AIDS LAW PROJECT, AIDS CONSORTIUM &

TREATMENT ACTION CAMPAIGN

SUBMISSION ON THE DRAFT NATIONAL HEALTH BILL, 2001

8 FEBRUARY 2002

DRAFTED BY JONATHAN BERGER

LAW AND TREATMENT ACCESS RESEARCHER

AIDS LAW PROJECT

Introduction

The AIDS Law Project (ALP), AIDS Consortium (Consortium) and the Treatment Action Campaign (TAC) welcome the release of the draft National Health Bill (the NHB or the Bill), published for public comment on 9 November 2001,[1] and to be tabled in Parliament later this year. In taking this opportunity to make representations on the proposed Bill, we recognise that the establishment of a national health system to "encompass public, private and non-governmental providers of health services" and the provision of "the best possible health services that available resources can afford" are essential components in addressing the apartheid legacy of injustice and inequity.

That the state has positive obligations to realise the right of access to health services is expressly recognised in the NHB. In developing the legislative framework that is intended to form an integral component of the state's constitutional obligations in

[1] *GG* No. 22824 at 12.

respect of health care services, the Bill recognises the need to "[e]stablish a health system of decentralised management, governance, research, enquiry and advocacy which encourages participation by everyone", as well as to "[p]romote a spirit of co-operation and shared responsibility among public, non-governmental and private health professionals and providers and other relevant sectors". Central to the concept of the co-operative management of health services is the recognition that national government is responsible for the development of "national guidelines, norms and standards", with "each province, municipality and district … address[ing] questions of policy and delivery of services".[2]

To the extent that such issues are addressed, the NHB will go some way towards the progressive realisation of the right of access to health care services. In particular, the ALP, Consortium and TAC recognise the important role to be played by the following provisions:

- the rights and duties of both health care providers and users;[3]
- the Minister's obligations regarding the rendering of basic health services;[4]
- the codification of legal requirements relating to informed consent and patient confidentiality;[5]
- the duties of users, particularly the requirement that health care providers be treated with dignity and respect;[6]
- the codification of the rights of health care providers to a safe working environment and non-discrimination on the basis of health status;[7]

[2] Preamble.
[3] Section 3.
[4] Section 4(1)(d).
[5] Sections 10, 11, 12 and 14.
[6] Section 22(c).

- the establishment of crucial health structures such as the national and provincial health authorities, the National Health Management Committee, provincial inspectorates for health establishments, the Essential National Health Research Committee and the National Health Ethics Council, to name but a few;[8]
- the requirements relating to the preparation of national and provincial health plans;[9]
- the establishment in law of the district health system;[10]
- the recognition that "a co-ordinated relationship between private and public health establishments in the delivery of health services" is crucial;[11]
- the codification of a non-profit blood transfusion service;[12]
- the setting of criteria by which health research priorities are to be determined;[13] and
- the national health department's acceptance of responsibility for norms and standards of health care for convicted persons and persons awaiting trial.[14]

It is our submission, however, that in key respects the NHB not only undermines the right of access to health services, as entrenched in section 27 of the Constitution and

---

[7] Sections 23 and 24.
[8] Sections 28, 35, 30, 38, 81 and 84 respectively. While the ALP, Consortium and TAC welcome the establishment of such bodies, we recommend that their relationship to each other be revisited. For a more detailed discussion of this issue, please see the analysis of chapter 3 below.
[9] Sections 32 and 39 respectively.
[10] Sections 40 – 46 inclusive.
[11] Section 57.
[12] Section 65.
[13] Section 82.
[14] Schedule 1: Part A(5)(f).

as understood in the light of the Constitutional Court decisions in *Soobramoney v The Minister of Health, Kwazulu Natal* and *Government of the Republic of South Africa and Others v Grootboom and Others*,[15] but also the Bill's stated objectives. Further, numerous provisions of the NHB raise concerns relating to constitutionally entrenched rights to privacy, bodily and psychological integrity, and academic freedom and freedom of scientific research. In addition, many provisions raise rule of law concerns. It is in respect of such provisions that this submission is primarily concerned.

Before analysing the NHB in detail, we believe that attention needs to be drawn to section 2 of the Bill which states that "where a conflict arises between the provisions of th[e NHB] and those of any other health legislation, with the exception of legislation that expressly amends th[e NHB], the provisions of th[e NHB] will apply." This provision arises in the context of legislation that fails to mention which statutes it repeals or amends. This is quite unusual, given that draft bills published for comment usually detail the extent to which they repeal or amend existing legislation.

In the absence of such a provision, the effect of the NHB is to render certain provisions of other health legislation of no force and effect, although still valid. This introduces into health legislation an unacceptable level of confusion, in conflict with the rule of law,[16] which at minimum requires that rules are sufficiently clear to enable the reasonable person to regulate his or her conduct accordingly. This will hopefully be resolved when the Bill is tabled, setting out the extent to which existing health legislation is repealed or amended.

[15] 1998(1) SA 765(CC) and 2001 (1) SA 46 (CC) respectively.
[16] The rule of law is entrenched in section 1(c) of the Constitution as a foundational constitutional value.

Chapter 1: Definitions, Purpose and Responsibility for Health

Definition of basic health services

The Minister is "responsible within the limits of available resources to ensure the rendering of basic health services",[17] which are defined in section 1 as "those services as prescribed by the Minister, after consultation with the National Health Authority". In essence, the definition empowers the Minister to make decisions that have the potential to limit access to health care services without any direction being given by Parliament regarding what factors to consider in making such a determination. This is in contrast with section 82 of the Bill, which sets out factors to be considered in determining health research priorities.[18]

Given that the majority of people in South Africa are reliant on the public sector for the provision of health care services, it is questionable whether a power to determine what in effect will be the extent of health care services that most people receive may be exercised without guidance from Parliament.[19] In addition, the NHB also confers authority on the Minister to make decisions regarding who may receive free health services in the public sector,[20] similarly without parliamentary guidance.

---

[17] Section 4(1)(d).

