

Chapter 2

Litigation and legal services

By Brian Honermann and Jonathan Berger

Over the past 18 months, the ALP has continued to use litigation and provide other legal services to protect and advance the rights of people living with HIV, as well as to achieve other key objectives set out in our mission statement. In this regard, we continue to push for increased access to health care services, for greater accountability on the part of government officials, and for health care workers – particularly in the public sector – to be permitted and enabled to provide the most appropriate medical care in the circumstances.

As always, access to justice, particularly for those living with HIV, has also remained a key theme of our work in general. However, as chapter 4 explains, the ALP decided in 2007 to close down its paralegal unit and to focus instead on building capacity within the broader law and human rights sector to deliver such services. As our previous 18-month review explained:

[T]here is a need to expand paralegal services more broadly – amongst advice offices and other social and legal organizations – so that the public is not solely reliant on the ALP. While our main objective is to undertake work that will have a public impact, we see ... that many complaints in fact deal with issues that have already been settled in law. For example, despite a strong legal framework that prohibits unfair discrimination in the workplace on the basis of HIV/AIDS status, a large number of complaints we receive deal with workplace issues. Fortunately, a single letter alerting the employer to the relevant provisions of the law is often all that it takes to resolve matters successfully.¹

Several of the cases considered in this review have been on the ALP's books for an extended period of time. We are happy to report that almost all of these cases have been successfully resolved. At the time of writing, only one case – *Treatment Action Campaign v Minister of Correctional Services and Another* – remains live. Judgment in this case, which deals with a request for access to a report of the Judicial Inspectorate of Prisons, was delivered on 30 January 2009. Three weeks later, the state filed its application for leave to appeal. As is explained below, the ALP already has a copy of what we have long referred to as the “MM report”.

This chapter focuses on three categories of cases: professional ethics, dual loyalties and political intimidation; holding the state to account; and ensuring access to health care services. In addition, it

1. At page 38

considers a number of important matters that do follow these trends. It does not address two central aspects of the ALP's work over the period under review: the struggle to bring the protocol dealing with the prevention of mother-to-child transmission of HIV (PMTCT) in line with international good practice; and the successful challenge to the military's HIV testing policy. Instead, these matters are addressed in Mark Heywood's introduction and chapter 1 respectively.

Professional ethics, dual loyalties and political intimidation

In our previous review, we reported that Dr. Costa Gazi – who, whilst working at Cecilia Makiwane Hospital in East London in 1999, was disciplined for publicly criticising a former Minister of Health – had been successful in his appeal before a full bench of the Pretoria High Court. In this review, we report on three similar matters involving public sector doctors who have suffered the consequences of exercising their right to freedom of conscience. The first case involves Dr. Malcolm Naude and his lengthy legal battle to overturn his unfair dismissal from service at Rob Ferreira Hospital in Nelspruit, Mpumalanga. The second and third matters involve Drs. Colin Pfaff and Mark Blaylock and their battles to withstand political intimidation at Manguzi Hospital in rural KwaZulu-Natal (KZN).

Naude v MEC for Health and Social Services, Mpumalanga

Naude's case arose as far back as 2001, shortly after he was appointed a junior medical officer at Rob Ferreira Hospital. At that time, the Greater Nelspruit Rape Intervention Project (GRIP) – another ALP client – was resisting eviction from the hospital by the then MEC for Health, Sibongile Manana. GRIP had found itself in the MEC's firing line because of the post-exposure prophylaxis (PEP) services it was providing to rape survivors.² So too did the hospital's superintendent, Dr. Thys von Mollendorff, who had given GRIP permission to do so.³

Naude's "sin" was to depose to an affidavit in support of GRIP's attempts to remain in the hospital and provide the much-needed services. Manana – a disciple of the former Minister of Health who had also publicly stated opposition to the use of anti-retroviral (ARV) medicines – took swift action. Whilst on a leave of absence to work in the UK to pay off his student debt, Naude was dismissed. It would take almost seven years for his case to come to trial in the Labour Court.

In response to his claim of unfair dismissal, Manana claimed that her department had not employed Naude after his term as a community service doctor ended. This was contrary to the established practice in Mpumalanga in terms of which community service doctors were routinely offered full-time employment, in large part because of the difficulties in recruiting and retaining medical personnel in the province. In his judgment delivered on 21 October 2008,⁴ Acting Justice Cagney Musi found that the MEC's witnesses were not credible in their denials that Naude had been employed, finding that he had indeed been dismissed for exercising his freedom of conscience:

[Naude] took a principled stance against the [MEC's] policy not to give rape survivors access to ARVs. [The MEC] did not even want doctors to prescribe ARVs for patients in order for them



Dr. Malcolm Naude, formerly of Rob Ferreira Hospital, Nelspruit, Mpumalanga

2. At the time, the public sector did not provide PEP services. Importantly, GRIP also provided much needed counselling services to rape survivors, as the hospital only had four counsellors in its employ. As a funded not-for-profit organisation, GRIP did not charge for its services.
3. Dr von Mollendorff was dismissed for allowing GRIP to operate within the hospital. While he was ultimately successful in challenging his dismissal, this happened only after he left the public sector's employ.
4. *Naude v Member of the Executive Council, Department of Health, Mpumalanga* (J5331/2004) [2008] ZALC 158 (21 October 2008)

to purchase it, with money that GRIP sourced, at a private pharmacy. Von Mollendorff was requested, no instructed, to convey this to the doctors at [Rob Ferreira Hospital]. He informed the doctors but also requested them to act according to their consciences.

[Dr Naude's] stance against the [MEC's] irrational policy in favour of his conscience and professional ethics was in my view the determinant and, dare I say, the only reason why he was dismissed. His dismissal was therefore automatically unfair.⁵



The Star (15 May 2008)

Naude was awarded R100 000 in compensation. After returning from the UK in early 2002 he continued studying and thereafter entered private practice. In January 2009, Naude left for a six-month contract in Australia. He is planning to return to South Africa thereafter.

