounding the registration of Nevirapine were inexcusable. TAC learnt indirectly via a letter to the Human Rights Commission that Nevirapine had received registration for 'prevention of intra-partum transmission' on 18 April 2001.⁴⁸ But minutes of MCC meetings requested by TAC, together with documents included by the government in its Answering Affidavit, later revealed that the registration had first been recommended on 24 November 2000 when it was considered that the drug was safe and effective. After this, inexplicably, there was a delay of a further six months as the wording of the package insert was finalised between the MCC and the manufacturer – something that ought to have taken a few days.⁴⁹

It is worth noting that these facts were only established through the legal process and after repeated requests by TAC's attorney for access to the relevant files, requests that were initially declined.⁵⁰ Once the files were obtained they showed that some of the public justifications provided for the delay by the MCC were misleading as the most important determinations regarding safety and efficacy had been made in 2000. They also suggested that those provinces that had delayed the start of pilot sites because Nevirapine had not yet been registered were, in reality, being delayed by a technicality that was probably politically motivated.⁵¹ According to one report, the Western Cape, which had commenced using

^{47 &#}x27;MCC Held Up Release of Free AIDS Drug' Cape Argus (7 April 2001).

⁴⁸ FD Letter from Dr A Ntsaluba, Director General Department of Health, to the SA Human Rights Commission (28 March 2001). Founding Affidavit (note 12 above) Annexure J 304-05.

⁴⁹ G Marcus & B Majola 'Supplementary Submissions on Behalf of TAC, Dr Saloojee and the Childrens Rights Centre' (16 May 2002).

⁵⁰ In their answering affidavit the government included two affidavits from members of the MCC which revealed confidential information about the registration process. TAC complained that the government was allowing selective access and demanded similar access to the files. See Answering Affidavit TAC v Minister of Health TPD 21182/2001 (hereafter 'Answering Affidavit) (25 October 2001, Budlender to State Attorney; 26 October, State Attorney to Budlender; 2 November, Ntsaluba to Budlender; 2 November, Budlender to Ntsaluba) 2047-54. See also 2121-22 (Ntsaluba to Budlender).

⁵¹ In the final stages of the legal case the actual date of registration of Nevirapine briefly became an issue. On 13 May 2002 the Constitutional Court unexpectedly requested supplementary argument from the parties concerning the date of registration. TAC's lawyers argued that the de facto date of registration had been November 2000. In the end Court decided that this matter was not crucial to their findings.

Nevirapine in January 2001, had been threatened with legal action by the national health department.⁵²

During this period relations between activists and the government worsened. They reached their nadir in June 2001 at a meeting between the Minister of Health, TAC, COSATU and paediatricians who had founded a campaign known as 'Save Our Babies'. At the beginning of the meeting TAC members were subjected to personal insults by the Minister, who then went on to berate the meeting over a range of issues, including the donation of the anti-fungal drug Diflucan. SA After the Minister of Health left the meeting senior health officials, including the Director General, Dr Ayanda Ntsaluba, and Chief Director HIV/AIDS and STDs, Dr Nono Simelela, attempted to salvage the situation. In the discussion that followed, however, when they were questioned by Dr Haroon Saloojee and Dr Ashraf Coovadia, the two founders of Save Our Babies, about how doctors should respond to women who know their HIV positive status and were requesting Nevirapine, they said that they had no answer to this ethical dilemma. SA

V LAUNCHING LEGAL ACTION

In April 2002 the formal registration of Nevirapine for the prevention of intra-partum transmission removed the last obstacle to legal action. TAC decided that both morally and politically it had no other options than to launch a case against the government.⁵⁵ TAC was able to elicit the support of some of the most experienced constitutional lawyers in the country,⁵⁶ whose commitment and professionalism were central to the success of the case.

On 17 July 2001, TAC's first letter of demand to the Minister of Health and the nine Provincial MECs for Health had been sent by its attorney. This carefully crafted letter set out the facts of the epidemic and the potential to save lives through an MTCT programme and asked that the Minister and MECs:

(a) provide us with legally valid reasons why you will not make NVP available to patients in the public health sector, except at the designated pilot sites, or alternatively to undertake forthwith to make NVP available in the public health sector.

^{52 &#}x27;Departmental Muddle causes AIDS Drug Delay' The Star (3 April 2001).

⁵³ Mail and Guardian (15 June 2001).

⁵⁴ TAC Press Statement 'Meeting With Minister of Health Reveals Serious Divisions' (12 June 2001) (available at http://www.tac.org.za); author's personal notes of meeting.

⁵⁵ TAC Press Release 'Statement of Mother to Child HIV Transmission Programme' (8 May 2001) (available at http://www.tac.org.za).

⁵⁶ TAC's legal team consisted of Geoff Budlender, an attorney and director of the Legal Resource Centre (LRC) Constitutional Litigation Unit, Adv Bongani Majola, and Adv Gilbert Marcus SC.

(b) undertake to put in place a programme which will enable all medical practitioners in the public sector to decide whether to prescribe NVP for their pregnant patients, and to prescribe it where in their professional opinion this is medically indicated'.⁵⁷

The provision of health services is a functional area of concurrent national and provincial legislative competence. Thus South Africa's nine provincial governments are given shared responsibility for health policy and provision. The State Liability Act 20 of 1957 permits MECs to be cited as representatives of the provincial government in legal proceedings. The decision to cite the nine MECs for Health in the case and to request responses from each of them to the questions in this first letter proved to have significant legal and political implications in the short and long term.

TAC was informed that the Minister had instructed the provinces not to reply individually and that her letter should be the only response from the Government. All the MECs complied with this. The Minister's letter, when it came, was couched in language of ostensible concern and commitment to addressing the HIV epidemic. But in essence it contained a list of barriers to the roll-out of a plan and to immediate access to Nevirapine for those who needed it. These were issues around Nevirapine-induced viral resistance, breastfeeding and the sustainability of the programme. However, none of the substantive questions posed in Budlender's letter were addressed and the Minister's letter concluded:

We do not underestimate the ethical dilemmas that confront health professionals in the public sector. However, at the same time we need to balance their desire to provide the best treatment that they can for their patients with the government's obligation to root our public policies in the practical realities of the daily life experiences of all of our citizens, equally.⁵⁹

This letter was the first admission by the Minister that she knew the policy was intruding on the ethical duties of doctors to act in the best interests of their patients. However, it is justified on the grounds of the duty on government to ensure equality in access to health care services. This is a misuse of the principle of equality. Whilst the notion of government rationing of health care services on the basis of cost has been accepted by the Constitutional Court, 60 the 'best treatment' being demanded here was neither expensive nor complicated. In fact, the Ministry of Health's own research had found that an MTCT programme using Nevirapine would cost only R1,99 per capita and that the result of this would be 'the lives of almost 14 000 babies would be saved . . . and

⁵⁷ Founding Affidavit (note 12 above) Annexure C 113.

⁵⁸ Constitution of the Republic of South Africa Act 108 of 1996. See Chapter 3 'Co-operative Government'; Chapter 6 'Provinces'. In Schedule 4, 'health services' are listed as an area of concurrent competence.

⁵⁹ Founding Affidavit (note 12 above) Annexure E 130.

⁶⁰ Soobramoney v Minister of Health 1998 (1) SA 765 (CC).

over 250 000 years of life saved with them'. ⁶¹ In the *TAC* judgment the Constitutional Court commented on the Minister's letter saying that it 'did not deny the restriction imposed by government on the availability of nevirapine; nor was any plan or programme to extend its availability mentioned. The undertakings requested were neither given or refused outright. The meaning of the Minister's letter is, however, quite unmistakable'. ⁶²

The Western Cape complied with the Minister's instruction not to reply individually. Nonetheless, the MEC for Health simultaneously wrote to TAC's attorney explaining that he had 'written to the National Minister of Health in order to provide details of the MTCT programme in the Western Cape Province with a view that this information be included in the Minister's reply to you'. 63 The MEC attached this report to his letter. Significantly, the Minister's letter had made no reference to this response from the Western Cape, or to the fact that at least one province had a different approach to preventing MTCT. TAC subsequently annexed the Western Cape's reply to the Minister to its Founding Affidavit. This set up a juxtaposition between the position adopted by eight provinces, each of whom claimed that they could do nothing outside of the pilot sites, and the Western Cape which explained that:

We would have liked to reach 100% coverage as soon as possible but estimate that at least 90% of HIV positive women will be reached by July 2002. This we believe, is comparable to the rollout of MTCT programmes in Thailand, Brazil and Botswana – the only developing countries that have embarked on MTCT programmes aimed at reaching the total population.⁶⁴

This early disjuncture between the provinces was to be the undoing of the government's legal case. By offering an example of what could be done, it created a moral pressure on other provinces to extend their programmes beyond the artificial boundaries of the pilot sites. Hereafter a divergence developed, sometimes openly, sometimes covertly, between those provinces who saw it as part of their constitutional duty to expand prevention programmes, and those who apparently did not.