[18] These factors include:

> "(a) the burden of disease;
> (b) the cost-effectiveness of interventions aimed at reducing the burden of disease;
> (c) the availability of human and institutional resources for the implementation of intervention at the level closest to the affected communities; and
> (d) the health needs of communities."

[19] That such decisions are to be taken after consultation with the National Health Authority in no way absolves Parliament of its obligation to provide the necessary framework for the determination of such crucial issues.

[20] Section 5.

Not only is Parliament's role desirable, it is also constitutionally mandated. Writing for a unanimous Constitutional Court in *Dawood and Another v Minister of Home Affairs and Others; Shalabi and Another v Minister of Home Affairs and Others; Thomas and Another v Minister of Home Affairs and Others*, Justice O'Regan held that "[i]n a constitutional democracy such as ours the responsibility to protect constitutional rights in practice is imposed both on the Legislature and on the Executive and its officials."[21] According to Justice O'Regan, it is the responsibility of the legislature to ensure that when it confers discretionary powers, the empowering legislation is drafted in such a way as to limit the risk of an unconstitutional exercise of such powers.[22] To remedy the unconstitutionality caused by a broad discretionary power granted in the absence of statutory guidance circumscribing its use, the Constitutional Court in *Dawood* referred the legislation back to Parliament to determine what guidance should be given to the decision-makers.[23]

That the Minister would be obliged to exercise her powers in accordance with the Constitution, in particular in a reasonable manner so as progressively to realise the right of access to health care services in section 27, is not in dispute. Despite the availability of legal recourse following any unconstitutional exercise of discretionary powers, the granting of such powers in the absence of guidelines is nevertheless problematic. "The fact … that the exercise of a discretionary power may subsequently be successfully challenged on administrative grounds", Justice O'Regan argued in *Dawood*, "does not relieve the Legislature of its constitutional obligations to promote, protect and fulfil the rights entrenched in the Bill of Rights."[24]

---

[21] 2000 (3) SA 936 (CC) at para 48.
[22] Ibid.
[23] See ibid. at para 63.
[24] Ibid.

The ALP, Consortium and TAC therefore recommend that the definition of "basic health services" be redrafted as follows:

> "Basic health services mean those services as prescribed by the Minister, after consultation with the National Health Authority. In prescribing basic health services, the Minister must have regard, amongst other things, to –
> (a) the health needs of communities;
> (b) the burden of disease;
> (c) the cost-effectiveness of interventions aimed at reducing the burden of disease;
> (d) the availability of human and institutional resources for the implementation of intervention at the level closest to the affected communities; and
> (e) mechanisms whereby the requisite human and institutional resources may be made available."[25]

Definition of disability

Section 1 of the NHB defines "disability" as "a long term or recurring physical or mental impairment which substantially limits a person's ability to perform an activity in the manner or within the range considered normal for a human being". This narrow definition of disability is problematic in that it runs contrary to a broadening international consensus on the understanding of disability. In short, disability is generally understood not to be limited to incapacity.

In numerous jurisdictions, disability as a legal concept is defined particularly broadly. In *Bragdon v Abbott*,[26] for example, the US Supreme Court was asked to decide

[25] In this regard, see *Treatment Action Campaign and Others v Minister of Health and Others* (Unreported decision of the High Court of South Africa (Transvaal Provincial Division), case no: 21182/2001, delivered on 14 December 2001), where Justice Botha held that "[o]nly if there is a coherent plan will it be possible to obtain the further resources that are required for a nationwide programme [to reduce the transmission of HIV from mother to child], whether in the form of a reorganisation of priorities or by means of further budgetary allocations." This holding, in line with the constitutional obligation in section 27(2) to take all reasonable steps towards ensuring that access to health care services is realised, means that the state is constitutionally obliged to take all reasonable measures to ensure that resources are available for the provision of health care services.

[26] 141 L Ed 2d 540.

whether the Americans with Disabilities Act of 1990 (ADA) regards HIV infection is a disability. The ADA defines disability as follows:

> "(A) a physical or metal impairment that substantially limits one or more of the major life activities of such individual;
> (B) a record of such an impairment; or
> (C) being regarded as having such impairment."[27]

On the basis of subsection (A), the Court held that—

> "[i]n light of the immediacy with which the virus begins to damage the infected person's white blood cells and the severity of the disease. we hold it is an impairment from the moment of infection. . . . HIV infection must be regarded as a physiological disorder with a constant and detrimental effect on the infected person's hemic and lymphatic systems from the moment of infection. HIV infection satisfies the statutory and regulatory definition of a physical impairment during every stage of the disease."[28]

In addition, it held that—

> "[t]he Act addresses substantial limitations on major life activities, not utter inabilities. Conception and childbirth are not impossible for [a person with] HIV … but, without doubt, are dangerous to the public health. This meets the definition of a substantial limitation. …There are added costs for antiretroviral therapy, supplemental insurance, and long-term care for the child who must be examined and, tragic to think, treated for the infection."[29]

In Australia, the Disability Discrimination Act 1992 (Cth) (the DDA) covers a broad range of people with disabilities. Section 4 of the Australian DDA defines disability as follows:

> "(a) total or partial loss of the person's bodily or mental functions; or

[27] § 12102(2) of 42 USC § 12101.
[28] Ibid at 556 - 557.

[29] Id at 559.

> (b) total or partial loss of a part of the body; or
> (c) the presence in the body of organisms causing disease or illness; or
> (d) the presence in the body of organisms capable of causing disease or illness; or
> (e) the malfunction, malformation or disfigurement of a part of the person's body; or
> (f) disorder or malfunction that results in the person learning differently from a person without the disorder or malfunction;
> (g) a disorder, illness or disease that affects a person's thought processes, perception of reality, emotions or judgment or that results in disturbed behaviour;
>
> and includes a disability that:
>
> (h) presently exists; or
> (i) previously existed but no longer exists; or
> (j) may exist in the future; or
> (k) is imputed to a person."