Pfaff, Blaylock and the MEC for Health in KwaZulu-Natal

In his introduction entitled "No easy walk to constitutional governance: the small matter of a health system", Mark Heywood describes the politics surrounding the MEC's attacks on Colin Pfaff and Mark Blaylock. This chapter sets out the facts of the two cases, as well as the steps taken by the ALP and others to protect the doctors. Tragically, as indicated in Heywood's introduction, the 2008 cases show that the only thing we learn from history is that we learn nothing from history. Despite "losing" the battle to discipline Pfaff and Blaylock, Nkonyeni's attacks resulted in the two doctors being driven out of KZN.



Dr. Mark Blaylock, formerly of Manguzi Hospital, Umkhanyakude District, KwaZulu-Natal (Reproduced with kind permission Health-e News Service)

Pfaff's case began in 2007, when – as Chief Medical Officer at Manguzi Hospital– he began to implement an improved PMTCT protocol using donor funds he had secured from a UK-based not-for-profit organisation. The key elements of the improved protocol, which are now an integral part of accepted Department of Health (DoH) policy, had not yet been implemented in the public sector outside of the Western Cape. Instead, the PMTCT programme was still making use of its initial protocol adopted as far back as 2001, at a time when the programme was restricted to two "pilot sites" per province.

Manguzi's PMTCT programme did not initially make headlines. Instead, Pfaff, Blaylock and their dedicated staff quietly went about their business of deliver-

5. At paragraphs 107 and 110

ing quality health care services in this rural part of the province. Towards the end of 2007, however, their programme caught the MEC's attention. Like Manana, Tshabalala-Msimang and Mbeki,

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For his efforts, Dr Pfaff was threatened in early 2008 with disciplinary action – for “wilfully and unlawfully” rolling out “dual therapy” for the purposes of PMTCT. The widely used misnomer – the intervention is prophylactic rather than therapeutic – refers to the use of two ARV medicines for PMTCT, ordinarily AZT from 28 weeks of pregnancy until delivery, as well as a single dose of nevirapine during labour and an additional dose of nevirapine for the newborn within 72 hours of

delivery. The old protocol is limited to a dose of nevirapine for both mother and child.

As if to up the ante, Nkonyeni visited Manguzi Hospital on 12 February 2008 and told hospital staff the following:

AZT is toxic and must be controlled. Dual therapy has not yet been agreed upon. ... We have a problem with doctors who work in rural areas. They do not care about people. It is all about profit, not about caring for people. ... I have heard that ARVs have bad side effects, especially [in] children.

Upon hearing of the MEC's speech attacking him, Pfaff and their colleagues, Blaylock removed a picture of her from the hospital wall. In anger and disgust, he placed it in the bin, an action for which he was subsequently required to apologise.

Although the ALP did not formally represent Pfaff in defending the disciplinary charges, it assisted him throughout his ordeal – drafting crucial letters to provincial health authorities on his behalf, providing legal advice and ensuring that his case received significant public exposure. Under pressure from many sides, Nkonyeni's department eventually withdrew the charges against him. But despite this, the MEC dispatched a task team to Manguzi Hospital to “investigate the conduct” of Pfaff and Blaylock.

Nkonyeni used her budget speech of 29 April 2008 to “justify” her decision to appoint the task team “as a matter of urgency”.⁶ After claiming that she had “been informed by media reports and managers and staff in the department of other allegations of racism, ill treatment of staff and abuse of departmental facilities by Dr Blaylock and some doctors operating at some ... rural facilities”, she proceeded to abuse her constitutional privilege to defame Blaylock by setting out the allegations in some detail.

While Pfaff was interrogated about the provision of HIV-related services at Manguzi Hospital, the task team questioned his colleague about the issues that Nkonyeni had already identified in the KZN Legislature. Blaylock denied the allegations, all of which were subsequently rebuked in a statement issued by his colleagues at the hospital. To date, the task team's report of its “investigation” has not been made public.

Acting on behalf of Pfaff and Blaylock, the ALP filed a complaint in early May 2008 with the South African Human Rights Commission (SAHRC). The complaint requested the SAHRC urgently to investigate whether the MEC's conduct – including the appointment of the task team – violated the rights of Pfaff, Blaylock and those who are reliant on Manguzi Hospital for their medical care. In particular, it asked the SAHRC to investigate the impact of the conduct on:

6. The budget speech is available at <http://www.kznhealth.gov.za/speeches/budget2008.pdf>

- The right to have access to health care services;
- The right to basic health care services for children;
- The right to just administrative action;
- The right to freedom of expression;
- The right to have one's dignity respected; and
- The right to fair labour practices.

Nkonyeni furnished her response to the complaint on 25 August 2008.⁷ It makes for interesting, albeit disturbing, reading. Importantly, the MEC admitted that disciplinary action was initiated against Pfaff “for implementing dual therapy prior to the national policy being approved for rollout throughout the country.” In addition, she confirmed that “Blaylock was charged following the incident where he allegedly threw an official photograph of [her] in the dustbin in the presence of patients and other health care professionals.”

Whilst reminding the SAHRC that “discipline is an administrative function ... which is implemented ... at institution level and supported centrally at head office”, Nkonyeni nevertheless admitted that she “only intervened where it was incumbent upon [her] to do so and where [she] was of the opinion that the behaviour of one or both of the doctors posed a risk to the treatment and lives of public health care users at Manguzi Hospital.” She expressly denied exceeding her legal authority, claiming instead that her interventions were statutorily required.

Nkonyeni’s response is replete with gratuitous attacks on the ALP, seeking to cast significant doubt on our bona fides. More serious, however, are the elements of AIDS denialism that pepper the document. At no point has anyone made out a case that Pfaff and Blaylock were providing patients with inappropriate or substandard care. To the contrary, they were providing the best care possible in the circumstances without imposing any additional burden on public sector resources. Yet, on more than one occasion, the MEC’s response raises the spectre of threats and risks to the health of public sector users.

