Treatment Action Campaign v. Minister of Health

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FACTUAL BACKGROUND

A History of Women's Human Rights

Women's rights movements have existed for at least two hundred years. Principles of non-discrimination based on sex have existed in international law since the United Nations created the UN Commission on the Status of Women and the Universal Declaration of Human Rights. While the Universal Declaration of Human Rights made it clear that the rights contained within also applied to women, any rights that would apply exclusively to women were not considered human rights. Practices that many recognize today as human rights violations, such as wartime rape and female genital mutilation, were considered private domestic problems.

The concept of women's rights as human rights is much more recent. In the 1970's and 1980's many women's groups pushed for greater recognition of women's rights. There were world conferences on women held in 1975, 1980, and 1985. In 1981 the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) was created by the United Nations and has slowly been ratified by all industrialized counties (except the United States) and most unindustrialized countries. At the 1993 World Conference on Human Rights in Vienna there was clear and explicit recognition of women's rights as human rights. The same year the General Assembly of the UN passed the Declaration on the Elimination of Violence against Women.

At the Fourth World Conference on Women held in Beijing in 1995 the focus was almost entirely on women's rights as human rights. The conference produced the Beijing Declaration and the Platform for Action. By this time women's human rights were securely in the mainstream.

As opposed to the political rights focus of the past, much of the focus on women's human rights has been on sex and reproduction since it is in this area that many of the most serious abuses take place. CEDAW explicitly recognizes sexual and reproductive rights as human rights, as do most recent women's human rights documents. Today, most countries recognize at least principles of non-discrimination through international or domestic law.

Many countries recognize women's rights in general as human rights. This legal recognition, however, has done little for the poorest and most vulnerable women in the world. Most of the world's poor and illiterate are women. Women are still subjected to female genital mutilation in many countries. Women are still subjected to violence in their homes and on the street. It is important to remember that while declarations, conferences and international covenants can be useful tools in the fight for women's human rights, their existence is only the beginning.

Additional Reading:

Cook, Rebecca, Reproductive health and human rights: integrating medicine, ethics, and law**,** Oxford: Clarendon Press (2003).

Lockwood, Carol Elizabeth (ed), et al, The International Human Rights of Women : Instruments of Change, Washington, DC : American Bar Association (1998).

HIV and Mother-to-Child Transmission (MTCT)

HIV/AIDS is a national crisis in South Africa. Women in South Africa are particularly vulnerable to HIV infection due to the structure of society, violence against women, and their physiology. In 2001 the HIV prevalence rate in pregnant women was about 24.5%.[1] The World Health Organization (WHO) reports that 1,600 infants are infected through birth every day. In South Africa alone approximately 70,000 children will be infected with HIV due to mother-to-

child transmission (MTCT) of HIV. HIV infection has increased the childhood mortality rate in Africa by 100%, with most infected children dying before the age of five. About 15-30% of infected mothers will pass along the virus to their child without treatment through pregnancy and labour (with most becoming infected through labour and not in utero), and a further 10-20% will infect their children through breastfeeding. Treatment with either AZT or nevirapine can lower the chances of MTCT.[2]

Governments and domestic and international NGO's have attempted to limit MTCT in a number of ways. These include the provision of antiretroviral drugs to lower the risk of transmission, the provision of formula to mothers to reduce breast feeding, taking steps to reduce the infection of women, and information and provision of safe contraceptive options and safe and legal abortions.

Additional Reading:

World Health Organization, *Sexual and Reproductive Health of Women Living with HIV/AIDS: Guidelines on Care, Treatment and Support for Women Living with HIV/AIDS and their Children in Resource-Constrained Settings* (2006). Available Online: http://www.who.int/hiv/pub/guidelines/sexualreproductivehealth.pdf (July 10, 2006)

PBS, The Age of AIDS [video recoding] , FRONTLINE (May 30, 2006). Available Online: http://www.pbs.org/wgbh/pages/frontline/aids/ (July 3, 2006).