This definition makes it plain that not only are perceptions of disability included, but also mere medical diagnoses of infections like HIV. In *X v Commonwealth of Australia and Another*, McHugh J of the High Court of Australia held that—

> "[s]ection 4(1) of the [Disability Discrimination] Act defines 'disability' to include 'the presence in the body of organisms causing disease or illness'; and 'the presence in the body of organisms capable of causing disease or illness'. HIV is an infectious disease which is transmissible by the exchange of bodily fluids including blood. That was common ground in the Commission proceedings. The Commissioner found that the HIV infection 'usually leads to the onset of Acquired Immune Deficiency Syndrome (AIDS) which is a fatal illness'. It was also common ground that being infected with HIV is a 'disability' within the meaning of s 4, under one or both of the limbs discussed."[30]

While broad definitions of disability arise primarily in the context of anti-discrimination legislation, there is no reason to restrict their application, unless the circumstances so dictate. The ALP, Consortium and TAC submit that the NHB is not one of those pieces of legislation requiring a narrow definition. To the contrary,

[30] 167 ALR 529 (HC of A) at para 20 (footnotes omitted).

legislation that will form the basis of a transformed health care sector needs to ensure that it sets the standard according to which all other health-related legislation conforms.

Definition of emergency treatment

Section 1 defines "emergency treatment" as "treatment which is needed to treat a life-threatening but reversible deterioration in a person's health status and it continues to be emergency treatment until the condition of the person has stabilised or has been reversed to a particular extent". In section 7, the NHB prohibits all public and private health establishments from denying "a person requiring emergency treatment such treatment if the establishment is open and able to provide the necessary treatment." This right to emergency treatment may be "[s]ubject to any limitations which the Minister or the relevant members of the Executive Council may prescribe".

Since the introduction of highly active antiretroviral therapy (HAART), AIDS may be categorised as a "life threatening but reversible deterioration in a person's health status". In the absence of regulations limiting this right, the combined effect of the definition of "emergency treatment" in section 1 with the obligation on health establishments to provide emergency treatment "if the establishment is open and *able to provide the necessary treatment*" may well lead to the result that all people with AIDS have a right to HAART at those health establishments that are providing such treatment. This would result in overburdening those establishments currently providing HAART, such as many private clinics as well as antiretroviral programmes such as those at the Perinatal HIV Research Unit at Chris Hani Baragwanath in Soweto and the Médecins Sans Frontières (MSF) ART programme in Khayelitsha.

The ALP, Consortium and TAC believe that the definition of "emergency treatment" in section 1 is problematic in that it substantially broader than the Constitutional Court's understanding of the concept. The essence of the Court's narrow construction of emergency treatment is that "it would make it substantially more difficult for the state to fulfil its primary obligations under sections 27(1) and (2) [of the Constitution] to provide health care services to "everyone" within its available resources".[31] In essence, "emergency treatment" is not the treatment of chronic or terminal illnesses, but rather treatment for someone "who suffers a sudden catastrophe which calls for immediate medical attention … [and who] should not be turned away from a hospital which is able to provide the necessary treatment."[32] The ALP, Consortium and TAC therefore recommend that the following definition of "emergency treatment" be adopted:

> "the treatment of a life-threatening condition that is not the direct result of a chronic or terminal illness, which shall be discontinued once the condition of the person has stabilised or has been reversed to a particular extent".

Eligibility for free health services in public health establishments

It is difficult to ascertain which of two possible meanings to attribute to section 5, dealing with the powers of the Minister to determine eligibility for free health services in public health establishments. On the first reading, the Minister may "determine that certain persons are eligible for free health services at public health establishments", with the Minister being further authorised to publish regulations relating to the conditions of such free access. This raises concerns relating to

[31] *Soobramoney*, supra note 15 at para 19.
[32] Ibid. at para 20.

Parliament's role in providing sufficient guidance for the exercise of a discretion that has the potential to substantially limit rights of access to health care services. In the absence of such legislative guidance, one would expect to see the NHB expressly requiring both broad public consultation and consultation with bodies such as the Human Rights Commission. Without such broad consultation, or at a minimum clear guidance from the legislature on the exercise of the discretion, it would be difficult to argue that the state is taking "reasonable legislative and other measures … to achieve the progressive realisation" of the right of access to health care services, as required by section 27(2) of the Constitution.

On the second construction of section 5, the Minister is required to determine eligibility on the basis of conditions as set out in regulations. As the Bill is silent regarding who may prescribe such conditions, and given the Minister's power in section 99 to issue regulations "on any matter in order to achieve the purpose of [the NHB]", the Minister clearly is empowered both to issue regulations determining conditions for eligibility, as well as determining which categories of person are eligible. While this construction still raises some concerns relating to the role of Parliament in providing guidance for the exercise of discretions, it is not as problematic as the first construction that does not require the setting of eligibility criteria at any point in the legislative process.

The ALP, Consortium and TAC recommend that the NHB set out criteria in terms of which the Minister determines those categories of persons eligible for free health services, with section 5 being redrafted as follows:

> "The Minister may prescribe conditions subject to which certain persons are eligible for free health services at public health establishments. In prescribing conditions, the Minister must have regard to –
>
> (a) the range of free services currently available;
> (b) the categories of persons already receiving free services; and
> (c) the impact of the conditions on access to health care services".

Chapter 2: Rights and Duties of Users and Health Care Providers

Emergency treatment

In section 7, the NHB prohibits all public and private health establishments from denying "a person requiring emergency treatment such treatment if the establishment is open and able to provide the necessary treatment." To avoid the type of problematic scenarios outlined earlier (dealing with the definition of "emergency treatment"), the ALP, Consortium and TAC recommend that section 7 be separated into two parts, the first of which sets out the right, with the second part setting out justifiable limitations of the right. In relation to the right, we recommend the following formulation:

> "Every person has the right to emergency treatment at a health establishment when it is required."

In relation to the second, we recommend that issues pertaining to the availability of equipment and medication, the status of a health establishment and whether or not it is open, and any other justifiable limitations of the right be set out in detail. Parliament's constitutional obligations in terms of section 7(2) "to respect, protect, promote and fulfil the rights in the Bill of Rights" are best discharged by following such a course of action.

