Chapter 3

Rethinking health reform: constitutionalism, law and policy

By Jonathan Berger and Adila Hassim

The ALP has been engaging with the subject of health sector reform since 2004, as an inevitable and necessary development of its work on protecting the health and equality rights of people living with HIV/AIDS. This is because the HIV epidemic places the failings of the health system as a whole in sharp relief.

The extreme shortage and inequitable distribution of human resources, the skewed expenditure on health between the private and public sectors, the inadequacies of the institutional and regulatory framework, and the disparities between provinces in the effective use of financial resources are some of the challenges that encumber the health system.

In order to realise progressively the rights of everyone to have access to health care services, all of these challenges need to be addressed. Our role, however, has to be somewhat more limited – we simply don't have the time, resources or capacity to deal with every challenge. Instead, the ALP focuses its attention on reforming two core aspects of the health system:

- The institutional and regulatory framework – to ensure that decision-making powers are allocated to the appropriate persons at the appropriate levels of the system; that the quality of services is improved; and that oversight, accountability and governance in general are effective; and
- Health financing – to ensure reform of the fiscal system so that the development and implementation of health budgets are efficient and effective; the introduction of a national health insurance (NHI) system – for which the ALP has long called – that will ensure access to health services regardless of ability to pay; and the appropriate regulation of private health service costs and health product prices.

In addition, the ALP has a history of focusing on the affordability, availability and accessibility of medicines. We have made use of constitutional law, administrative law, intellectual property law and competition law in order to promote access to essential medicines. Our work in this area will continue.

The priorities broadly outlined above are consistent with a number of research areas that were identified in early 2008, such as fiscal federalism, budgeting processes and governance. These issues

proved to be central to the crisis that emerged in the Free State in late 2008.

As stated in the introduction to this review, the MEC for Health in the Free State announced a moratorium on the initiation of new patients on antiretroviral (ARV) treatment in November 2008. This decision – which was part of a general cutback on health service delivery in the province – was made as a result of a financial crisis brought on by improper budgeting, a lack of oversight of expenditure, the erroneous implementation of the Occupation Specific Dispensation for nurses, and spending pressures due to medical inflation.

The ALP – together with a range of partners including the Treatment Action Campaign (TAC), the Southern African HIV Clinicians Society, the South African Council of Churches, the Mosamaria Catholic Mission, and individual health care workers in the Free State – brought the moratorium and its implications to the attention of the provincial and national departments of health and finance.

TAC members protest outside Parliament against the ARV moratorium in the Free State, 11 February 2008 (Budget Day) (Reproduced with kind permission of Health-e News Service)

The ALP also undertook site investigations and interviews that formed the basis of a report into the Free State that was sent to the Minister of Health in February 2009. While a fuller report of our intervention in the Free State will be the subject of the next review, it is important to note here that we are witnessing the direct effect of the mismanagement of the health system for the past ten years. In short, the new Minister of Health is now saddled with the burden of picking up the pieces of a crumbling health system.

The financial and health crisis in the Free State is not restricted to that province. A number of provinces – Mpumalanga and the Eastern Cape in particular – are in a similar predicament. The broad issues of national oversight of the provinces and accountability between spheres of government, as well as the budgeting process and financial governance, will therefore remain key focus areas of the ALP's work in 2009.

In this chapter, we elaborate on the health sector reform work we have undertaken during the period under review. We start first with an examination of the ALP's activities in health policy reform. Thereafter, we consider our participation in various law reform processes, including amendments to national health statutes and the development and processing of other health-related legislation. Finally, we briefly look at a key ALP publication that focuses on the National Health Act 61 of 2003.

Policy development in health

At the ANC's 52nd National Conference held in Polokwane in December 2007, health and education were confirmed as priorities for reform and policy development by the ANC. This is also reflected in the ANC election manifesto that states that –

> The ANC government will aim to reduce inequalities in our health system, improve quality of care and public facilities, and boost our human resources and step up the fight against HIV and AIDS and other diseases. Health reforms will involve mobilisation of available resources in both private and public health sectors to ensure improved health outcomes for all South Africans.

A direct consequence of Polokwane has been an increased drive by the ANC to convene processes aimed at implementing the resolution, with the development of policy and law for the implementation of NHI at the top of its agenda. As part of its updated health agenda, the ANC reaffirmed its 1994 Health Plan commitment to introducing NHI. While this has long been a part of ANC health policy, its development and implementation has been slow.

ANC's NHI Committee

In June 2008, the ANC formed a committee to kick-start a plan for NHI implementation. Initially, the committee did not include anyone with specialist knowledge of law and human rights. This omission was brought to the attention of senior ANC leaders who agreed that the ALP's head of litigation and legal services – Adila Hassim – would join the committee to provide a legal and human rights perspective. The ANC stressed that this was an internal process and that its deliberations were confidential. This was fully supported by the ALP.

However, during the course of working on this committee, several ANC members questioned the bona fides of Hassim's participation. It seems that this was a result of her submissions that pointed out not only the strengths of the proposed policy and legislation, but also its weaknesses. In so doing, the ALP sought to ensure, as far as is reasonably possible, that any resultant law and policy would be insulated from legal attack. Eventually, the ALP had no choice but to discontinue its participation on the committee in order to retain its integrity and independence.

Apart from the informal contributions made to the committee, the ALP submitted two memoranda for the committee's consideration: the first addressed the principles for NHI and a process for implementation;[1] and the second concerned the three key pieces of health legislation that were before Parliament at the time and are discussed below in this chapter.[2]

Later in the year the committee's policy on NHI was finalised and adopted by the ANC's National Executive Committee. According to the 2009/2010 health budget summary, a working group has been established within the Department of Health (DoH) to "develop policy proposals and the legislative framework to facilitate the creation of NHI by 2011/12".[3]

The ALP fully supports – and always has – the development of policies to ensure universal access to health care services, regardless of one's ability to pay and where one lives in the country.

The ALP fully supports – and always has – the development of policies to ensure universal access to health care services, regardless of one's ability to pay and where one lives in the country. However, we have concerns with the current proposal of a full implementation of NHI within five years. This does not mean that critical steps that are aimed at increasing access to quality health care services should not take place with urgency,[4] but rather that the premature introduction of a poorly conceptualised NHI will further destabilise an already weakened health system.

