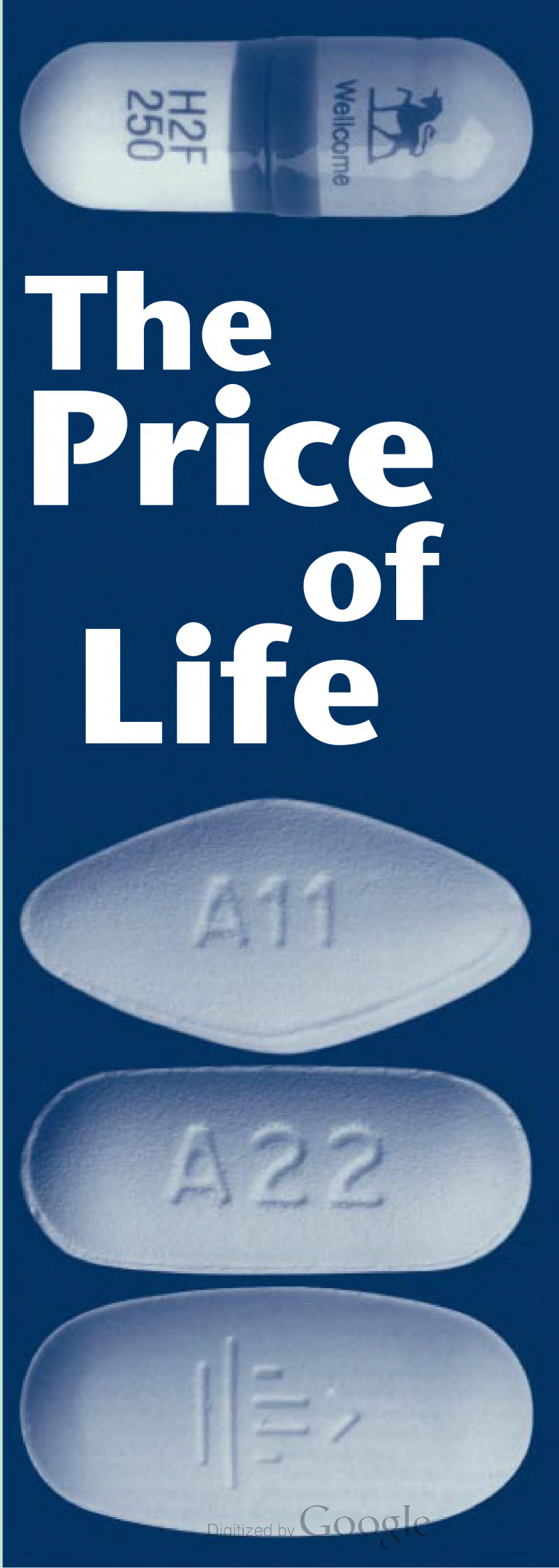

The Price of Life

Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim:

A report on the excessive pricing complaint to South Africa's Competition Commission

This report was published by the Law and Treatment Access Unit of the AIDS Law Project (ALP) and the Treatment Action Campaign (TAC), and was funded by the Ford Foundation. Opinions expressed in this report are those of the authors and do not necessarily reflect the views of the Foundation.

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- Dr Steven Andrews
- Dr Mark Cotton
- Professor Robert Dorrington
- Mr James Love
- Dr Leon Regensburg
- Mr Alexander van den Heever
- Professor Robin Wood

The legal team representing the complainants is:

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The Price of Life

**Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim:
A report on the excessive pricing complaint to
South Africa's Competition Commission**

July 2003

A joint publication of the Law and Treatment Access Unit of the AIDS Law Project
and the Treatment Action Campaign

The AIDS Law Project is a part of the Centre for Applied Legal Studies (CALS), based at the University of the Witwatersrand, and a Joint United Nations Programme on HIV/AIDS (UNAIDS) Collaborating Centre.

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Executive summary

As part of a national campaign to lower the costs of essential drugs for the treatment of HIV/AIDS, the AIDS Law Project (ALP) lodged a complaint in September 2002 with the Competition Commission of South Africa. Established in terms of the Competition Act, 89 of 1998, the Competition Commission is an independent body entrusted with ensuring that companies compete fairly in the market and where they dominate a particular market, that companies do not abuse their powerful position. In addition to the Treatment Action Campaign (TAC), the complaint was lodged on behalf of a number of people living openly with HIV/AIDS, health care workers treating people with HIV/AIDS, the Congress of South African Trade Unions (COSATU), the Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union (CEPPWAWU) and the AIDS Consortium. With approximately two million members, COSATU is the largest trade union federation in South Africa.

The complaint is the first of its kind in South Africa. It is a unique and novel step that engages South Africa's sophisticated and fairly new competition regulatory system in an effort to secure justice and rationality in drug pricing in the context of a worsening AIDS epidemic. In South Africa, tens of thousands of people are dying every year because excessive prices are charged for life-saving antiretroviral medicines (ARVs). This is made worse by a government that lacks the determination and political will to take appropriate action to ensure that such medicines are affordable.

The complainants allege that GlaxoSmithKline and Boehringer Ingelheim are acting in violation of competition law by charging excessive prices for their ARVs to the detriment of consumers. In short, the complainants allege that the prices charged by the drug companies for these essential medicines are directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS, including adults and children. A comparative analysis of the prices of these patented medicines and generic alternatives shows that even when allowance is made for the costs of research and development, higher profits, licensing fees and the incentive to develop new drugs, the prices of these patented medicines remain excessive.

TAC and its allies have lodged this complaint to ensure that the right to life is placed before profiteering. In particular, the complaint seeks to ensure that people living with HIV/AIDS who are working can afford to buy medicines to save their lives; that medical schemes treat people living with HIV/AIDS without going bankrupt; and that employers are able to pay for the treatment of workers on a sustainable basis.

The Commission has up to a year to investigate the complaint. If at the conclusion of its investigation the Commission establishes that GlaxoSmithKline and Boehringer Ingelheim have engaged in prohibited excessive pricing, it will refer the matter to the Competition Tribunal for adjudication, where it will seek appropriate relief. Upon referral, the complainants are urging the Commission to seek an order that GlaxoSmithKline and Boehringer Ingelheim stop their excessive pricing practices, as well as a declaration that their conduct is a prohibited practice for purposes of damages claims by all persons who can establish that they have suffered loss or damage as a result of the excessive pricing. In addition, the Commission is urged to seek the imposition of a substantial administrative penalty against GlaxoSmithKline and Boehringer Ingelheim.

International support for the complaint has already gained momentum. Pickets were held in late 2002 against Boehringer Ingelheim in Germany. An online petition in support of the complaint has been launched by Action for Southern Africa (ACTSA). A number of organisations, including Médecins Sans Frontières (MSF), Oxfam, ACTSA, the Canadian HIV/AIDS Legal Network and the Consumer Project on Technology have submitted vital information, documents, cases and reports to the Commission in support of the Complaint.

In the next few months the complainants will continue to co-operate with the Commission in its investigation, to raise greater public awareness of the complaint, and to generate additional local and international support for the complaint. In addition, the complainants will continue to exert public pressure on the multinational pharmaceutical industry to demand that they grant unrestricted voluntary licenses on reasonable terms, for the local production and/or importation of essential generic medicines.

Glossary of terms

Abuse of market dominance – when a firm takes unfair advantage of its powerful position in a particular market. Legal safeguards against abuse of market dominance automatically come into play when a firm controls 45% or more of a given market.

Actuarial scientist – someone who calculates statistics on life, death and illness. Actuaries are often employed by the life insurance industry.

Antiretroviral medicines (ARVs) – medicines used to fight HIV infection and thereby treat people living with HIV/AIDS. By targeting HIV directly, ARVs allow for the immune system to rebuild itself.

Antiretroviral therapy/treatment (ART) – treatment using a combination of antiretroviral medicines (also known as highly active antiretroviral therapy (HAART)).

Available (as compared to accessible) – medicines or other forms of treatment are available when they exist and could theoretically be used by people needing them. However this does not mean they are accessible. For example, antiretroviral drugs are available in South Africa, but are not accessible to most people needing them.

CD4 cell – a type of white blood cell which forms part of the immune system. CD4 or "helper" t-cells are directly attacked by HIV.

CD4 cell count – a measure of the CD4 cells to find out how seriously a person's immune system has been damaged by HIV, or to find out how well a person's immune system has recovered with antiretroviral therapy.

Cryptococcal meningitis – a fungal infection of the brain fairly commonly seen in people living with AIDS.

Competition Commission/Competition Tribunal/Competition Appeal Court – statutory regulatory and adjudicatory bodies created by and for the purposes of enforcing the provisions of the Competition Act, 89 of 1998.

Compulsory license – a licence granted by a government or a court that allows for the importation and/or production of generic versions of products still under patent protection (against the wishes of the patent holder).

Council for Medical Schemes (CMS) – regulatory body that oversees the medical schemes industry, created by the Medical Schemes Act, 131 of 1998.

Demographer – a person who specialises in the statistics of birth, deaths and disease.

Demographic projections – estimated statistical analysis of populations, derived from data using mathematical models.

Fixed-dose combination medicine – a single tablet or capsule that contains two or more medicines in a fixed ratio.

Generic – a copy of a product that is (or was) under patent protection.

Generic medicines – copies of medicines that are (or were) under patent protection. While generic medicines are usually substantially cheaper than medicines that are or have been under patent protection, they must be as safe and efficacious (and of the same quality) as their patented counterparts to be registered for use in South Africa.

Immune deficiency – seen when a person's immune system has been damaged or weakened. Some degrees of immune deficiency can be caused by a number of factors, but the almost exclusive cause of serious immune deficiency in South Africa is HIV infection. HIV attacks the immune system and over several years will destroy it, leading almost inevitably to death unless proper treatment is given.

Immune system – the complex defence system of the body that fights both external infections and internal defects eg cancers.

Kaposi's sarcoma – a form of cancer of the skin which was considered rare in the general population until the advent of HIV/AIDS. Kaposi's sarcoma is now an AIDS-defining illness.

Lactic acidosis – a metabolic disease with a high fatality rate which is a rare side-effect of certain antiretroviral drugs. With proper monitoring, lactic acidosis can be controlled.

Market dominance – a situation where a firm controls a large proportion of a given market.

Medical Research Council (MRC) – independent statutory body which funds and co-ordinates research into a wide range of medical-related issues.

Medical scheme – an organisation that helps pay for the medical care for its members, in exchange for a monthly premium. Sometimes known as a medical aid.

Medical scheme administrator – an organisation or company which administers a medical scheme and receives a fee in exchange. Medical Schemes and administrators are separate legal entities.

Medicines Control Council (MCC) – regulatory body charged with ensuring the safety, efficacy and quality of all medicines registered for sale in South Africa.

Monopoly – when a firm is the sole supplier of a particular product or service in a given market and so is able to control the market without having to consider competition. Monopolies lead to higher prices. In terms of South Africa's Competition Act, the holding of monopoly power itself is not necessarily prohibited. Instead, the abuse of such power is prohibited.

Nucleoside analogue reverse transcriptase inhibitors (NRTIs)/Non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs) – two classes of antiretroviral drugs which interfere with the replication of retroviruses (such as HIV) by inhibiting the action of the reverse transcriptase enzyme. NRTIs and NNRTIs interfere with the reverse transcriptase enzyme at different points.

Opportunistic infection – an infection which takes advantage of a person's damaged or compromised immune system.

Oesophageal candidiasis (or thrush) – fungal infection of the digestive tract. This form of thrush is a common opportunistic infection found in people living with HIV/AIDS.

Oral candidiasis – a fungal infection of the mouth commonly seen in people living with HIV/AIDS.

Paediatric formula – a form of a drug, usually a liquid, which is suitable for children. Paediatric medicines are often measured according to the weight of the child.

Patent – legal protection granted to a new invention (such as a medicine) for a period of 20 years, which prevents anyone from making, importing or selling the product without the patent holder's permission. By excluding all competition, patent protection usually results in high prices.

Pneumocystis carinii pneumonia (PCP) – a form of pneumonia rare in people without a compromised immune system and common in people living with HIV/AIDS. PCP is an AIDS-defining illness.

Prescribed minimum benefits (PMBs) – a package of benefits which private medical schemes must provide to members. PMBs are roughly equivalent to the benefits offered in the public sector.

Private health care sector – sector where patients pay for medical treatment, often with the help of medical schemes. Spending on the private health care sector, which services only a small part of the population, is far higher than state spending in the public health care sector.

Protease inhibitors (PIs) – antiretroviral medicines which control the replication of HIV by inhibiting the action of the protease enzyme.

Public health care sector – health facilities and care provided and paid for by the state. Patients pay little or nothing for medical treatment in the public health care sector.

Research and development (R&D) – process of discovering, creating, testing and developing an innovative product.

Side effects or adverse drug events – unwanted results of taking medicines.

Adverse drug events range from mild to life threatening.

Toxicity – inability to tolerate the side effects of medicines or significant organ dysfunction.

Treatment literacy – the understanding of the issues involved in treatment, including how medicines work and their side effects.

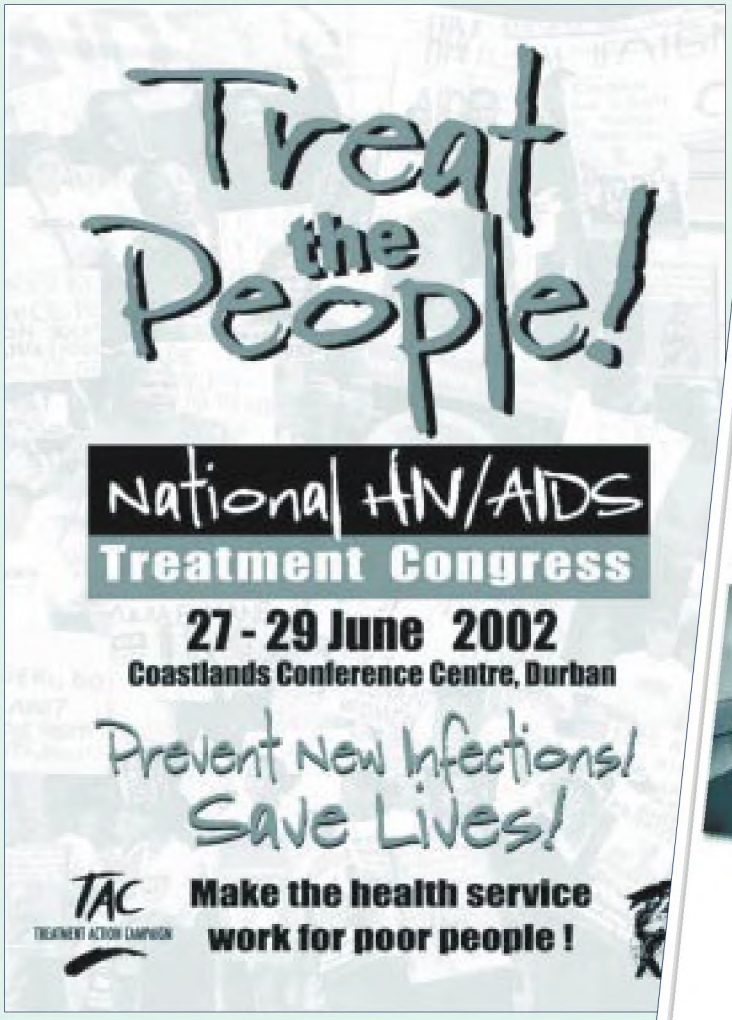
Vaginal candidiasis – fungal infection of the vagina.