Some of the most stark examples of the impracticality of the MinMEC policy were found in Gauteng, where large teaching hospitals with capacity to provide the programme were initially excluded as pilot sites. To illustrate this, TAC's Founding Affidavit included an affidavit signed by two senior members of the SA Pediatric Association (SAPA), both doctors working in large public hospitals, who described some of the

⁶¹ M Henscher 'Confidential Briefing: The Costs and Effectiveness of Using NVP or AZT for the Prevention of Mother to Child Transmission – Current Best Estimates for SA'. Founding Affidavit (note 12 above) Annexure T 381-88.

⁶² Minister of Health v Treatment Action Campaign (note 1 above) para 11.

⁶³ Letter from MEC for Health, Western Province to TAC Attorney (27 July 2001). Founding Affidavit (note 12 above) Annexure D 117-29.

⁶⁴ Letter from Western Cape Province MEC for Health to Minister of Health (27 July 2001).

measures that were being taken by doctors to circumvent a policy that prevented them from acting in the best interests of their patients. Both were working at hospitals that were not pilot sites but which did have capacity to provide the full service. A letter from the CEO of Johannesburg Hospital was also attached stating that he was 'keen to see the implementation of a cost effective and affordable prevention programme . . . in the immediate future' but that the hospital had not then been appointed a pilot site. Under the pressure of the litigation, the hospital became a pilot site on 1 October 2001. However, to illustrate the irrationality of the original decision, Professor Cooper explained how, although the hospital was now an officially designated site, 'it has not been given any additional staff resources' the only difference being that it was 'no longer necessary for us or our patients to rely on donations'. 67

This was the first example of how the mere fact of commencing litigation created pressure on national and provincial governments and resulted in immediate and tangible benefits for people with HIV. The launch of the application precipitated an extension of the programme in a number of provinces, as if to contradict TAC's claims of irrationality and unreasonableness. Once the 'two pilot sites per province rule' had been breached, it became unenforceable, encouraging health officials at provincial level to move ahead. By December 2001, Gauteng had 12 pilot sites covering many of the major hospitals in the province.

In KwaZulu Natal the pressure of the litigation brought about a split between the MEC for Health, Dr Zweli Mkhize, and the Premier of KwaZulu Natal, Lionel Mtshali, over the roll out of the programme. Initially the province had responded in the manner instructed by the Minister, explaining under oath that 'no public health facilities outside the present pilot programme ... have the capacity to immediately implement a comprehensive MTCT programme'. ⁶⁸ This seemed highly improbable in a province with 61 hospitals and 390 clinics. Indeed, some hospitals admitted to having the requisite capacity. TAC attached to its Replying Affidavit an affidavit from a doctor Andrew Grant, the Acting Medical Superintendant of Bethesda Hospital in Ubombo, a rural area in Northern KwaZulu Natal. Grant explained that:

my colleagues and I are convinced that our counselling framework is already in place, and that we are in a position to safely and effectively implement a programme ... through the administration of Nevirapine For this reason, Doctors at this hospital have bought Nevirapine with their own money and are already administering it to

⁶⁵ Affidavit of Prof KD Bolton and Prof PA Cooper in Founding Affidavit (note 12 above) Annexure M 331-35.

⁶⁶ Letter to M Heywood from S Pillay, CEO Johannesburg Hospital (27 July 2001). Founding Affidavit (note 12 above) Annexure N 335.

⁶⁷ Replying Affidavit (note 23 above) Annexure F 1968.

⁶⁸ R W Green-Thompson (fifth respondent) Answering Affidavit (note 50 above) 1606-18.

⁶⁹ Affidavit of Dr Andrew James Grant in Replying Affidavit (note 12 above) Annexure X 2095-98.

patients who are confirmed to have HIV and who give informed consent \dots It is an easy drug to administer and we have seen no side effects on this regime (except extreme gratefulness). ⁶⁹

Faced with the evidence of these doctors, the pressure increased on those who resisted the extension of the pilot programme to other hospitals. The division created in KwaZulu Natal became obvious early in 2002 when the Premier issued a press statement that 'commended the courageous decision of doctors who have committed themselves to supply anti-retroviral drugs to pregnant mothers at Empangeni, Bethesda and other hospitals in those parts of KwaZulu Natal which are ravaged by the scourge of HIV and Aids'. Days later, during the opening of the provincial legislature, the Premier announced plans to expand greatly the scale of the programme. The state of the programme.

By contrast, provinces such as Mpumalanga and the Free State stuck rigidly to the MinMEC position, with MECs obstructing access to life-saving services, closing down NGOs, causing avoidable HIV infections and fostering a conflict between health professionals and politicians. ⁷² In Mpumalanga for example, in April 2002 TAC resorted to providing Nevirapine directly to Philadelphia Hospital, one of the biggest hospitals in the Province, after requests and petitions from the doctors to the provincial government were repeatedly ignored. ⁷³

VI 'MOST IF NOT ALL OF THE DISPUTATION IS BESIDE THE POINT'

(a) The case is filed

TAC, together with Save Our Babies (SOB), a loose coalition of paediatricians, ⁷⁴ and the Children's Rights Centre (CRC) in Durban⁷⁵ filed a constitutional claim against the government on 21 August 2001. The parties sought a declaration that the current policy was unconstitutional and asked further that:

[the government be] ordered to make Nevirapine available to pregnant women with HIV who give birth in the public health sector, and to their babies, where in the judgment of the attending medical practitioner or health professional this is medically indicated.

- 70 Office of the Premier KwaZulu, Natal Media Statement (21 January 2002).
- 71 State of the Province Address by the Premier of KwaZulu Natal (25 February 2002) (Annexure A in Application by the Premier to replace the MEC for Health as 5th Respondent in the proceedings before the Pretoria High Court).
- 72 See respondents answering affidavits in *MEC for Health, Mpumalanga v Greater Nelspruit Rape Intervention Project (GRIP)* TPD 10373/2002. These detail the campaign of harassment to stop GRIP providing anti-retroviral medicines to rape survivors.
- 73 Petition to MEC Manana by medical specialists, medical practitioners, doctors in community service, intern doctors, dentists, dentists in community service, pharmacists and pharmacists in community service at Philadelphia Hospital, Mpumalanga (25 April 2002).
- 74 Annexed to the SOB affidavit were the names of over 150 doctors who declared their support for the litigation and gave consent for their names to be declared to the Court.
- 75 Dr H Saloojee in Founding Affidavit (note 12 above) 523-35; Ms CJ Vawda in Founding Affidavit (note 12 above) 585-90.

[the government] plan and implement in a reasonable manner an effective national programme to prevent or reduce the mother-to-child transmission of HIV, including the provision of voluntary counselling and testing, and where appropriate, Nevirapine or other appropriate medicine, and formula milk for feeding.

Taking the lead from Cape High Court's judgement in *Grootboom v Oostenburg Municipality*, ⁷⁶ TAC asked that government be ordered to meet these demands within clear time frames and subject to further scrutiny by the court. A series of affidavits set out the scientific, economic, legal and moral reasons as to why such an order was justifiable and why the government's policy was unreasonable. These included affidavits on the efficacy and safety of Nevirapine (Dr Robin Wood); the cost-effectiveness of its use (Prof Nicoli Nattrass); the epidemiology of HIV and MTCT (Dr Quarraisha Abdool Karim), and the impact of the 'policy' on doctors, nurses, parents and women with HIV.

Unsurprisingly, the government opposed the application and on 22 October 2001 served on TAC's attorneys 1000 pages of papers that sought to persuade the court that their Nevirapine 'pilot programme' was reasonable, rational and not a violation of constitutional rights.