DBSA and the Health Roadmap

In July 2008, Jay Naidoo of the Development Bank of Southern Africa (DBSA) and Zweli Mkhize – head of the ANC's influential health and education committee – co-chaired an open and broadly consultative process aimed at providing a plan for health reform for the next administration. Participants generally acknowledged that South Africa's health outcomes are worsening, and that our health indicators compare badly with countries that have been ravaged by war or are less developed.

The process followed a path of diagnosing the state of the public health care system, evaluating the system, reaching findings, and making recommendations for short-term interventions.[5] Five working groups were formed: human resources for health; health financing; strategic health

1. ALP Comment on NHI Proposal, 22 August 2008 (on file with Adila Hassim)
2. The Three Health Bills, 24 August 2008 (on file with Adila Hassim)
3. Budget summary for health at page 285
4. Some of these steps were identified in the DBSA process described below.
5. The final phase would be to facilitate the implementation of the recommendations.

programmes (including the national *HIV & AIDS and STI Strategic Plan for South Africa, 2007-2011* (NSP)); diagnosis of the health system; and results-based improvement of service delivery. The ALP participated in the first three of these working groups, as well as in all the plenary discussions. During the roadmap process, the sudden political turn of events occurred with the ANC's recall of Thabo Mbeki as President. This was accompanied by a mini-Cabinet reshuffle, which included removing Manto Tshabalala-Msimang from her health portfolio and appointing Barbara Hogan in her place.

In November 2008, a document recording the findings and recommendations of the roadmap process was produced. This was the basis of the development of a 10-point plan that was agreed to by all the participants, and adopted by Minister Hogan. As articulated above, some of the key aspects of the 10-point plan are part of the ALP's work agenda on health sector reform.

ALP seminars

Apart from participation in these formal processes, the ALP felt that wider knowledge and debate on critical areas of health reform and the constitutional framework that governs this was necessary. Two seminars were held in 2008, with the objective of deepening discussion of the issues.

Deputy Chief Justice Dikgang Moseneke at the ALP's seminar on "Rethinking Health Reform"

Rethinking Health Reform

On 21 July 2008, the ALP hosted a public seminar on health sector reform. Its primary aim was to deepen our understanding of the policy and legal developments that have taken place since 1994 regarding health sector reform. Attended by trade union officials, human rights and health activists, members of the private health sector, academics and health policy-makers, the seminar was addressed by Prof. Larry Gostin (Georgetown University Law Center), Deputy Chief Justice Dikgang Moseneke, Jody Kollapen (South African Human Rights Commission), Tebogo Phadu (NEHAWU and ANC) and the ALP's Adila Hassim.

5. The final phase would be to facilitate the implementation of the recommendations.

Prof. Larry Gostin and Dr Adila Hassim at the ALP's seminar on 'Rethinking Health Reform".

The seminar was important for bringing together people who do not ordinarily speak to each other and who do not necessarily agree on what type of health sector reform is necessary and how it should be undertaken. The value of the debate was to distil the points of consensus so that there is at least a common basis for moving forward. The ALP will build on the discussion that took place in this seminar in order to grow a coalition that supports basic principles underpinning health sector reform and the appropriate introduction of NHI.

TB, public health and individual rights

On 7 November 2008, the ALP hosted a seminar entitled "Protecting Public Health and Human Rights in the Response to TB in South Africa: State and Individual Responsibilities". As with the earlier seminar on health sector reform, participants were addressed by a wide range of speakers: Dr. Lindiwe Mvusi (DoH); Bruce Margot (Church of Scotland Hospital, KZN health department); Dr. Virginia de Azevedo (City of Cape Town and Médecins Sans Frontières); Desire Schouw (TB/HIV Care Association), the TAC's Lesley Odendal and the ALP's Mark Heywood and Adila Hassim.[6]

The seminar brought together civil society organisations, business representatives, public and private TB doctors and government departments to discuss the current response to the TB epidemic in South Africa. In particular, the seminar focused on the government policy of using forced isolation as a preventative measure against the spread of drug-resistant TB (DR-TB) and whether this policy sufficiently protects individual human rights to dignity, liberty and freedom.

Brian Honerman (ALP researcher) and Fatima Hassan (former ALP senior attorney) join fellow activists in drawing attention to the lack of progress globally in dealing with TB/HIV co-infection, XVII International AIDS Conference, Mexico City, 3-8 August 2008 (Courtesy of the International AIDS Society/Mandaphoto)

6. All the presentations are available at *http://www.alp.org.za/index.php?option=com_content&task=view&id=68&Itemid=13#P1*

The ALP's position on isolation as a response to DR-TB is that any policy that sufficiently understands and respects the human rights of patients will not undermine public health, and, in fact, will promote public health by encouraging TB patients to trust the public health system. In its implementation, however, the current policy of isolation fails sufficiently to respect the rights of individuals, without any corresponding public health benefit. If anything, the policy undermines public health.

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Over several months in 2008, the ALP visited seven of the DR-TB facilities in the country as well as both of the community-based care programmes for DR-TB that are operating in KZN and the Western Cape. Based on the various site visits undertaken by the ALP and the presentations at this seminar, the ALP has drafted a report on a legal and human rights approach to TB. Unfortunately, the finalisation and distribution of this report has been delayed. The ALP hopes to release this report in the near future.

Law reform

The dying days of an administration are often characterized by a frantic last-minute attempt to change the legislative framework. Departing ministers, eager to ensure that they leave behind a legacy, rush into overdrive. Unfortunately for South Africa, the period under consideration in this review was no different, with almost 110 bills being tabled in Parliament.

The third and fourth quarters of 2007 saw the formal tabling of 13 and 14 bills respectively, with a further 14 being tabled in the first quarter of 2008. From April to June 2008, however, the quarterly average increased by almost 3.5 fold – to 47. Thereafter, the third quarter returned to normal, with the tabling of 13 bills. Only eight bills were tabled in the shortened fourth term.

A few factors help explain the autumn rush. First, the end of June 2008 was Parliament's cut-off date for the processing of legislation in 2008. Second, the last term before the 2009 elections – the first quarter of 2009 – was largely devoted to the State of the Nation Address and the national budget. Third, the incoming Parliament is likely to include many new members.

The flurry of activity in Cape Town had an impact on the workload of the ALP. In addition to a dedicated focus on three health bills developed and tabled during this period, the ALP also contributed in one way or another to five health-related bills, covering a range of diverse topics – refugee and prisoner rights, intellectual property, substance use and insurance.