South Africa's Policy on Preventing MTCT

During the apartheid when AIDS was first appearing in South Africa and around the world the government paid it almost no attention. After the apartheid ended and Nelson Mandela was

elected President little changed. The state was in turmoil and faced a number of challenges, so little attention was paid to AIDS. During Mandela's presidency HIV infection rates doubled every year.[3] In 1999 Thabo Mbeki ran for president with the campaign that he would deal with the AIDS crisis. He even wore an AIDS ribbon on his lapel during the campaign. Once elected, however, Mbeki took a controversial stand on AIDS by questioning the link between HIV and AIDS. He also repeatedly questioned the safety of anti-retroviral drugs.

Following studies which showed the efficacy and safety of a drug called nevirapine for the reduction on MTCT of HIV and an offer by Boehringer Ingelheim to supply nevirapine free to the South African government for five years, the South African government produced the Protocol for Providing a Comprehensive Package of Care for the Prevention of Mother to Child Transmission of HIV in South Africa. This Protocol called for the establishment of two pilot sites in each province that would offer nevirapine to HIV infected pregnant women along with counselling and breast milk alternatives.

The pilot sites were to be monitored and studied for two years before the government would decide whether to make a similar comprehensive health care package, including nevirapine, more widely available. Doctors in South Africa's private health care system were already permitted to provide nevirapine to their patients as they saw fit. The reason the government gave for limiting the availability of nevirapine to these pilot sites was that they needed "to gain better understanding of the operational challenges of introducing the intervention on a wider scale".[4] Following this the Medicines Control Council (MCC) formally registered nevirapine for the prevention of MTCT of HIV.

Unorthodox Views of the Cause of AIDS

There are a small number of scientists who claim that HIV does not cause AIDS. They claim that HIV is a harmless virus and that AIDS is caused by poverty, drug use and the drugs used to

fight AIDS such as AZT. The scientific community overwhelmingly dismisses these claims and there is a large and well developed pool of scientific data showing HIV causes AIDS.

The President of South Africa, Thabo Mbeki, has repeatedly shown sympathy for the views of these dissidents. Soon after he was elected he made a speech to South Africa's parliament in which he stated, "You see, when you ask the question, 'Does HIV cause AIDS?' the question is, 'Does a virus cause a syndrome?' How does a virus cause a syndrome? It can't."[5]

He again displayed his scepticism during his opening speech at the Durban 2000 AIDS conference where he stated that you cannot "blame everything on a single virus."[6] In a letter to world leaders sent in 2000 Mbeki likened the treatment of HIV denialists to "heretics…burnt at the stake" and radicals under the apartheid. He spoke of freedom of speech and ideas. Though he made a compelling argument for the right of these dissidents to speak he did not supply any reason for paying so much heed to them when the overwhelming scientific evidence contradicts their conclusions.

Additional Reading:

Duesburg, Peter and Rasnik, David *The AIDS Dilemma: Drug Diseases Blamed on a passenger virus,* GENETICA 104: 85-132 (1998). Available online: http://www.duesberg.com/images/genetica.pdf (June 29, 2006)

Government of South Africa, *President AIDS Panel Advisory Report*, (2001). Available online: http://www.info.gov.za/otherdocs/2001/aidspanelpdf.pdf (June 29, 2006)

Heywood, Mark, *Price of Denial*, DEVELOPMENT UPDATE 5(3) (2004). Available online: http://www.tac.org.za (July 23, 2006).

LITIGATION: USING THE COURT SYSTEM TO GAIN ACCESS TO DRUGS TO PREVENT MTCT OF HIV

Following a number of failed attempts to convince the Minister of Health to broaden the prevention of MTCT program, the Treatment Action Campaign (TAC) and two other plaintiffs filed a notice of motion with the Pretoria High Court alleging that the National Minister of Health as well as the Ministers of Health for all the provinces were in breach of their Constitutional and International obligations in failing to provide nevirapine to women outside the limited pilot sites.