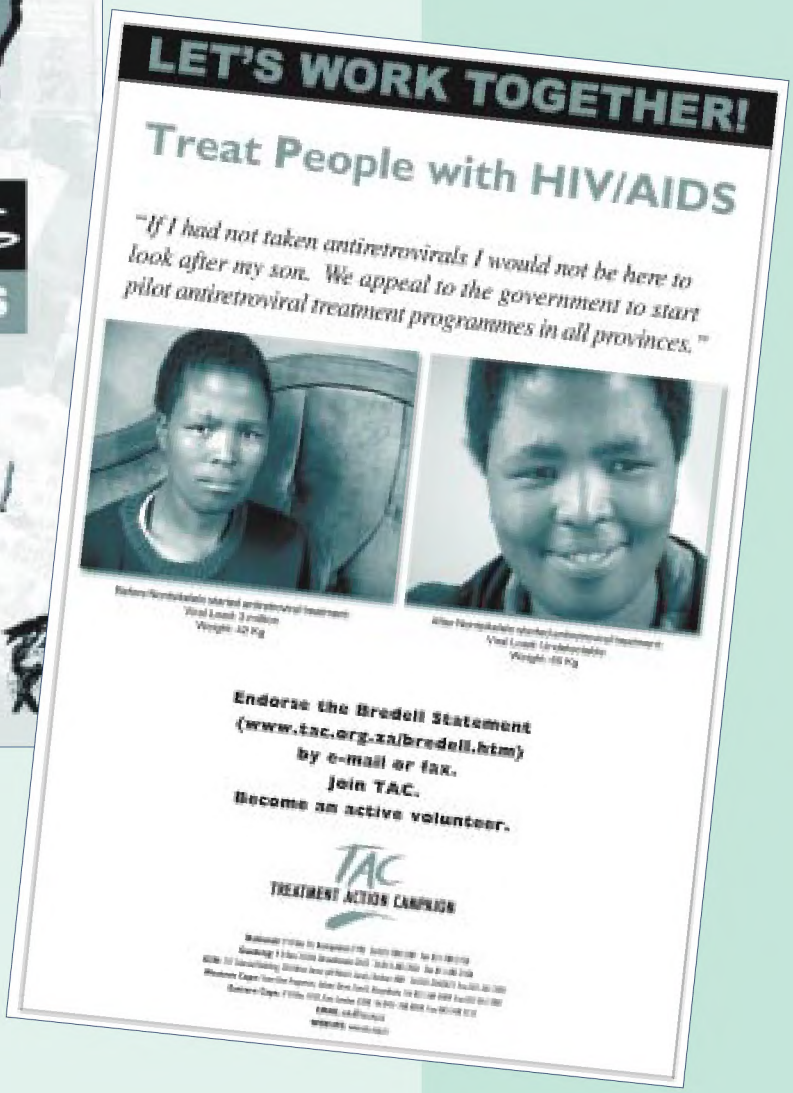
Viral load – the level of HIV in the blood, measured in copies of HIV per millilitre of blood or viral particles present in a person's blood. High viral loads tend to correlate with higher levels of sickness and greater infectiousness. An undetectable viral load means that the levels of virus are so low that ordinary tests cannot detect the virus in the blood – it does not mean that the virus has been totally cleared from the body. This is the ideal outcome of effective antiretroviral therapy.

Voluntary license – when a patent holder voluntarily grants a license to allow for the importation and/or production of generic versions of products still under patent protection.

World Health Organisation (WHO) – an international body charged with researching and disseminating information on medical care worldwide.

WHO Model Essential Medicines List – list of drugs the WHO considers should be available in all countries to ensure minimum public health standards.





Background

For hundreds of thousands of people in South Africa who are living with HIV/AIDS, staying alive is too expensive. It is estimated that up to half a million people are living with AIDS. Many will not live very long unless they have access to comprehensive treatment which includes access to antiretroviral medicines (ARVs). It is not that such treatment is unavailable, but rather that it is largely inaccessible.

A largely untreated AIDS epidemic has profound implications not only for the people who are needlessly suffering and their loved ones, but also for the country as a whole. The epidemic is concentrated among young adults, with women more heavily affected than men. So it is often the breadwinner or family head who dies of an AIDS-related illness, frequently tipping the family into destitution as they also struggle to cope with the costs of a prolonged and painful loss.

By maintaining substantially higher prices in the private sector, access to treatment is significantly limited

Rising levels of sickness and death place severe strain on the state, which is under growing pressure and a constitutional obligation to provide adequate forms of support to families affected by HIV/AIDS. There is also an increasing burden on the public health system, as people living with HIV/AIDS require repeated treatment of opportunistic infections. The incidence of opportunistic infections can be substantially reduced with access to comprehensive treatment.

Nor is the private sector immune to falling productivity, increased absenteeism, increased sick leave and low staff morale when workers and their families are living with and affected by HIV/AIDS.

But this can be prevented. A comprehensive treatment plan, which includes but is not limited to the use of ARVs, allows people to live longer, more productive and healthier lives.

Most people in South Africa who are living with HIV/AIDS are reliant on the public sector for their health care. But the state does not provide comprehensive treatment for HIV/AIDS through the public health system. While there are indications that government is moving towards committing itself to beginning a public sector HIV/AIDS treatment programme, this will come too late for most people living with AIDS who desperately need access to treatment now.

At current drug prices, approximately 20 000 people are accessing treatment through the private sector. If prices were significantly lower, these numbers would grow. Yet the preferential pricing deals offered by many multinational drug companies are limited to governments and the not-for-profit sector. By maintaining substantially higher prices in the private sector, access to treatment is significantly limited.

In September 2002, the Law and Treatment Access Unit (LTAU) of the AIDS Law Project (ALP) filed a complaint with the Competition Commission against GlaxoSmithKline and Boehringer Ingelheim. Filed by the ALP on behalf of 13 individuals and organisations that together represent several million people, the complaint focuses on the excessive prices charged for ARVs in the private sector.

As part of a multi-faceted campaign to increase access to essential medicines, this complaint follows the successful defence in 2001 of the Medicines and Related Substances Control Amendment Act, 90 of 1997, as well as the recent Constitutional Court judgment on the state's policy on the prevention of mother-to-child transmission of HIV. Using the law to enforce people's rights of access to treatment has been – and remains – a key component in the campaign for access to essential medicines.

HENNER FRANKENFELD / PICTURENET AFRICA

Coffins for babies being manufactured at the RIP coffin factory on the KwaZulu-Natal South Coast. Due to the high HIV infection rate in the province, the number of funerals has increased dramatically.

HIV/AIDS in South Africa

South Africa is considered to be the country with the highest number of people living with HIV in the world. Government estimates are that in 2001 there were 4.74 million people living with HIV in South Africa, or approximately one in five adults.

But often highly acrimonious debate rages on about how many people are actually living with HIV and how many are dying from AIDS-related illnesses, in part driven from the paucity of national data. The National Department of Health produces annual estimates drawn from a survey of pregnant women attending public ante-natal facilities. Reputable alternative estimates are regularly given by the Actuarial Society of South Africa (ASSA) based on modelled projections.

There are slight differences between the two sets of estimates. In 2001 the Depart-

Professor Rob Dorrington
EXPERT WITNESS

Rob is the Head of the Department of Actuarial Science at the University of Cape Town (UCT). He is also a Director at the Centre for Actuarial Research (CARE), which is also based at UCT. Rob is one of the country's leading actuarial scientists and demographers. In addition to the positions he holds at UCT, he is also a Fellow of both the London Institute of Actuaries and the Actuarial Society of South Africa, where he has served in a number of capacities.

Rob also serves on a number of non-academic bodies including the South African Statistics Council; the Research, Monitoring and Evaluation Task Team of the South African National AIDS Council (SANAC) and the National Reference Group, which is assisting Statistics South Africa (SSA) to produce official mortality tables and population projections for South Africa.

ment of Health said 24.8% of pregnant women were HIV positive, compared to 24.5% in 2000. The ASSA model gives estimates of 27.3% among women attending public antenatal clinics, up from 25.2% in 2000.

For the population as a whole, the Department of Health estimates that 4.74 million people were living with HIV at the end of 2001, up from 4.7 million twelve months before. The ASSA estimates are that in 2001 5.97 million people were living with HIV, rising to 6.56 million by the end of 2002.

A Medical Research Council (MRC) report released last year on AIDS-related mortality in South Africa said that AIDS is now the biggest cause of mortality in South Africa, and that about 40% of adult deaths in 2000 were due to HIV/AIDS. In 2001, the report estimated, approximately 200 000 people died as a result of the epidemic.

Whatever the exact number of people in South Africa living with HIV/AIDS, the magnitude of the epidemic is clear. The Department of Health has itself acknowledged the destructive nature of the AIDS epidemic, describing it as "the greatest threat to public health in our country".

To draw together different assessments of the extent of the HIV/AIDS epidemic in South Africa, Professor Robert Dorrington of the University of Cape Town deposed to an expert affidavit in support of the complaint. Professor Dorrington is one of the creators of the ASSA model and also the first author of the MRC report on AIDS-related mortality.

Professor Robert Dorrington

According to the demographic projections that have been conducted, about 6 million people are currently infected with HIV and, unless they receive treatment that would increase their life expectancy, most of these people will die within the next 10 years. It is clear that HIV/AIDS is estimated by all demographers (at least outside Government) to be having a devastating effect on the population and it is undoubtedly the leading cause of death these days in South Africa....

The work of the Medical Research Council (MRC) team ... clearly identified that not only was there an increase in the number of deaths but that there was a change in the age distribution of the deaths. The research went on to investigate the likelihood that this change could be due to some other factors (such as violence, the reincorporation of the "homelands", etc). This investigation found that none of the explanations proffered were plausible accounts of the pattern and level of deaths being observed. In addition, it was also observed that the patterns of mortality increase observed in South Africa closely matched those seen in Zimbabwe some eight years previously (roughly the lag between the time of the rise in prevalence rates in the two countries).

On the basis of this and other research it was concluded that AIDS deaths accounted for approximately 25% of all deaths in South Africa in the year 2000, and 40% of the deaths in the 15-49 age range, making it the single biggest cause of death in South Africa.... Projections using the ASSA2000 model ... suggest that by the year 2010 this proportion will, without treatment, have risen to something in the region of two thirds.

By the year 2010 it is estimated that without treatment some five to six million people in South Africa will have died of HIV/AIDS.

Extract from **Annexure RD – Expert Affidavit: Robert Edwin Dorrington**

While assessing the impact of the HIV/AIDS epidemic at the national level is reliant on actuarial modelling, the impact at community level is clearly experienced by health care workers.

As co-ordinator of the HIV Clinic at Helen Joseph Hospital in Johannesburg and the fifth complainant, Sister Susan Roberts has personal experience of the direct impact of the epidemic. In her affidavit, she recounts that when the clinic opened in 1992, there were just 263 patients.

Eleven years later, the clinic now serves 1 837 patients, and the hospital is now

By the year 2010 it is estimated that without treatment some five to six million people in South Africa will have died of HIV/AIDS

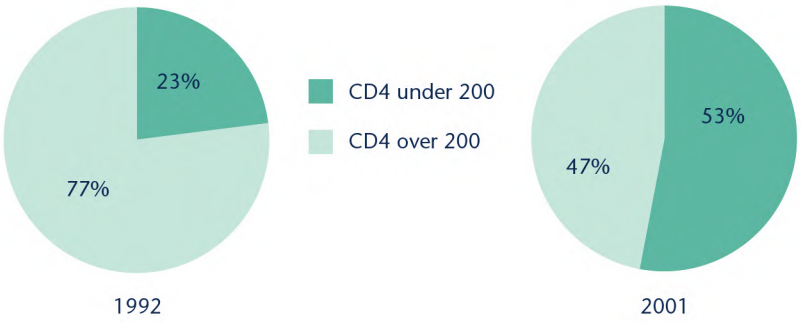
diagnosing between 80 and 90 new HIV infections each week. Sister Roberts has kept detailed records of the clinic's work over the years. She recounts:

Sister Susan Roberts

In 1992 more than 40% of patients had a CD4 count above 500, 23% of patients had a CD4 count below 200 and 15% of patients had a CD4 count below 50. A patient's CD4 count is a measure of white blood cells to find out how seriously a person's immune system has been damaged by HIV.

In 2001 53% of our patients had a CD4 count below 200; 26.5% of patients had a CD4 count below 50. Patients with such a low CD4 count need to be put on treatment to lessen morbidity and mortality. Due to the growth in the epidemic we now have eight medical wards in which patients with HIV/AIDS are admitted. In 1992 we only had four medical wards.

The numbers of patients who are very sick (anyone with CD4 under 50) has risen quite dramatically.



The numbers of patients who should be on treatment (anyone with CD4 under 200) has also risen dramatically.

Sister Susan Roberts
FIFTH COMPLAINANT

Sue is a nurse at Helen Joseph Hospital in Johannesburg. She has had extensive experience with patients who are living with HIV/AIDS over the last ten years. She is also a prominent AIDS health care activist in South Africa. About ten years ago she was responsible for starting Helen Joseph's HIV clinic. She is the co-ordinator of the HIV clinic. Sue looks after an increasing number patients living with HIV/AIDS every day, and also attends to a growing number of patients who are getting sick and dying because they do not have access to life saving treatment.

HENNER FRANKENFELD / PICTURENET AFRICA

An employee of the Debswana diamond company in Botswana receives his antiretroviral drugs from a mine pharmacy. Debswana provides antiretroviral medicines to all employees who need and want the treatment.

Saving lives

The Lazarus drugs

Antiretroviral drugs (ARVs) have been called Lazarus drugs because as the second complainant Nontsikelelo Zwedala says in her affidavit, they can take one "from a deathbed to working."