This part of the review considers these areas of law reform, with a particular focus on the work of the ALP in this regard. In addition, it summarises the ALP's submissions on a range of other legislative developments, including the KwaZulu-Natal (KZN) Health Care Bill, 2007 and a range of draft regulations published by the DoH for comment.

Amendments to national health statutes

On 2 June 2008, the former Minister of Health published bills in the *Government Gazette* seeking to amend three key pieces of health legislation: the Medicines and Related Substances Amendment Act 101 of 1965, the Medical Schemes Act 131 of 1998, and the National Health Act 61 of 2003. In so doing, she noted her intention to table the bills in Parliament.

Some six weeks before, the DoH had published draft versions of these bills for public comment. Despite very tight timeframes, the ALP made written submissions to the DoH on two of the three draft bills – the first dealing with the regulation of medicines and the second with the regulation of private health service pricing. Both submissions were followed by oral presentations.

In this section the review reflects on the ALP's interventions in respect of these bills. While the ALP made a significant contribution in the area of medicines regulation, it was unable to convince the

DoH of the need for more appropriate private sector regulation. It was also unable to ensure that much needed amendments to the Medical Schemes Act were processed.

Medical Schemes Amendment Bill [B 58—2008]

In a letter addressed to the speaker of the National Assembly (NA) and the chairperson of the National Council of Provinces (NCOP), the ALP and TAC expressed concern "that Parliament … [had] been inundated with a flurry of legislative proposals" that were likely to place "severe pressure … [on it] to process … [the bills] with undue haste."

With this in mind, the ALP and TAC recommended that only one of the three bills be processed. In expressly recognising that all three carried "significant ramifications for the future of health service delivery and health sector transformation in the country", the letter noted that only the Medical Schemes Amendment Bill required "urgent attention and passage through Parliament".

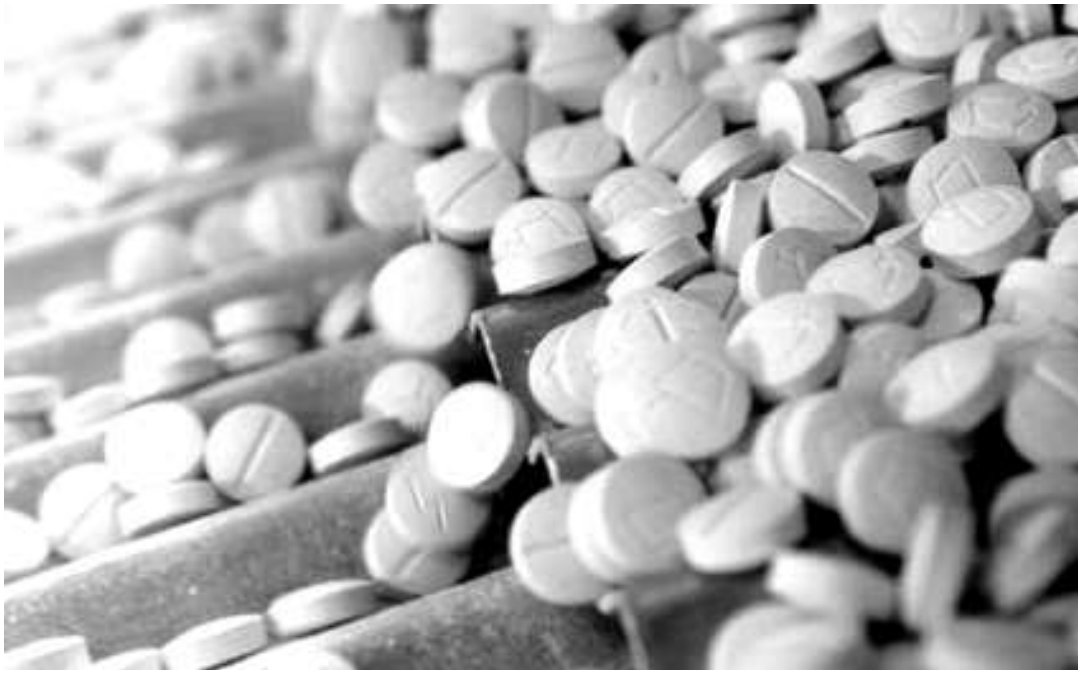
Despite these and other compelling arguments, the Portfolio Committee on Health – without responding to the letter or providing any public explanation – decided to proceed only with its deliberations on the proposed amendments to the Medicines Act.

In particular, the letter noted that a failure to process the bill in 2008 would leave open a legal loophole for "financial service providers to begin introducing health insurance products designed to lure young and healthy persons away from the medical schemes environment." In turn, this would "leave older and sicker persons behind, effectively undermining the ability of schemes to keep contributions and benefits at current levels."

Despite these and other compelling arguments, the Portfolio Committee on Health – without responding to the letter or providing any public explanation – decided to proceed only with its deliberations on the proposed amendments to the Medicines Act. The Medical Schemes Amendment Bill was effectively put on ice indefinitely, seemingly regardless of the consequences.

Medicines and Related Substances Amendment Bill [B 44—2008]

Bill B 44—2008 was formally introduced into Parliament on 17 June 2008, with public hearings before the Portfolio Committee on Health scheduled for 5 and 6 August 2008. This made it plain that the



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intention was to process the Bill before the end of the year. Given the need for fundamental amendments, the ALP and TAC – who made a joint submission – believed it more prudent for the Bill to be finalised after the 2009 elections. This was not to be.

In addition to a number of substantive concerns, the process in terms of which the Bill had been developed was also troubling. In this regard, we identified two fundamental flaws. First, we noted problems with the composition and conduct of the ministerial task team whose report was to have formed the basis of the Bill. Second, we drew attention to the DoH's failure seriously to consider public submissions on an earlier version of the Bill.

Yet despite our concerns with process, we focused primarily on substance. In particular, we argued that contrary to its stated purpose, the Bill – if enacted into law – would not ensure the effective and efficient regulation of medicines and other health products in South Africa. Instead, we submitted that it had the potential "to undermine the scientific governance of medicines and other health products" in either or both of two ways.

First, we described the Bill as "inappropriately – and arguably unconstitutionally – allocating broad powers to the Minister."[7] Second, we saw the Bill "[r]eplacing a semi-independent Medicines Control Council with a health products regulatory authority that is effectively to operate as a line function within the DoH". In addition, we alleged that much of the Bill's substance was not supported by the task team report, with many of its provisions being understood to undermine key recommendations in the report.