(b) The Western Cape

The Western Cape adopted a different approach. Its raised a number of criticisms of the relief sought by TAC, such as the argument that to leave decisions solely to the judgment of the medical practitioner was to risk budgetary and other distortions. But it also set out the province's plans for a comprehensive MTCT roll-out programme that aimed to reach 90 per cent of pregnancies by mid 2002 and 100 per cent coverage by 2003. The affidavit explained its approach to making formula feed and voluntary counseling and testing services available, as well as its intention to take advantage of both Nevirapine and AZT. Importantly, it explained that it had made provision to ensure that mothers in areas that were not yet reached by the Western Cape roll-out were able to access Nevirapine through the public health service, as long as this is done according to proper procedures set out in medical protocols. In addition, the Western Cape attached annexures that included documented records of the acceptability of the programme and the significant numbers of women opting for voluntary counselling and testing (VCT) and Nevirapine.⁷⁷

On the basis of this affidavit, TAC decided not to seek an order against the Western Cape nor to claim costs. However, it continued to cite the Western Cape as a defendant because all provinces in South Africa – even those that were doing the right thing – would benefit from a rational national policy. In response to the Western Cape affidavit, TAC amended its order to extend its claim for treatment of HIV positive

^{76 2000 (3)} BCLR 277 (C).

⁷⁷ Tenth Respondent in Answering Affidavit (note 50 above) 1680-782A.

pregnant women to include Nevirapine or any 'other appropriate medicine'.

(c) The government opposes

The state opposed the TAC case on grounds that the relief was unaffordable, that the efficacy and safety of Nevirapine was not fully proven and that its widespread use risked a public health catastrophe. It is significant that the architects of the MTCT 'policy', particularly the Minister of Health, did not personally depose to the replies that sought to justify their policy. This task was left to the Director General of Health, the Chief Director of HIV/AIDS and a number of lesser officials from the national and provincial health departments. This point was not lost on the judges of the Constitutional Court who noted that '[a]lthough the two main issues relate to government policy, as distinct from mere administration, neither the Minister nor any of the MECs was a deponent'.⁷⁸

The government admitted that Nevirapine has been registered by the Medicines Control Council for use in reducing risk of HIV transmission. Included in its reply was an 'information to patient and informed consent' sheet that stated that Nevirapine 'has been found to be safe and effective' and that 'side effects have not been commonly reported for one dose'. But despite this, on numerous occasions the court papers cast doubt on the safety of the medicine for individual women (often mixingup documented adverse effects in adults using Nevirapine as part of 'combination therapy' with its single-dose use for MTCT). Repeatedly claims were made that the use of Nevirapine would pose a threat through the possible development of resistance and other variants of HIV that could be 'catastrophic for public health'. 80 Doctors prescribing Nevirapine outside of the pilot sites were described as 'acting irresponsibly and risking a serious public health crisis'. 81 These allegations were not made by experts in virology or pharmacology but by officials of the Department of Health. The allegations were also made despite conclusive scientific evidence to the contrary. The intention appears to have been to confuse the court and to try to persuade it that the matter was of such great scientific complexity that it was inappropriate for a court to rule on it (an early flighting of the separation of powers argument).

The government's reply pointed out that breastfeeding carries the risk of HIV transmission even for a child who has avoided infection as a result of Nevirapine use. Essentially, it argued that this future risk justified denying the intervention to women and children at the point when its

⁷⁸ Minister of Health v Treatment Action Campaign (note 1 above) para 7.

⁷⁹ Dr N Simelela 'Information to Patient' in Answering Affidavit (note 50 above) 1397.

⁸⁰ Dr A Ntsaluba in Answering Affidavit (ibid) 658; 665; 705; 816.

⁸¹ Ibid 696.

benefits are undisputed – because it made the intervention less cost effective. ⁸² It argued that until breastfeeding habits in South Africa changed or until formula feed and clean water could reach all poor people who would need it, access to the medicine should be limited. Effectively its policy was to deny parents the opportunity to make choices, or keep control over their own lives, through access to a medically proven intervention.

The government also argued that the most effective use of Nevirapine was as part of a programme that included voluntary counseling and testing, counselling about breastfeeding practices and access to formula milk. The provision of such a programme, it claimed, was impossible because, beyond the identified pilot sites, there was no capacity to provide this service. Affidavits from heads of health in the provinces, sometimes apparently drawn from a common template, so drew a picture of the readiness of the health service that is contradicted by fact and by the government's own documentation. For example, the Head of Health in the Eastern Cape, which had set up pilot projects in East London and Rietvlei, stated that there was no capacity to do this in other parts of the province, including major urban areas such as Port Elizabeth, Grahamstown and Bisho.

Despite a report in the 2001 Intergovernmental Fiscal Review (attached as an annexure in the government's replying affidavit) showing under-spending of the health budget of R473 million in 2000/01, it was claimed by all but three of the Provincial Heads of Health that budget limitations constrained their ability to do what was necessary. Several of the Provincial Health Departments provided estimates of what full provincial rollout of the programme would cost, totaling approximately R250 million – less than half of what the government failed to spend from its current budget. Much emphasis was placed on the lack of trained counselors and the difficulties this presented. Here, too, the real situation was wildly misrepresented. For example, the Free State Health Department claimed that there were 'no NGOs which the department could work through in order to manage lay counsellors and in order to support a programme of infant feeding choices'. St

In his affidavit Ntsaluba, the Director General, admitted that 'the argument that MTCT [anti-retroviral] programmes are cost-effective may

⁸² Ibid 679

⁸³ Affidavits that were filed in the Government's answering affidavit in the Application for Leave to Execute so closely resembled each other that they repeated typographical errors. For example, in the affidavits of Green Thompson (KwaZulu Natal), Rena Charles (Mpumalanga), Michael Hendricks (Northern Cape), Hlamalani Manzini (Northern Province) the same error of 'pubic hospitals' occurs at the same point in each affidavit.

⁸⁴ See affidavits of Mjekevu (ibid 1553); Litlhakanyane (ibid 1571); Green Thompson (ibid 1609); Charles (ibid 1627-28); Hendricks (ibid 1634); Thobejane (ibid 1651). Significantly, only Gauteng and the North West chose not to use resource constraints as an excuse.

⁸⁵ Third Respondent Answering Affidavit (note 50 above) 1565-74.

well be sustained'. 86 However, he argued that this would not make it affordable. Again, deceptive arguments were deployed such as a claim that TAC had not given consideration to the individual cost borne by parents who must have money to use public transport to reach public health clinics, purchase formula feed and sterilise bottles. 87 This ignored the affidavit of Thembisa Mhlongo, supplied by TAC, which detailed the financial and personal costs, particularly to women, of looking after young children as they sicken as a result of HIV infection and eventually AIDS. 88 Indeed, on 11 September 2001, Sibongile Mazeka, the child referred to in this affidavit, died at the age of 5 of AIDS. A picture of her small coffin was later used by TAC in a poster to mobilise support for the case.

Although intimidating in volume, once deconstructed it was clear that the government papers were full of deception and contradiction. Health Department officials sought to undermine established science and scientific institutions. There seemed to be very little of a sense of urgency to come to the assistance of pregnant women with HIV or to resolve the dilemmas expressed by hundreds of doctors in the TAC papers about not being able to treat women properly. Sometimes the lack of compassion is quite startling. For example, in one affidavit by Dr Lindi Makubalo of the Department of Health an effort is made to contest an assertion by one of the TAC experts that the HIV epidemic in SA is 'explosive'. Makabulo claimed this was an incorrect depiction because the epidemic had peaked and was levelling off. 89 However, several pages later, a report from one of the pilot sites provided by the government showed that 49,5 per cent of women who entered the programme had tested positive for HIV infection. In his affidavit, the Director General accused Sarah Hlalele, the mother who gave an affidavit describing her valiant efforts to protect her child, as being 'neglectful of her health and the health of her baby'. 90

TAC had ten days in which to reply to these papers. Although initially the task seemed to be near impossible, information that contradicted and exposed the falsifications and misrepresentations was quickly obtained and turned into affidavits. TAC's local and international networking paid dividends here. For example, contact was made with Dr Mark Wainberg, one of the world's leading virologists, based in the United States, who agreed to depose to an affidavit countering the selective quotation of one of his own articles by Ntsaluba around the issue of

⁸⁶ Ntsaluba (note 80 above) 722; 742.

⁸⁷ Ibid 725

⁸⁸ TC Mhlongo in Founding Affidavit (note 12 above) Annexure DD 481-84: 'Ms Mhlongo is woken in the middle of the night by health emergencies and pays between R50 and R250 in transport costs to get the child to hospital. Ms Mhlongo has lost her previous employment because of constant absenteeism related to Sibongile's AIDS related illnesses and is in danger of losing her current employment'.

⁸⁹ Answering Affidavit (note 50 above) 1490-510.

⁹⁰ Ntsaluba (note 80 above) 771 para 197.8. See also note 45 above.