ARVs work by directly interfering with the lifecycle of HIV. They target the root of AIDS – HIV infection itself – rather than treating opportunistic infections associated with immune deficiency. By preventing HIV from replicating, ARVs allow the patient's immune system to recover, largely preventing the onset of opportunistic infections.

HIV colonises the human body by integrating itself into the genetic material of cells. It then uses the reverse transcriptase enzyme to hijack the cells and use them to produce more HIV.

Nontsikelelo Zwedala
SECOND COMPLAINANT

Nontsikelelo is thirty-one years old and has one son. She lives in an informal settlement in Cape Town. She was diagnosed with HIV in 1998 when she was told by her doctor to "wait for her death". In 2000 Nontsikelelo became very ill from various AIDS-related illnesses. Fortunately in 2001 she was able to access treatment when she agreed to take part in a clinical trial. In 2001 her partner and boyfriend, Christopher Moraka, died from an AIDS-related opportunistic infection. He would have lived if he had access to drugs that would have treated his infection.

Nontsikelelo's own health has substantially improved since taking part in the clinical trial. At present she is responsible for her 10-year-old son, her mother and her sister. Nontsikelelo knows that being on the trial means that she has access to treatment and that once the trial is over in March 2004 she will have to pay about R2000 for the same drugs. If Nontsikelelo has to pay for her own treatment she will not be able to continue with treatment because she will simply not be able to afford to pay for the drugs at current prices.

A particularly refined twist is that HIV is well designed to fit onto certain cells, mainly CD4 cells, which make up part of the human immune system. Initially the body is able to cope with the loss of these key defences by producing more CD4 cells. Eventually, however, the level of HIV becomes so high that the body is no longer able to replace the cells that are being depleted.

With one of its components in increasingly short supply the human immune system becomes systematically weaker. An increasingly dysfunctional immune system becomes less able to combat the infections and cancers which, when healthy, it could easily fight off. For this reason, the so-called AIDS-defining diseases are often those which in a healthy person are almost never seen: Kaposi's sarcoma, for example, was once almost exclusively confined to elderly men of Mediterranean origin. The cumulative effects of these opportunistic infections eventually lead to the collapse of the immune system.

In the earlier stages of HIV, the best treatment is to protect and boost the immune system as much as possible. This has led to the phrase "living positively", which means taking care of a person's diet, avoiding stress, getting exercise, sleeping, being optimistic, and speedily treating any infection as effectively as possible.

Internationally accepted guidelines indicate, however, that once a person's CD4 count (a measure of the strength of the immune system) has fallen below 200, antiretroviral therapy should be started.

In South Africa it takes an average of 7 to 10 years before a person gets to this point. The HIV/AIDS epidemic has been widespread in South Africa for more than a decade, although for much of that time it was unrecognised because people were living with HIV and not getting ill. Now the country is seeing a growing number of people who are sick with AIDS-related illnesses and who, without access to proper treatment, are dying.

To facilitate the investigations of the Competition Commission, the ALP supplied an expert affidavit by Professor Robin Wood, a doctor with substantial experience in the use of antiretroviral therapy.

Robin Wood

HIV/AIDS is a progressive disease of the immune system that is caused by the Human Immunodeficiency Virus (HIV). A recent Ugandan study shows that the majority of people with HIV/AIDS in Africa have a median survival rate from HIV infection to an AIDS-related death that ranges from 8.3 to 12.1 years. This is comparable with survival rates in Europe and North America prior to the introduction of [highly active antiretroviral therapy or] HAART.... Evidence indicates that without HAART, the majority of people with HIV/AIDS die prematurely of [opportunistic infections or] OIs that further destroy their immune systems, quality of life and dignity... Early diagnosis, clinical management, medical treatment of opportunistic infections and the appropriate use of HAART prolongs and improves the quality of life of people with HIV/AIDS ... In my clinical practice, use of HAART has decreased the incidence of HIV-associated ... hospitalisation by 80% and deaths by 94%.

Extract from **Expert Annexure RW – Expert Affidavit of Dr Robin Wood: Highly Active Antiretroviral Therapy (HAART)**

What are the drugs?

Most available antiretroviral drugs have been registered for use in South Africa by the country's regulatory body, the Medicines Control Council (MCC). The drugs registered in South Africa fall into three classes: nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors. There is one drug in a fourth class, a nucleotide reverse transcriptase inhibitor, but it is not yet registered for use here.

In my clinical practice, use of HAART has decreased the incidence of HIV-associated ... hospitalisation by 80% and deaths by 94%.

The drugs registered for use in South Africa are:

Nucleoside analogue reverse transcriptase inhibitors (NRTIs):

- zidovudine (AZT)
- lamivudine
- abacavir (ABC)
- stavudine (d4T)
- didanosine (ddI)
- zalcitabine (ddC)

Non-nucleoside reverse transcriptase inhibitors (NNRTIs):

- nevirapine
- efavirenz

Protease inhibitors (PIs):

- nelfinavir
- indinavir
- ritonavir
- saquinavir (hard & soft gel capsule)
- amprenavir
- lopinavir

Two fixed-dose combination medicines– one pill containing two or more drugs – are registered for use in South Africa. These are Combivir® (AZT/lamivudine) and Kaletra® (lopinavir/ritonavir).

How antiretrovirals work

All the drugs within a certain class work by affecting a particular point of the reproduction cycle of HIV or by affecting viral interaction with human cells. But different groups of drugs work in different ways.

Both NRTIs and NNRTIs interfere with the reverse transcriptase enzyme, which is crucial for the early stage of viral reproduction. NNRTIs attach themselves directly to the reverse transcriptase enzyme, therefore reducing its effectiveness. NRTIs have a more Trojan horse approach. They are incorporated into the DNA strand being created by the enzyme and then stop further growth of the sequence.

PIs work later in the HIV lifecycle, by handicapping the work of the protease enzyme that converts the viral genetic material into proteins. These are then modified further by other enzymes, producing new virions (daughter viruses).

HIV mutates rapidly and can swiftly become resistant to any one individual antiretroviral. As a result, ARVs should be given as a cocktail of at least three drugs, also known as highly active antiretroviral therapy, or HAART.

Antiretroviral therapy

In April 2002, the World Health Organisation (WHO), the international body that researches and disseminates information on medical care worldwide, issued its first guidelines for the use of ARVs in resource-poor countries.

The WHO considers a combination of prevention, treatment and care as crucial to the public health response to combat HIV/AIDS. The guidelines seek to provide a rational and effective approach to the use of ARVs by prescribing appropriate combinations of medicines, simplifying the therapy and training health care workers.

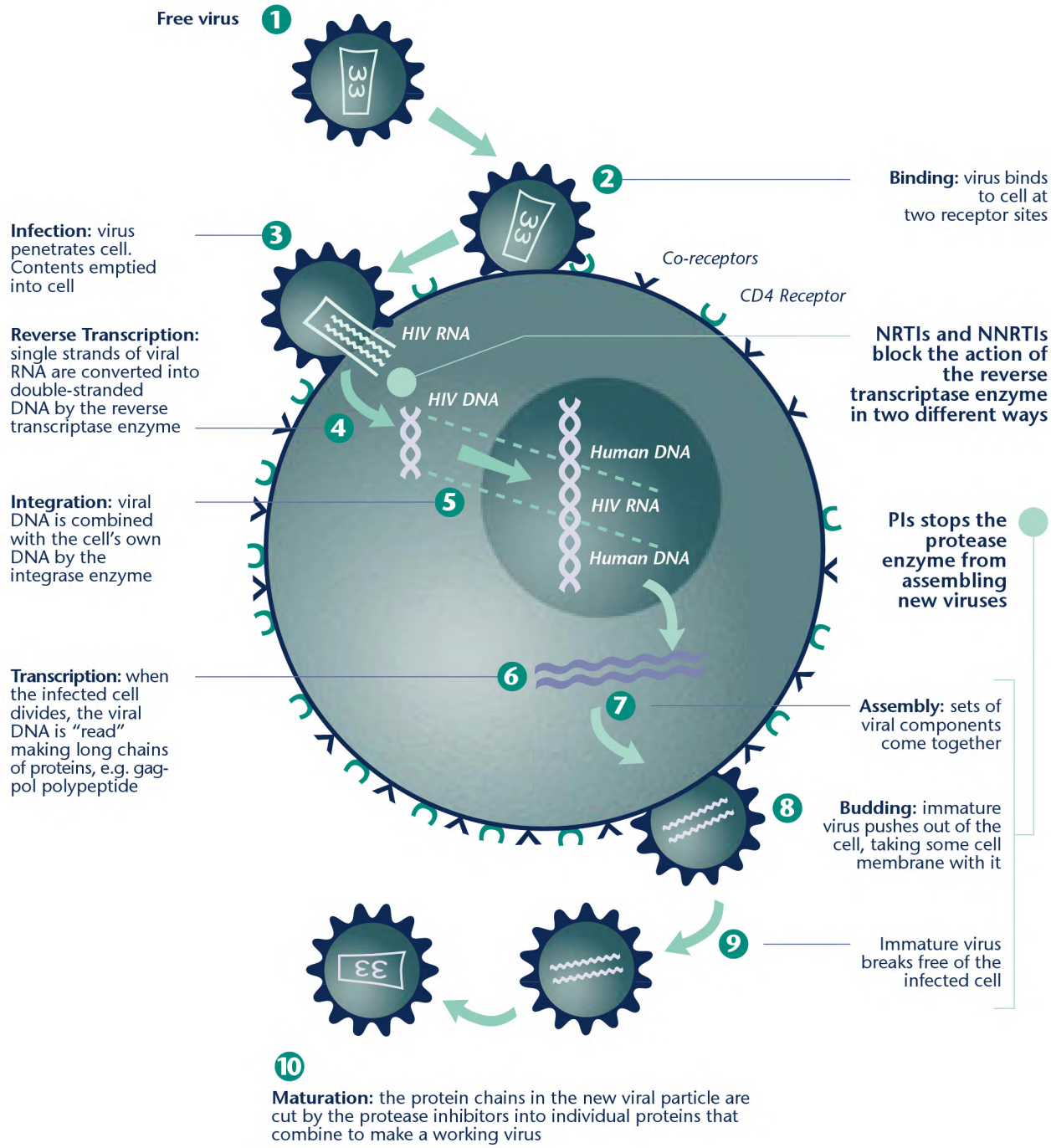
When including ARVs on the Core List of its Model Essential Medicines List, the WHO committee dealing with the issue concluded that access to treatment for HIV/AIDS requires access to (almost) all ARVs. The committee reasoned as follows: "While accepting that there were many circumstances in medicine where one essen-

Professor Robin Wood
EXPERT WITNESS

An HIV/AIDS specialist, Robin is registered to practise medicine in three countries including South Africa. He has published widely and is a recipient of a number of prestigious fellowships and degrees. He has an international reputation as an AIDS researcher and a clinician. He has worked at a number of the world's prominent tertiary institutions.

At present Robin is the Head of the Department of Medicine at Somerset Hospital in Cape Town, where he is the Director of the Diana Princess of Wales HIV Research Unit. His work includes researching and completing clinical trials, evaluating new drugs and new treatments for HIV/AIDS and treating patients who are living with HIV/AIDS.

Life cycle of HIV and targets for antiretroviral therapy



Entry inhibitors act at steps 2 and 3
Integrase inhibitors act at step 5

Reverse transcriptase inhibitors act at step 4
Protease inhibitors act at steps 7–10

S Miller, *The Clinician's Guide to Antiretroviral Resistance*, 2001

tial drug may substitute easily for other members of a class, thus allowing the placement of a single agent on the Model List (with appropriate advice about substitution), this was not possible with HIV treatment. Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens…."

Because of the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART. At present no single registered ARV is fully substitutable by another.

In essence, treatment with ARVs requires the attending doctor to consider not only the effectiveness of each individual drug, but also of the combination as a whole. Certain combinations of medicines need to be avoided, and the doctor must also plan for the future – what alternative drug regimen a patient can be given if the existing one fails or produces unbearable side effects.

In his affidavit Professor Robin Wood explains why patients need to have access to all ARVs:

Prof Robin Wood

In the selection of HAART regimens, both at the programme and individual patient level, the WHO guidelines recommend that the following considerations be addressed:

- Potency and side effect profile;
- Potential for maintenance of future treatment options;
- Anticipated adherence of the patient population to a regimen;
- Co-existent conditions, such as co-infections and metabolic abnormalities;
- Pregnancy or the risk thereof;
- Use of concomitant medications and the potential for drug interactions;
- Potential for primary acquisition of resistant viral strains; and
- Costs and broader issues of access.

Additional considerations relevant to developing countries include:

- Access to a limited number of ARVs;
- Limited health service infrastructure;
- Need to deliver medicines to rural areas;
- High incidences of TB and hepatitis B and/or C; and
- Presence of varied HIV groups and subtypes.

There is no single ARV regimen which will be ideal for either all patients or for all clinical situations. Therefore, it is necessary to have access to a combination of drug choices both within and between drug classes.

HAART may need to be changed because of toxicity or treatment failure... Toxicity relates either to the inability to tolerate the side effects of the medicines or to significant organ dysfunction. If the reason for change is related to toxicity, an entirely new second line regimen may be used, or, where toxicity relates to an identifiable drug in the regimen, another drug in the same therapeutic class can replace the offending drug if that drug does not have the same side effects.

The nature of HAART, coupled with a further narrowing of choices in respect of pregnant women and women of childbearing potential, children and people with TB and HIV co-infection, leads to only one reasonable conclusion – that ARVs, even within the same therapeutic class, cannot be considered as fully substitutable for each other. Because of the matrix of interconnected factors relating to toxicity and effectiveness of treatment, access to a wide choice of ARVs is required in order to effectively administer HAART. At present no single registered ARV is fully substitutable by another.

Extract from **Expert Annexure RW – *Expert Affidavit of Dr Robin Wood:* Highly Active Antiretroviral Therapy (HAART)**

Dr Mark Cotton
EXPERT WITNESS

Mark is a senior specialist at the Tygerberg Children's Hospital where he works in the field of child health care and infectious diseases. He is also a member of the Faculty of Medicine at Stellenbosch University. He has extensive experience as a paediatrician both in South Africa and the United States. Mark graduated from the University of Cape Town and spent three years after that as a Fellow in Paediatric Infectious Diseases at the Children's Hospital in Colorado. In 1995 he was selected as a Paediatric AIDS Foundation Scholar at the National Jewish Centre for Immunology and Respiratory Medicine in Colorado.

Mark returned to South Africa to help with improving the management of HIV/AIDS amongst children. Since 1996 when he joined Tygerberg Hospital he has taken care of many children living with HIV/AIDS. In 1997 he helped to establish a specialist family clinic for HIV/AIDS at the Tygerberg Academic Hospital. In addition to his clinical work, Mark is also completing his PhD.