Despite receiving a somewhat hostile response from the Portfolio Committee's chairperson, many of our substantive concerns were in fact considered and addressed. In our view, the committee made real progress in addressing the more egregious aspects of the former Minister's draft legislation in Bill B 44B—2008, which it adopted on 3 September 2008. While some concerns remained, the amended bill represented a decisive break from its executive-minded predecessor.

Once adopted by the NA, the amended Bill was put before the Select Committee on Social Services in the NCOP for consideration. In its deliberations, the committee considered further amendments aimed at strengthening the health products regulatory authority's mandate and independence. On 22 October 2008, it adopted a set of further amendments. The new proposals, which were adopted by the NCOP some three weeks later, only went part of the way towards addressing our remaining concerns.

The Portfolio Committee considered the NCOP's version of the bill shortly thereafter, rejecting a handful of key proposed amendments. On 21 November 2008, the NA passed Bill B 44D—2008 – only a slight improvement on its earlier version. While still representing a significant departure from the former Minister's Bill, this final version does not go far enough to ensure that the new regulatory authority will be able to operate independently, accountably and openly, as the Constitution requires.

Once the amendment is enacted, which will happen if and when the President assents to and signs the Bill, the focus will shift back to the DoH and its regulation drafting process. Given the relative lack of detail in the bare-bones legislation, as well as its repeated references to regulations, this process is likely to provide the ALP and TAC with further opportunities for our concerns to be addressed expressly in law.

National Health Amendment Bill [B 65—2008]

Although described by the ALP as one of "the most important pieces of health legislation to be proposed in recent years", the draft National Health Amendment Bill ("the draft Bill") presented us with cause for concern. On the one hand, the draft Bill introduced – for the very first time – a statutory mechanism for the regulation of all prices in the private health sector.[8] As our submission to the DoH noted, this "is central to the constitutional project of progressively realising the right of access to health care services."

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7. At the time of the oral presentation, the ALP and TAC made it clear to the Portfolio Committee on Health that this was not a personal attack on the former Minister. Instead it was a principled objection to a Minister having broad powers over an independent regulatory authority. We stand by our principled opposition to the overly broad powers.
8. To date, only medicine prices have been subjected to regulation.

On the other hand, the ALP noted that the draft Bill – in its published form – would not be able to meet its objective of "regulating the manner in which the cost and prices of health care services are arrived at in order to limit unreasonable and unsustainable cost escalation through profiteering from private health care." Thus, while we recognised the need – and constitutional duty on government – to regulate the private sector appropriately, we took issue with what we submitted was a fatally flawed piece of draft legislation.

In particular, we raised the following concerns, arguing that these deficiencies would render the legislative intervention ineffective, open government up to a barrage of unnecessary and avoidable litigation, and delay any reasonable regulation of private health services:

- The lack of consultation in the process of developing the draft Bill;
- The lack of independence of the proposed regulatory mechanism, which, if brought into existence in the manner proposed in the draft bill, would potentially be subject to undue political interference;
- Provisions authorising the inappropriate and/or largely unguided delegation of authority; and
- Numerous ambiguities and gaps in the draft Bill.

Despite our input, which proposed that the draft Bill be rewritten to achieve its aims in a constitutionally defensible manner, the DoH apparently succumbed to industry pressure. Bill B 65—2008, the version that was tabled in Parliament in June 2008, departs significantly from the draft originally published for public comment. In particular, it proposes a self-regulation mechanism that is unlikely to satisfy any party other than those whose conduct requires regulating. If adopted in its current form, the Bill will not assist government in discharging its constitutional duties.

As already mentioned, the Bill has not yet been processed by Parliament. This is unlikely to occur until sometime after the 2009 national and provincial elections. Given Minister Hogan's fresh and rational approach to the regulation of the private health sector, which seeks to limit the possibility of conflict whilst recognising the need for appropriate state intervention, we are optimistic that the Bill will be subject to a significant rewrite. As always, the ALP remains willing and able to assist in this regard.

Other legislative developments in health

Subordinate health legislation

In addition to these submissions on draft health statutes, the ALP also focused some attention on the development of subordinate health legislation. During the period under review, we commented on a draft set of guidelines for the management of DR-TB as well as draft regulations relating to –

- The nomination and appointment of members to the Nursing Council;
- The labelling and advertising of foodstuffs;
- Foodstuffs for infants, young children and children; and
- Communicable diseases

The submission on the draft **guidelines for the management of DR-TB**, which was made jointly with the TAC and the AIDS and Rights Alliance for Southern Africa (ARASA), focused primarily on the fact

that the proposals – whilst significantly better than the previous guidelines – fell short of international best practice. In particular, they did not incorporate the *World Health Organization Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis Emergency Update 2008*.

Further, the draft guidelines, whilst beginning to address human rights considerations, "contain[ed] several omissions [and] misstatements of law and the contents of rights." In addition, they failed to provide "specific guidance to health care workers on how to enforce the policies … such as isolation and the treatment of patients without [their] consent", such as would sometimes be the case when forced isolation is justified. The joint submission provided recommendations on how to address these human rights concerns.

In short, we argued that the primary legislation did not permit the ministerial role envisaged in the draft regulations, in effect breaching the constitutional principle of legality.

Our submission on the draft **Nursing Council regulations** focused primarily on the disconnect between the Minister of Health's statutory powers set out in the Nursing Act 33 of 2005 and those in the proposed regulations.[9] In short, we argued that the primary legislation did not permit the ministerial role envisaged in the draft regulations, in effect breaching the constitutional principle of legality. Our concerns were not addressed, with the promulgated regulations being largely indistinguishable from the published draft.

In a follow-up letter to the former Minister of Health, we argued that the Act "does not provide authority for the promulgation of the final regulations in their current form" and that she had therefore "acted unlawfully". We requested that the nomination and appointment process be placed on hold, and that she "convene an urgent meeting with all relevant stakeholders to consider how best to remedy the constitutional defects in the final regulations." The letter was copied to the Portfolio Committee on Health in the NA.

Despite reminder letters to the former Minister and the Committee's chairperson, neither responded. Eventually, some six months after the first letters were sent, the ALP received a substantive response from the Director-General of Health, denying that the former Minister had acted unlawfully. In the meantime, the members of the new Nursing Council had already been appointed. Given other more pressing areas of work and limited capacity, the ALP decided not to pursue this matter for now.