The ALP filed its reply on 2 December 2008. At the time of writing, some three months later, the SAHRC has yet to make any public pronouncements on its investigation. Unfortunately, this is not the first time the SAHRC has taken its time to investigate HIV-related matters. If and when its report is finalised, it will be too late for the two doctors at the centre of the controversy. At the time of writing, Pfaff was no longer working in Manguzi, but had opted instead to work for a not-for-profit service provider in Mpumalanga. Blaylock, who has left both KZN and the country, is now based in Ghana.

The aftermath

Recent developments in the Free State suggest that the conduct of the former Minister of Health and a few of her provincial counterparts – Manana and Nkonyeni in particular – has given rise to the development and festering of a climate of fear amongst health care workers in the public sector. As we noted in a report on the ARV treatment moratorium in the Free State that lasted from November 2008 to February 2009 and resulted in at least 30 additional deaths each day:⁸

Few public sector doctors working in the provinces from which we have received complaints are willing to go on the record. Most are fearful of retributive action being taken against them, as happened to public servants such as Drs Pfaff and Blaylock (2008 at Manguzi Hospital, KwaZulu-Natal), Dr Costa Gazi (1999 at Cecilia Makiwane Hospital, East London) and Drs

7. The ALP has a copy of the response on file.

8. Information provided by Dr. Francois Venter, president of the Southern African HIV Clinicians Society.

Naude and von Mollendorff (2001 at Rob Ferreira Hospital, Nelspruit, Mpumalanga). We believe that many more complaints and much better information would be available if health care workers were actively encouraged to speak out about their concerns in the public health facilities in which they work.⁹

Shortly before its public release, the report was sent to Barbara Hogan, the new Minister of Health. In a statement that was to have been read out on the Minister's behalf at a civil society meeting in the Free State on 26 February 2009, Hogan addressed these concerns head on.¹⁰ In contrast to her predecessors, who had sought to prevent health care workers from speaking out, the new Minister praised those who had done so:

I would particularly like to applaud health care providers and community organisations who raised the alarm about these issues. By doing so, you are working in the public interest and I wish to encourage you to continue to alert us to these issues through the appropriate channels without any fear of reprisal. My door is open and you are welcome to contact my offices at any time. ...

... At the National Health Council later this week, I will be requesting all provincial health departments to alert us to any stock-outs and shortages that they may face BEFORE any stock-outs occur. However, the continued vigilance of health care providers and members of [civil] society in drawing attention to problem areas as and when they occur is crucial to providing early warnings so that we can intervene timeously.¹¹

Holding the state to account

While ensuring a rights-based response to the HIV epidemic and access to health care services remain at the core of the ALP's work, much of our work seeks to locate health sector reform within a context informed by the Constitution and the broader obligations it places on the state. As chapter 3 shows, this increasingly means a dedicated focus on issues of governance and accountability.

Treatment Action Campaign v Minister of Correctional Services and Another

MM,¹² an inmate at Westville Correctional Centre (WCC) and an applicant in the case that resulted in the Minister of Correctional Services and others being compelled to ensure access to ARV treatment at WCC, died in August 2006.¹³ MM's medical records showed that he was HIV positive, but had only been put on ARV treatment a few weeks before his death. According to government's own ARV treatment guidelines, MM should have been initiated on ARV treatment in November of 2003 – some 32 months earlier.

Shortly after MM's death, the TAC – a co-applicant in the WCC case – requested that the Judicial Inspectorate of Prisons (JIOP) conduct an investigation into MM's death and other related matters at WCC. This investigation took place and was completed in or around December 2006. According to the JIOP, its report on the investigation ("the MM report") was sent to Ngconde Balfour – the Minister of Correctional Services – shortly thereafter. Our repeated efforts – as TAC's legal representatives – to gain access to the MM report were unsuccessful.

As there is strong evidence to suggest that MM's death was caused by the delay in accessing ARV treatment, the TAC felt compelled to invoke legal proceedings to secure a copy of the MM report. After

9. *Antiretroviral Treatment Moratorium in the Free State: November 2008 – February 2009*, available at http://www.alp.org.za/pdf/PressReleases/ConsolidatedReport_FreeState_final20090211.pdf 10

10. The meeting was postponed until a later date

11. The statement is on file with the ALP

12. We use the initials MM in order to protect the privacy of his family.

13. An update on this case is provided below.

the provisions of the Promotion of Access to Information Act 2 of 2000 ("PAIA") were exhausted, the TAC instructed us to file an application on its behalf in the Pretoria High Court to compel the Minister to act.

Amongst other things, the TAC requested the court to direct the Minister to ensure that it is provided with a copy of the MM report. No order was sought against the JIOP, the second respondent in the case. The JIOP did not oppose the application and was cited only for its interest in the matter. The matter was argued in the Pretoria High Court on 11 December 2008.

Court orders Balfour to release report to TAC

FRANNY RABKIN

THE Treatment Action Campaign (TAC) on Friday won a two-year battle to force Correctional Services Minister Ngconde Balfour to release a report on the death of an HIV-positive inmate at the Westville Correctional Centre in Durban.

The inmate, referred to as MM to protect the privacy of his family, died of AIDS in prison in August 2006 after being denied early access to antiretroviral treatment.

Judge Brian Southwood of the Pretoria High Court ordered the minister to hand over unedited, electronic and hard copies of the report. Balfour, who was not present in court, was also ordered to pay all punitive costs.

According to the TAC, the prisoner's condition was such that he should have been on antiretrovirals from November 2004.

MM's medical records showed that he was HIV-positive and a few months prior to his death a medical report said he suffered "bleeding piles, painful rashes on both ears, fungal infections, TB, body rash, general itchiness, oral thrush, lesions, penile sores, mouth sores, septic sores on knees and painful feet".

But he was put on treatment only three weeks before he died and after a court ordered this.

It was for this reason, and because of other deaths in the prison, that the TAC requested the Judicial Inspectorate of Prisons to investigate "culpability" in his death. The Inspectorate said it sent its report to the department in December 2006.

Southwood ordered that the report be given to the TAC, saying that Balfour and the department's conduct in dealing with the TAC's application was "reprehensible".



JUSTICE DELAYED: Jonathan Berger of the AIDS Law Project says it shouldn't have taken two years to get access to the report on an HIV-positive man who died in jail.