Of all the affected families, only three were able to fund HAART for their children in our clinic.

So to provide optimal antiretroviral therapy, doctors should have access to all of the ARVs available. But in South Africa this is complicated by cost – doctors are being forced to give the drugs patients can afford, rather than those they need. This has implications not only for the patients themselves, but also for public health, as sub-optimal treatment can lead to increasing drug resistance.

In South Africa more women are infected with HIV than men. Since the epidemic is also largely driven by unprotected sex, the result is that a very high proportion of women living with HIV/AIDS are of childbearing age. This has implications for treatment, since only a few ARVs are recommended for use by pregnant women. The combination of d4T and ddI cannot be used unless there is no alternative because it can trigger a potentially fatal metabolic illness called lactic acidosis. Efavirenz is not recommended for women who may become pregnant because it may have a damaging effect on the development of the foetus in the first trimester.

Treating children

The slowness in implementing a reasonable public health programme to prevent mother-to-child transmission of HIV has contributed to a rising number of HIV positive children, many of whom require antiretroviral therapy in their early years of life. Without treatment about a quarter of children in South Africa with HIV will die before the age of two. Given the correct antiretroviral therapy, children can respond astonishingly well, often far better than adults.

Treatment is complicated because not all the registered drugs are available in a form suitable for children, where treatment dosage is related to weight. Also, some ARVs (such as indinavir and saquinavir) do not exist in a paediatric form. Others such as efavirenz cannot be used for children under three because the correct dosages are not yet known.

The issue of treating children is addressed in an affidavit deposed to by Dr Mark Cotton, a paediatric HIV/AIDS specialist. Some idea of the impact of the HIV/AIDS epidemic among children is provided in Dr Cotton's affidavit. Dr Cotton has analysed data on hospitalisation of children over 11 years, producing a set of graphs showing the human and financial toll of untreated paediatric HIV.

Dr Mark Cotton

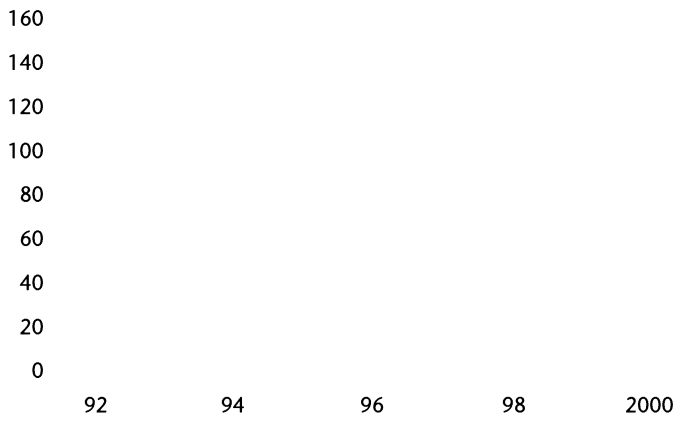
Children with HIV who require hospitalisation are invariably symptomatic and thus require HAART. Should these children receive HAART, the number of them admitted for treatment of infections such as pneumonia, gastroenteritis and tuberculosis will be reduced, as will the average number of days spent in hospital for those admitted. Crucially, the use of HAART will also result in a substantial reduction in the number of HIV-related deaths. But for many children who develop permanent lung damage and spend long periods of time in our hospitals, access to HAART at a late stage is unlikely to reverse their outlook.

The use of HAART for treating children with HIV/AIDS will not only result in substantial savings both for the hospital and the families of children with HIV/AIDS, but it will also alleviate unnecessary, avoidable and predictable suffering. In my opinion, the majority of parents have insight into the need for HAART and show immense sadness at their inability to provide adequate care for their children.

But the prices that are currently charged for ARVs, including those that are the subject of this complaint, move treatment beyond the reach of most of our patients. Of all the affected families, only three were able to fund HAART for their children in our clinic.

Total estimated annual cost of treating opportunistic infections in HIV positive infants because of recurrent diseases at Tygerberg Children's Hospital

Number of infants with symptomatic HIV admitted to Tygerberg Children's Hospital



Extract from **Expert annexure MFC – Expert Affidavit of Dr Mark Fredric Cotton: paediatric treatment for HIV/AIDS and cost implications**

The implications of high prices

When Hazel Tau decided to be a complainant in this case, she had no access to ARVs and was becoming ill. Since then, a donor (who prefers to remain anonymous) has offered to pay for her treatment. She is now on treatment and is recovering speedily. Of course she is deeply grateful to the donor. But Hazel would prefer to be able to afford it herself rather than having to rely on a donation.

Hazel Tau
FIRST COMPLAINANT

Hazel was diagnosed as living with HIV in 1991. Her doctor at the time failed to counsel her properly. Two years later, after receiving proper counselling Hazel was able to access AZT from the Johannesburg General Hospital. At that time monotherapy was the best antiretroviral treatment available. She took AZT for about six months and the cost of the drug was borne in some part by a medical aid scheme of which she was a beneficiary. In 1994 she publicly disclosed her HIV status.

By early 2002 Hazel had lost a third of her body weight, her CD4 count had dropped below 200, and she was beginning to experience a number of opportunistic infections. Hazel joined the complaint knowing that antiretroviral drugs can keep her alive and working longer. Because she is the sole breadwinner in her family, she will not be able to pay for antiretroviral treatment herself at the prices currently charged. Fortunately, towards the end of last year, a donor (who prefers to remain anonymous) offered to pay for Hazel's treatment.

Hazel Tau

I am very committed to the struggle to ensure that all people living with HIV have the choice to take antiretroviral (ARV) treatment if they need it. I am aware of how ARV treatment works and how highly active antiretroviral therapy (HAART) can change the lives of people who are living with HIV allowing us to live longer and healthier lives. Because of attending various treatment literacy workshops conducted by the TAC, I know about opportunistic infections and the management of HIV and AIDS.

In 2000 I was employed by the HIV/AIDS Help Line, where I am presently working. I am earning R4,800 a month after deductions.

I am aware that I need to go onto HAART given that my CD4 has dropped below 200. ...But I cannot afford to pay even R1,000 a month for this.

If the prices of ARVs were reduced to between R400.00 to R500.00 a month I could afford treatment on my present salary. I am aware that I will have to sacrifice some things, but I know that this treatment will help me and keep me healthy.

Extract from **Annexure HT – Affidavit of complainant: Hazel Tau**

For people living with HIV/AIDS who are unable to pay for their own treatment, one of the few ways of accessing ARVs is through a clinical trial. One person who has managed to do this is the second complainant, Nontsikelelo Zwedala:

Nontsikelelo Zwedala

In March 1998 I ... had a fungal infection on my hands and feet – my hands and feet were cracked – if I put water on it then blood used to come out from the cracks on my hands and feet. My TB and the fungal infection were treated at the Nyanga clinic. At the clinic they also told me that my CD4 count was 150.

But in 2000 I had TB again all over my body and a fungal infection on my hands and feet. I was told at the Nyanga clinic that my CD4 count was 14. My weight also dropped from 76kg to 42kg. I was given treatment for TB.

When I went for a viral load test in 2001 at the Nolungeile clinic it was three million. My doctor at that time was Dr Hermann Reuter.

Dr Hermann spoke to a doctor called Dr Bekker at the Lung Institute in Observatory. In early 2001 they advised me to start a clinical trial because I was very sick.... They told me they wanted to start me off with a combination of d4T, 3TC and nevirapine to see if this combination would work. I was told the trial was for one year and that I would get free treatment for two years after that. I was told that after the two years were over I would have to buy my own drugs.

I agreed to take part in the trial and started taking these ARV drugs in March 2001. The trial ended in March 2002. I will get the drugs for another two years. After the two years are over, I have been told that I will get treatment from the Gugulethu programme.

After I started treatment my weight is now 58kg. My CD4 count is now 242. I do not know what my viral load is.

I feel happy and healthy now that I am on treatment. I am working now.

When I was sick my mind was not working well. My skin was rough. I had a rash all over. I used to forget everything even my child. But now my mind is working well and everything is all right. Now that I am working I can help other people living with HIV and I can help my son and sister and mother. My family knows that I am on treatment and happy now that I am healthy and not sick like before. They got very worried when I was sick....

The doctors have told me that the drugs that I am on now cost about R2,000 a month and I am told that some ARV regimes cost about R1,300. If Gugulethu will not provide me with the drugs after the years come to an end there is no way that I can afford to buy such expensive drugs.

Extract from **Annexure NPZ – Affidavit of complainant: Nontsikelelo Patricia Zwedala**

Isaac Skosana has a job, but his salary is too low for him to pay for ARVs himself. It is also too low for him to afford comprehensive medical scheme coverage. In his affidavit as the fourth complainant, he explains what this means for him:

Isaac Skosana

In June this year I collapsed at work and was admitted to hospital. I was told that my CD4 is 250 and that my sugar level is down. …

The doctors have advised me to come for regular check ups to monitor my health. They have told me that they are concerned about my sugar level dropping. The doctors asked me if I knew about antiretroviral (ARV) drugs. I told them that I cannot afford to pay for ARV drugs. Maybe I would be able to afford the drugs if they were about R400–R500 per month. I have been told and have read that they cost much more than this and that an appropriate regime wouldn't be less than about R1,300 a month.

I was told by the doctors and I know from my own experience that most people who have a CD4 of 200 or less should be given ARV treatment. Because of my particular clinical history combined with my count I am advised that I should be on treatment.

At the moment I am not on any ARV treatment. I have thought about trying to go on treatment but the only wall for me is the affordability. If the treatment was available at a cheaper price I would go on treatment.

What worries me is that recently I have experienced many opportunistic infections – such as boils as well as swollen glands behind my ears. I cannot take time off from work that easily so I have not received treatment for these infections.

If I could get treatment I think it would help me. I know people who are on this treatment and they are now stronger and are working and have been able to recover.

Extract from **Annexure IMS – Affidavit of complainant: Isaac Mthuthuzeli Skosana**

The impact of high prices on doctors and patients in the public sector is set out in the affidavit of Dr Francois Venter, the eighth complainant. Dr Venter works at the HIV clinic at Johannesburg General Hospital, which sees about 80 patients a week. Of these about a third are accessing ARVs.

Patients on ARVs at Johannesburg General can be divided into three groups:

Post-clinical trial group
These are patients who have post-clinical trial drug access through a clinical sponsor. The sponsorship is not indefinite and will end within a stipulated period of time, when patients will have to fund their continued treatment personally. Because of these clinical trials, patients are now locked into particular treatment regimens. Most, if not all, of these patients will not be able to pay for these drugs when their sponsorship expires.

Employees
These are patients whose treatment is funded by their employers (or in some cases family members). We have many patients who are domestic workers… However, if these patients lose their jobs or their employers do not continue to fund their treatment, they will not be able to pay for treatment themselves.

Self – funding
These are patients who earn approximately R3,000 – R5,000 per month. Most do not belong to a medical scheme. Of the few who are members of medical schemes, none have access to ARVs. This means that all the patients in this group pay for their own treatment.

Isaac Skosana
FOURTH COMPLAINANT

Isaac found out that he is living with HIV in 1996. After he was diagnosed in 1996 he left his job but later started a support group for people living with HIV/AIDS. He also worked as a volunteer counsellor and trainer.

At present his immune system is getting weaker. He is working as an AIDS counsellor, but on his current salary he is unable to pay for antiretroviral drugs that he needs. Because he does not have access to treatment, Isaac often gets sick. It is not always easy for him to get time off from work to treat his opportunistic infections.

Isaac is the sole breadwinner in his family, which consists of his parents, brothers, sister, wife and two children. He is a member of the Executive Committee of the AIDS Consortium and the Treatment Action Campaign (TAC), and was formerly the chairperson of the National Association of People Living with HIV/AIDS (NAPWA) in the East Rand.

Dr Francois Venter
EIGHTH COMPLAINANT

A qualified doctor, Francois is a Fellow of the College of Medicine and has a postgraduate training in tropical and infectious diseases. At present he is the clinical director of the Reproductive Health Research Unit (RHRU) at Chris Hani Baragwanath Hospital in Soweto. He is also a member of the University of the Witwatersrand Deans' AIDS Advisory Committee.

Francois is also a consultant to the Johannesburg General Hospital where he runs their HIV clinic on a voluntary basis. Francois has been treating patients living with HIV/AIDS for a number of years. He has also been active in researching and running clinical trials through the Wits Health Consortium.

Francois is also a member of the Southern African HIV/AIDS Clinicians Society Advisory Group. In 2001 he assisted the society in drawing up guidelines on providing adult antiretroviral treatment and the treatment of opportunistic infections for Southern Africa.

Most of our patients choose the most affordable regimen ...because they cannot afford to use more appropriate regimens.

Quite clearly, the cost of medicines adversely affects treatment. Dr Venter explains:

Francois Venter

Most of the patients at the clinic are on a treatment regimen of stavudine (d4T) and didanosine (ddI) and either efavirenz or nevirapine. This is not an ideal regimen. I would prefer to prescribe first-line regimens that are easier to comply with, have been proven to be effective and are generally much better tolerated.

We consult with all our patients about their health, their drug choices and the long term cost implications of using ARVs. Most of our patients choose the most affordable regimen ... because they cannot afford to use more appropriate regimens. But, there are many problems associated with taking d4T and ddI together, not least of which are the often intolerable side-effects.

If the cost of drugs was not an issue I would ordinarily advise my patients to start on a first-line regimen of Combivir® with either efavirenz or nevirapine, or d4T and 3TC® with either efavirenz or nevirapine. Unfortunately, because of the high prices of drugs that are currently being charged, many patients use d4T with ddI. This adversely affects their health, particularly in the case of patients with TB.

In the Clinic, treatment regimens may be changed for various reasons. These include:

- currency fluctuations and the weak rand/dollar exchange rate which affects the costs of drugs;
- the patient's family may experience unforeseen family-related costs which means that there is less money in the family money pool in a given month to pay for the drugs of one family member;
- patients may lose their jobs;
- patients may experience adverse drug events which requires a regimen change; and
- a particular treatment regimen may stop being effective after a period of time.

About 20% of the Clinic's patients (30% including our TB patients) have had adverse drug events and have experienced [peripheral neuropathy]. These patients have to be switched to another treatment regimen. The logical medical option is one including Combivir®. But most of our patients cannot pay for Combivir® at the high prices currently being charged. When patients cannot afford some or all of their drugs as doctors we are sometimes forced to be creative by fiddling with drug choices and regimens - this is medically very risky and places doctors in an extremely difficult position.