Participation in decisions

The ALP, Consortium and TAC are concerned that the right to participate in any decision affecting a user's personal health treatment is limited to the user, and only where it is "reasonably practicable for the user to participate". It is accepted that there may well be circumstances within which it is not reasonable to afford users a right to participate in decision-making, but to what extent should matters of practicality override constitutional rights to autonomy? We submit that the test should be reasonableness, not practicality. Further, should it not be reasonable for a user to participate in such decision-making processes, it is appropriate to afford such a right to the user's spouse or partner, or other appropriate person.

Users' access to records

Section 16(1) sets out the circumstances in which a person who holds parental authority over a user who is a minor is to be refused access to the health records of that user. Section 16(1)(b) makes it plain that a user's consent is always required for the contents of his or her health records to be disclosed to a person holding parental authority over him or her. Without such safeguards, which clearly include all information relating to sexual and reproductive health, efforts to reduce the numbers of new HIV infections amongst youth will be severely undermined.

While welcoming this provision, we are concerned about a number of problematic issues it raises. In particular, we are concerned that in many cases it will result in a minor being put in the position where he or she is forced to refuse access to his or her health records. To minimise this negative aspect of what is otherwise a desirable

provision, the ALP, Consortium and TAC recommend the following reformulation of section 16(1):

> "(a) A person who holds parental authority over a user who is a minor is entitled to have access to the health records of that user if a request for such access is made to the head of the health establishment, and –
>
> (i) the head of the health establishment concerned does not have reasonable grounds for believing that the disclosure of the content of that record to the holder of parental authority could be prejudicial to the user;
>
> (ii) the user, after being consulted by the head of the health establishment, permits the contents of his or her health records to be disclosed to the holder of parental authority; and
>
> (iii) the access would not be in contravention of the rights of the user contained in the Choice on Termination of Pregnancy Act, 92 of 1996.
>
> (b) If access to the health records of that user is denied, the head of the health establishment concerned may not disclose the specific reason for the denial of access."

Section 16(2) permits the temporary denial to a user of access to information in his or her health record "if disclosure of that information would be likely to be seriously prejudicial to the user". It is difficult to understand how such a provision would operate, given the lack of statutory guidance regarding what is to be considered as prejudicial to the user, or what is understood by the concept of temporary denial.

The ALP, Consortium and TAC recognise the need, in limited circumstances such as severe depression, to permit the temporary denial of access to information. Nevertheless, it is difficult to understand the purpose served by section 16(2)'s overbreadth. In the result, we recommend that the period of denial be expressly limited, that the denial be re-evaluated at the expiry of this limited time period, and

that section 16(2) expressly set out guidelines for the determination of what may be considered as being "seriously prejudicial" to the user.

A general concern raised by the provisions dealing with users' access is the potential for conflict between section 16 of the NHB and the Promotion of Access to Information Act, 2 of 2000 (the Access to Information Act). As the Access to Information Act can in no way be categorised as health legislation for the purposes of section 2 of the NHB, the Bill needs to set out the extent to which the NHB amends the Access to Information Act in respect of access to health records. In addition, the Access to Information Act should be amended by the insertion of the following provision:

> "This Act does not apply to any person to whom and to the extent to which the National Health Act, 2002, applies."

Health care provider access to health records

Where a health care worker requires access to a user's health records for purposes of treating that particular user, there can be no objection to such access, provided that the user's confidentiality is respected. However, in relation to access for purposes of study, teaching or research, in the absence of a user's consent such access should only be allowed as long as the identity of the user remains anonymous and the information is unlinked to any person. While it is in the public interest that such information be available for purposes of study, teaching or research, there is no public interest served by knowledge of the user's identity. As such, a limitation of a user's right to confidentiality would be unjustifiable and thereby unconstitutional.

Protection of health records

The ALP, Consortium and TAC welcome the inclusion of section 19, which requires that measures be set up to prevent unauthorised access to users' details and files. Implicit in the limited rights of access afforded administrative staff and health care providers in sections 17 and 18 respectively is that a user's rights to confidentiality, as set out in section 14, are to be respected. As section 19 currently reads, it is an offence to make unauthorised copies of a user's record but it is not an offence to distribute such records. To correct this inconsistency and to ensure that a user's rights to confidentiality are indeed respected, we recommend that section 19(2) be expanded so as to include a provision that makes it an offence to breach a user's confidentiality.

Complaints procedures

To give full effect to the rights of users in respect of the laying of complaints regarding health services, we recommend that section 21 be redrafted to read as follows:

> "The relevant Member of the Executive Council, with the concurrence of the Provincial Health Authority, must –
>
> (a) prescribe clear, open and user-friendly procedures to be followed by users for laying complaints regarding the provision of health services; and
>
> (b) establish mechanisms to inform the users of the procedures."

Duties of users

While the ALP, Consortium and TAC welcome provisions setting out the duties of users, we question the appropriateness of requiring users to "assist in maintaining health establishments in habitable conditions". While it reasonable to require that users refrain from engaging in conduct that renders health establishments

uninhabitable, the creation of positive obligations could lead to the unacceptable situation of users—many of whom may be particularly sick—being expected to provide basic cleaning services without pay.

Non-discrimination on grounds of health

Perhaps most disturbing in this chapter is section 24(2) which grants heads of hospital establishments discretion regarding the rendering of services by health care providers on the basis of health status. This raises concerns relating to potential conflict with the Promotion of Equality and Prevention of Unfair Discrimination Act, 4 of 2000 (the Equality Act). While section 24(2) clearly states that it is "subject to any other law", which includes the Equality Act, the express authorisation regarding conditions relating to the rendering of services by health care providers is nevertheless problematic.

While the exercise of the discretion is subject to the Equality Act and the Constitution, and has to be exercised "in accordance with any guidelines determined by the Minister", the provision clearly falls foul of the requirement set out in *Dawood* regarding the role of the legislature in protecting, promoting and fulfilling constitutionally entrenched rights. This will be even more pronounced in the absence of ministerial guidelines, which are not required by the Bill. To limit an unlawful exercise of discretion, the ALP, Consortium and TAC recommend that section 24(2) set out objective criteria to prevent unfair discrimination against or the victimisation of health care providers who may have stigmatised medical conditions.