Balfour had opposed the application largely on technical grounds. Southwood said it was "disturbing that (Balfour) has relied on technical points which have no merit and instead of complying with its constitutional obligations has waged a war of attrition in the court".

He also dismissed the minister's assertion that he didn't have the report, saying it was "so far-fetched and untenable that it must be rejected".

Southwood also rejected the argument that to deliver the report would be disclosing confidential personal records.

MM's father had said in an affidavit that he objected to access being granted and that it was "an invasion of privacy of the deceased and our family. As a family we would like the deceased's soul to rest in peace."

But Southwood said MM's name had not been disclosed and there was no evidence that there

would be an unreasonable disclosure of personal information.

Jonathan Berger of the AIDS Law Project, which represented the TAC, said: "There was no violation of anyone's rights and there is also a broader public interest in identifying if negligence on the part of any correctional service official was responsible for MM's death."

He said the AIDS Law Project was pleased that it was vindicated but it left a "bit of a sour taste, that it took two years to get access".

Berger said the Promotion of Access to Information Act was being used by some government departments to deny people access to information — rather than to facilitate access, which was its purpose.

Correctional Services spokesman Manelist Wolela said the department "noted the judgment" and had instructed its lawyers to study it, after which a decision on how to proceed would be taken.

In his judgment of 30 January 2009,¹⁴ handed down just a few days shy of two years since the TAC first requested the document, Justice Brian Southwood harshly rebuked the Minister for effectively forcing the TAC to litigate. In ordering the MM report to be provided to the TAC, he commented on the shameful manner in which Balfour and his department had handled the request for the document:

The papers in this case demonstrate a complete disregard by the Minister and his department of the provisions of the Constitution and PAIA which require that records be made available. There is no indication in the first respondent's papers that the Department complied with its obligations under PAIA at any stage. The information officer allowed both the request and the internal appeal to go by default and did not consider it necessary to provide the applicant or the court with any reasons for doing so. Only after proceedings were instituted did the Minister and the Department attempt to justify the failure to hand over the report and then on spurious grounds. It is disturbing that the first respondent has relied on technical points which have no merit and instead of complying with its constitutional obligations has waged a war of attrition in the court. This is not what is expected of a government Minister and a state department. In my view, their conduct is not only inconsistent with the Constitution and PAIA but is reprehensible. It forces the applicant to litigate at considerable expense and is a waste of public funds.¹⁵

On 10 February 2009, the ALP received a copy of the MM report from the JIOP. Despite being requested by the TAC to "investigate culpability in the death of 'MM'",¹⁶ former Inspecting Judge Nathan Erasmus relied almost exclusively on the evidence supplied by the TAC and an in-house "investigation" conducted by the Department of Correctional Services (DCS). Most disturbingly, there is no evidence in his report to suggest that he consulted any independent experts at any point. In considering why it took 32 months for MM to be initiated on ARV treatment, the former inspecting judge appears to have relied largely – if not exclusively – upon explanations provided by DCS and its officials.

It is therefore unsurprising that no one in the department is held to account. Instead, some blame is apportioned to McCords Hospital, a not-for-profit private institution that assists the state by putting public sector patients onto ARV treatment. Without any evidence to support his conclusion that McCords was "supposed to treat [MM]", and notwithstanding the fact that the facility is not a designated public sector site, Justice Erasmus nevertheless refers to it as the "designated hospital". Implicit in his finding is that McCords is – at least in part – responsible for the delay.

Amongst others, the MM report also raises the following concerns:

- The report provides no evidence to support its finding that MM's "medical condition was also of such a nature that the onset of treatment was not possible due to secondary infections."
- The report correctly identifies the issue as whether MM would have survived had he been initiated earlier. But instead of addressing the 32-month delay head on, it suggests that "the onset of other infections" or other "external factors" may have "prevented the introduction of a treatment regime". There is no evidence to suggest that this was put to an independent medical expert.

14. *Treatment Action Campaign v Minister of Correctional Services and Another* (18379/2008) [2009] ZAGPHC 10 (30 January 2009)

15. At paragraph 36

16. Annexure AA2 to the founding affidavit, at paragraph 1

- The report correctly notes that MM "would have at least qualified for ARV treatment during 2003." But, once again, it raises the possibility of ill health being responsible for non-initiation: MM "was constantly ill with opportunistic diseases that could have delayed the activation of ARV treatment." Again, no evidence is provided for this conclusion.
- Despite being prescribed, the report suggests that ARV treatment may not have been the solution to MM's "myriad of medical problems", and that "without fully investigating the connection between the collective diagnosis and treatment ... [i]t is impossible to conclude whether any of the actions or omissions above contributed to the ultimate death."

Nevertheless, Justice Erasmus's report concludes with four important recommendations: first, HIV/AIDS in prisons must be addressed as a matter of urgency; second, government agencies and departments must co-operate with and assist DCS to deal with HIV/AIDS in prisons; third, access to ARV treatment and HIV testing services in prisons must be promoted as a matter of urgency; and fourth, medical parole provisions are not working and should be revisited.

So where to from here?

As already mentioned in the introduction to this chapter, Balfour has applied for leave to appeal against Justice Southwood's judgment and order. If leave to appeal is granted, whether by the High Court, Supreme Court of Appeal or the Constitutional Court, the matter will not be argued until after the 22 April 2009 elections. By then, the current Minister – against whom findings were made in his official capacity – may very well be out of office. Further, we already have a copy of the report, which by then will have been made public, further rendering the appeal academic.

Of greater concern than any potential appeal is the reality that PAIA, which is meant to give effect to the constitutional right of access to information, is frequently used by many government departments to frustrate access – to delay the provision of information for months and years without explanation and few ramifications. At most, courts may hand down a punitive costs order, as Justice Southwood did in this case. Ultimately, however, this becomes the burden of tax-payers. Unless and until Ministers are compelled to pay themselves, such orders will have no impact on their errant behaviour.