As a medical practitioner it is disconcerting to have to see patients stopping treatment because of financial problems. This is especially so after we get them to adhere to taking their drugs and adhering to their treatment regimen. These are patients who sacrificed a lot to pay for their drugs but because of financial circumstances they have to stop treatment. This is very frustrating because HIV/AIDS is a chronic manageable disease. Every week I see mothers who but for the unaffordability of one other drug would be better. This is also very demoralising.

If patients lose their jobs or their access to sponsored treatment stops, continuation with treatment is difficult because of the high prices charged for ARVs. It also presents a host of long-term medical complications such as drug resistance.

In my experience, amongst a range of factors, cost is the main factor that influences treatment options. A combination of three drugs makes all the difference to human life – and if patients could afford to pay for these drugs then doctors like myself could help them to prolong their lives.

Extract from **Annexure FV – Affidavit of complainant: Dr Willem Daniel Francois Venter**

JOAO SILVA / PICTURENET AFRICA

Ennie Gamgushe (64) sits with her orphaned grandchildren in the family home in KwaZulu-Natal days after the AIDS-related death of her second daughter. The grandmother is now the sole caregiver of all the children.

According to Sr Susan Roberts, her clinic is ready and willing to administer HAART to patients if it could afford to do so. In her affidavit, she argues that AIDS is not only devastating patients and their families, but also putting a huge strain on healthcare workers and the health system. She reports that Helen Joseph Hospital is on average between 80% and 85% full, with approximately 80% of patients with TB also having HIV, and with many hospital admissions as a direct result of AIDS-related illnesses. But, she explains, this could be prevented:

Sr Susan Roberts

If we could treat these patients with HAART we would be able to reduce the burden on the hospital sector and reduce the demand for hospital beds.

At present, we have about 100 patients on ARV treatment. Therefore, less than 5% of our patients have access to HAART. This is because most of our patients cannot afford treatment at the prices currently charged.

Patients who do well on HAART are a great moral boost for staff at the hospital because when you see patients changing from skeletons to functional human beings it is very uplifting. It makes me feel more positive about the work that I am doing.

I feel sorry for the nurses working in the wards who see very ill patients with opportunistic infections on a daily basis. Because of a shortage of hospital beds, patients are often discharged early and while they are still sick. Almost daily, the nurses see sick patients who are not getting better. More and more patients are getting sick and they are not getting treatment because they cannot afford to pay for it at the high prices currently being charged. Our diabetic clinic does not refuse to treat diabetes; however, the HIV Clinic only treats opportunistic infections and not HIV itself.

I cannot emphasise sufficiently the crucial importance of making the ARVs which are the subject of this complaint available generally both through public health services and through private chemists (on prescription) at affordable prices. It is impossible to exaggerate the detriment to consumers and to society as a whole of excessive prices charged for these drugs by the companies holding the exclusive rights to manufacture and distribute them.

Extract from **Annexure SR – Affidavit of complainant: Sr Susan Roberts**

The sixth complainant, Dr William Mmbara, agrees with Sr Roberts and Dr Venter. Dr Mmbara works for the not-for-profit Rhema Christian Service Foundation (RCSF), where he provides medical care to poor people in Hillbrow, Johannesburg. Dr Mmbara highlights some of the social and public health problems resulting from the lack of access to ARVs due to the high prices charged. He also points out that lack of access to proper treatment puts a high burden on health care providers, because patients repeatedly return for treatment for opportunistic infections.

Dr William Mmbara
SIXTH COMPLAINANT

William is the medical superintendent at the Rhema Christian Service Foundation (RCSF) in Hillbrow, Johannesburg. He is responsible for clinical care for people living with HIV/AIDS and for children orphaned by HIV/AIDS. He also provides palliative care to patients who are very ill and dying. William also attends to patients outside of the RCSF as a free service to the community. His work goes beyond his clinical practice. He also produces training manuals on HIV/AIDS for health care workers and develops treatment and prevention programmes for the corporate sector. At present he is studying for an advanced diploma in management through the Manchester Business School.

Dr William Mmbara

The majority of patients at the RCSF are not on ARVs. This is because they cannot afford to pay for the drugs because they are too expensive at the current prices. We battle even to provide prophylaxis for opportunistic infections. We are only able to provide co-trimoxazole (an antibiotic) or fluconazole (an antifungal). Co-trimoxazole is used, amongst other things, to prevent various potentially fatal infections, such as pneumocystis carinii pneumonia (PCP), an AIDS-defining infection. Fluconazole is used, amongst other things, to treat oral, vaginal and oesophageal candidiasis, and to prevent and treat cryptococcal meningitis (also an AIDS-defining illness). Fluconazole is supplied to us by the government through the Diflucan Partnership Programme. We purchase co-trimoxazole because it is affordable.

If the prices of ARVs were lower than they are now and were affordable, it would also improve our ability to provide other life saving drugs to our patients.

Most of the patients that come to the RCSF should be on ARV treatment... Some of the patients who have some money for drugs use ddI and d4T because they are more affordable than Retrovir®, 3TC®, or Combivir®. The high costs of the drugs thus also result in many patients getting access to sub-optimal treatment when complications occur.

If patients living with HIV can get ARVs, they feel as if they have something to live for. They live longer, modify their sexual and health behaviour, and prevent new infections or cross infections. Proper treatment makes people more productive and gives them a better outlook on life.

At the moment I treat many opportunistic infections, which could be prevented by the use of ARVs. If patients do not get sick that often it helps to reduce long queues and helps to lessen my stress. Every day I see people suffering. Even people who work with me have no access to treatment – they cannot afford to buy life-saving drugs.

Extract from **Annexure WNM – Affidavit of complainant: Dr William Nkhangweni Mmbara**

The impact of high prices is not limited to poor people accessing some level of care through not-for-profit organisations. Those who access health care services through the private sector are also affected.

Dr Steven Andrews is a highly renowned private sector doctor driven to join the complaint because of the impact of high drug prices on his patients. He explains:

It is difficult to define what it means to be a doctor, but when I am denied the tools to treat my patients because of money, I am not in any way conforming to the ethos of the Hippocratic oath. I am compromised as a professional, as a caregiver, and, in many senses, a compassionate and ethical member of the human race.

Dr Steven Andrews

My ability to select drug regimens for my patients according to internationally and locally accepted regimens … is hampered by the high prices that are currently being charged for vitally important ARVs.

Approximately 50% of my patients [with HIV] now have access to medical funding of some form. The majority of this funding, however, makes limited or no provision for HIV management. This results in poor access to life-saving drugs, including those that are the subject of this complaint.

Approximately 35% of patients [with HIV] in my care are on maintenance antiretroviral therapy. This means that they are predominantly on triple therapy regimens with a small percentage (less than 2.5%) on dual therapy regimens while awaiting access to triple therapy options.

About 35% of patients [with HIV] require triple therapy anti-retroviral drugs but cannot afford to pay for it at the high prices currently being charged.

Of the number of patients who are currently on antiretroviral therapy (35- 40%), about 10% co–fund the cost of their regimen. Many patients experience financial problems towards the end of the year. If they belong to large managed care schemes these schemes usually plan for such eventualities. But patients on most of the other medical schemes continue to have problems when funds run out towards the end of the year, leaving patients with an inability to pay for prohibitively expensive anti-retroviral drugs and accompanying investigations.

When patients run out of funding for anti-retroviral drugs before the end of the year, their regimen is interrupted because they stop taking the drugs that they have been on for the most part of the year. Once they stop treatment, medical complications arise.

At the high prices currently being charged, virtually all anti-retroviral drugs are unaffordable to most patients who need them….

It is morally debilitating to see many of my patients suffer needlessly because they cannot afford to pay for drugs that could save and enhance their lives at the prices that are currently being charged. As a doctor, I realise that I cannot cure, but that I can care. With HIV/AIDS I have witnessed breadwinners removed from their families, plunging people further into poverty; I have witnessed families torn apart by this epidemic. In the presence of such life-saving agents I often wonder whether caring means much without the ability realistically to alter peoples' lives using antiretroviral drugs.

I have witnessed many children dying because they do not have access to treatment, because their parents cannot afford to pay for them at the prices currently being charged. I know that the tools to stop or at least substantially reduce these eventualities are within my grasp but that they are restrained by the financial and political impediments imposed by the rich on the poor.

It is difficult to define what it means to be a doctor, but when I am denied the tools to treat my patients because of money, I am not in any way conforming to the ethos of the Hippocratic oath. I am compromised as a professional, as a caregiver, and, in many senses, a compassionate and ethical member of the human race.

Extract from **Annexure SMA – Affidavit of complainant: Dr Steven Murray Andrews**

Dr Steven Andrews
SEVENTH COMPLAINANT

Steve runs a specialised HIV/AIDS medical practice and training centre in Cape Town. Some of his patients are using anti-retroviral therapy. Most of his patients cannot afford to pay for their own treatment. Steve has extensive experience as a doctor specialising in HIV/AIDS. He also researches all aspects of using antiretroviral therapy and helps Médecins Sans Frontières (MSF) on a weekly basis by providing comprehensive medical care for people living with HIV/AIDS who make use of the MSF clinics in Khayelitsha. Steve's involvement and work with Aid for AIDS has given him the additional experience of providing treatment to private sector patients in South Africa, Zambia, Malawi, Tanzania and Botswana.

SUZY BERNSTEIN/PICTURENET AFRICA

A woman and her son take their ARV medication at Nkosi's Haven, a refuge in Johannesburg. Both mother and child are living with HIV/AIDS.

Paying for treatment

Most people in South Africa who are receiving antiretroviral therapy are able to access treatment because they can afford to belong to private medical schemes. The extent to which the private sector is providing access to ARVs is documented in a 2002 report published by the Centre for Actuarial Research (CARE) at the University of Cape Town. Based on a survey of 77 schemes (representing 80% of all scheme beneficiaries), the CARE report confirms that most schemes use disease management programmes (DMPs) to administer their HIV/AIDS treatment programmes, with 89% of beneficiaries being covered by some kind of DMP.

The largest DMP in Southern Africa is Aid for AIDS (AfA), a subsidiary of the private medical scheme administrator, Medscheme. The clinical director of AfA is Dr Leon Regensberg. He submitted an expert affidavit on the cost implications of providing antiretroviral therapy in the private medical schemes sector.

Dr Leon Regensberg
EXPERT WITNESS

Leon is the director of Aid for AIDS (AfA), a disease management programme (DMP) formed in 1998 with the aim of providing specialised treatment programmes and technical assistance to medical scheme beneficiaries who are living with HIV/AIDS.

AfA is contracted to 35 medical schemes and a number of private companies in Southern Africa. At present about 16 000 people are registered on AfA, of which 10 000 are receiving highly active antiretroviral therapy (HAART). It is estimated that about 36% of patients who are receiving HAART in South Africa are beneficiaries of schemes that are contracted to AfA. AfA therefore has substantial information about the provision and effectiveness of providing HAART in Southern Africa.

As a result of studies conducted by AfA about the effectiveness of providing HAART to its clients, Leon has shown that making antiretroviral therapy available at the appropriate time and in the correct manner is both cost effective as well as a vital public health intervention. Returning people to better health through the use of proper antiretroviral treatment dramatically cuts the costs of treating recurrent opportunistic infections. This in turn reduces the need for hospitalisation.

Leon Regensberg

The experience of AfA shows that HAART has reduced hospitalisation costs as well as resulted in a significant reduction in viral load of those who use it. There have also been significant increases in CD4 counts amongst patients currently receiving HAART.

The CARE report indicates that while many schemes are now offering HAART, some are still offering sub-standard mono- and dual therapy as well. This is because the high costs of drugs limit access to HAART within the available benefit structure.

Reductions in drug prices over the last few years have resulted in greater access to antiretroviral drugs (ARVs) in the uninsured private sector. This is because over time the drugs have become more affordable.

In the insured private sector, price reductions have improved the quality of care rather than the quantity of care. In other words, for the same benefit, a scheme or company can now fund HAART rather than dual nucleoside therapy. Greater price reductions will mean greater universal and standard access to triple therapy in the funded sector.

Where drug prices have been reduced, schemes contracted to AfA which were previously concerned about the long-term costs of funding HAART and the sustainability of providing HIV-related benefits are now less concerned. Schemes are gradually getting to a point where they can make a reasonable benefit available that allows access to HAART. Further reductions in the prices of ARVs will make this possible more generally and more widely within the sector. This will in all probability also allow more schemes to put a DMP in place, which in turn will increase access to HAART, which is the internationally accepted standard of care.

Extract from **Expert Annexure LDR – Expert Affidavit: Dr Leon Derek Regensberg**

By the end of 2002 there were more than 150 medical schemes registered with the Council for Medical Schemes, the industry regulator. In total, these schemes account for about 7 million beneficiaries.

In terms of the Medical Schemes Act, 131 of 1998, a medical scheme cannot

unfairly discriminate against beneficiaries on a number of grounds, including health status. This means that people living with HIV/AIDS cannot be refused admission to medical schemes solely on the basis of their HIV status. This is to prevent schemes from only providing cover to the young and healthy where the public sector bears the burden of the old and sick.

To give effect to this progressive policy, the Medical Schemes Act introduced the concept of prescribed minimum benefits (PMBs), which are a defined set of benefits for certain conditions which must be provided by every medical scheme, including in at least one network of hospitals. Schemes cannot impose financial limits on the costs of diagnosing and treating conditions listed under the PMBs.

At present the PMBs do not include the provision of antiretroviral therapy. But schemes are obliged, amongst other things, to cover the treatment of all opportunistic infections, the screening of and preventive therapy for TB, and the diagnosis and treatment of sexually transmitted infections.

In addition, many schemes do offer benefits in excess of the PMBs, that is, access to antiretroviral therapy. The high costs of ARVs therefore have a significant impact on the costs of medical coverage.

The AIDS Law Project asked health economist Alexander van den Heever, who is also a technical advisor to the Council for Medical Schemes, to provide information on medical schemes and the costs of the coverage of HIV/AIDS-related benefits.

Alex van den Heever

The sustainability of medical schemes and the benefits that they offer depend to a large extent on a scheme's ability to manage HIV/AIDS in a cost-effective manner. Price reductions and the active involvement of all medical scheme beneficiaries in cost-containment are two essential components for ensuring the sustainability of benefits and ultimately the sustainability of schemes as well.

Since the reduction of ARV prices in 2001, many schemes have undergone substantial benefit design changes. However, not all schemes provide comprehensive HIV/AIDS benefits, thereby denying members adequate coverage. While some schemes offer reasonable coverage by offering HAART (a minimum of three ARVs), many schemes are still offering sub-standard mono- and dual therapy.