Nevirapine resistance.⁹¹ Similarly, Dr Laura Guay, the principal investigator on the HIVNET012 trial, was contacted and supplied an affidavit countering a number of distortions made with regard to this trial.⁹²

It was also in this period that TAC compiled an expert affidavit to counter the claims of lack of capacity in the state, which was to prove decisive in turning the judgment in TAC's favour. At short notice Dr Helene Schneider, the Director of the Centre for Health Policy (CHP) at the University of the Witwatersrand, provided an affidavit on the capacity of South Africa's health system to support a programme of MTCT. Drawing largely from the government's own published reports she showed how there was in fact significant latent capacity to support the provision of Nevirapine in eight out of nine of South Africa's provinces and concluded that '[t]he complexity of a PMTCT programme is no greater than tackling malnutrition, tuberculosis and other chronic diseases – aspects that the SA health system has committed itself to dealing with'. ⁹³

VII POLITICS AND MOBILISATION

In essence TAC's challenge was about public health policy. It should have been managed by government as a legitimate challenge, envisaged and encouraged by the Constitution, similar for example to the *Soobramoney* case. ⁹⁴ But it was not. Throughout this period the President's denialist AIDS policy was under fierce attack. This case, because ultimately it was a manifestation of the President's AIDS policy, was therefore fiercely defended. In a number of instances there were also examples of what appeared to be political interference in the case.

After the case had been set down, two organisations applied to join as amicus curiae. One was the South African Human Rights Commission (SAHRC). The SAHRC has a constitutional mandate to protect human rights, a special interest in socio-economic rights and a direct interest in this case because of its involvement with related investigations, such as that lodged by Dr Costa Gazi. 95 However, shortly before the hearing, it instructed its attorneys to withdraw its application to be amicus curiae. The reasons for this emerged in newspaper articles where it was alleged that the government's senior counsel had phoned SAHRC chairperson

⁹¹ Replying Affidavit (note 23 above) Annexure D 1961.

⁹² Ibid Annexure V 2055.

⁹³ Ibid Annexure J 1995.

⁹⁴ Note 60 above. *Soobramoney* involved a constitutional challenge to a policy of the KwaZulu Natal Health department limiting access to kidney dialysis in the public sector by setting criteria for patients.

⁹⁵ Gazi, a doctor from the Eastern Cape Province, has lodged a complaint with the SAHRC accusing the Minister of Health of manslaughter for failing to implement an MTCT programme. This led to an investigation by Commission.

Barney Pityana to complain about the case, and that the President's legal adviser had contacted another member of the Commission. This prompted an internal discussion in the SAHRC, with some commissioners suddenly deciding that the SAHRC had nothing to add to the case. A vote took place among commissioners, which led to a narrow five to four vote in favour of withdrawing. Thus, despite some commissioners wanting to continue, the instructions to the attorneys remained to withdraw. The SAHRC later denied that it had come under political pressure, claiming that 'the decision to withdraw was based on the fact that we had nothing new or additional to contribute to the TAC case'. ⁹⁶

TAC, however, was prepared for the politics that surrounded the case. This was because TAC believed that the MTCT policy was based upon a political decision taken at the highest level of government. TAC's constitution empowers it to engage in litigation as a means of challenging 'any type of discrimination relating to the treatment of HIV/AIDS in the private and public sector'. 97 This allows it to take legal action to enforce any right that is explicitly recognised in the Constitution. The reference to litigation in TAC's Constitution occurs in the same paragraph as a reference to 'lobbying, advocacy and all forms of legitimate social mobilisation'. For TAC, litigation both emerges from and feeds back into a social context. Resort to litigation is not exclusive of other strategies. Litigation can also help to catalyse mobilisation and assist public education on the contested issues, as well as to bring about direct relief to individuals or classes of applicants. 98 Thus, between August and December 2001, TAC engaged in intensive public mobilisation, attracting enormous support and media interest.

However, support within TAC for a strategy of litigation could not be taken for granted. Internally numerous workshops were conducted with TAC volunteers to explain the case. Externally, and amongst some of TAC's main allies, particularly the Congress of South African Trade Unions (COSATU), there was reluctance publicly to endorse taking 'our' government to court. Therefore the right of civil society to use litigation to claim and enforce rights had to be argued in meetings and workshops against those who considered it 'disloyal' or 'unpatriotic'. Although COSATU welcomed each judgment in TAC's favour, it never openly supported the litigation.

The mobilisation culminated on 25 and 26 November, when rallies and marches took place around South Africa, including an all-night vigil of 600 TAC volunteers outside the court before the hearing commenced. For the two days of the hearings the court was packed by people with

^{96 &#}x27;HRC "Has Nothing New to Add" 'Mail and Guardian (23 November 2001).

⁹⁷ Available at http://www.tac.org.za/documents/other/other.htm.

⁹⁸ See M Heywood 'Debunking Conglomo-talk: A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation' (2001) 5 Law, Democracy & Development 133.

HIV wearing TAC's trademark 'HIV-positive' T-shirt, health professionals and journalists, listening intently to the evolution of the argument. 99

The urgency of the case seemed to be understood by Judge Chris Botha, who handed down his judgment to a tense and expectant court on 14 December 2001. On all the key issues Botha found in favour of TAC, commenting that in the government's arguments there was 'no unqualified commitment to reach the rest of the population in any given time or at any given rate . . .a programme that is open-ended and that leaves everything to the future cannot be said to be coherent, progressive and purposeful'. Botha declared that '[a] countrywide MTCT programme is an ineluctable obligation of the state'. ¹⁰¹

Botha's order was bold and original. He instructed the government to allow Nevirapine to be prescribed where it was 'medically indicated' and where, in the opinion of the doctors acting in consultation with the medical superintendent, there was capacity to do so. ¹⁰² Botha also ordered the government to develop 'an effective comprehensive national programme to prevent or reduce MTCT' and return to the Court with this programme for further scrutiny before 31 March 2002.

Botha's judgment was welcomed in South Africa and worldwide. ¹⁰³ The acclaim, however, was not universal. In South Africa it attracted the ire not only of the government but also of a number of legal academics, one of whom declared it a case of 'when judges go too far'. ¹⁰⁴ The accusation now arose that Botha had breached the principle of separation of powers between judiciary and the executive by interfering in health policy and ordering the government to supply a specific medicine. Thus, on 18 December 2001 when the Minister of Health announced that she would seek leave to appeal directly to the Constitutional Court, it was claimed that the appeal was 'aimed at clarifying a constitutional and

⁹⁹ M Heywood 'Judgment Awaited in MTCT Case' (Dec 2001/Jan 2002) 12 AIDS Analysis Africa.

¹⁰⁰ TAC v Minister of Health 2002 (4) BCLR 356 (T) para 67.

¹⁰¹ Ibid para 80.

¹⁰² During the hearing the TAC had amended the relief sought in its original notice of motion to reflect concurrence with the points made by the Western Cape on the need for decisions to be taken 'in consultation with the medical superintendant'.

¹⁰³ M Heywood 'Pretoria High Court Hands Down Precedent Setting Judgment' (April/May 2002) 12 AIDS Analysis Africa. The Sunday Times (16 December 2001) carried an editorial headed 'Thanks to Our Constitution' stating: 'The outcome shows that even strongly dominant political opinion cannot stand in the way of a Constitution that is supreme. Every child born free of HIV as a result of this week's decision will be living proof of the wisdom our society showed in opting for this form of democracy.'

¹⁰⁴ K Hopkins 'Shattering the Divide – When Judges go Too Far' (March 2002) De Rebus 23-6. Hopkins argued that the judgment was an illustration of 'when judges forget themselves and exceed the powers that they are entrusted with in performing their judicial functions . . . Government policy is a political creature and this is why it is governments which make policy, not judges. The remedy for unpopular government policy should rightfully be political, not legal.' Ibid 23-4.

jurisdictional matter which, if left vague, could throw executive policy making into disarray and create confusion about the principle of the separation of powers, which is a cornerstone of our democracy'. 105

In an attempt to soften the decision to appeal, the Minister's press statement promised that the policy would be reviewed and that the Department of Health would host an 'inclusive' national consultation involving all stakeholders 'to share the lessons of the pilot sites and to chart plans for the future on the basis of broad consensus'. ¹⁰⁶ These promises were not kept. However, an instruction was sent to speed up an interim evaluation of the existing 18 pilot sites that was being conducted by the Health Systems Trust (HST) on behalf of the Department of Health. This was completed in late January 2002, but became yet another example of the clash between political agendas and the recommendations of scientists and researchers. On 31 January 2002 the evaluation was presented to a meeting of the Health MinMEC. The report provided a comprehensive assessment of each of the pilot sites and made a number of salient recommendations. In its Executive Summary it recommended that

[t]here are no good reasons for delaying a phased expansion of PMTCT services in all provinces. The pilot sites have already generated a lot of useful and important lessons that can now be put to use. The systemic weaknesses and infrastructural complaints identified by this evaluation are not reasons for delaying action, but are important for informing the planning and expansion of MTCT services. ¹⁰⁷

It also proposed that

[w]hile a phased and systematic expansion of comprehensive MTCT services is being planned, NVP can and should be provided immediately to all pregnant women who are already known to be HIV positive, with appropriate counseling and information. ¹⁰⁸

For several weeks, the HST report was kept under wraps as politicians pondered how not to comply with its unpalatable recommendations. Then, contrary to its recommendations, the Minister announced that it would not be possible to take a decision on expansion of the programme

¹⁰⁵ Ibid 24.