Our primary aim in making a submission on the **draft foodstuffs regulations** was to ensure the existence of a comprehensive legal framework that protects the health of the public against those involved in advancing anti-science agendas. In particular, our submission sought to ensure that "the public is reasonably protected from false or misleading labels and/or advertisements which could potentially endanger their health." We wanted to ensure that the final promulgated regulations "serve as an effective tool to enforce appropriate labelling and advertising, … and allow the people of South Africa to make informed, evidence-based decisions about their nutrition and diet."

In a joint submission with the TAC on the **draft regulations on foodstuffs for infants, young children and children**, we focused on the manner in which the proposals sought to regulate the advertising and provision of breast-milk substitutes. In particular, the submission raised concerns regarding the draft regulations' failure to deal appropriately with those circumstances in which breast-milk poses a danger to infants – such as is the case when a lactating mother is HIV-positive. Our submission thus proposed that "the regulations must provide sufficient room for information (including advertising by manufacturers) to be disseminated which accurately describes circumstances in which formula feeding is a safer option for infants."

Despite the ALP's work on TB having revealed the urgent need for updated **regulations on communicable diseases**, we found ourselves having to call for redrafted regulations to be published for public comment. As we explained in our submission in April 2008:

9. For example, the Act makes provision for the appointment of three members of the 25-person council to "represent communities". (Section 5(1)(b)(vii)) It also expressly grants all interested parties the right to submit nominations from which the appointments are to be made. (Section 5(2)(a)) Yet the regulations make it plain that MECs for Health are each to nominate a person to represent communities. (Regulation 3(1)(g)) From these nine nominees, the Minister of Health is tasked with appointing three.

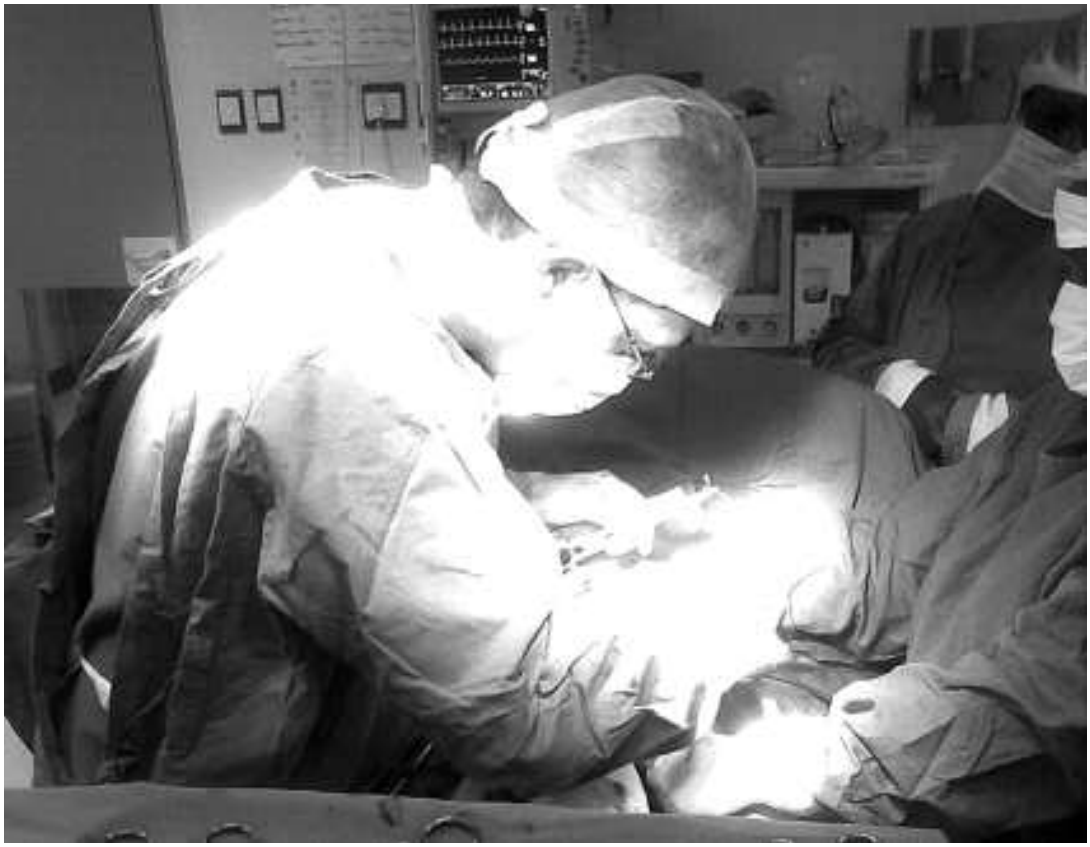
> Because of the poor conditions of the draft regulations as they have been put out for comment, it is difficult to make all the substantive recommendations which the ALP and the TAC would have were the draft regulations in better condition. For that reason, as well as the important constitutional concerns which result from these regulations, we recommend that, prior to finalising these regulations, they are re-drafted based on the comments received and put through an additional period for public comment prior to being finalised.

Despite our difficulties in making sense of the draft regulations, we provided input on a range of substantive issues, focusing on the need for redrafted provisions to establish a framework for the implementation of a proper infection control policy. In addition, the submission drew attention to a number of technical and procedural concerns, such as definitional errors, apparent contradictions between different provisions, and the lack of sufficient space for community involvement.

Despite the urgent need for redrafted regulations, the ALP had received no response to our submission on the draft regulations by as late as September 2008. Through informal communication with the DoH, the redrafted regulations were provided to us. Upon perusal, however, it was evident that little had changed since the previous draft. Thus on 18 September 2008, we provided further comment on the draft regulations, suggesting the reformulation of a number of provisions. At the time of preparing this review, the regulations have still not been finalised.

KZN Health Care Bill, 2007

In welcoming the publication of the draft KZN Health Care Bill, the ALP noted that it "ha[d] the potential to complement the broad legislative framework provided by the National Health Act, 2003". Nevertheless, our submission was quick to focus on what the ALP had identified as the two funda-



Doctors performing surgery at Manguzi Hospital, KZN.

mental flaws in the Bill: an expansion, in certain areas, beyond the express provincial mandate set out in the National Health Act; coupled with a failure to discharge certain obligations required by the national statute.