The CARE report, which covers approximately 5,290,000 (or 80%) of all scheme beneficiaries, shows that 8% of beneficiaries have no access to any form of ARV therapy, with 2% having access to either mono- or dual therapy but not HAART. If one takes a conservative estimate that 264,500 (or 5%) of scheme beneficiaries are living with HIV/AIDS, at least 5290 beneficiaries who either need or will need treatment have access only to substandard forms of treatment, with at least 21,160 beneficiaries who either need or will need treatment having no access to any form of ARV therapy.

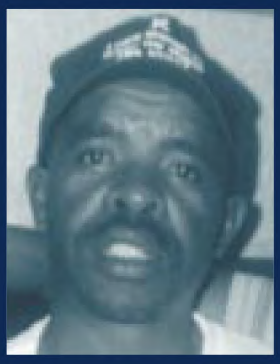
Further, while 90% of medical schemes beneficiaries surveyed may have access to HAART, the medical schemes industry is not fully experiencing the total costs of providing treatment. This is because only 0.1% of beneficiaries have registered for DMPs, which is often a pre-requisite for accessing ARV benefits.

A reduction in the current prices of ARVs would allow for HIV/AIDS to be treated as a chronic condition on a cost-effective basis. This, in turn, would allow for increased access to treatment via the employer. In addition, more beneficiaries with access to HAART would result in reduced hospitalisation costs for both the public and private sectors, thereby freeing up resources for increased benefits or the reduction of scheme contributions. Finally, a reduction in ARV prices would allow for a comprehensive approach to the treatment of HIV/AIDS, which in turn would go some significant way towards mitigating the impact of the HIV/AIDS epidemic in South Africa. This is through extending lives, and providing incentives for early testing and treatment, and reducing the number of orphans.

Extract from **Expert Annexure AVDH – Expert Affidavit by Alexander Marius van den Heever: Medical Schemes and Pricing Analysis**

Alexander van den Heever
EXPERT WITNESS

Alex is a health economist with a specialised interest in social and health development. Alex also works as a technical advisor to the Council for Medical Schemes. He was one of the key drafters of the Medical Schemes Act and is active through his role as technical advisor to ensure that the Act is properly implemented. More recently, he was appointed as the co-ordinator of the Social Security Committee of Inquiry (the Taylor Committee), which considered, among other issues, introducing a Basic Income Grant.



Matomela Paul Ngubane
TWELFTH COMPLAINANT

Paul died of an AIDS-related illness on 16 June 2003.

He was a policeman who recently publicly disclosed his HIV status, despite being diagnosed in 1999. He worked for the South African Police Service (SAPS) for 12 years. He was a specialist in crowd management and control.

Paul had been on antiretroviral drugs for some time. On two occasions he interrupted his treatment because the cost was becoming unaffordable.

Because Paul worked for the SAPS he was a member of the Police Medical Aid Scheme (POLMED). POLMED paid for his treatment for HIV/AIDS, although this chronic medication benefit is limited to R 15 400 per family per year.

Paul's youngest daughter has a heart condition that will be treated by the state until she turns six. One of Paul's greatest fears was that his family's annual chronic medication benefit would not cover the costs of both treatments.

Matomela Paul Ngubane personally experienced the impact of belonging to a medical scheme that provides limited cover for the treatment of chronic conditions, including HIV/AIDS.

Matomela Paul Ngubane

I was back in KZN (based in Pietermaritzburg) on detached duties when the Treatment Action Campaign (TAC) had a protest in Durban on 5 March 2001. It was a Monday. I had read in the newspaper that the TAC would be campaigning for drugs in Durban. I took a taxi on my own and went to Durban. It was explained that ARV drugs are too expensive for most people to pay, which is why people do not have access to these drugs. I felt that I was one of these people who did not have access to these drugs. It was the first time I got involved in the TAC. I joined them because they were campaigning for something that I needed to live.

In April to June 2002 I was in KZN again on special duty. I got very sick. I had pneumonia and other AIDS-related illnesses. I tried many different medications.

When I came back to Johannesburg at the end of June I went to another doctor. He put me on ARVs. He got authorisation from the South African Police Service Medical Scheme (POLMED) quickly. My CD4 count was 92 at that time. My viral load was very high. I started to take Videx®, nevirapine (branded as Viramune®,) and Zerit®. The drugs were delivered to my house by Direct Medicines. After two months, I went back to my doctor for a check-up. My CD4 count was 127 and my viral load was undetected.

For the next two months the medication was not delivered to me. I didn't know what the problem was. I phoned POLMED. They said that I had insufficient funds.

I was admitted to the Brenthurst Clinic in November 2002 for 5 days. I had pneumonia. It was treated and I was given ARVs. After I was discharged my ARVs were once again delivered to my house by Direct Medicines. Until today, the medicines are delivered once a month.

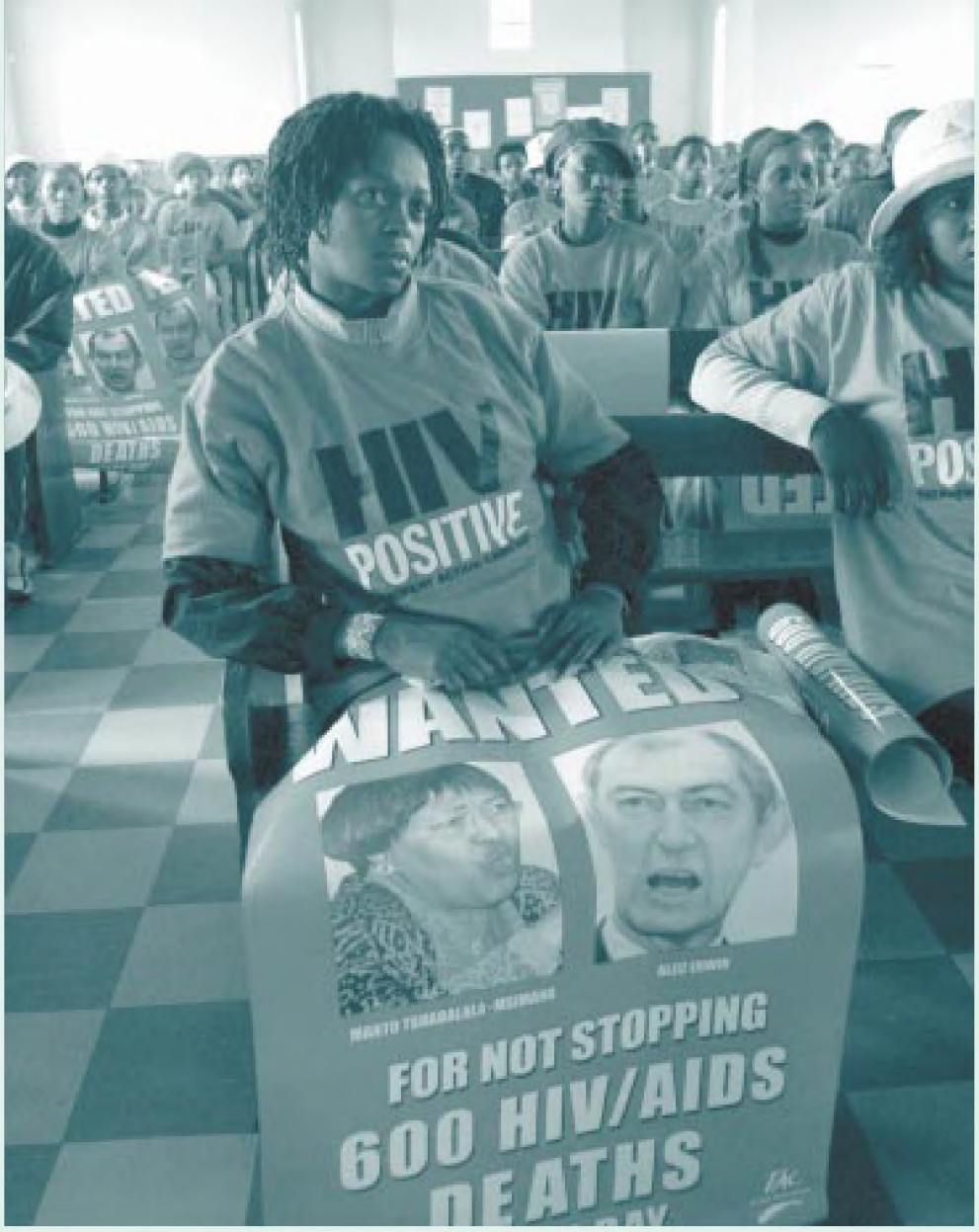
I also have Kaposi's sarcoma, an AIDS-related cancer of the skin. I started chemotherapy to treat the Kaposi's sarcoma in October 2002. I did not get treatment in November because I was too sick and weak for chemotherapy. I started again in December.

At the moment I am doing counselling within the SAPS. They are using me because I am openly living with HIV. I want to tell others that they must not be scared to come out because there is treatment available.

At the moment I am doing great on ARVs, but I am afraid that if I stop the treatment I am on now my health will deteriorate. I am afraid of running out of funds again in POLMED because the ARVs which I need now and those I may need in future are very expensive. At times I think of the money that goes to the ARVs as my daughter also has a chronic disease. Both she and I are on chronic medicines. I have taken her to Chris Hani Baragwanath because I am afraid that my funds will run out quickly. Once she is six she will not be able to get free medication from government hospitals. There is a limit on the amount that POLMED will pay annually for chronic medication for me and my dependents. I am advised that this limit at present is about R15 400 and this includes for ARVs.

Extract from **Annexure MPN – Affidavit of complainant Matomela Paul Ngubane**

On 16 June 2003, Paul died of an AIDS-related illness. He is survived by his wife, an 18-year-old son, a seven-year-old son and a three-year-old daughter.



THE STAR

On 20 March 2003, only days before her death, Kebareng Moeketsi prepares to march on Sharpeville Police Station as part of the TAC Civil Disobediance Campaign

Complaint to the Competition Commission of South Africa

Who, why, what, when?

South Africa, like many other countries, has laws to prevent and eliminate anti-competitive behaviour of companies. The relevant piece of legislation is the Competition Act, 89 of 1998, which created a number of new statutory regulatory and adjudicatory bodies. These are the Competition Commission, the Competition Tribunal and the Competition Appeal Court.

In September 2002, the complaint was filed with the Competition Commission against two multinational drug companies – GlaxoSmithKline (GSK) and Boehringer Ingelheim – and their associated companies.

The complaint was made in terms of section 8(a) of the Competition Act, one of a number of provisions that prohibit companies dominating any particular market from abusing their positions of strength. In terms of the particular section used, dominant firms are prohibited from setting excessively high prices for their products to the detriment of consumers.

Congress of South African Trade Unions
NINTH COMPLAINANT

COSATU is the largest trade union federation in South Africa, with about 2 million worker members and 19 affiliates. COSATU represents about 40% of formally employed workers (excluding domestic and farm workers). COSATU's General Secretary, Zwelinzima Vavi, deposed to an affidavit on behalf of the federation.

The Chemical, Energy, Paper, Printign, Wood and Allied Workers' Union (CEPPWAWU)
TENTH COMPLAINANT

CEPPWAWU is an affiliate of COSATU and represents about 190 000 workers in the chemical, energy, paper, printing, wood and allied workers sectors. CEPPWAWU's General Secretary, Welile Nolingo, deposed to an affidavit on behalf of the union.

[E]xcessive pricing is directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS.

Section 8(a)

Section 8(a) of the Act prohibits dominant firms from charging "an excessive price", which is defined as "a price for a good or service which –
(aa) bears no reasonable relation to the economic value of that good or service; and
(bb) is higher than the value referred to in subparagraph(aa)"

The complaint

"The complainants allege that the companies…have engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by section 8(a) of the Competition Act… The excessive pricing is directly responsible for the premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults".

The complaint contends that the drug companies are charging excessive prices for ARVs sold to the private sector. In particular, the complaint alleges that the prices at which the ARVs are sold cannot be justified, even when the full costs of manufacturing, research and development (R&D) and licensing fees (where applicable) are taken into account, a more than fair rate of return (profit) is considered, and additional profits needed as an incentive to develop new drugs are included.

What is the procedure?

The complaint was lodged in September 2002 on behalf of 11 complainants. Thereafter interested parties were invited to make submissions in support of the complaint and/or to join as additional complainants. By February 2003 two new complainants were included. In addition, a number of interested parties and organisations had submitted information to the Competition Commission in support of the complaint and/or the need for the investigation into the complaint. The list of interested parties includes Action for Southern Africa (ACTSA), Oxfam International, Médecins Sans Frontières (MSF), the Canadian HIV/AIDS Legal Network, the Consumer Project on Technology and the Council for Medical Schemes.

In terms of the Act, the Competition Commission has one year to investigate the complaint whereupon it will either refer the matter to the Competition Tribunal or issue a certificate of non-referral. If such a certificate is issued, the complainants are free to refer the matter themselves.

Once a matter is referred to the Competition Tribunal for adjudication, an open hearing is held. In making its decision, the Tribunal may order appropriate relief. If either party is unhappy with the decision of the Competition Tribunal, it may lodge an appeal with the Competition Appeal Court.

Who are the complainants?

Five of the eleven complainants are people living openly with HIV/AIDS. They are:

- Hazel Tau;
- Nontsikelelo Patricia Zwedala;
- Sindiswa Godwana;
- Isaac Mthuthuzeli Skosana; and
- Matomela Paul Ngubane (deceased)

Four of the complainants are healthcare workers who experience the impact that HIV/AIDS has on their patients and the public and private healthcare systems. They are:

- Sr Susan Roberts;
- Dr William Nkhangweni Mmbara;
- Dr Steven Murray Andrews; and
- Dr Willem Daniel Francois Venter

Two of the complainants represent organised labour. They are:

- The Congress of South African Trade Unions (COSATU); and
- The Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union (CEPPWAWU)

The final two complainants are civil society organisations working directly in the area of HIV/AIDS. They are:

- The Treatment Action Campaign (TAC); and
- The AIDS Consortium

Who are the respondents?

The complaint is against two multinational companies and their South African operations: the UK-based pharmaceutical conglomerate GlaxoSmithKline and the German-based group of pharmaceutical companies, Boehringer Ingelheim.

For ease of reference, the respondents are referred to as GlaxoSmithKline (GSK) and Boehringer Ingelheim.

Why choose these two companies?

This complaint to the Competition Commission is part of a long-running campaign by the TAC, health care workers and organised labour to increase access to essential medicines – in particular, life-saving medicines that are needed by people living with HIV/AIDS. Of the companies that are at present selling ARVs in South Africa, GSK and Boehringer Ingelheim stand out because they charge excessive prices for their drugs while at the same time refusing to allow competition in the private sector.