¹⁰⁶ Minister of Health, Press Release (18 December 2001) available at: http://www.doh.gov.za/mediaroom/index.html. This line of argument was developed further in an article by the Minister of Health in the Sunday Times (30 December 2001): 'Government, not courts must decide on HIV/AIDS and other social policy.' As is often the fashion with politicians, this article misrepresented the judgment by claiming that it was extremely prescriptive and that 'it amounts to a position that policy should be in the hands of the judges'. What the Minister failed to recognise here and in subsequent legal papers was that the decision to use Nevirapine as the drug of choice was made by her, not judge Botha, and that Botha's order had dictated only the parameters of the programme not its detail.

¹⁰⁷ Health Systems Trust 'Interim Findings on the national PMTCT Pilot Sites, Lessons and Recommendations' (February 2002) iv.

¹⁰⁸ Ibid v.

until May 2002, after it has been running for one year. ¹⁰⁹ At the time, tensions ran high in the Department and several persons inside the Department claimed that during the MinMEC meeting Director General Dr Ayanda Ntsaluba had left the room saying that he could no longer 'defend the indefensible'. ¹¹⁰ This was the second occasion on which politicians took decisions directly counter to those recommended by senior officials in the Department. However, whilst the MinMEC members were trying to work out ways in which to save face and defend their policy, two other processes were taking place. On the one hand TAC's lawyers were preparing a new application to the Pretoria High Court to seek an order to execute part of the Botha judgment, and on the other a political division around the issue was developing that saw the Premiers of Gauteng and KwaZulu Natal publicly announce and defend decisions to expand their PMTCT programmes.

VIII THE POLITICAL AND LEGAL UNRAVELING OF THE GOVERNMENT CASE

When President Mbeki opened Parliament in February 2002 he appeared to signal a shift in government policy by promising that 'continuing work will be done to monitor the efficacy of anti-retroviral interventions against mother-to-child transmission in the sites already operational and any new ones that may be decided upon'. 111 A few days later this shift seemed to be confirmed in a live television interview when Mbeki explicitly stated that provinces should be able to provide an MTCT programme according to their respective capacities and that 'provinces with the resources to extend the programme should not be delayed by provinces that did not have the resources'. 112 This new approach was cautiously welcomed by TAC and seems to have been read by a number of senior ANC politicians as condoning the roll out of programme to health facilities where capacity existed or could easily be created. Thus, on 18 February 2002, Mbahzima Shilowa, the Premier of Gauteng,

- 109 A press statement issued by the Ministry stated that: 'Provincial MECs for Health and respresentatives of SALGA will take the report presented back to their respective provinces, study it and consult with the aim of formulating a response that is appropriate and in line with the national protocols on managing MTCT. They will subsequently report back to MinMEC to consider the appropriate response.' Outcomes of the MinMEC Meeting of 31 January 1 February, available at http://www.doh.gov.za/mediaroom/index.html.
- 110 Throughout this case there was much evidence of a conflict of loyalties manifesting itself in the duties that should arise as a health professional and the duties to government or the ANC (which seems to have perceived itself as the target of this case). This was often evident among senior officials of the Department of Health who privately claimed to have sympathy with the TAC case, some even encouraged it, and yet allowed themselves to be made deponents to affidavits they cannot have believed in. The tragedy is that, despite the fact that the role of doctors in the killing of Steve Biko and others has led to introspection about dual loyalties in SA, during this case a misconstrued understanding of loyalty to the government/ANC seems to have held sway.
- 111 State of the Nation Address to the Joint Sitting of the Two Houses of Parliament (8 February 2002). See http://www.anc.org.za/ancdocs/history/mbeki.
- 112 Newshour SABC 3 (10 February 2002).

announced a bold roll-out of the programme. He promised that '[d]uring the next financial year, we will ensure that all public hospitals and our large community health centers provide Nevirapine'. He also named 9 further hospitals that would commence the programme 'within the next 100 days'. 113

However, once again falling foul of public opinion and her own Department, which had initially claimed the Gauteng roll-out was 'within the parameters set by the Health MinMEC', the Minister of Health publicly rebuked Shilowa. Earning herself the name of 'Dr No' from *The Star*, one of the biggest newspapers in the country, the Minister made a statement to the press disassociating herself from Gauteng's pronouncement and claiming that it was in breach of the resolution taken by MinMEC on 30 January 2002. In behind the scenes meetings over the following days the impression was conveyed that an understanding had been reached between the Minister and Shilowa. Although Shilowa gave the appearance of backing down, his programme continued. By October 2002 he was in a position to announce that Nevirapine was available at 70 per cent of all health facilities in the province.

During this period politics and law developed an interesting dialectic. The pressure of the ongoing legal action forced the government back into court, and the different stages of the appeal and application for an execution order spurred further advocacy and social mobilisation – which in turn placed new pressures on government. At its National Executive Committee in January 2002 and in discussion with its legal team, TAC had decided to embark on an offensive in response to the appeal and to return to the Pretoria High Court to seek an order of execution on the part of the judgment that instructed that Nevirapine be made available where capacity existed. The justification for this was that it could save up to ten lives a day during the period in which the legal process around the appeal took place – approximately six months. In the words of Sipho Mthati, the deponent in TAC's new affidavit: 'every day in which the implementation of paragraphs one and two of the order is delayed, results in unnecessary infection and death of ten children'. 116 Outside and inside the court TAC argued that this approach was validated by developments in the political arena, such as Mbeki's 'State of the Nation' address and the extension of the programme in Gauteng and KwaZulu

The legal test for deciding whether an order should be executed

¹¹³ Address by Premier Shilowa at the Opening of the Gauteng Provincial Legislature, available at http://www.gpg.gov.za/docs/sp/2002/sp0218.html.

¹¹⁴ Statement on the Meeting Between Minister Tshabalala-Msimang and Premier Shilowa (22 February 2002) available at http://www.doh.gov.za/mediaroom/index.

¹¹⁵ M Shilowa Speech at the Opening of Gauteng AIDS Summit (8 October 2002).

¹¹⁶ Sipho Mthati in the Founding Affidavit in the Application for Leave to Execute 4-17 para 15 (29 January 2002).

pending the final decision on appeal is whether it would cause 'irreparable harm' to either party to the proceedings. TAC argued that the harm to government of providing a medicine and encouraging doctors to do their job would be minimal, compared to the irreparable harm that would be suffered by women whose children were refused a life-saving intervention. 117 Again, the Ministry opposed the application, now claiming that it would cause irreparable harm to 'patients other than HIV-positive pregnant women' by diverting resources away from 'the services they so direly need' and that the orders could 'have the real potential of crippling an already overburdened public health care system'. 118

On 1 March 2002 new demonstrations took place at the Pretoria High Court hearing of the government's application for leave to appeal to the Constitutional Court and TAC's application for an execution order (which were heard together). Ten days later, on 11 March 2002, another judgement was handed down in favour of TAC. In this judgment Botha J drew attention to the fact that TAC's argument that up to ten lives a day could be saved by execution of Orders 1 and 2 'is not denied' by the government. Then, deliberating on the consequences of granting leave to appeal on his decision to order execution, he wrote:

If order 2 is implemented, and the appeal succeeds, the result will be that health facilities will have suffered some inconvenience here and there and that resources, especially human resources, will have been strained. In many cases that will be an inconvenience that ethically motivated health workers will gladly assume. At the same time there will be a gain in lives saved which cannot be considered a loss even if the Constitutional Court should find that parallel access to Nevirapine should not have been granted at all. If the order is suspended and the appeal were to fail, it is manifest that it will result in loss of lives that could have been saved. It would be odious to calculate the number of lives one could consider affordable in order to save the respondents the sort of inconvenience they foreshadow. I find myself unable to formulate a motivation for tolerating preventable deaths for the sake of sparing the respondents prejudice that can not amount to more than organisational inconvenience. 119

Inexplicably, the government decided to seek leave to appeal against this judgment directly to the Constitutional Court. In response, TAC's legal team quickly filed a counter application arguing that government's main purpose for further legal action was solely to 'stultify the execution order'. New legal issues arose as to whether interlocutory orders could be appealed. TAC argued 'no'; government argued 'yes'. The matter was heard on 22 March and judgment was handed down three days later.