We argued that the Bill, if passed in its published form, "raise[d] constitutional concerns by unnecessarily departing from or narrowing the broad framework provided by the Act." We further submitted that this "risk[ed] undermining the manner in which the Act and the Constitution contemplate the provision of provincial health care services." In support of our broad submissions, we provided detailed comment on the manner and the extent to which the Bill was at odds with the Act.

But in other respects, the Bill is disappointing, such as by limiting access to health care services to citizens, permanent residents and those entitled to care in terms of international treaties, arguably in conflict with section 27 of the Constitution.

A revised Bill, tabled in the KZN Legislature in 2008, reflects significant changes from the previous draft, including a large number of new provisions that seem to have been drafted with our recommendations in mind. For example, it now sets out the powers and functions of the MEC for Health in some detail. But in other respects, the Bill is disappointing, such as by limiting access to health care services to citizens, permanent residents and those entitled to care in terms of international treaties, arguably in conflict with section 27 of the Constitution.

Health-related legislation

Recognising that the legislative framework relevant to the delivery of health care services extends far beyond the world of the DoH, the ALP remained actively involved in a range of non-health law reform and development processes during the period under review. Interestingly, the ALP's focus in this area went beyond the health-specific provisions of the Bills under consideration. This was most noticeable in our submission to Parliament on the Correctional Services Amendment Bill.

Correctional Services Amendment Bill [B 32—2007]

The ALP's submission on Bill B 32—2007 focused primarily on the proposed amendments to the structure, mandate and staffing of the Judicial Inspectorate of Prisons (JIOP), "an independent office under the control of the Inspecting Judge" tasked with facilitating "the inspection of prisons in order that the Inspecting Judge may report on the treatment of prisoners in prisons and on conditions in prisons".[10] Instead of strengthening the JIOP, as we recommended, the Bill sought to remove its independence completely and locate it firmly within the Department of Correctional Services (DCS).

For example, it sought to replace the Inspecting Judge with an Inspector-General for Correctional Services, either a sitting or retired judge, or simply a legal practitioner with "not less than 10 years' experience in legal practice". Unlike the Inspecting Judge, the Inspector-General was to have no power to appoint assistants, determine his or her staffing requirements, or hold his or her staff to account. Instead, the Bill envisaged staff being seconded directly from and accountable to DCS. Simply put, the JIOP was to be turned from an independent oversight body into an in-house DCS directorate.

The ALP was not alone in its concern. A range of other organisations – including the Civil Society Prison Reform Initiative at the University of the Western Cape's Community Law Centre, the Centre for the Study of Violence and Reconciliation, the South African Human Rights Commission and the Legal Resources Centre (LRC) – expressed similar positions on the proposed changes to the JIOP. In response, the Portfolio Committee on Correctional Services – under the strong leadership of Dennis Bloem – expressly recognised the need for an independent oversight body such as the JIOP.

The Correctional Services Amendment Act 25 of 2008 retains the JIOP, albeit now renamed as the Judicial Inspectorate for Correctional Services.[11] Once in force, the Amendment Act should go some

10. In addition, we addressed provisions of the Bill dealing with three other areas of concern: the rights of inmates (including the provision of health care services); the rights of members (including potential conflicts between the Bill and members' ethical and professional obligations); and the unjustifiable expansion of the Minister's authority (mostly in relation to granting of parole). In respect of each area of concern, we made specific recommendations.
11. The JIOP will change names as soon as the Amendment Act comes into force.

way towards strengthening the body. This is because in addition to the appointment of a Chief Executive Officer, who is to be identified by the Inspecting Judge, it makes provision for greater technical and organisational support. Importantly, all staff and assistants will be required to perform their functions "as authorised and directed by the Inspecting Judge".

Refugees Amendment Bill [B 11—2008]

Given that Parliament gave interested parties only 16 days to make submissions on Bill B 11—2008, as well as the fact that the ALP endorsed the detailed submissions made by Lawyers for Human Rights and the LRC, our submission focused primarily on those provisions of the Bill dealing with access to health care and social services for refugees and asylum seekers. As a secondary focus, it addressed health-related concerns in respect of immigration detention centres, asylum application queues and police holding cells, such as shelter, water, sanitation and food.

In our submission, we considered the proposed amendments to section 27 of the Refugees Act 130 of 1998. Amongst other things, subsection (g) of that provision states that a refugee "is entitled to the same basic health services and basic primary education which the inhabitants of the Republic [of South Africa] receive from time to time." In contrast, the Bill proposed a redrafted section that excludes any direct reference to health and education. Despite our and others' protestations, section 21 of the Refugees Amendment Act 33 of 2008 – which inserts a new section 27 into the principal Act – is largely indistinguishable from that proposed in the Bill.

The Amendment Act expressly sets out certain rights of asylum seekers, including, for example, the right to remain in the country pending the finalisation of an application for asylum. Unfortunately, however, the Amendment Act also expressly limits the rights of asylum seekers to those rights in the Bill of Rights that "apply to an asylum seeker", without providing any guidance on what this means. In addition, by making no reference to certain rights contained in the revised section 27 (such as the right to seek employment), the Amendment Act further limits the rights of asylum seekers (which are likely to be clarified by way of litigation).

Prevention of and Treatment for Substance Abuse Bill [B 12—2008]

In recognising that "several higher-risk groups, such as … drug users, face barriers to accessing HIV prevention and treatment services, because their activity is unlawful", the NSP recommends the "finalisation and implementation of the Prevention [of] and Treatment for Substance Abuse Bill, and its incorporation of HIV harm reduction measures." With this in mind, the ALP sought to play a catalysing role in ensuring strong civil society participation in the processing and finalisation of this key piece of legislation.

Prior to the period under review, the ALP had worked closely with ARASA on its submission to the Department of Social Development (DSD) on an earlier draft version of the Bill. That submission – which the ALP and TAC endorsed – welcomed the draft Bill, noting its potential to advance "a set of medically sound interventions regarding substance use." Disturbingly, it also noted the following fundamental failures of the draft Bill:

- To acknowledge that substance use is a chronic and relapsing medical condition;
- Sufficiently to recognise the links between substance use, HIV/AIDS and other infectious diseases; and
- To include key interventions to prevent and treat substance use and associated harms.