GSK markets and sells several ARVs and fixed-dose combination ARV drugs that are authorised for use in South Africa. They are:

- zidovudine (AZT), branded as Retrovir®;
- lamivudine, branded as 3TC®;
- abacavir (ABC); branded as Ziagen®;
- amprenavir, branded as Preclir®; and
- AZT/lamivudine, branded as Combivir®

Combivir® is a popular fixed-dose combination that helps to reduce the number of pills or capsules that patients have to take each day.

Boehringer Ingelheim distributes one ARV in South Africa:

- nevirapine, branded as Viramune®.

Some of these drugs are also available in paediatric formulations. This is important because there are now an increasing number of children who are living with HIV/AIDS in South Africa.

The Treatment Action Campaign (TAC)
ELEVENTH COMPLAINANT

The TAC was formed in December 1998. Its mandate is to ensure access to comprehensive treatment for people living with HIV/AIDS. As such, it focuses much attention on improving access to essential HIV/AIDS medicines and health care services.

The TAC is internationally and locally recognised for its lobbying efforts. Like social movements under Apartheid, it too has used civil protest, public and private lobbying and litigation to focus attention on the needs and rights of people living with HIV/AIDS. The TAC has a strong grassroots membership with thousands of volunteers. The organisation has developed a number of literacy programmes that over the years have educated people living with and affected by HIV/AIDS about health, the law and treatment.

TAC draws on its alliances with other social movements and community organisations as well as the labour and religious sectors. Pholokgolo Ramothwala, TAC's Gauteng co-ordinator and an ex-officio member of the National Executive Committee, deposed to an affidavit on behalf of the organisation.

THE AIDS CONSORTIUM

The AIDS Consortium
THIRTEENTH COMPLAINANT

The AIDS Consortium is an umbrella body of more than 1000 AIDS service organisations and individuals working in the area of HIV/AIDS. The Consortium's mandate is to promote openness and non-discrimination. It is actively involved in health policy reform and HIV/AIDS literacy and education programmes.

The Consortium was formed in 1992 and was originally a part of the Centre for Applied Legal Studies (CALS) at the University of the Witwatersrand. It is now an independent NGO. Sharon Ekambaram, the Consortium's Advocacy Officer, deposed to an affidavit on behalf of the organisation.

Why nevirapine?

Nevirapine is a highly symbolic drug in South Africa because of its role in curbing mother-to-child transmission (MTCT) of HIV. One tablet of nevirapine given to a woman in labour and a single dose of syrup given to her newborn child within three days of birth can cut by up to half the chances of the child being infected with the virus during the birthing process. The government's refusal to provide universal access to nevirapine as part of a package of care to prevent MTCT led the Treatment Action Campaign to take the national and provincial departments of health to court. A lengthy battle – during which the Treatment Action Campaign won every court decision along the way – culminated in the state losing its final appeal before South Africa's highest court, the Constitutional Court. The publicity generated by the court case means that nevirapine is probably the most well known ARV in South Africa. While Boehringer Ingelheim offers to provide the state with nevirapine at no cost for its constitutionally mandated MTCT prevention programme, it continues to charge an excessive price for the same drug as part of chronic treatment for the management of HIV infection. The complaint before the Competition Commission addresses this issue.

Establishing the abuse of market dominance

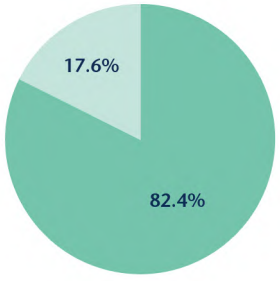
The lack of competition in respect of ARVs, has led to drug companies effectively having monopoly powers. Some have abused these powers by charging excessive prices. This is important because the Competition Act does not prohibit the holding of monopoly power, but rather the abuse of such power. In addition, only firms that control at least 45% of any particular market are automatically subject to the abuse of dominance provisions.

Both GSK and Boehringer Ingelheim exceed this amount, if the relevant markets to be considered are based on the therapeutic classes of ARVs. In 2001 for example, GSK accounted for an astounding 82.4% share of sales for nucleoside analogue reverse transcriptase inhibitors (NRTIs). In the same period, Boehringer Ingelheim had a 52% share of sales for non-nucleoside reverse transcriptase inhibitors (NNRTIs).

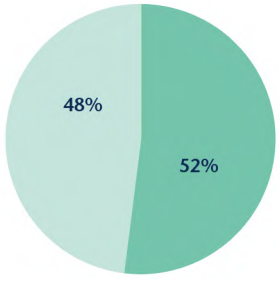
It is by no means clear that the relevant markets should be so generously defined. Instead, the complainants argue that the relevant markets to consider are the markets for each individual drug. This is because even within therapeutic classes, the science of treatment dictates that ARVs cannot be considered as substitutable for each other. If this is correct, GSK and Boehringer Ingelheim control 100% of the market in respect of each of their ARVs.

Market dominance

Nucleoside Reverse Transcriptase Inhibitors



Non-nucleoside Reverse Transcriptase Inhibitors



Proving excessive pricing

The basis of the complaint to the Competition Commission is that the drug companies are using their market dominance to charge excessive prices for ARVs to the detriment of consumers. The complaint draws a comparison between the private sector prices of patented ARVs; the prices charged for patented ARVs to certain developing country governments and not-for-profit treatment programmes; the prices of generic ARVs recognised by the World Health Organisation (WHO) as being of acceptable quality, efficacy and safety; and the prices of the cheapest generic ARVs available.

The prices listed reflect the state of play at the time the complaint was lodged. In April 2003, GSK further reduced its prices for governments and not-for-profit treatment programmes, while its private sector prices – the subject of the complaint – remain untouched.

The prices at which the relevant antiretroviral drugs are sold to the private sector in South Africa were provided by GSK and Boehringer Ingelheim themselves.

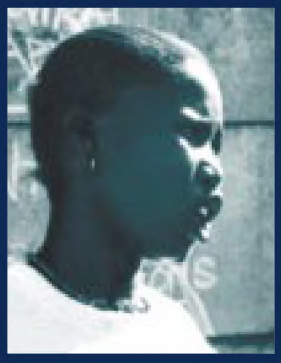
Best price offers are the special deals which GSK and Boehringer Ingelheim had made to developing countries. For nevirapine this "best price offer" was approximately the same as the private sector price. The best price offer for the GSK drugs was lower than private sector price – but the offer does not apply outside the state and not-for-profit sectors.

The generic drug prices are for bio-equivalent drugs which are certified to be as good as the brand name drugs.

As a guide to how low manufacturing costs may be, the table includes the very lowest prices charged for the drugs by generic manufacturing companies. Despite including a profit margin, these generic prices are substantially below the brand name prices. For purposes of the analysis, an exchange rate of US$1 = Rand 10,50 was used.

Annual costs of antiretroviral therapy per adult or child

Product		Price sold to private Sector	International best price offer – branded product	WHO pre-qualified generic	International best price offer – generic
AZT	Rand	7,082.46	4,599.00	1,890.00	1,470.00
(300mg)	US$	674.52	438.00	180.00	140.00
Lamivudine	Rand	7,786.67	2,457.00	1,050.00	693.00
(150mg)	US$	741.59	234.00	100.00	66.00
AZT/lamivudine	Rand	9,733.33	6,515.25	2,782.50	2,142.00
(300mg/150mg)	US$	926.98	620.50	265.00	204.00
Nevirapine	Rand	4,380.00	4,599.00	1,743.00	1,176.00
(200mg)	US$	417.14	438.00	166.00	112.00
AZT	Rand	5,545.52	-	1,290.42	-
(50mg/5ml solution)	US$	528.14		160.60	
Lamivudine	Rand	4,288.90	-	919.80	-
(10mg/ml solution)	US$	408.47	_	113.88	_



Sindiswa Godwana
THIRD COMPLAINANT

Sindiswa is thirty-two years old. She has two children. She was first diagnosed with HIV in 1999. In the same year she publicly disclosed her status. At present she is a member of the Treatment Action Campaign's National Executive Committee.

In 2001 Sindiswa was told that her CD4 count was below 200, and that her viral load was high. She was advised that she should begin taking antiretroviral drugs. Because Sindiswa was unemployed at the time she agreed to take part in a clinical trial that was taking place in Cape Town. In April 2001 she commenced the trial where she was given free antiretroviral treatment. At the moment she is taking a combination of lamivudine, d4T and efavirenz. After starting treatment, Sindiswa's CD4 count is now more than 400, and her viral load is undetectable.

"When the trial ends next year my fear is that I will not get the drugs anymore, and that my viral load will go up and that I will get infections again and my CD4 count will be low again. I cannot afford to pay for these drugs, and I do not want to get sick.

I would like those who are not on treatment to also get these drugs. I see them suffering and this does not make me happy. Some people do not get drugs because they are scared of becoming known and they just stay at home and die."

But these disparities, glaring as they are, do not in and of themselves make out a case of excessive pricing. The complaint is not that the drugs are being sold at too high a price, but rather that there is no justifiable or reasonable basis for setting the prices so high.

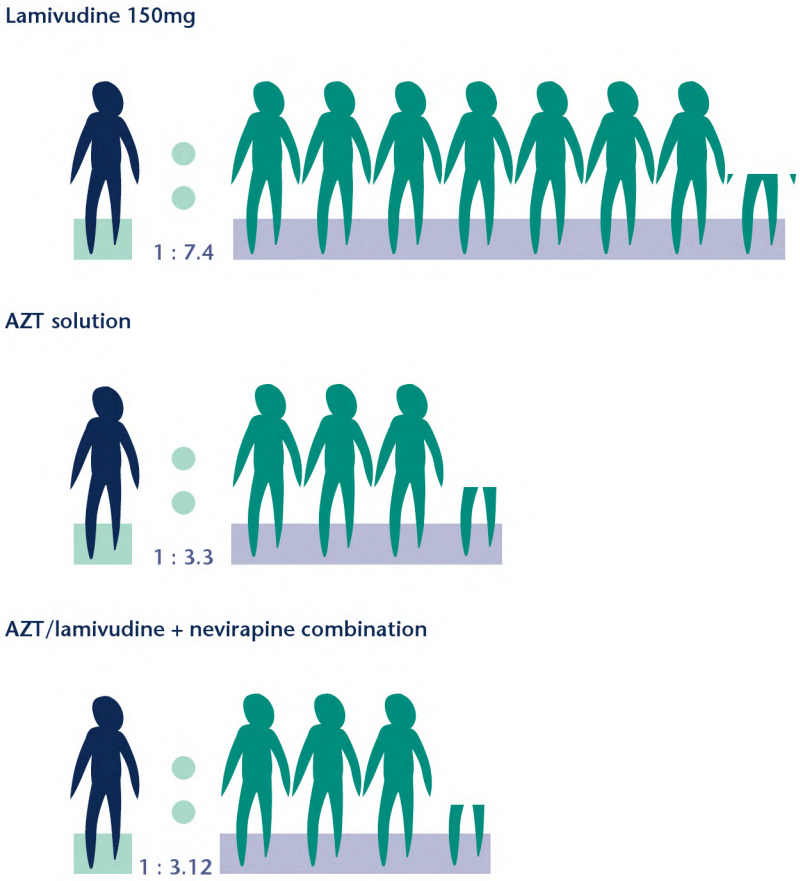
The complainants make out a case of excessive pricing based on the average costs of R&D, as provided by the drug companies themselves. But the evidence suggests, however, that the actual costs of R&D incurred in respect of the ARVs that are the subject of the complaint, are substantially lower than the average R&D costs relied on.

The complainants have therefore requested that the Competition Commission use its legal powers to:

> "obtain detailed information from the respondents and others in order to ascertain both the true relevant R&D costs and the actual rates of return which they are enjoying in respect of the ARVs which are the subject of the complaint. The pharmaceutical industry is notorious in its refusal to make publicly available this information. However, the respondents cannot withhold the [information] from an investigation carried out in terms of the Act."

Statement of Complant to the Competition Commission

How many people can be treated (per year) using generics for every person using brand-name drugs



To prove excessive pricing, the Act requires a complainant to show that the price charged for the product in question "bears no reasonable relation to the economic value" of that particular product. But the Act provides no definition of economic value, and there are not yet any decisions of the Competition Tribunal dealing with the issue.

In calculating a reasonable economic value for the drugs, the complainants have deliberately been generous in favour of the drug companies. Estimating the economic value of the various ARVs in question involved an analysis of the estimated costs of manufacturing, R&D, licensing fees (where applicable) and the average rate of return on revenue for the pharmaceutical industry.

Because information about the true manufacturing costs of the drugs is difficult to obtain from the drug companies, the pricing analysis considers the retail prices of WHO-approved generic drugs as manufacturing costs. But such prices already include a profit margin for the generic manufacturer, meaning that the "manufacturing cost" used by the complainants is already an inflated cost.

Calculating economic value

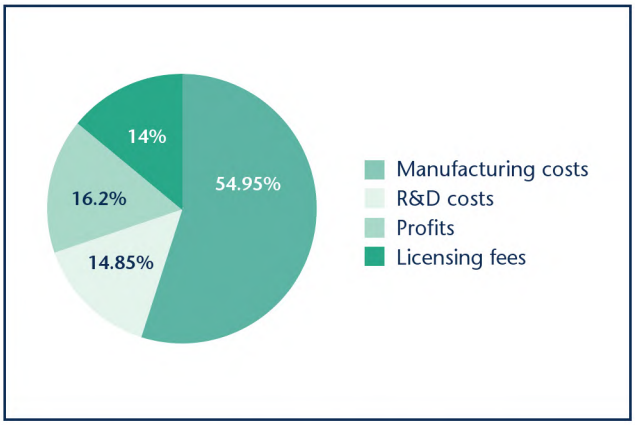
The complainants argue that the estimated economic value of any patented drug is made up of the following components:

* Manufacturing costs;
* Additional profit margins;
* R&D costs, where applicable; and
* Licensing fees (or royalties), where applicable.

Take 3TC® (lamivudine) as an example:

According to Fortune Magazine, the top performing pharmaceutical companies recorded a 16.2% average return on revenue (or profits) in 2001. In addition, GlaxoSmithKline (GSK) claims that it spends 14.85% of its revenue on R&D. Further, it is estimated that GSK pays a 14% royalty for the right to manufacture and market the drug which it did not discover or develop.

Taking these three figures into account (even though R&D costs were not actually incurred by GSK in this case), 45.05% of the estimated economic value of 3TC® is made up of additional profits, R&D costs and licensing fees, with manufacturing costs accounting for 54.95% of the economic value. Looked at differently, the estimated economic value of 3TC® is 1.82 times (100% divided by 54.95%) the manufacturing cost.