Only one province, Western Cape, cooperated early on by sending TAC's lawyers details of the intensive programme Western Cape had in place to reduce mother-to-child transmission of HIV and submitting an affidavit to the court to the same effect. Therefore, TAC decided not to seek an order against the Western Cape but did site it as a defendant in the High Court case because "all provinces in South Africa – even those that were doing the right thing – would benefit from a rational national policy."[7]

On December 14, 2001 the High Court ruled in favour of TAC and ordered the Minister of Health to make nevirapine available in all public hospitals and clinics where testing and counselling facilities existed. The High Court also ordered the Minister of Health to come up with a comprehensive programme to prevent or reduce MTCT and to submit reports to the court outlining that programme.

The Minister of Health requested leave to appeal this decision to the Constitutional Court of South Africa and TAC requested an immediate execution order to force the Minister of Health to make nevirapine available before the case reached the appeal court. The High Court granted the Minister of Health leave to appeal and granted TAC the execution order. The Minister of Health

appealed the execution order at the Constitutional Court, but the Constitutional Court upheld the High Court's decision.

On July 5, 2002 the Constitutional Court found that the Minister of Health did have a constitutional duty to give pregnant, HIV positive women access to nevirapine.

PLAINTIFFS' / RESPONDENTS' ARGUMENTS

The plaintiffs argued that a short course of nevirapine is a safe and effective way to reduce mother-to-child transmission (MTCT) of HIV. They based this argument on the numerous studies done on nevirapine, on the recommendation of the WHO, and on the findings of the MCC.

They pointed out that the safety of nevirapine and its tendency to create resistant strains of HIV have only been questioned in relation to long course treatments, and that there is no evidence of similar problems with a single dose.

TAC agreed with the governmental policy of only providing nevirapine to women once they have been properly counselled and tested for HIV and that a comprehensive program that includes the provision of breast milk substitutes is ideal. However, the plaintiffs argued that there are many hospitals capable of providing counselling and testing that are not being utilized and while a basic programme consisting of only testing, counselling and the provision of nevirapine is not ideal, it is not irresponsible either.

The plaintiffs contended that the policy that was in place to reduce MTCT of HIV was in breach of the Constitution in a number of ways. First and foremost it breached the right to health guaranteed by section 27 of the South African Bill of Rights. Section 27 contains two main parts. Section 27(1)(a) says that everyone has the right to heath care including reproductive care.

Section 27(2) says that the state must take reasonable measures to achieve the progressive realization of these rights.

Two of the interveners in the Constitutional Court case (the Institute for Democracy in South Africa (IDASA) and the Community Law Centre (CLC)) characterized section 27 as containing two separate rights which the government was in breach of. They argued that s.27(1)(a) contains a right to a minimum core of health care services that are necessary for the life and dignity of a person and are not limited by s.27(2), and that section 27(2) imposes a duty on the government to create a comprehensive program for the progressive realization of other universal though less essential health care services. This minimum core of services must include testing, counselling, and the administration of nevirapine if necessary to pregnant, HIV positive women because both the life of the child and the ability of the mother to make informed medical decisions are at risk if it is not.

The interveners further argued that the government was in breach of s.27(2) because it has not laid out a comprehensive plan to progressively realize the health care rights of women and children in relation to MTCT of HIV. The Protocol for Providing a Comprehensive Package of Care for the Prevention of Mother to Child Transmission of HIV in South Africa only called for the introduction of pilot sites for two years. The government made no promises after this two year period and instead declared they would consider the issue again when the trial period was over.

The CLC and the IDASA also maintained that the primary burden of supplying health care services to children falls on the state due to s.28 (1)(c) of the Bill of Rights which guarantees children the right to basic health care services. If the parents are unable to supply these basic health care services for the child it is the state's constitutional duty to protect the health of the child. This duty must create a minimum core obligation on the state even if the state has no such obligation under s.27 because s.28 does not contain anything that can be read as a limiting clause.