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Access to health care services

Ensuring access to health care services remains at the core of the ALP's work. In the period under review, we initiated legal action to address a concern already highlighted in the previous review (MSD), invoked the provisions of PAIA once more (Western Cape budget cuts) and sought to ensure final resolution of two existing cases (WCC and Khayelitsha). These cases, which were all aimed at realising the right to have access to health care services, are discussed below.

Treatment Action Campaign v MSD and Merck

In our previous review, we anticipated filing a new complaint in the second half of 2007 against various patent holders regarding their refusals to license generic drug companies on reasonable terms.¹⁷ After further discussions with Abbott Laboratories, which went some way towards addressing our concerns, we decided only to pursue the matter against US-based Merck & Co. and its local subsidiary MSD (Pty) Ltd. On 6 November 2007, the ALP – acting on behalf of the TAC – filed its complaint with the Competition Commission of South Africa.¹⁸

17. At pages 31 – 31

18. Case number 2007Nov3328

Prior to filing the complaint, the ALP – once again on behalf of TAC – had engaged with MSD for almost six years regarding the need for it to grant multiple licences on reasonable terms for the local production and/or importation of a range of generic efavirenz (EFV) products. Progress over the years was agonizingly slow:

- MSD first licensed Thembalami Pharmaceuticals to produce stand-alone EFV products in April 2004. Thembalami, a joint venture between South Africa's Adcock Ingram and the South African subsidiary of India's Ranbaxy Laboratories, did not survive long enough to bring any EFV products to market.
- Some time after Thembalami's collapse, MSD licensed Aspen Pharmacare – in July 2005 – on substantially similar terms. Only in February 2008 did Aspen manage to get an EFV product registered by the Medicines Control Council (MCC).
- In late August 2007, three months after the ALP sent a final letter of demand to MSD, a second generic company – Adcock Ingram – was licensed. While TAC welcomed this move, it recognised that this did not address all of its concerns, necessitating the filing of the complaint.

Two thirds of people starting ARV treatment in the public sector take EFV as one of their three drugs. Yet at the time the complaint was lodged, the state was paying far more for EFV than the combined price of the other two drugs in the regimen. Even though several generic companies across the world manufacture a wider range of cheaper EFV products than are produced by Merck, most of these could not be sold in South Africa unless and until such companies were licensed by Merck. Furthermore, there had been at least three stockouts of EFV in southern Africa as a result of supply problems.

The main reason for these three problems is that Merck – through MSD – effectively had a monopoly on the sale of EFV in South Africa. As the exclusive rights holders, MSD and Merck had refused licences to at least two generic manufacturers. While they had granted licences to two local companies, the terms of such licences were unreasonable, with neither company being able to bring generic EFV products to market until early 2008. In contrast, the two companies that had been refused licences had registered generic EFV products with the MCC and could have brought their medicines to market immediately if and when licensed.

The complaint alleged that MSD and Merck were violating the Competition Act 89 of 1998. In particular, it argued that their refusal to license EFV to a sufficient number of generic companies on reasonable terms threatened access to comprehensive treatment for HIV/AIDS by:

- Preventing cheaper generic EFV products from being brought to market;
- Preventing co-formulated and co-packaged ARV products containing EFV and at least one other ARV medicine from being brought to market;¹⁹ and
- Placing the sustainability of supply of EFV products in South Africa under threat because of the risk of stockouts.

TAC's complaint was also aimed at helping to implement the national *HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011* (NSP), which states as follows:

19. Co-packaged products are products which contain two or more drugs in a single blister-pack or package. Co-formulated products are products which combine two or more drugs into a single pill.

The cost implications of the NSP are large, in some options exceeding 20% of the health budget without considering the costs arising from the effect of the epidemic on hospital and primary care services. In attempting to increase the feasibility of this plan ... [a]ttention should be placed on increasing the affordability of medicines.

Throughout the course of the Commission's investigation, TAC remained open to further discussions with MSD. It publicly stated that it had no interest in protracted litigation, preferring instead for the parties to negotiate a settlement in the public interest. TAC made it clear that if such a settlement could be reached, as was the case in 2003 with GlaxoSmithKline and Boehringer Ingelheim, it would be prepared to withdraw its complaint.²⁰

No formal settlement was reached. Instead, MSD acceded to TAC's demands. Thus on 30 May 2008, TAC announced that MSD was no longer acting in an anticompetitive way, paving the way for the market entry of a wide range of affordable EFV products. Based on correspondence between the ALP on the one hand and MSD and the Competition Commission on the other, TAC announced that MSD had:

- Licensed four generic drug companies – two local producers and two locally-based importers – to bring stand-alone EFV products to market;
- Agreed that all four licensees are entitled to bring co-packaged products containing EFV to market;
- Agreed that all four licensees will not unreasonably be refused consent to bring co-formulated products containing EFV to market;
- Agreed that all licensed products can be sold to both public and private sectors in South Africa and ten other southern African countries (Angola, Botswana, the Democratic Republic of the Congo (DRC), Lesotho, Madagascar, Mauritius, Namibia, the Seychelles, Swaziland and Zimbabwe); and
- Waived any right to a royalty.

On the basis of these significant developments, the Competition Commission had informed the ALP that there was no reason to refer the complaint to the Competition Tribunal for adjudication. Both the ALP and TAC agreed with this assessment. Because MSD had agreed to grant multiple licences on reasonable terms, which was always the central demand, TAC decided that it too would not refer the matter to the Tribunal. It was of the view that there was no compelling purpose served by referring what by then was largely a historical complaint. Instead, TAC committed itself to ensuring that the reasonable terms of the licensing agreements were appropriately implemented.

The impact of these developments has been profound. In terms of the 2008 ARV tender, for example, the state is now able to procure 600mg EFV tablets – the adult formulation – for less than half the price it secured in the 2004 tender. The same cannot be said in respect of other formulations, largely because of delays in securing MCC registration. On a more positive note, the MCC finally registered the first co-packaged product containing EFV in December 2008 – a product that also contains the fixed-dose combination product of AZT and lamivudine. We trust that additional combination products will soon follow.