As no actual manufacturing cost for 3TC® is known by anyone other than GSK, the estimated economic value is based on the price of the cheapest generic lamivudine recognised by the WHO as being of acceptable quality, efficacy and safety. In other words, the estimated economic value of one 150mg tablet of 3TC® is 1.82 x US$0.14 = US$0.25.

The two tables below compare the estimated economic values of each ARV in question with the price charged by GSK or Boehringer Ingelheim to the private sector. In respect of each product, the tables set out the ratio of private sector price to estimated economic value, to give an idea of the extent to which the prices charged are in excess of what might be considered as a reasonable or justifiable price.

Comparison between prices charged and economic value for adult antiretroviral therapy

Product		Price charged to private sector	WHO pre-qualified generic	Estimated economic value	Ratio: private sector to economic value
AZT	Rand	9.70	2.59	3.76	2.58
(300mg)	US$	0.92	0.25	0.36	
Lamivudine	Rand	10.67	1.46	2.66	4.01
(150mg)	US$	1.02	0.14	0.25	
AZT/lamivudine	Rand	13.33	3.81	5.94	2.24
(300mg/150mg)	US$	1.27	0.36	0.57	
Nevirapine	Rand	6.00	2.39	3.49	1.72
(200mg)	US$	0.57	0.23	0.33	

Comparison between prices charged and economic value for paediatric antiretroviral therapy

Product		Price charged to private sector	WHO pre-qualified generic	Estimated economic value	Ratio: private sector to economic value
AZT	Rand	69.06	16.07	23.29	2.97
(50mg/5ml solution)	US$	6.58	1.53	2.22	
Lamivudine	Rand	97.92	21.00	38.22	2.56
(10mg/ml solution)	US$	9.33	2.00	3.64	

In order to make out a case that the prices charged are unjustifiable and that there is no "reasonable relationship" between such prices and the estimated economic values of each ARV in question, the complaint takes the following considerations into account:

- The price in a competitive market (where there is no patent protection), which includes a normal rate of profit;
- A reasonable surplus to recoup the R&D costs involved in developing the drug in question;
- An additional level of profit to encourage drug innovation;
- The extent to which consumers are adversely affected by the high prices of drugs; and
- The impact of price on human rights, especially those that are protected by the Constitution.

After weighing up these various factors, the complainants argue that the prices charged by GSK and Boehringer Ingelheim for their ARVs are "grossly disproportionate" to the economic value of the drugs and are therefore excessive.

In his affidavit, health economist Alex van den Heever provided an expert opinion on the pricing analysis. He confirmed that the calculation of the economic value of the drugs was skewed in favour of the drug companies. In his view, the values attributed to the drug companies' R&D costs were overly generous, since a large part of such R&D was actually funded by public institutions and not by the drug companies themselves.

In addition, van den Heever argued that the pricing analysis did not take into account the profits already received by the drug companies and did not set those off against the capital costs of creating and manufacturing a new drug. Further, the analysis did not take into account lower per unit costs that would result from making the drugs more widely available.

Alex van den Heever

> Taking the above into account, I am able to conclude that in respect of the ARVs that form the subject of this complaint, excessive prices are being charged to the private sector. My support for the conclusions reached is subject to the proviso that, in all probability, the complainants understate the extent of the excessive pricing. The full extent of this under-statement would require further investigation by the Commission.

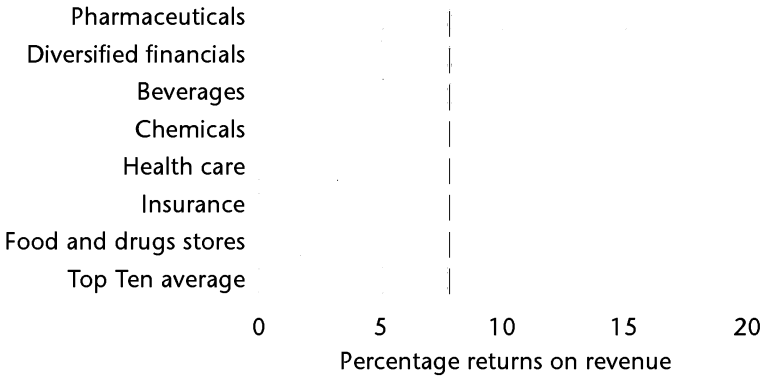
Extract from **Expert Annexure AVDH – Expert Affidavit by Alexander Marius van den Heever: Medical Schemes and Pricing Analysis**

Will the real research and development costs please stand up!

Drug companies usually attempt to justify charging high prices by pointing to R&D costs which they argue are very high. They further argue that of the many compounds that they research, only a small number actually make it to market and an even smaller number are commercially successful. As a result, successful drugs have to cross-subsidise the others.

Such an argument makes no sense when one considers just how profitable the pharmaceutical industry really is. According to Fortune Magazine's 2002 Global Report on the Top Performing Companies and Industries (which is referred to by the complainants), the average return on revenue in the pharmaceutical industry is 16.2%. This is more than double the average return on revenue of 7.92% for the top ten industries.

Market dominance



Jamie Love, an international expert on intellectual property rights and trade issues, was asked by the complainants to submit an expert affidavit on R&D costs. Love is highly critical of those studies that, in his view, vastly inflate the real costs of R&D involved in drug discovery and development. In his affidavit, Love uses hard data to show that the actual costs of R&D spent by drug companies in respect of many ARVs cannot be more than a small fraction of the figures claimed by the industry. He explains:

Jamie Love
EXPERT WITNESS

Jamie is the Director of the Consumer Project on Technology, which is part of the Center for the Study of Responsive Law in Washington DC. Jamie is an expert on intellectual property law and has a special interest in protecting and educating consumers about their rights. He has done extensive work on the legal options available to developing countries to improve access to medicines. He is also a consultant to a number of international organisations.

Jamie Love

There was considerable confusion over a series of studies of drug development costs that were based upon the work of Joseph DiMasi and his colleagues …

There were several misunderstandings regarding the estimates based upon DiMasi's work. The US$ 231 to US$ 802 million figures [for development of a new drug] were estimates of the costs of doing both the early discovery and pre-clinical work, the clinical trials and FDA regulatory approval. For many drugs, the US government paid for either the pre-clinical or the clinical work. In those cases, the companies' costs were lower.

In addition, these figures were largely based upon adjustments for both risk and huge cost of capital assumptions, and not actual expenditures on R&D. Few policy makers, journalists or analysts bothered to make the distinctions. The cost of capital assumptions were also controversial. Some estimates were based upon extremely aggressive estimates of the capital costs, as high as 15% plus inflation for some cases, and this was on top of the adjustments to compensate for R&D failures.

The high capital cost was also based upon assumptions of very long lead times for development, something that does not reflect either recent industry experience, or historical data on AIDS drugs.

Extract from **Expert Annexure JPL – Expert Affidavit: James Packard Love**

When considering drug development costs it is important to examine the various stages of R&D that the drug has undergone, and who was responsible for the funding of these particular stages. Most basic science research, where the chances of making a significant breakthrough stand at approximately 1 in 10 000, is publicly funded. In fact, many new drugs are partially or wholly discovered and developed by public sector bodies (such as public universities) or private bodies receiving public sector funding (such as private universities).

Further, as a compound moves through various human clinical trials (which test safety and efficacy), the risks of failure drop dramatically. For example, approximately 20% of drugs in Phase 1 trials (which include very small numbers of people) make it to market, compared to 50% in Phase II and 70% in Phase III. Phase III trials also have much larger numbers of participants. Drug companies usually enter the picture only when the risks of failure have been reduced to these levels.

This is clearly demonstrated by the development and commercialisation of AZT, which was substantially researched and developed using public funds.

AZT was initially synthesized in 1964 by Dr Jerome Horowitz of the Michigan Cancer Foundation, under a grant from the National Cancer Institute (NCI). In 1974, Wolfram Ostertag of the Max Planck Institute demonstrated the effect of AZT on animal retroviruses.

NCI staff, working with Duke University, developed and first applied the technology to find out whether AZT and similar drugs could suppress HIV in human cells. The researchers, none of whom were employees of GSK or any of its constituent companies, were the first to give AZT to a person with AIDS, and also conducted the first clinical trial into the drug.

Using this extensive and advanced research, Burroughs Wellcome (BW), now GSK, received approval from the US Food and Drug Administration to market AZT on 19 March 1987. BW was also entitled to receive a tax credit of 50% of the costs of conducting US clinical trials, because AZT was designated as an orphan drug (one that targets a disease affecting less than 200 000 people).

In the 2002 financial year, sales of AZT in South Africa were R9 251 000 or 1.1% of total world sales of US$80 million. Considering GSK's R&D costs to commercialise AZT (on the basis of Love's analysis of orphan drugs), the total costs of R&D that would need to be recouped from South African sales are approximately R438 000, or roughly 4.7% of sales for a single financial year (2002).

In July 2002 the ALP conducted research into the extent to which public money

has funded ARV clinical trials. The investigation found that of all 21 current clinical trials involving AZT in the US, not one is wholly sponsored by a private company. Twenty of the trials are being wholly sponsored by a range of publicly funded health institutes. The remaining trial is jointly sponsored by the US National Institute of Allergy and Infectious Diseases, and three private firms, of whom one is GSK.

Jamie Love concludes his analysis of R&D costing by focusing on R&D costs in respect of ARVs:

Jamie Love

> HIV drugs have smaller populations in clinical trials and shorter time to market than do many other products ... HIV drugs also benefit from significant US government support for all phases of research and development, including support for clinical trials, although the exact nature of such support varies widely from drug to drug. There is also evidence that many commonly held views on the costs of new drug development are not supported by the empirical evidence concerning the costs of clinical trials.

Extract from **Expert Annexure JPL – Expert Affidavit: James Packard Love**

Under what circumstances would the complainants withdraw the complaint?

If the drug companies issued non-exclusive and unrestricted voluntary licenses for the importation and local production of generic ARVs, in return for a royalty fee of 4 to 5% of sales, the complainants would seriously consider withdrawing their complaint. In effect, this would mean that the only condition to be attached to the licenses would be registration with the South African Medicines Control Council (MCC), the regulatory body responsible for the registration of all medicines in South Africa. By law the MCC may only register drugs of proper safety, efficacy and quality. By mid-2003 a number of generic ARVs had already been registered by the MCC for use, with many other registrations in the pipeline.

Alternatively, government could use the provisions of the Patents Act to issue compulsory licenses for the importation and local production of generic ARVs. In short, nothing less than the opening of the private sector to generic competition would suffice.

What is at stake?

If the Competition Tribunal finds that the drug companies have contravened the provisions of the Competition Act, GSK and Boehringer Ingelheim could be faced with one or more of the following orders:

- An order to the effect that they must stop charging excessive prices for their drugs;
- An order to the effect that their conduct is a prohibited practice in terms of the Competition Act, which would open the door for a class action suit for civil damages by people who have suffered actual loss as a result of the unlawful conduct; and
- An administrative penalty of up to 10% of each company's annual turnover in South Africa.

Any adverse finding by the Competition Tribunal and/or the Competition Appeal Court against the drug companies would result in negative publicity both locally and internationally. Such publicity may be more costly than authorising generic competition. One need only remember the course of events accompanying the challenge by the Pharmaceutical Manufacturers' Association of South Africa to the Medicines and Related Substances Control Amendment Act, 90 of 1997, to recognise this.

PHOTO:JOAO SILVA/PICTURENET AFRICA

TAC activists hold hands during a march through Pretoria protesting the high cost of ARVs and other essential medicines. The march was triggered by pharmaceutical company attempts to stop legislation which would allow government to increase access to affordable medicines.

The way forward

On 16 June 2003, the price of life eventually proved to be too expensive for Paul Ngubane, the twelfth complainant. At the age of 41 and on the anniversary of the Soweto uprising, he died of an AIDS-related illness, long before the complaint to the Competition Commission will reach finality.

Although any resolution of the excessive pricing complaint will come too late for Paul, it has already contributed to a renewed focus on the pricing practices of multinational pharmaceutical companies, increasing pressure on them to reduce their prices.

In May 2003, for example, the Organisation for Economic Co-operation and Development (OECD) published a peer review report on competition law and policy in South Africa.[1] In its report, the OECD makes a number of references to the legal and social importance of the complaint to the Competition Commission.

In discussing the Competition Act's abuse of dominance provisions, the report

states that the complaint may compel the Competition Commission and the Tribunal—

> "to decide about how the Competition Act can be used to control prices in a case that presented two complicating factors: the relationship between competition policy and intellectual property rights, including international recognition of those rights; and the public interest in dealing with the large-scale public health problem represented by AIDS." [2]

The report also states that:

> "[t]he subject is timely and important, not only to South Africa but to many other countries. The legal, economic and policy issues raised are at the cutting edge of developments in international competition and intellectual property law and policy. The case could be an occasion … to compare views about the thornier legal and analytical issues about intellectual property rights and the relationships with international trade commitments and obligations."[4]

In early 2001, the legal challenge brought by the Pharmaceutical Manufacturers' Association of South Africa against the South African government's attempt to amend medicines legislation in order to increase access to medicines resulted in a spotlight being turned onto the greed and profiteering of the pharmaceutical industry. Litigation launched to defend its "interests" caused the industry immense embarrassment worldwide.

In order to contain their embarrassment, the prices of many antiretroviral medicines (ARVs) tumbled. In South Africa, for example, the price of triple combination antiretroviral therapy fell quickly by over 60%. However, when the attention shifted from drug company profiteering to the South African government's own indefensible omissions of policy in the treatment of people living with HIV/AIDS, the prices settled at a level which, whilst affordable for some, remained out of reach for many more.

TAC's engagement with the multinational pharmaceutical companies is based on the understanding that the right of access to health care services, which includes a right of access to essential medicines, is a fundamental human right. By restoring health and improving the quality of life, essential medicines uphold the right to dignity, a fundamental human right.

Apart from raising important legal issues, the complaint to the Competition Commission will resume the pressure on lowering the prices of essential medicines for treating HIV/AIDS. It is probably no coincidence that in March 2003, GSK announced significant new price reductions on its ARVs.

But these price reductions, although welcomed by TAC and its allies, will not lead to the complaint against GSK (or Boehringer Ingelheim) being withdrawn, because the preferential prices are only available to governments, not-for-profit organisations and employer-funded workplace treatment programmes. The excessively high private sector prices, the focus of the complaint, remain unaffected.

1 "Competition Law and Policy in South Africa: an OECD Peer Review", available online at http://www.oecd.org/pdf/M00042000/M00042198.pdf.

2 At 26-27.

3 At 71-72.