¹¹⁷ Applicants' Heads of Argument on Application for Leave to Execute.

¹¹⁸ Ayanda Ntsaluba, Answering Affidavit in the Application for Leave to Execute para 13.5.

¹¹⁹ TAC v Minister of Health TPD Case 21182/2001 (8 March 2002) 12-13.

¹²⁰ Notice of Application for Leave to Appeal (15 March 2002) 176-86; Counter Application Answering Affidavit in the Application for a Certificate in Terms of Constitutional Court Rule 18 (18 March 2002) 187-98.

Once more Botha J cut to the core of the case. In the days immediately before the hearing, government had taken advantage of the decision by Boehringer Ingelheim to withdraw its application to the Food and Drug Administration (FDA) for the registration of Nevirapine for prevention of intra-partum HIV transmission. ¹²¹ Inside (and outside) of court government cast this as a safety issue, justifying their caution in making the medicine more widely available. However, Botha J saw it for what it was: a red-herring that was put back into the sea. In a few sentences he explained that if the registration of Nevirapine was withdrawn it would be for all uses of the drug, including at the government pilot sites. On the issue of whether by granting the execution order he had exercised his discretion properly, he had this to say:

In essence I had to balance the loss of lives against prejudice that could never amount to more than inconvenience. I find it unlikely that another court will conclude that the choice that I made was wrong. It was argued that the assumption of the loss of ten lives a day was speculative. It was no more speculative than the fears of chaos and disruption expressed by the deponents of the respondents. 122

During this time it seemed as if sensible legal advice to the government was the last thing driving its case. It was as if a nerve had been touched and the pain was driving an irrational response that took everything to the extreme, regardless of public perceptions, lives lost or the cost of ongoing legal action. Thus, on 26 March, one day after the Pretoria High Court had dismissed the attempt to appeal the execution order, the government launched a further and final application for leave to appeal—this time directly to the Constitutional Court. 123 The application was heard on 3 April 2002. In the court of public opinion, the announcement of this was lambasted by political cartoonists and newspaper leader writers. It was also a failure of legal strategy. This was because although the legal issues that the Constitutional Court had to decide were narrow, and different from those it would consider in the main appeal, these could

¹²¹ See below at text accompanying note 128.

¹²² Botha J, Certificate ito Rule 18(6) of the Constitutional Court Rules (25 March 2002) 10.

¹²³ TAC v Minister of Health (ibid) Notice of Application for Leave to Appeal (26 March 2002). TAC responded by filing a counter-application requesting that 'pending the appeal. . the applicants are ordered to give effect to paragraph 2 of the order of the High Court granted on 14 December 2001'. In the affidavit of Abdurrazack Achmat (para 13), TAC argued that government was abusing the legal process by its ongoing efforts to appeal: 'it is clear from the course of conduct which the Appellants have adopted, that they seek to prevent the Respondents exercising their statutory and common law right to seek execution of the order of 14 December. They do this by seeking leave to appeal against any order which is made with that effect. Because appeal proceedings in the ordinary course suspend the order against which the appeal is taken, they attempt thereby to stultify the execution order or any order to similar effect.' Government's Replying Affidavit was filed on 1 April, 24 hours before the hearing. Because it raised new matter, implying again that Nevirapine was unsafe, TAC filed a further Replying Affidavit on 2 April that attached the unambiguous statements of UNAIDS, the CDC and the NIH for the attention of the Court. A month later a further affidavit from Ntsaluba stated 'categorically that I did not deliberately conceal this information from the above Honourable Court' (para 6.2).

not be approached without consideration of the actual issues, including the rationality of the MTCT policy. The result was that the government itself created a situation that allowed the issues to be aired in the highest court in the land a month before the dates set for the full appeal.

During the hearing the Constitutional Court judges frequently appeared to be at a loss as to why government was so fiercely opposed to the execution order. In answer to a question from Chief Justice Chaskalson about how infants would suffer from being provided by a potentially life saving drug, the government's advocate, Moerane SC, referred to 'drug resistance'. When asked by Madala J whether government had documented any adverse events resulting from the use of Nevirapine in the past 11 months, Moerane answered 'no'. Yet, when O'Regan J later asked precisely what harm would be caused by the execution of the order, his answer was that there was 'potential for great, great harm'. The judges seemed frustrated by the answers and at one point, for example, Sachs J appealed that 'in the interests of the nation government come up with an approach that would meet the issues raised by TAC' before the hearing of the appeal. He asked whether in government's approach, 'the good was not being made a victim of the best'. 124 Not surprisingly, on 4 April the Constitutional Court refused government leave to appeal against the order of execution. 125 The next day, the headline of The Star was 'YES, you will, Dr No'. 126

IX WHEN POLITICIANS GO TOO FAR

The role of the Minister of Health throughout this period had arguably brought both the government and the country into disrepute. Repeatedly her public utterances concerning the case seemed in direct conflict with the rights entrenched in South Africa's Constitution and the corresponding duties imposed on the government. She seemed prepared to misuse medical information to confuse public opinion and the courts. For example, in March 2002, Boehringer Ingelheim, the manufacturer of Nevirapine, withdrew its application for registration of the drug for preventing intra-partum transmission with the Food and Drug Authority (FDA) in the USA. However, it was clearly stated that this was because the clinical trials in Uganda had not been conducted to meet the standard expected to qualify for FDA approval, and that a preliminary reevaluation of the trials had noted a number of technical irregularities.

¹²⁴ Personal notes taken during the hearing (3 April 2002).

¹²⁵ The Constitutional Court reserved judgment and handed down its decision on this matter together with its main judgment on 5 July 2002. When Chief Justice Chaskalson announced that leave to appeal against the order of execution was refused, he issued a cautionary note that the decision should not be read as in any way determining the issues that would heard in the main Appeal. Despite this, TAC's lawyers, and every other observer, could see that the Court were far from thinking that this was a case where judges had 'gone too far'.

¹²⁶ The Star (5 April 2002).

There was no questioning of the safety of the drug or the validity of the trial results. Within hours of hearing of the withdrawal of the FDA application from the MCC, she distorted this information in an address to a public rally hosted by the National Association of People Living with HIV/AIDS (NAPWA). She claimed that new information suggested that the drug may be unsafe and that government's caution with its use was justified. 127 This also found its way into the State's legal papers in a new affidavit filed hastily in the name of the Director General of the Health Department, suggesting that the 'safety' of the medicine was now at issue and that it was 'not in the public interest that an order as prescriptive as the execution order be enforced. It is not inconceivable that ... the registration of Nevirapine may be withdrawn altogether'. ¹²⁸ Documents from the WHO and UNAIDS stating the contrary were available to the Minister, but were not offered to the Court. This deception was noticed by Kriegler J, who went as far as to suggest that the Health Department was deliberately trying to mislead the Court. 129

The Minister of Health also displayed a questionable attitude to democracy and principles of justice. The most startling example came in a television interview given on SABC News on 24 March 2002. When asked whether she would be prepared to 'follow what the court says, given these new concerns around the drug', she replied:

My own view is that the judiciary cannot prescribe from the bench – and that we have a regulatory authority in this country that is interacting with the regulatory authority FDA of the USA and I think we must allow them to assist us in reaching conclusions.

Interviewer: Mmm, so you think it's inappropriate that this is in court, but nevertheless it's there. Will you stand by whatever the Court decides?

Minister: No, I think the court and the judiciary must also listen to the regulatory authority, both of this country and the regulatory authority of the US.

Interviewer: So you're saying no? Minister: I say no. I am saying no. 130

In the fierce controversy that surrounded this statement, Penuell Maduna, the Minister of Justice, was called in to rebut the comment

¹²⁷ The decision by Boehringer Ingelheim to withdraw it application was communicated to the MCC, who then communicated it to the Minister in a letter of 20 March 2002. The letter from the MCC stated only that '[q]uestions have been raised about the reporting and documentation of the HIVNET 012 study'. It said nothing about safety. An audit of HIVNET 012 had revealed deficiencies in documentation that would not have met the stringent requirements of the FDA. At the time TAC gave wide circulation to a number of important press statements that should have clarified the issue. See WHO/UNAIDS Joint Press Statement 'WHO and UNAIDS Continue to Support Use of Nevirapine for Prevention of MTCT' (22 March 2002); Statement by National Institute of Allergy and Infectious Disease 'Review of HIVNET 012' (22 March 2002); Centre for Diseases Control (CDC) Media Q&A 'Response to the NIAID Statement on HIVNET 012' (21 March 2002); Boehringer Ingelheim Press Release 'Comments on the HIVNET 012 Trial' (22 March 2002).