20. Information on the complaint against these two companies is available at http://www.tac.org.za/newsletter/2003/hs10_12_2003.htm

EN and Others v Government of the Republic of South Africa and Others

In our last review, we highlighted this case that sought primarily to ensure timely access to ARV treatment for all inmates with HIV at WCC in Durban. As we explained, our settlement talks in the case – which started some time after government began implementing Justice Pillay’s original order – had led the ALP and TAC to work closely with DCS and DoH officials in developing and finalising a *National Framework for a Comprehensive HIV and AIDS Plan for Correctional Services*. At the time, all parties appeared to be keen to resolve the case by dealing comprehensively with HIV and AIDS throughout the correctional service system.

Through no fault of our own, the National Framework did not form the basis of a final settlement in the case. Instead, as the review noted, we were “keen to finalise the already agreed-upon National Framework as a sector-specific strategic plan” – to have the substance of the document formally included in official DCS policy. Notwithstanding some degree of optimism on this front, we were nevertheless still concerned about the situation at WCC. We took the view that “[u]nless and until the provision of ARV treatment at WCC [was] indeed done in accordance with the Operational Plan [for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa], as required by the ... order of Justice Pillay, the resumption of legal proceedings seemed all but inevitable.”²¹

After much deliberation, we decided against going back to court. Amongst other reasons, we recognised that the formal legal process of a supervisory order – which would have involved returning to the Durban High Court for a decision on the reasonableness of government’s revised plan for providing ARV treatment at WCC – would not have addressed the fundamental challenge of implementation. Simply put, the court proceedings in question – based on somewhat outdated papers – were not best suited to addressing this concern. In addition, the TAC was actively involved at facility level in solving problems directly with DCS officials.

Amending DCS policy

Despite our decision to focus on the broader policy, movement was slow. In early September 2007, we were asked by a senior DCS official to finalise the National Framework and put it in a form ready for principals to sign – not as a settlement in the case but rather simply as an agreement between the parties. This request was apparently made on behalf of Loretta Jacobus, the Deputy Minister of Correctional Services. Yet the agreement was never signed. Instead, DCS finalised its own *National Framework for the Implementation of Comprehensive HIV and AIDS Programmes for Offenders and Personnel* in October 2007.

On 21 November 2007, we wrote to the Deputy Minister noting that “[w]hile we had hoped for the parties to adopt the [earlier] framework as a written agreement, our primary concern [was] that the substantive issues it addresses ... expressly be incorporated into existing DCS policy and programmes.” When the parties met on 13 December 2008, we focused primarily on how best to reconcile the two separate documents, with the ALP committing itself first to making written comments on the DCS policy. As we explained in a follow-up letter to the Deputy Minister:

In particular, these submissions will consider possible areas of conflict between the DCS policy and the task team framework, as well as substantive issues in the task team framework that may not have been addressed – adequately or at all – by the DCS policy. In addition, the submissions will consider aspects of the adopted DCS policy that may need to be strengthened.

At the end of January 2008, the ALP provided detailed comments on the DCS policy. In turn, these provided the basis for further discussions and debates. Over the following five months, the parties narrowed down the areas of disagreement, with the ALP making one final submission on proposed wording at the end of March. In a final meeting held on 24 June 2008, broad agreement was reached on most of the outstanding issues.

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Where agreement could not be reached on the substance of any particular matter, we agreed on the process in terms of which it would be addressed. Importantly, Dr. Nomonde Xundu – at the time a senior health official – committed the DoH “to discussing and debating the relevance of the soon-to-be released Southern African HIV Clinicians Society [(SAHCS)] ... guidelines on the prevention and treatment of HIV infection in detention centres.”²²

SAHCS guidelines

The process to develop the guidelines to which Dr. Xundu referred began in early September 2007 when the SAHCS brought together a group of experts to develop a set of guidelines for dealing comprehensively with HIV within prisons and other detention centres in southern Africa. Because of our work at WCC, the ALP’s Jonathan Berger was invited to join the group. So too was the director of HIV and AIDS at DCS, who was unfortunately unable to secure the requisite permission.

The guidelines were published in the Autumn 2008 edition of the *Southern African Journal of HIV Medicine*. They “are primarily aimed at promoting best practice for the prevention and treatment of HIV infection and related co-morbidities in detention facilities.” In particular, they are intended to:

- Provide guidance to [health care workers] working with prisoners, whether within or outside a detention facility ... with a particular focus on their ethical and clinical responsibilities;
- Frame the expectations of prisoners and their families regarding appropriate levels of health care; and
- Guide governments, professional bodies and other organisations involved in the development and implementation of HIV-related policy in respect of prisoners.

PRISONERS & HIV

GUIDELINES FOR THE PREVENTION AND TREATMENT OF HIV AMONGST ARRESTED, DETAINED AND SENTENCED PERSONS

- ETHICAL DUTIES**
 - The ethical duty of the health care worker is to treat prisoners in a manner that gives the patient best possible care.
 - 4 Key Ethical Principles:**
 - The right to health care
 - The right to be treated with dignity
 - The right to refuse treatment when being fully informed
 - Detention facilities should have:**
 - Adequate ventilation
 - Enough to sunlight
 - Appropriate nutritional protection treatment for health care workers, who should be substantially protected from their inmate's acts of physical violence
- ON ADMISSION**
 - On admission to detention facilities:
 - Check for previous medical history and current treatment plans
 - Enforce programs
 - Comprehensive medical history and examination, including height, weight, blood pressure, urine and toxemia status assessment
 - HIV counseling and rapid offer of testing – if HIV positive, stage using laboratory and clinical judgement
 - Children should be screened as above, including immediate screening and uptake of antiretrovirals as required
 - OT screening followed by treatment where necessary
- TB AND HIV CO-INFECTION**
 - TB screening and sputum investigation
 - TB culture and drug susceptibility should be the STANDARD OF CARE
 - Do not initiate TB treatment for B6 compromised and HIV co-infection
 - ARV to commence 2-4 weeks after a diagnosis of TB treatment – except for latent B6 mycobacter
 - All patients with drug resistant TB should be on ARV (subject to approval of CME)
 - TB patients must be transferred to a separate designated facility and not the facility, with which with ventilation, sunlight and infection control
 - If a patient is diagnosed with MDR TB, he or she may be transferred urgently to a specialist treatment site
 - After diagnosis of TB, HIV positive should be given until leaving from a HIV treatment
- CARE MUST INCLUDE:**