Aside from the right to health of women and children, TAC pointed to the s.11 right to life, the s.10 right to dignity of the mother and of the child, the s.9 right to equality (because the policy of the government discriminated against poor women and thus black women by allowing nevirapine to be available in the private health care system and not allowing it to be widely available in the public health care system), and finally the s.12(2)(a) right to psychological integrity including the right to make decisions regarding reproduction.

Aside from the rights contained in the South African Bill of Rights, TAC asserted that by preventing doctors from providing life saving medication to their patients the government was in breach of s.195 of the Constitution which states that a high standard of professional ethics must be promoted and maintained. Far from promoting professional ethics, the government was forcing doctors to act unethically, or as was often the case, to buy nevirapine themselves and supply it to their patients.

TAC also pointed to the Patient's Rights Charter which was issued by the Ministry of Health which states that all patients have the right to counselling and information on all their options related to their pregnancy and childbirth. Many hospitals did not provide counselling on MTCT of HIV even though existing counsellors would only need a few extra hours of training on the subject. TAC argued that the Patient's Rights Charter was legally binding and thus the government must provide these counselling services.

Along the same lines, TAC stated that the numerous promises and policy statements issued by the various branches of the government created a legitimate expectation that the government would take reasonable steps to prevent MTCT of HIV and that the government was legally obligated to fulfill these legitimate expectations.

Along with domestic legal obligations the plaintiffs pointed to a number of international agreements that the government of South Africa had signed and ratified. These include:

- Article 1 of the Universal Declaration of Human Rights (All human beings are born free and equal in dignity and rights),
- Article 6 of the International Covenant on Civil and Political Rights (Right to Life),

- Article 12 of the International Covenant on Economic, Social, and Cultural Rights (Right to Health),
- Article 12 of the Convention on the Elimination of Discrimination against Women (Discrimination against Women in Health Care),
- Article 24 of the Convention on the Rights of the Child (Child's Right to Health),
- Articles 2 and 5 of the Convention on the Elimination of All Forms of Racial Discrimination (Racial Discrimination, Equal Access to Health), and
- Article 16 of the African Charter of Human and Peoples' Rights (Right to Health).

The plaintiffs asked the court for two things. First, they asked for an order compelling the government to supply nevirapine to all public hospitals where testing and counselling facilities exist and to allow doctors to proscribe nevirapine on a case by case basis. Second, they asked for an order requiring the government to commit to a detailed action plan for the further prevention of MTCT of HIV.

DEFENDANTS' / APPELLANTS' ARGUMENTS

The Ministers of Health argued that this issue is not justiciable due to the principle of the separation of powers. The legislature alone has the power to make policy decisions and if the court declared the government's action plan unconstitutional and forced it to implement a different plan the unelected judges would be making policy, which is not their role.

Even if this matter is justiciable, the Ministers of Health claimed that the plan proposed by TAC would be ineffective, irresponsible, and too costly. They alleged that testing and counselling facilities were seriously lacking and that providing hospitals outside the pilot sites with these facilities would be too expensive. Further, if doctors were permitted to medicate patients at will health care budgets would be seriously strained.

They also argued that a comprehensive plan which included the collection of follow up data and the provision of breast milk substitutes would be necessary since, among other reasons, the positive effects of nevirapine can be reduced through breast feeding. Even though nevirapine could be provided at little or no cost, they maintained that the true cost of the program is in counselling, testing, formula, and other hidden administrative costs and because of this a comprehensive program would be far too expensive to roll out all at once.