¹²⁸ Answering Affidavit to the Application to Allow Execution of Judgment Pending Appeal (21 March 2002) para 5.2.

¹²⁹ See notes 138-39 below and accompanying text.

^{130 &#}x27;More Damage Control after Manto Says No' The Star (25 March 2002).

and give assurances that the Government would respect the Constitution. He was able to calm the storm that had broken around the Minister of Health who had subsequently issued a statement stating that 'we have no intention of circumventing the courts . . . We stand ready to abide by the final decision of the courts on the execution order'. The Minister of Justice was praised for his quick and unambiguous intervention. His response prevented perceptions taking root that the case might bring the country to the brink of a constitutional crisis. It reconfirmed government's commitment to a constitutional order and human rights, even in situations where its policy was found wanting. As an aside, however, it is worth noting that Maduna's opinion was not the universal view of people in the ruling party. A statement issued by the ANC Youth League called upon the government 'not to comply with this order':

We would like to point out that judges are not elected to govern the country, they are not qualified to make political decisions about government not to mention prescribing policies to the people's government.

We wonder why does the court reduce itself to become an agent to drum profit for multinational pharmaceutical companies whose only interest is to make money out of sick people. [132]

X CONSTITUTIONAL ADVOCACY ON THE STREETS AND IN COURT

Sometimes, in the political circus of irrationality, the real life traumas that fed the case seemed to get lost. The people whose lives were being irreparably damaged seemed to have the quietest voices and on 14 April 2002 one of those voices was stilled. Sarah Hlalele had first encountered TAC in July 2001. She was a volunteer counsellor for Bambanani, a support group in the Vaal area. When she had heard about the pending legal case, she volunteered to depose an affidavit telling her own story. 133 At the time she was very ill with AIDS. Her son had been born prematurely, failed to receive Nevirapine and remained in hospital for the first month of his life. The TAC case, together with access to medicines and care, literally brought Sarah back to life. She spoke at the first TAC press conference the day the papers were served, at that time unwilling to be identified. Several months later, with her health and dignity restored, Sarah's story became symbolic of the case as a whole. She attended all the court hearings, often with her son, K. Tragically however she became seriously ill as a result of severe side-effects of the anti-retroviral medicines she was taking, and died in Johannesburg on 14 April. 134

¹³¹ Ministry of Health 'Media Statement' (27 March 2002).

^{132 &#}x27;ANC Youth League Statement on the Order to Provide Nevirapine' (26 March 2002). See http://www.anc.org.za/yiuth/docs/pr/2002/pr0326.html.

¹³³ SB Hlalele Founding Affidavit (note 12 above) Annexure CC 476-81.

^{134 &#}x27;Death of an Activist' Mail and Guardian (19 April 2002).

Three days after Sarah's death the Cabinet took South Africa and the world by surprise by releasing a Statement on HIV/AIDS that, amongst other things, promised 'a universal roll out Plan to be completed as soon as possible, in preparation for the post December 2002 period'. In addition, for the first time the Cabinet publicly acknowledged that anti-retroviral drug treatments 'could help improve the conditions of people living with AIDS if administered at certain stages in the progression of the condition, in accordance with international standards'. 135

It was with people like Sarah in mind that TAC mobilised for the last leg of the case. A decision was taken to organise 'Stand up for Your Rights' marches on the first day of the Constitutional Court hearing and demonstrations were prepared in Johannesburg, Cape Town and Durban. In Johannesburg over 5000 people marched to the court, affirming the Constitution, the importance of social mobilisation to claim rights and the constitutionally assigned role of the judiciary in determining disputes over government policy.

On 2 May 2002 the Constitutional Court itself was filled with activists, doctors, nurses and the media. Proceedings began with a last ditch attempt by the AIDS denialist faction to be admitted as amicus curiae, so as to question the validity of the HIVNET 012 results. This application was dismissed for being out of time and not in the interests of justice. 136 Thereafter, for two days, the judges directed their questions at the two parties, only occasionally revealing their frustrations with the misconduct that appeared to characterise much of the government's case. For example, during his summing up the government's senior counsel, adv Moerane, stated that he was 'disturbed about perceptions that some of the deponents might have been deliberately lying' cautioning that it was inevitable 'that some people might err and make mistakes'. 137 This probably referred to an earlier exchange between Moerane and Kriegler J, during the hearing of the government's attempt to appeal the execution order, over why government had failed to disclose press statements from the WHO and NIH that clarified issues around the HIVNET 012 trial and why the application to the FDA had been withdrawn. At that time Kriegler J had commented that he 'found the use of the MCC letter [to the Minister of Health] a strange way to go about with the truth from a very senior government official [referring to the affidavit of Dr Ntsaluba]'. In response Kriegler J interjected 'said it Mr Moerane ...

¹³⁵ Cabinet Statement on HIV/AIDS (17 April 2002) available at http://www.gov.za/speeches/cabinetaids02.htm.

¹³⁶ Affidavit of Samuel Mhhlongo in the Application to be heard as an amicus curiae. In this affidavit Mhlongo, revealed that he had recently proposed to the Minister of Health 'that she establish the MCC's intentions in the light of the American developments, and I provided her with a suggested draft letter of enquiry, but time didn't allow the execution of this proposal' (para 40).

¹³⁷ Personal notes taken during the Constitutional Court hearings (3 April; 3-4 May 2002).

I gave you an opportunity to rebut it \dots I will deal with it in a separate judgment if necessary'. 138

Three months later, on 5 July 2002, the judgments of the Court in the TAC case and related matters were handed down. 139 Unanimously, the court decided that the government's policy had not met its constitutional obligations to provide people with access to health care services in a manner that is reasonable and takes account of pressing social needs. 140 Government's arguments on the efficacy of Nevirapine were said to be contradictory. 141 On safety there was said to be no evidence justifying government's claims; on resistance the court declared that when 'the prospects of the child surviving if infected are so slim and the nature of the suffering so grave ... the risk of some resistance manifesting itself at some time in the future is well worth running'. 142 In addition the Court confirmed TAC's view that the policy discriminated against poor people noting that 'there is a difference in the positions of those who can afford to pay for services and those who cannot. State policy must take account of those differences'. 143 Drawing on its own prior judgments and foreign jurisprudence the judgment confirmed the rights of the courts to issue instructions to government to amend policies, where policies were found to be unconstitutional. 144 The judgment also insisted on the Court's right to 'ensure that effective relief is granted' and exercise 'supervisory jurisdiction'. 145 Without contradicting Botha, it stopped short of setting timeframes for government on the basis that it accepted the bona fides of commitments made by government 'whose policy is now no longer as

¹³⁸ Ibid.

¹³⁹ In addition to the judgment in the Appeal, the Court handed down its decisions on: the application for leave to appeal to the Constitutional Court against the execution order (Minister of Health v TAC 2002 (10) BCLR 1075 (CC); the late application to be admitted as amicus curiae by AIDS denialist Prof Mhlongo (In Re Certain Amicus Curiae relating to Minister of Health v TAC 2002 (10) BCLR 1023 (CC); and the dispute between the Premier and MEC for Health in KwaZulu Natal (MEC for Health, KwaZulu Natal v Premier of KwaZulu Natal 2002 (10) BCLR 1028 (CC).

¹⁴⁰ The Court stated: 'The question in the present case, therefore, is not whether socio-economic rights are justiciable. Clearly they are. The question is whether the applicants have shown that the measures adopted by the government to provide access to health care services for HIV-positive mothers and their newborn babies fall short of its obligations under the Constitution'. Note 1 above, para 25. It went on to find that '[o]nce a drug that has the potential to reduce mother-to-child transmission is available, it is desirable that it be made available without delay to those who urgently need it'. Ibid para 130.

¹⁴¹ Note 1 above para 58.

¹⁴² Ibid para 59.

¹⁴³ Ibid para 70.

¹⁴⁴ Ibid para 96-114.