NOTE: DUE TO HIGH RISK OF TB, HIV TREATMENT SHOULD COMMENCE AT CD4 < 350

 - Adverse events and laboratory values:**
 - Be prepared to recognise and when give antiretroviral
 - Screen and manage once it leads to poor adherence
 - Substance use is often highly coercive – maintain a high index of suspicion
 - Encourage smoking and substance use
 - Adherence:**
 - Encourage a health-DC
 - Recognize a target weight should be maintained
 - If patients, including TB patients, and pregnant and lactating women should have their daily evaluated
- CONTINUITY OF CARE**
 - On Arrival:**
 - Arrange immediate ongoing supply of all chronic medications
 - Advise patients who cannot access ART facilities to stop all treatment other than continue with a single drug
 - At all times:**
 - A number of current treatment and medical history should be kept in the prison in the event of unavailability of stock or release
 - When leaving:**
 - A summary should be given to patients in anticipation of leaving with appointments made to clinical site
 - Don't adequate supply of medical to be sent until returned to community
- SPECIAL CONCERNS**
 - Medical records:** Should be consistent for patients with unique complications or symptoms of TB
 - Termination of HIV-positive pregnancy:** This is unnecessary and should be discouraged
 - Overnight urine detection test kit:** Independent evaluation of urine specimen should be a regular feature of all kits programmes within these institutions
 - Antiretroviral resistance:** Patients with HIV must be warned of side effects, drug interactions and the risk of vitamin deficiencies on their immune system

Contact Information:
 Tel: +27 08 71 561 800
 Fax: +27 08 71 241 670
 E-mail: southern@saahcs.org
 Web: www.saahcs.org
 Tel: +27 08 71 256 400
 Fax: +27 08 71 256 401
 E-mail: info@wcc.org.za
 Web: www.wcc.org.za

22. ALP letter to the Deputy Minister of Correctional Services dated 30 June 2008

While the document is not official policy, “it should nevertheless be considered as current good practice when policy is formulated.”

The guidelines were formally released at a press conference at the TB Conference in Durban in early July 2008. In addition, their publication in the journal meant that they were distributed to the thousands of SAHCS members across the region – the vast majority of whom are employed in the public sector. Included in the publication was a full-colour, easy-to-read poster that captures the key elements of the guidelines. The poster was jointly published by the ALP and the SAHCS.

Way forward

In July 2008, Jonathan Berger – who had been leading the ALP’s work in this area – went on six months’ sabbatical leave. Unfortunately, the member of staff tasked with taking this matter forward failed to do so. At the time of writing, we do not know whether the agreed changes have indeed been incorporated into DCS policy and implemented.

Based on frequent complaints we continue to receive from inmates across the country, we are doubtful that there has been progress in the absence of pressure.

Based on frequent complaints we continue to receive from inmates across the country, we are doubtful that there has been progress in the absence of pressure. Further, there is no tangible evidence to show that DCS has implemented an appropriate monitoring and evaluation (M&E) system to deal with the twin epidemics of HIV and TB. This strongly suggests the need for independent M&E by bodies such as the JIOP and the SAHRC.²³

One final issue remains: the status of the appeals against two of Justice Pillay’s orders.²⁴ Despite numerous requests to the State Attorney in KZN for information on whether the

respondents intend to prosecute the appeals, the ALP has yet to receive any response. Our most recent communication made it plain that we are of the view that the appeals are now deemed to have lapsed, and in the result, we are proceeding to prepare a bill of costs.

Western Cape budget cuts

In late 2007, the Western Cape began implementing the *Comprehensive Service Plan for the Implementation of Healthcare 2010* (CSP). The CSP’s intention was to expand access to primary health care by increasing the number of primary health care level beds available throughout the province. To cover the costs of this expansion, tertiary level facilities – including academic training hospitals and specialist units – were to have many of their beds cut. The provincial health department argued that the current structure of the health care system was resulting in the oversupply of costly higher-level secondary and tertiary services at the expense of ensuring access at the primary level.

While the goal of the CSP is admirable, the ALP and TAC were concerned about its implementation and impact over the long term. In particular, we focused on two issues: first, the cutting of tertiary level services had already begun without any corresponding increase in primary level services; and second, the manner in which the CSP was to be implemented threatened to disrupt the necessary balance between the provision of primary, secondary and tertiary level health care services. But before we could act, we needed to ensure that we were in possession of all the relevant facts.

Our early requests for information resulted in official responses demanding that we invoke the provisions of PAIA to apply for access to particular documents. An internal communication, which appears to have been inadvertently included in correspondence with the ALP, indicated that the provincial health department was intent on using PAIA to deny access to as much information as it was able to do. Despite not getting access to everything we needed, our investigations came to a halt when the provincial health department managed to secure an additional R332 million from both national and provincial treasuries. The additional funds allowed the hospitals to halt any further bed cuts and to re-instate many of those that had already been cut.

23 Such roles for the JIOP and the SAHRC were identified in the negotiated framework that was originally to have formed the basis of a settlement in the case.

24. These relate to the merits of the original case as well as the application for Justice Pillay’s recusal.

Treatment Action Campaign and Others v Minister of Health, Provincial Government of Western Cape and Others

Our previous review discussed this case regarding the summary dismissal of 41 striking health care workers in June 2007 and the ALP's and TAC's innovative response focusing on access to health care services. The dismissals – which occurred in the context of a nation-wide public sector strike – were challenged on the basis that they (and not the strike itself) were responsible for the disruption of essential health care services at particular public sector facilities in Khayelitsha. In his order handed down on 26 June 2008, Justice Siraj Desai effectively compelled the respondents “to restore and guarantee the provision of reasonable functioning health services in Khayelitsha, including emergency, chronic, child and reproductive services”. The respondents were further ordered to return to court on 20 August 2007 to “show cause ... why final orders should not be made”.²⁵

Political developments superseded the legal issues – the affected health care workers were reinstated within days of the order. This did not, however, stop the respondents from filing an application for leave to appeal. Argument in this application had to be postponed because the written judgment had yet to be delivered. The original return was set for 20 August 2007 – the date upon which the written decision was finally handed down. But once again the matter was postponed, again by agreement of the parties. The matter eventually lapsed after the respondents failed to have it set down.