Even if the plan was affordable, the Ministers said that the provision of nevirapine would be irresponsible since the registration of nevirapine to prevent MTCT was based only on one scientific study (HIVNET 012) and that it was of questionable validity. They also pointed out that the registration by the MCC came with the condition that the manufacturer of the drug continues to supply it with data on the safety of the drug and that there are studies showing that nevirapine can cause drug resistant strains of HIV. They claimed that until more is known about the safety of the drug it should not be given to the general public.

The Ministers of Health portrayed the program they had for the prevention of MTCT of HIV as comprehensive and claimed that it fulfilled their Constitutional duties under sections 27 and 28 of the Bill of Rights. S.27(1) and s.27(2) must be read together, according to the Ministers, and so there is not a free standing right to a minimum core of health care services. Even though s.28 does not have a limiting clause within it, as s.27 does, it also does not guarantee children an unlimited right to health. Instead, they argued that s.28 must be read in relation to s.27 and children's right to health must be interpreted as an obligation on the state to take reasonable measures to progressively realize the health of children within the available resources, which they have done by creating pilot sights.

The defendants also argued that they were not in breach of equality rights because equality should not be defined as access to the same resources but as ability to achieve the same results. The result everyone wants is healthy children. Since the Ministers claimed that the safety and efficacy of nevirapine, especially over the long term, is unknown, it can not be discriminatory to

refuse nevirapine to some people. More simply put, the methods of treatment cannot be discriminatory until it is known if they lead to unequal results.

As to the international agreements the plaintiffs cited, the Ministers claimed that they are not legally binding in a domestic court. International law, according to the defendants, is not domestic law until it has been enacted into law by the parliament of South Africa. Therefore the domestic courts cannot interpret the international agreements nor determine the legal consequences flowing from them. They also argued that though the court must take into account international law when interpreting the Bill of Rights due to s.39 of the Constitution, the court is not bound by international law and is free to make its own interpretation of the rights contained within.

DECISIONS OF THE COURTS

High Court

Botha J determined that the issue should be approached as a s.27(2) matter, but that it was relevant that other sections of the Bill of Rights were at issue. He determined that the government had breached both the negative obligation not to interfere with the realization of heath, and the positive obligation to provide a comprehensive and systematic plan to progressively realize the right to health. Botha J did not discuss the possible breach of any other domestic or international obligations except to rule that the principle of legitimate expectation cannot confer a substantive right, and that "the phased implementation of a health care programme is discriminating, that it causes inequality and that it denies access to those who find themselves outside the reach of the sites where implementation is being effected." He did not, however, rule on whether this particular phased implementation of a health care programme breached the right to equality guaranteed in s.9 of the Bill of Rights.

Botha J relied on *Republic of Africa v Grootboom* to conclude that positive rights are justiciable and judging the reasonableness of governmental policy does not breach the principle of the

separation of powers. He instead called it "a perfect example of how the separation of powers should work" when the judicial arm sits in judgment of the reasonableness of the decisions of the executive arm.

As for the disagreements about the scientific evidence between the two sides, Botha J came down firmly on the side of TAC. He concluded that the side effects and mutations were only shown for long term use and there was no evidence of safety issues for short term use. He characterized the conditional registration of nevirapine by the MCC as normal under the circumstances and not indicative of specific safety concerns in relation to the drug.

Botha J also agreed with the plaintiffs as to the irrationality of waiting until the state could afford a comprehensive MTCT of HIV prevention programme to make nevirapine more widely available. He concluded that while a comprehensive programme is optimal and testing facilities such as the pilot sites are necessary, widespread availability of nevirapine is the rational first step. As to the cost concerns the Ministers raised for the provision of a basic programme of testing, counselling and nevirapine, Botha J found that "there is in my view incontrovertible evidence that there is a residual of latent capacity in the public sector outside the 18 pilot sites to prescribe nevirapine." He also found that allowing doctors to prescribe nevirapine without restraint would not cause too much strain to the health care budget.

For these reasons the court found that "the policy of the first to nine respondents in prohibiting the use of nevirapine outside the pilot sites in the public health sector is not reasonable and that it is an unjustified barrier to the progressive realization of the right to health care."