Chapters 3 and 4: National and Provincial Health Structures

The ALP, Consortium and TAC welcome the establishment of key national and provincial health structures—the National Health Authority (NHA), the provincial health authorities (PHAs), the National Health Management Committee (the Management Committee), and provincial inspectorates for health establishments (health inspectorates).[33] From our reading of the NHB, however, there appears to be an unnecessary and problematic overlap of functions, membership and lines of accountability. We believe that this is easily remedied by ensuring that—

- the NHA and PHAs are responsible primarily for the development of policy and health legislation, with the NHA being accountable to Parliament and the Human Rights Commission, and the PHAs being accountable to their respective provincial legislatures as well as to the NHA;
- the Management Committee is primarily responsible for the co-ordination of policy implementation and the making of recommendations to the NHA on matters arising from such co-ordination, being accountable to the NHA;
- the health inspectorates are primarily responsible for the monitoring and evaluation of compliance, being accountable to their respective PHAs; and
- the composition of each structure reflects the functions to be performed, as well as the need to "[p]romote a spirit of co-operation and shared responsibility among public, non-governmental and private health professionals and providers and other relevant sectors".[34]

These issues are dealt with in greater detail below, including a discussion regarding what is understood by the concept of accountability.

[33] Sections 28, 35, 30 and 38 respectively.
[34] Preamble.

Performance of national functions by the provinces

While we welcome the provisions relating to the delegation of national department functions in the circumstances contemplated in section 26(1), we submit that the current formulation of subsection (3) may frustrate the efficient working of the delegation provisions as a whole, and may indeed serve to discourage MECs from making requests for delegation in terms of section 26(1)(a). To address these concerns, we recommend that section 26(3) be redrafted to read as follows:

> "The Minister may impose any such *reasonable* conditions as he or she deems necessary upon any delegation referred to in terms of subsection (1), and may at any time vary or withdraw such conditions *if good cause exists*."

Composition of the National Health Authority

If the NHB is indeed meant to "[e]stablish a health system of decentralised management, governance, research, enquiry and advocacy which encourages participation by everyone", as well as to "[p]romote a spirit of co-operation and shared responsibility among public, non-governmental and private health professionals and providers and other relevant sectors", it is difficult to see how this can be achieved—if not frustrated—by the exclusion from the NHA of key stakeholders, such as civil society organisations and organisations representing the interests of users. At best, the NHA "may in its discretion consult or receive representations from any person, body or authority."[35]

This is not reflected in bodies such as the National Health Ethics Council (Ethics Council), established in terms of section 84 of the Bill. Compared to the narrow composition of the NHA, the Ethics Council requires persons with specialised skills

[35] Section 29(4).

(such as research ethics and ethics education), as well as representatives of key organisations and constituencies (such as "community representatives"), persons from both the public and private health care sectors, as well as a representative from the Medicines Control Council. While there may be good reason not to include people with specialised skills on the NHA directly, receiving their contributions through the work of specialist subcommittees instead, there is no good reason for the formal exclusion of civil society participation. To the contrary, civil society participation in bodies like the NHA is a necessary component of rational and reasonable policy-making processes.

If the Bill is serious about participation, it needs to formalise the role of key stakeholders. Such a formalised role for civil society finds support in the recommendations coming out of the Health Summit held in Johannesburg from 18 to 20 November 2001. In particular, the summit gave rise to an Action Team—to be convened by the DG and including key sectors of civil society—that is tasked primarily with "ensuring that the major recommendations of the Summit produce results for the people".[36] Under the title of "Consulting those who count", the Minister is quoted as saying that "health for all will only be achieved through the focused action of every organization involved in health and if we draw on the energy of the communities we serve." The ALP, Consortium and TAC submit that the logical consequence of such an approach is full participation for civil society bodies on the NHA.

[36] Department of Health, "Health Summit 2001: Reaching Out for Better Health for All", Sowetan (26 November 2001) at 23.

Ministerial membership of the NHA

As a member of the NHA, the Minister has a single vote, and may therefore be overruled by a simple majority on all matters falling within the authority's jurisdiction.[37] As Minister, however, he or she effectively has powers of veto, given that the NHA's powers are advisory in nature. Further complications arise as a result of section 29(6), which requires the Minister (or his or her nominee) to preside over the NHA.

It is difficult to understand how any person may be a voting member of the very body tasked with advising him or her, particularly when that person heads the body in question. While the ALP, Consortium and TAC strongly believe that the Minister remain a member of the NHA and participate fully in its deliberations, we believe that the dictates of good governance and accountability require that the body tasked with advising the Minister be empowered to reach decisions independently. This would entail a redrafting of section 29(3)(b) to read as follows:

> "where decisions cannot be reached by consensus the decision of the majority of the members of the National Health Authority, *excluding the Minister*, is deemed to be the decision of the National Health Authority."

Powers of the NHA

The NHA's lack of decision-making authority leaves the Minister with the discretion to accept or reject its advice, being under no express duty to justify or advance good reason why he or she is not acting on such advice. While the principles of administrative law render the Minister's discretion particularly circumscribed, the lack of guidelines in the Bill regarding the exercise of such discretion has the potential

[37] In terms of section 29(3)(b), the NHA is empowered to reach decisions by a simple majority if it is unable to reach consensus.

to undermine the NHA's operation and effectiveness. Clear legislative guidance will go some way to remedy this problematic scenario, such as a requirement that the Minister provide written reasons if he or she at any time rejects the advice of the NHA. To entrench further accountability and to give full effect to the separation of powers doctrine, such information should form part of a required annual report of the NHA, to be submitted both to Parliament and the Human Rights Commission (HRC), the latter being expressly tasked by the Constitution with "monitor[ing] and assess[ing] the observance of human rights in the Republic."[38] The HRC's participation in the process is desirable given the constitutional recognition of access to health care services as a human right.