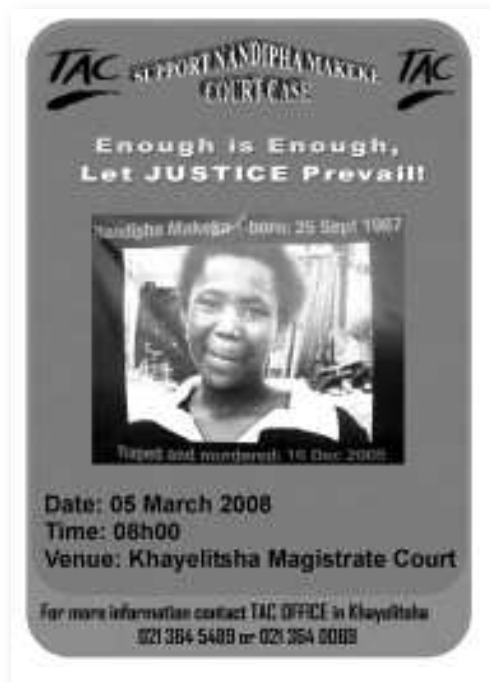
Responding to clients' needs

Although the ALP closed down its paralegal unit in 2007, it continues to respond to client-initiated requests for legal services. In addition to providing legal advice and referral services as a matter of course, we also take legal action on behalf of clients on a case-by-case basis. While such cases needn't fall within ALP-identified areas of focus, they must nevertheless advance our broad mandate in respect of HIV/AIDS and access to health care services. Below are two examples of cases taken up in this way.

Treatment Action Campaign and Others v Yanga Janet

On 16 December 2005, 18 year-old Nandipha Makeke – a TAC member from Khayelitsha – was kidnapped, gang-raped and murdered. Along with three others, Yanga Janet was arrested two months later.²⁶ After several delays, Janet and one of his co-accused were released on 31 March 2008 due to a lack of evidence – the remaining two co-accused were convicted of the crimes on 2 April 2008.

Upon his release from custody, Janet and other members of his gang began a campaign of harassment and intimidation in which TAC members were threatened with assault and murder. Due to concerns for the safety of TAC members in Khayelitsha generally, as well as the safety of three activists in particular, TAC members in Khayelitsha



TAC poster calling for members of the community to attend the trial of Nandipha Makeke's murderers (Reproduced with kind permission of the TAC)

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26. Janet was also charged with the attempted murder of TAC activist Mandla Nkunkuma – the former allegedly shot the latter in the back on the same day Makeke was murdered. While this case of attempted murder remains open, there has been little movement by the investigating officers – despite Nkunkuma having followed up on several occasions.

were asked to stop wearing their “HIV positive” t-shirts. On 1 April 2008, the three activists were moved into a safe house at TAC’s expense.

On 8 April 2008, the ALP filed papers on TAC’s behalf seeking an immediate interdict preventing Janet, either personally or through others, from intimidating, harassing or assaulting any TAC members and/or damaging and/or destroying any property owned by TAC or TAC members. The interdict was granted on the same day and remains in effect.

LM v SpectraMed

In October 2008, LM and her dependant child became members of SpectraMed, a registered medical scheme. In so doing, she dealt with SpectraMed’s direct sales department through a “product specialist” agent. During the consultation, LM voluntarily disclosed her HIV status while asking questions regarding the scope of SpectraMed’s ARV treatment programme.

During the consultation, LM was encouraged by the agent to purchase additional “top-up” cover to provide additional coverage in the event that a doctor charged rates above those reflected in the National Health Reference Price List. Concerned that she might be liable for such charges in the event she was involved in an accident and required emergency medical care,²⁷ LM chose to purchase the additional cover. Only then was she informed that another company provided the top-up cover.

A month later, LM was informed that the separate company required additional information to approve her top-up cover package, specifically information regarding her HIV diagnosis and clinical condition. At this point, she approached the ALP for advice and assistance. Thereafter, we assisted her in lodging a complaint with the Council for Medical Schemes (CMS), which has acknowledged receipt and is continuing to investigate the matter.

The ALP recognises that some of the problems in this matter may have arisen from the Supreme Court of Appeal’s decision in *Guardrisk Insurance Co (Ltd) v Registrar of Medical Schemes and Another*,²⁸ which opened the door for short-term insurers to offer products similar to those offered by medical schemes but without having to meet the additional regulatory requirements as set out in the Medical Schemes Act 131 of 1998.²⁹

But in addition, the complaint also raises concerns regarding the following four practices: first, a top-up cover provider discriminating against applicants with HIV; second, a medical scheme selling both medical scheme coverage and short-term insurance packages offered by third parties; third, a medical scheme disclosing a client’s HIV status to a short-term insurance provider; and fourth, a medical scheme selling short-term insurance products that complement cover they are already required to provide in terms of the Act.

On 24 February 2009, the CMS informed LM that it expects to finalise its investigation in March 2009. Given the issues at stake, it is likely that the matter will require further attention.

Conclusion

As this chapter shows, only few cases were pursued during the period under review. Collectively, however, they teach the ALP at least three valuable lessons. First, successful litigation does not end with a court judgment. To the contrary, turning a legal victory into substantive change requires ongoing monitoring, advocacy and engagement. Second, one may win the battle but nevertheless lose the war – our decade-long struggle to defend doctors who act in accordance with their ethical obligations and consciences bears testament to this conclusion. Third, realising a right to have access to health care services necessarily requires a focus on broader questions of governance and accountability. These lessons have already been incorporated into our plans for 2009 and beyond.

27. We were advised that this was an example that was frequently used by the sales agent

28. [2008] ZASCA 39 (28 March 2008)

29. For more on this issue, see chapter 3.