Botha J also found that the government had a positive duty to create a comprehensive plan to reduce MTCT of HIV under s.27 (2) of the Bill of Rights. He concluded that "a programme that is open-ended and that leaves everything for the future cannot be said to be coherent, progressive and purposeful." Therefore, the state was in breach of its obligation to provide a comprehensive plan to prevent MTCT of HIV.

As remedy to these breaches the High Court ordered the Ministers of Health to make nevirapine available in all public hospitals that have the necessary testing and counselling facilities. It also ordered the Ministers to come up with a comprehensive plan for the reduction of MTCT of HIV and to submit reports to the court outlining the progress they have made on this plan.

Constitutional Court

The Constitutional Court made most of the same determinations as the High Court. They found that socio-economic rights were justiciable and that s.38 of the Constitution conferred on the court the power to give "appropriate relief" when a right in the Bill of Rights has been infringed. They found that "appropriate relief" included the ability to force the government to change its policies.

They also agreed with the High Court's fact finding, including the finding that nevirapine is efficacious, safe, and affordable and that there was some capacity in hospitals and clinics outside the pilot sites to properly test, counsel and administer nevirapine. They found that the government's policy to limit nevirapine to the pilot sites was unreasonable and constituted a violation of s.27(2).

The Court considered whether s.27(1) conferred a right to a minimum core of health care services and found that "section 27(1) of the Constitution does not give rise to a self-standing and independent positive right enforceable irrespective of the considerations mentioned in section 27(2)."[8] The Court did find, however, that the concept of a minimum core obligation was relevant to reasonableness under s.27(2).

The Court also considered the right to health of children guaranteed under s.28 and found that while parents who can afford to provide medical care for their children have the primary responsibility to do so, this does not relieve the state from its obligation to insure the health of children. The Court did not discuss whether to read s.28 as limited in the same way as s.27, but made no mention of reasonableness in their discussion of the possible breach of s.28. This

leaves open the possibility of reading s.28 as a stand-alone positive right to essential health care for children.

The Court also did not discuss the possible violation of any other domestic or international obligations or the legal status of international covenants in domestic courts.

The Court found that the government was in violation of s.27 and s.28 in not making nevirapine widely available and in not providing a comprehensive plan for the gradual elimination of MTCT of HIV. They ordered the government to provide nevirapine to all public hospitals and clinics that have the necessary testing and counselling facilities and to come up with a comprehensive plan for the further reduction of MTCT of HIV. The Constitutional Court overturned the High Court's order to have the Ministers of Health submit reports to the court outlining their progress, due to the government's track record of complying with decisions of the court.

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1 The National Department Of Health, *Protocol for Providing a Comprehensive Package of Care for the Prevention of Mother to Child Transmission of HIV in South Africa: Draft Version 5,* (April 2001) at 4.

2 World Health Organization, *Mother-to-Child Transmission of HIV*, Available online: http://www.who.int (June 26, 2006).

3 PBS, *The Age of AIDS*, FRONTLINE (May 30, 2006). Available Online: http://www.pbs.org/wgbh/pages/frontline/aids/ (July 3, 2006).

4 *Supra* note 1.

5 *Supra* note 3.

6 Mbeki, Thambo, *Speech at the Opening Session of the 13th International Aids Conference 9 July 2000* Available Online: http://www.anc.org.za/ancdocs/history/mbeki/2000/tm0709.html (June 26, 2006).

7 Heywood, Mark, *Preventing mother-to-child HIV transmission in South Africa: Background, strategies and outcomes of the Treatment Action Campaign's case against the Minister of Health*. SOUTH AFRICAN JOURNAL ON HUMAN RIGHTS, 19(2) 295 (2003). Available Online: http://www.law.wits.ac.za/sajhr/ (June 26, 2006).

8 At 39.