Bill B 12—2008, which was tabled in Parliament in February 2008, did not go particularly far in addressing our concerns. A new submission, once again endorsed by the ALP and TAC, pointed out that while the DSD had indeed taken some of the earlier proposals into account, the tabled Bill

similarly failed to address what ARASA had previously identified as "fundamental failures". In addition to joining ARASA in making oral submissions on the Bill before the Portfolio Committee on Social Development, the ALP also joined forces with a range of other civil society organisations arguing for similar amendments. Despite all their efforts, progress was limited and slow.

A new submission, once again endorsed by the ALP and TAC, pointed out that while the DSD had indeed taken some of the earlier proposals into account, the tabled Bill similarly failed to address what ARASA had previously identified as "fundamental failures".

The ALP then approached the Minister of Social Development, Dr. Zola Skweyiya, requesting an urgent meeting to address two key concerns: first, the Bill's failure to incorporate HIV reduction measures, as recommended by the NSP; and second, the apparent reluctance of the Committee – as exhibited at its public hearings on the Bill – to implement such measures. While pointing out that the Committee's subsequent deliberations had suggested "some movement" on the issues, the ALP's letter asked Skweyiya "to ensure that the processing of the Bill … [did] not take place in a manner that undermines the NSP and our collective response to HIV and AIDS." In his response, Skweyiya stated that he would "personally raise the matter with Mr Mike Masutha, Chairperson of the Portfolio Committee".

On 18 November 2008, Masutha's committee adopted Bill B 12D—2008.[12] This Bill, which expressly recognises the link between substance abuse and "HIV and AIDS and other health conditions", also calls for the Central Drug Authority – an intersectoral statutory body – to develop effective HIV prevention strategies as an integral part of prevention, early intervention, reintegration and aftercare services. It does not, however, recognise substance use as a chronic and relapsing medical condition. Nor does it include key interventions to prevent and treat substance use and associated harms. Thus while HIV prevention in the context of substance use is clearly on the agenda, the NSP's call for harm reduction measures will have to be addressed by the regulation drafting process. We trust that Minister Skweyiya – or his successor – will ensure that this indeed takes place.

Insurance Laws Amendment Bill [B 26—2008]

In mid-2008, the ALP became aware of proposed amendments to the Short-term Insurance Act 53 of 1998 that – if passed in the proposed form – would have permitted the Minister of Finance to control a key area of private health sector regulation. In particular, the proposals would have permitted the Minister, *after* consultation with his or her counterpart in health, effectively to exempt a number of health insurance products from the operation of the Medical Schemes Act 131 of 1998. As noted in an ALP letter to the Director-General of the National Treasury dated 4 June 2008:

> "[W]e are concerned about the effect that the Bill may have on the medical scheme environment …. With regard to risk-rating, our concern is that younger and healthier individuals may choose to subscribe to the minimum cover of [a] medical scheme, and 'top-up' through a separate health insurance product. The movement of healthier individuals out of medical schemes will undermine the cross-subsidisation of risk that takes place through community rating. … If this occurs, the cost of medical scheme cover will rise as will the dependency on the public sector. This is precisely the situation that the Medical Schemes Act attempted to reverse in 1998."

The ALP subsequently established that these concerns, which were shared by the Council for Medical Schemes, were considered and – in large part – addressed. Thus in our follow-up letter to the National Treasury dated 12 June 2008, we indicated that – having read the latest draft of the Bill – we were "largely satisfied that our concerns … [had] been addressed in relation to the overlap between insurance products and the medical schemes environment." While the Bill still made provision for the exemption of certain health insurance products, it entrenched a number of safeguards.

12. Bill B 12D—2008 is the version of the Bill as amended by the Select Committee on Social Services in the NCOP.

Section 52 of the Insurance Laws Amendment Act 27 of 2008 inserts a new section 70(2A) into the Short-term Insurance Act that empowers the Minister of Finance, *in* consultation with the Minister of Health, to make regulations allowing for exemptions. In addition, the section sets out a number of conditions that must be met in making the regulations, including the following:

- There must be consultation between the National Treasury, the Registrar of Short-term Insurance and the Registrar of Medical Schemes; and
- The Minister of Finance must have "regard to the objectives and purpose of the Medical Schemes Act" and must publish draft regulations for public comment and "submit the regulations to Parliament, while it is in session, for parliamentary scrutiny at least one month before their promulgation."

These safeguards will go a long way towards ensuring that the exemption power is not used to allow for health insurance products to be introduced by stealth. Further, the consultation requirements and the need for parliamentary scrutiny will ensure that substantive concerns such as those raised in the ALP's letter to the National Treasury are in fact addressed. The power to grant exemption may remain, but its exercise is now heavily constrained.

Intellectual Property from Publicly Financed Research & Development Bill [B 46—2008]

Unlike its interventions in respect of other bills, the ALP's input in this important area focused on the Bill's development *before* it was tabled in Parliament. In our previous review, we wrote about the ALP's participation in the development of the Intellectual Property Rights from Publicly Financed Research Framework, including our participation in a consultation hosted by the Department of Science and Technology (DST). Since then, we have made two further submissions on earlier drafts of the Bill.

In July 2007, we made a written submission on the first draft Bill published by the DST for public comment. That submission, which noted that the draft bill went "a significant way towards ensuring access to the benefits of publicly funded research", focused on three areas – licensing conditions, private funding and government walk-in rights. In respect of each of these three areas the ALP's submission sought to ensure that the private sector does not unduly benefit from publicly financed research.

In March 2008, the ALP participated in a further stakeholder consultation on a revised version of the Bill. Following the consultation, we made one final submission that focused primarily on a handful of technical issues. In addition, it addressed a number of substantive issues raised by participants at the consultation. Some of these inputs had sought unreasonably to advance narrow private interests at the expense of the broader public interest.

In addition, it addressed a number of substantive issues raised by participants at the consultation. Some of these inputs had sought unreasonably to advance narrow private interests at the expense of the broader public interest.

On 17 December 2008, the President assented to the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008. The main object of the Act is to ensure that "intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic [of South Africa], whether it be for a social, economic, military or any other benefit." Amongst other further objects, the Act "seeks to ensure that … where necessary, the State may use the results of publicly financed research … in the interest of the people of the Republic.