¹⁴⁵ Ibid para 106.

rigid as it was when the proceedings commenced'. ¹⁴⁶ Instead, it ordered government 'without delay' to:

- (a) Remove the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites.
- (b) Permit and facilitate the use of nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV and to make it available for this purpose at hospitals and clinics when in the judgment of the attending medical practitioner acting in consultation with the medical superintendent of the facility concerned this is medically indicated, which shall if necessary include that the mother concerned has been appropriately tested and counselled.
- (c) Make provision if necessary for counsellors based at public hospitals and clinics other than the research and training sites to be trained for the counselling necessary for the use of nevirapine to reduce the risk of mother-to-child transmission of HIV.
- (d) Take reasonable measures to extend the testing and counselling facilities at hospitals and clinics throughout the public health sector to facilitate and expedite the use of nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV 147

Ironically, in light of the April Cabinet resolution, this was arguably a more intrusive order than Botha's had been. Timeframes and an instruction to return to court were replaced by instructions requiring immediate action. Despite this, some observers have argued that given the life and death nature of the human rights issues and history of government's conduct in the case, a supervisory order was both justified and necessary. They argue that such an order would have made it easier to monitor and oversee compliance. ¹⁴⁸

XI CONCLUSION:

The Constitutional Court judgment leaves no room for doubt that the case involved a notorious breach by government of its human rights obligations and legal duties. The consequences of the policy for doctors who felt an ethical duty to have access to Nevirapine in order to reduce the risk to infants were such that it is not far-fetched to suggest that there are parallels between the government's PMTCT policy and the other great touchstone that is evoked in discussions about medical ethics: the Tuskegee experiment. In 1972 the *New York Times* exposed the conduct of doctors of the US Public Health Service who acted unethically by deceiving 399 black men and by withholding treatment for syphilis for nearly forty years. It described Tuskegee as 'the longest non therapeutic experiment on human beings in history'. ¹⁴⁹ As a result between 28 and 100 men died and hundreds of people and their families were harmed. ¹⁵⁰

¹⁴⁶ Ibid para 118. See also para 132 where the court says: 'Government policy is now evolving. Additional sites where nevirapine is provided with a 'full package' to combat mother-to-child-transmission of HIV are being added. In the Western Cape, Gauteng and KwaZulu-Natal, programmes have been adopted to extend the supply of Nevirapine for such purpose throughout the province. What now remains is for the other provinces to follow suit. The order that we make will facilitate this.'

¹⁴⁷ Ibid para 135.

¹⁴⁸ Personal correspondence with Dr S Liebenberg (19 November 2002).

¹⁴⁹ New York Times (26 July 1972).

¹⁵⁰ JH Jones Bad Blood: The Tuskegee Syphilis Experiment (1993).

By contrast, in the South African case, the decision to deny pregnant women medicine was not taken by researchers but by elected political officials. The effect however was the same. Doctors all over South Africa were instructed to act against their consciences and ethics by withholding medicine. This policy was devised by politicians who seemed to ignore information and act directly contrary to advice given to them by senior officials in the Department of Health, organised professional medical bodies such as SAPA and multilateral institutions like the WHO. For example, the slide below, which formed part of a presentation on an MTCT programme made by a Deputy Director in the Health Department, is just one example of the evidence that politicians were advised of the benefits of implementing a large-scale intervention to prevent MTCT. ¹⁵¹

The Rough Figures NATIONAL TRANSMISSION *WITHOUT* ANY INTERVENTIONS: 900.000 Birth p/a x 24.5% HIV prevalence x 35% MTCT = 77.175 infants infected pa

PROJECTED NATIONAL TRANSMISSION *WITH* INTERVENTION: 900.000 p/a x 24.5% HIV prevalence x 13% MTCT x 90% up-take = 28.665 infants infected p/a (at 14–16w based on SAINT)

This slide suggests that, in the history of medical ethics, the South African experiment ranks far worse than Tuskegee. Despite knowledge that up to 250 000 children per annum were at risk of HIV infection, and that 'approximately 100,000 HIV-positive babies are born each year, most of whom die by the age of five' 152 the government took a decision to limit access to a potentially life-saving medicine to ten per cent of pregnant women and to consciously refuse the medicine to women who requested it outside the 'pilot sites'. 153

- 151 C Serenata, Deputy Director HIV/AIDS and STIs, Department of Health 'Preventing Mother to Child Transmission of HIV Programme' (overheads from an internal presentation) included in the TAC Founding Affidavit (note 12 above) 361-65.
- 152 PC Onyebujoh, a member of the MCC, deposed an affidavit on behalf of the government that sought to create confusion about the nature of the registration the MCC had granted for the use of Nevirapine. His CV made reference to an article he had co-authored in the SA Medical Journal, in which he had written that 'Anti-retrovirals for mother-to-child transmission should form part of an integrated approach to maternal and infant health care'. PC Onyebuyoh TITLE? (2000) SAMJ PAGES?? The TAC referred to this article, revealing Onyebujoh's contrasting views, in its Replying Affidavit (note 23 above) 1992-94) The reasons for Onyebujoh's about-turn are unclear.
- 153 M Tshabalala-Msimang 'Press Briefing' (13 August 2002) included in the TAC Founding Affidavit (note 12 above) 338-42.

Tuskegee involved the exploitation of a vulnerable group, so did MTCT. Tuskegee denied a group of people access to medically proven medicines, so did MTCT. Tuskegee caused irreparable harm to the lives of those affected, so did MTCT. The difference is a qualitative one of context and scale. Tuskegee implicated the actions of a small group of government researchers, abusing their position to act unethically against several hundred vulnerable subjects. MTCT was the policy of South Africa's Cabinet. Unethical behaviour was defended at great cost in lives and resources through a legal battle that could have been avoided. The social costs are too great to determine, because they are not being measured. Unlike Thalidomide or Tuskegee, there is no list of MTCT parents and babies, because most of the victims of this policy and children to young to have a voice or parents too poor or legally illiterate to pursue further action.

The judgment of the Constitutional Court has not ended the disputes over the provision of MTCT services. In the words of Budlender, the judgment 'was simply the conclusion of a battle that TAC had already won outside the courts, but with the skilful use of the courts as part of a broader struggle'. Further, the case demonstrated that 'social and economic rights are only as strong as the willingness of civil society to enforce them'. 154

Afterwards pressure continued to be necessary to get provinces to comply with the Court's order. TAC held meetings with MECs in the three least compliant provinces; with the Director General of the Health department; and with the Deputy President of South Africa. In September 2002 a decision to launch rolling legal action through contempt of court proceedings against individual provinces was taken by the TAC NEC, and communicated to the Director General. This led to the first serious attempt to provide TAC with the information that the Constitutional Court had said government had a duty to make available. It was inadequate, but it reflected a creeping compliance that benefited parents and children. For example, on 16 October 2002, an e-mail was received from a doctor Limpopo Province saying the Provincial Health Department had 'at long last' given 'permission for the implementation of the PMTCT program. I think this was due to pressure from TAC/ courts. The initiative came from their side this time and they seem to be in quite a hurry to get the program up and running'. 155

The MTCT case was not closed and indeed in December 2002 contempt of court proceedings were filed against the National Minister of

Health and the MEC for Health in Mpumalanga. ¹⁵⁶ But the Constitutional Court's decision meant that it was possible for TAC to switch to other campaigns, buoyed particularly by the recognition of the Constitutional Court that:

The magnitude of the HIV/AIDS challenge facing the country calls for a concerted, coordinated and co-operative national effort in which government in each of its three spheres and the panoply of resources and skills of civil society are marshaled, inspired and led. This can be achieved only if there is proper communication, especially by government. In order for it to be implemented optimally, a public health programme must be made known effectively to all concerned, down to the district nurse and patients. Indeed, for a public programme such as this to meet the constitutional requirement of reasonableness, its contents must be made known appropriately. 157

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¹⁵⁶ TAC v MEC for Health Mpumalanga Case no 35272/02. See also M Heywood 'Contempt or Compliance? The TAC Case after the Constitutional Court Judgment' (2003) 4(1) ESR Review 7-10.

¹⁵⁷ Note 1 above, para 123.

^{*}The author is the National Secretary of the TAC and was centrally involved in TAC's non-legal and legal campaigns to try to persuade the government to develop and implement a nationwide programme to prevent MTCT. Although this paper occasionally provides information that was only gleaned because of the author's close proximity to the case, it attempts at all times to base its conclusions on objective information and on medical facts that have been accepted in pereviewed medical journals or social facts that were endorsed in this case by the Constitutional Court. It is, of course, difficult to be dispassionate about a conflict over policy that has blighted many lives. The author would like to acknowledge the following people who commented and advised on drafts of this paper: Gilbert Marcus, Fatima Hassan, Marlise Richter, Edwin Cameron, Sandy Liebenberg. This paper is dedicated to Sarah Hlalele.