National Health Management Committee

It is difficult to understand the rationale behind extending the duties of the National Health Management Committee (the Management Committee) to include the making of recommendations to the NHA on "any matter relating to health",[39] and the investigation and consideration of "any matter relating to health",[40] rather than limiting its functions to the co-ordination of policy implementation,[41] and the making of recommendations to the NHA on matters arising from such co-ordination. This broad jurisdiction unnecessarily duplicates certain functions of the NHA.

Further, membership of the Management Committee needs to be expanded to include employee representation if the Management Committee is to be able to deal competently with matters arising from the implementation of policy. In short, the

[38] Section 184(1)(c).
[39] Section 31(1)(b).
[40] Section 31(1)(a).
[41] Section 31(1)(c).

contributions of decision-makers as well as implementers are crucial to the efficient and effective functioning of the Management Committee.

Preparation of national health plans

Section 32, dealing with the preparation of national health plans, recognises that the preparation of strategic medium term and annual health plans is central to the "exercise of the powers and the performance of the national department" as well as the budgetary process. This is to be welcomed. It echoes the finding of Justice Botha in *Treatment Action Campaign* that proper planning is central to the marshalling of resources required for the implementation of health programmes.[42] Only with such planning "will it be possible to obtain the further resources that are required … whether in the form of a reorganisation of priorities or by means of further budgetary allocations."[43] Express statutory recognition of the obligation to develop health plans provides a much needed framework for the taking of reasonable measures for realising the right of access to health care services.

Provincial Health Services

In terms of section 34 of the NHB, "[e]very provincial health department must act in accordance with policy determined by the National Health Authority in terms of section 29 when establishing and operating its health services". Although health services are clearly a functional area of concurrent legislative competence, section 146(2) of the Constitution permits national policy to override provincial legislation in circumstances where—

[42] Supra note 25.
[43] Ibid.

> "a matter that, to be dealt with effectively, requires uniformity across the nation, and the national legislation provides that uniformity by establishing—
>
> (i) norms and standards;
> (ii) frameworks; or
> (iii) national policies."

Thus in terms of the Constitution, provincial legislation would clearly prevail where it can be shown that uniformity across the nation is not required for effectively dealing with matters relating to specific health services. Our concern is that the NHB does not recognise such constitutional limits on the legislative competence of Parliament. Therefore, to the extent that section 34 of the NHB suggests that the provision of provincial health services must always take place within the framework of national policy, it is problematic. In the result, the ALP, Consortium and TAC recommend that section 34 be redrafted as follows:

> "Every provincial department must act in accordance with policy determined by the National Health Authority in terms of section 29 when establishing and operating its health services, *provided that such policy provides uniformity across the nation where this is necessary for matters to be dealt with effectively*."

Provincial Health Authority

While the composition of a Provincial Health Authority (PHA) is similar to that of the NHA, it does allow for the participation (in an ex officio capacity) of "any other person whom the relevant Member of the Executive Council considers appropriate". Thus participation is at the MEC's discretion. While we submit that participation by other relevant stakeholders should be formalised and not left at the discretion of the relevant MEC, the discretionary power does raise the question of why broader participation at provincial level is deemed appropriate, but not at national level.

We further recommend that the provincial health authorities and their subcommittees function in a similar manner to the NHA and its committees. This would require that all provincial health structures be accountable to their respective PHA, with an allocation of functions to the respective committees that avoids unnecessary duplication. The PHAs, in turn, would be accountable to their respective provincial legislatures, as well as the NHA. For the same reasons as advanced regarding the relationship between the Minister and the NHA, we recommend that the relevant MEC be obliged to provide written reasons if he or she at any time rejects the advice of the relevant PHA, and that such information form part of a required annual report of the PHA, to be submitted both to the relevant provincial legislature and the NHA.

Inspectorate for Health Establishments

The establishment of an Inspectorate for Health Establishments in each province is to be welcomed. In particular, we welcome the role of such bodies to "monitor and evaluate compliance by health establishments" with the requirements of the NHB. Of concern, however, is the NHB's ambivalence regarding the functioning of the provincial inspectorates in relation to a complaints procedure. Section 20 of the NHB clearly entitles any person "to lay a complaint about the manner in which he or she is treated at a health establishment and to have the complaint investigated", with section 21 requiring MECs—with the concurrence of the respective provincial health authorities—to regulate the procedures governing such complaints.

In respect of complaints arising from people other than users (such as health care providers), as well as complaints in respect of matters other than individual treatment (such as complaints about failures to comply with the provisions of the legislation),

the NHB is silent. It is submitted that the provincial health inspectorates would be able to operate in a more effective and efficient manner if section 21 were to be redrafted so as to broaden the scope of the complaints as well as the class of people entitled to initiate complaints.

Provincial Health Plans

Unlike national health plans, provincial plans are not the sole responsibility of the head of the relevant health department. According to section 39(1) of the Bill, the head of the provincial department is obliged to prepare provincial health plans "with the concurrence" of the PHA. Further, once the provincial health plans have been developed—in line with national policy—they must be submitted to the DG of the national department. A summary of these plans, along with a summary of the national health plans, is then submitted to the NHA.[44] It is unclear what happens at this stage, as section 29, which sets out the duties and powers of the NHA, is silent on the issue of health plans. It seems as if the NHA does not have the authority to determine whether health plans (including provincial health plans) comply with national policy. This lack of clarity needs to be resolved.

Chapter 5: the district health system

Establishment of the district health system

Section 40 of the NHB is silent on the purpose underpinning the establishment of the district health system. To underscore the objectives of the NHB and the state's constitutional obligations regarding the progressive realisation of the right of access to

[44] Section 32(2).

health care services, the ALP, Consortium and TAC recommend that the section be redrafted as follows:

> "In addition to this chapter, provincial legislation must provide for the establishment of a district health system in a province *so as to facilitate the provision of services in an equitable and efficient manner*."

Variation of health district boundaries

Section 42 empowers the relevant MEC, in consultation with the Minister, to vary an existing health district boundary, create a new district or abolish an existing one. The Bill is silent as to what would constitute a good reason for such a decision.[45] This raises issues similar to those dealt with *Dawood*, relating to the necessity of legislative guidance for the exercise of this discretionary power. A simple remedy would be for the Bill to set out factors, or guidelines, to assist the relevant MEC in determining if and when existing health districts should be varied or abolished, or new districts created.