Importantly, section 14(1) of the Act – which makes provision for the acquisition of intellectual property rights by the state – makes it plain that the "rights acquired by the State … are additional to the rights granted to the State in terms of any other legislation". For example, the state remains

entitled to make use of its various powers in the Patents Act 57 of 1978, such as the authority in section 4 to use an invention for a public purpose. The new Act simply grants additional powers in respect of inventions that owe their existence – even if only in part – to public funding.

Draft Regulations in terms of the Criminal Law (Sexual Offences and Related Matters) Amendment Act

Having been actively involved in making submissions on various drafts of the legislation, both on our own and as a member of the Sexual Offences Working Group, the ALP felt it necessary to use the regulation drafting process to raise concerns that had yet to be addressed. In addition to raising concerns about alleged procedural irregularities and a rushed public consultation process, the submission focused on three key issues that have implications for the rights of rape survivors and their alleged offenders: HIV testing; access to post-exposure prophylaxis (PEP) services; and time-consuming procedures.

We therefore recommended that all health facilities should be able to initiate rape survivors on PEP and then refer them to designated facilities for further care.

On **HIV testing**, the submission recommended that the regulations specify that a polymerase chain reaction (PCR) test be used to establish the serostatus of rape survivors and their alleged offenders. This is because the window period for standard antibody tests can last anywhere from three weeks to six months. A PCR test, on the other hand, can establish HIV status within days of infection. The empowering provision in the Amendment Act merely refers to "any validated and medically recognised test for determining the presence or absence of HIV infection in a person".

The focus of our concerns regarding **access to PEP services** considered the limitation of service provision to "designated health facilities". While recognising "that full PEP requires training of health care workers who are able to monitor and explain the importance of PEP and how the treatment works", we expressed concern that the designated facility requirement did not "adequately consider the need for PEP to be started as soon as is reasonably possible after the incident." We therefore recommended that all health facilities should be able to initiate rape survivors on PEP and then refer them to designated facilities for further care.

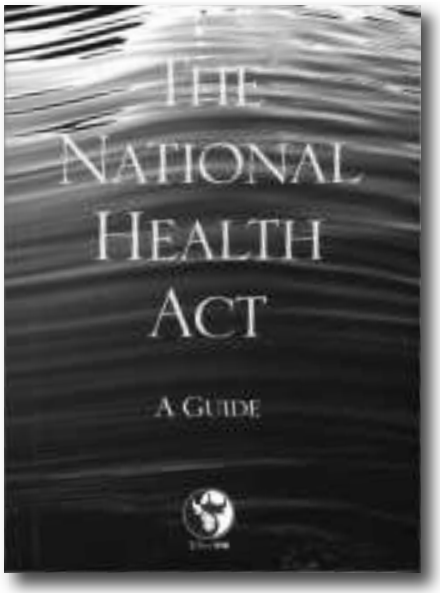
Finally, the submission pointed out that the **time-consuming procedures** to be followed before a compulsory HIV test could be performed on an alleged sexual offender would mean that it would be "the exception rather than the rule" for the provisions to be used so as to "provide the survivor of a sexual assault with any closure within a reasonable timeframe." We therefore argued that should the Department of Justice and Constitutional Development (DoJ&CD) be unable to "find a way to significantly streamline this process", the "constitutionality of the draft regulations and the Act itself" would be drawn further into question.

Unfortunately, our submission had no impact on the final form of the published regulations. This is unsurprising, given the tight timeframes within which the draft regulations were finalised. Given the lengthy delay in processing the amendment legislation in Parliament, the DoJ&CD appeared intent on rushing the regulation drafting process. Interested parties were only given three weeks to make input, with the final regulations being published less than two months after the closing dates for submissions. The result, unfortunately, reflects this rush.

Publications

In addition to the numerous submissions and policy documents discussed above, a number of ALP staff members also worked on a range of other publications during the period under review. A full list of published book chapters, journal articles and opinion pieces is set out in the annexures to this review. In addition to these, the ALP developed and finalised a guide to the National Health Act 61 of 2003, which was published in late 2008 by *Siber* Ink as Hassim, Heywood, Berger and Honermann, *The National Health Act: A Guide*.

The NHA is arguably the most important statute passed by Parliament to give effect to the right



of everyone to have access to health care services. The ALP's guide aims to make the legislation easily accessible to the public at large, putting an annotated text of the NHA into the hands of ordinary people in communities and organizations. In so doing, the guide should help to ensure that that they can start to organise and mobilise to demand the full implementation of their health rights.

The guide starts by locating the Act in its proper context and providing commentary of three key issues: getting access to health care, getting involved in the health system, and health planning and budgeting. Thereafter, it provides a running commentary on the full text of the legislation. Amongst other things, it notes which sections have and have not been implemented, provides information on the status of regulations referred to by the text, and identifies relevant case law.[13]

Conclusion

Over the past 18 months, the ALP has made a number of written and oral submissions on law reform and health policy. However, the impact of these submissions is questionable. Judging from the comments of independent reviewers, the submissions are generally thought to be of a high quality. Yet there is very little evidence that they are considered by the DoH. Indeed, the ALP has experienced resistance to our submissions and recommendations by Parliament as well, which is somewhat more disturbing.

The constitutional premise of accountable and responsive government, as well as that of participatory democracy, has been severely undermined in our interactions with the DoH under the leadership of the former Minister. The elemental nature of these principles was voiced by Justice Ngcobo in *Doctors for Life v The Speaker of the National Assembly:*

> The very first provision of our Constitution, which establishes the founding values of our constitutional democracy, includes as part of those values "a multi-party system of democratic government, to ensure accountability, responsiveness and openness". Commitment to principles of accountability, responsiveness and openness shows that our constitutional democracy is not only representative but also contains participatory elements. This is a defining feature of the democracy that is contemplated. It is apparent from the preamble of the Constitution that one of the basic objectives of our constitutional enterprise is the establishment of a democratic and open government in which the people shall participate to some degree in the law-making process.[14]

Given our experience, the ALP has questioned the value of continuing to produce submissions on draft laws and policies where we are not certain that they will even be considered. Through our focus on various aspects of health law and policy, we have developed the capacity for continued applied work in this area. With the appointment of Barbara Hogan as the new Minister of Health, we are hopeful that we will be able to have our ideas heard through means other than litigation.

13. The guide ends with three appendices: a list of regulations published under the Act; brief summaries of other important health legislation and policy documents; and contact information for important regulatory councils, oversight bodies and other health organisations.
14. 2006 (6) SA 416 (CC) at paragraph 111