A further problem is that the Bill does not expressly give a right to be heard to those affected by such a variation. While the requirements of just administrative action would demand a right to be heard, *Dawood* suggests that this right be expressly included in the provisions of section 42. An alternative solution is to ensure that the composition of the District Health Authority (DHA) is sufficiently representative, given the requirement in section 42(2)(a)(i) that the DHA be consulted before such decisions are made. This may entail the redrafting of section 43(2).

[45] Section 42.

Chapter 6: Health Establishments

Hospital boards

In terms of section 47(b), the Minister may make regulations determining the establishment of hospital boards, and in the case of public health establishments, their management system. Further, in terms of section 53(4), the Minister is obliged to "appoint a hospital board for each central hospital or for a group of central hospitals" after consultation with the NHA. In terms of section 53(6), similar powers are afforded the relevant MECs for the appointment of all other hospitals in their respective provinces.

It is unclear whether this applies to private hospitals, as the Bill provides no definition of what constitutes a hospital. Private clinics, however, are clearly excluded, as management systems of only public health establishments (excluding hospitals) are to be determined by the Minister. Further, in terms of section 58(1), every private health establishments "must appoint an administrative officer for purposes of liaison with district health authorities, provincial and national departments." Read together, these provisions suggest that section 47(b) does not apply to private hospitals. It is submitted that this should be made express in the Bill, by expressly referring to public hospitals. A failure to do so may result in unnecessary confusion.

Regarding the composition of central hospital boards, we welcome the participation afforded to representatives of "communities served by the hospital, including special interest groups representing users",[46] as well as "representatives of staff and

[46] Section 53(7)(e).

management".[47] We similarly welcome the provisions of section 54(2)(ii) that formalise participation by "members of the community served by the health facility" on clinic and community health centre committees. That participation is limited to the local level, however, and restricted to non-policy making bodies, is again noted as cause for concern.

In terms of section 53(6), the relevant MEC is tasked with appointing hospital boards other than those of central hospitals, after consulting the relevant PHA in question. Unlike in relation to central hospital boards, the Bill does not determine the composition of such boards, nor does it determine whether the composition should be determined in terms of provincial legislation, or whether the power of the MEC to appoint the Board includes the power to determine the types of persons required. The Bill needs to provide clarity on this issue. There is no good reason why the matter should not be resolved in terms of provincial legislation.

As a general rule, the ALP, Consortium and TAC would like to see all powers relating to the establishment of health establishment management structures (in section 47(b)) and the provision of health services at hospitals (in section 53(1)) being exercised in consultation with the relevant local hospital board and local or provincial government structures, wherever applicable. Such a requirement would go some way to ensuring that the decision-making is informed by local knowledge and experience.

[47] Section 53(7)(f).

Provision of health services at non-health establishments

To give effect to the national health department's acceptance of responsibility for norms and standards of health care for convicted persons and persons awaiting trial,[48] we recommend that section 55(1)(a) be extended to expressly mention prisons as a type of non-health establishment location in respect of which the Minister may prescribe minimum standards and requirements for the rendering of health services.

Inter-relationship between public health establishments

Section 56(3) of the Bill permits the use of "a health establishment other than a health post, clinic or community health centre without an appropriate referral letter". Ordinarily, users of health establishments are first required to visit a health post, clinic or community health centre before accessing other health establishments. If such health establishments are by-passed in cases other than emergencies, a "by-pass fee" is to be charged.

This provision is problematic in that it permits queue jumping, in effect allowing for socio-economic status to be the determinant of access to health care. The impact of queue jumping is that referral procedures are weakened, users who cannot afford the requisite "by-pass fee" are required to wait even longer for health care services, and the goals of primary health care are undermined. If we are seriously to address the inequities inherited from the past, we cannot allow for access to health care services in the public sector to be determined by ability to pay, particularly when such conduct serves to reduce existing levels of access.

[48] Schedule 1: Part A(5)(f).

Evaluating the services of health establishments

While welcoming the obligations in section 59(1) of all health establishments in respect of quality requirements, we notice with concern that the express requirements set out subsection (2) do not include any reference to standards of user care. As the ALP, Consortium and TAC believe that the quality of user care must be seen as a priority, we recommend the following reformulation of section 59(2):

> "The quality requirements contemplated in subsection (1) may relate, but need not be limited to staffing, equipment, hygiene, safety or cost-effectiveness of services, *and must relate to standards of user care*."

Chapter 7: Academic Health Service Complexes

The NHB's National Council for Academic Health Service Complexes will replace the Policy Council for Academic Health Centres, as established in terms of the Academic Health Centres Act, 86 of 1993. A comparison of the compositions of the two councils raises concerns relating to the role to be played by the Medical Research Council (MRC). In particular, the ALP, Consortium and TAC are concerned that the President of the MRC, currently a member of the Policy Council for Academic Health Centres, will no longer remain a member of the regulatory authority responsible for academic health service complexes. Our cause for concern is heightened by the fact that the MRC's policy-making functions relating to research are to be stripped away, resulting in the effective downgrading of the MRC.[49]

Chapter 8: Control of the use of tissue and organs in humans

The provisions relating to the use of human tissue and organs have their origins in the Human Tissue Act, 65 of 1983. Despite advances in science and scientific research

[49] See the submissions on chapter 9, below, relating to the role of the MRC.

over the last two decades, and the shift in South Africa to a constitutional democracy based on the respect for fundamental human rights (which includes a right of academic freedom and the freedom of scientific research), these provisions in the NHB bear a remarkable similarity to their Human Tissue Act counterparts. Scientific, legal and political change suggests that a thorough re-evaluation of these problematic provisions is appropriate.

Purposes for which tissue, blood or gametes of living persons may be used

In terms of section 68(2)(d), foetal tissue and placental or umbilical cord tissue or blood may only be used for certain purposes—including research—with the consent of the Minister, and subject to any conditions attached to such consent. This raises problematic concerns about academic freedom and the freedom of scientific research, both entrenched in section 16(1)(d) of the Constitution. While there may well be justification for limiting such forms of research, the constitutional guarantees cannot be limited in such a way.

In terms of section 36(1) of the Constitution, rights may only be limited as long as the limitation takes place by law of general application, and provided "the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors". In terms of section 36(2), if these conditions are not satisfied, a constitutionally entrenched right may not be limited. At minimum, the law of general application requirement serves a three-fold purpose: first, to ensure that legal rules that limit rights are accessible; second, to ensure that such rules are sufficiently clear to enable the reasonable person to regulate

his or her conduct accordingly; and third, to ensure that laws apply generally.[50] It is highly questionable whether the manner in which the NHB limits freedom of scientific research satisfies this requirement. Further, considerations relating to Parliament's obligations to provide a framework for the exercise of such a power also arise.

Prohibition on the transplant of gonads

According to section 69 of the Bill, transplants of gonads (whether removed from a deceased or living person) where the transplant could result in procreation, require the Minister's prior written authorisation. A failure to comply with these provisions constitutes an offence. This provision raises similar concerns to those raised by section 68(2)(d), dealing with foetal tissue and placental or umbilical cord tissue or blood. In addition, it raises concerns about the right to "security in and control over [the] body", entrenched in section 12(2)(b) of the Constitution, as well as rights to dignity and privacy, entrenched in sections 10 and 14 of the Constitution respectively.

Post-mortem examination of bodies

We recommend that section 78(b), relating to the consent of persons other than the deceased person in relation to a post-mortem, be amended so as to include the partner (whether same or opposite sex) of the deceased person. A failure to do so would result in unfair discrimination on the basis of sexual orientation and marital status,

[50] *President of the Republic of South Africa and Another v Hugo* 1997 (4) SA 1 (CC) at para 102, per Mokgoro J. Despite Mokgoro J's somewhat controversial and broad understanding of what qualifies as a law of general application (which does not necessarily reflect the Court's position on the matter), the general purpose of the requirement of legality (as expressed in her judgment) is not in dispute. It is only the application of the facts that is placed in dispute by Kriegler J's dissent. See *also Dawood*, supra note 21 at para 47.

both prohibited grounds of discrimination as set out in section 9(3) of the Constitution.

Chapter 9: Health Surveillance, Research and Information

The introduction of a comprehensive regulatory framework within which health research will be conducted is to be welcomed, particularly given the inadequacies of the current regulatory framework. Currently, statutory regulation of research on human subjects is limited to—

- the regulation and control by the MRC of research conducted by its employees, and people performing such research for or on its behalf, or with its financial assistance or other aid;[51]
- the approval for and the regulation of clinical trials by the Medicines Control Council (MCC); and
- clinical trial guidelines issued by the Department of Health in 2000.[52]

It is in the context of a weak existing regulatory framework that the proposals in the NHB are assessed.

While statutory regulation of research is clearly a necessary and justifiable limitation of the right to academic freedom and the freedom of scientific research, the manner of regulation has to be such so as to ensure that, as far as is reasonably possible, independence of operation is guaranteed. In relation to the Essential National Health Research Committee and the National Health Ethics Council,[53] therefore, the ALP, Consortium and TAC submit that such bodies operate independently of the NHA,

[51] Section 17(1) of the South African Medical Research Council Act, 58 of 1991.
[52] Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa.
[53] Sections 81 and 84 respectively.

being accountable to Parliament directly. This could be facilitated by requiring that they report to Parliament on an annual basis on all clinical research involving human subjects in the Republic.

Essential National Health Research Committee

The Essential National Health Research Committee (Health Research Committee) will have the authority, amongst other things, to determine the type of health research to be carried out by public health authorities and the "development and application of an integrated national strategy for health research".[54] While the committee's composition rightly includes key figures from national and provincial levels of government, as well as experts in the field of research (including research managers, basic researchers, clinical researchers and community researchers), it's composition is nevertheless problematic.

First, it includes two private sector representatives "with a special interest in or knowledge of research", and second, it omits to include any representation of people affected by these decisions, as well as organisations representing such people. Given the nature of private sector research, which has historically meant that diseases of the poor remain largely marginalised, the presence of private sector representatives—which is sufficiently broad to include representation from the brand-name pharmaceutical industry—on its own raises significant concern. Further, in the absence of any representation of people affected by these decisions and organisations representing such people, these concerns take on added significance.

[54] Sections 81(3)(a) and (c) respectively.

Research on human subjects

That research on human subjects may only be carried out "as determined by the Minister" raises further problematic concerns about academic freedom and the freedom of scientific research. That section 83 of the Bill—which grants broad ministerial discretion in this regard—limits the rights in section 16(1)(d) of the Constitution is clear. According to the Constitutional Court, such a limitation will be justified only if the purpose of the limitation is proportional to its impact. In assessing proportionality, a court will consider the nature and importance of the right concerned, the extent of the limitation, as well as the availability of less restrictive means to achieve the same purpose.[55]

While it is clear that research on human subjects raises complex ethical issues, it is difficult to understand why this particular form of limitation is required. In particular, it is difficult to understand why the initiation of research requires ministerial permission, and not the permission of the Ethics Council. Of concern is that the role of the Ethics Council in relation to research on humans and animals is limited to the "setting of norms and standards for conducting research",[56] "providing advice to the national and provincial departments on ethical issues",[57] and "any other activities that may be required to maintain and improve ethical practice in research".[58] It is our submission that the limitation of the right to academic freedom and the freedom of scientific research is not justifiable.

[55] *Dawood*, supra note 21 at para 40, per O'Regan J [footnote omitted].
[56] Section 84(3)(c).
[57] Section 84(3)(g). This role is not limited to research issues.
[58] Section 84(3)(h). This role is also not limited to research issues.

The role of the Medical Research Council

The NHB's impact on the integrity, independence and efficacy of the MRC is potentially threefold. First, in terms of the South African Medical Research Council Act, 58 of 1991 (MRC Act), the MRC is expressly empowered to "undertake research of its own accord",[59] as well as to "undertake research on behalf of the State or any other authority, or on behalf of any person or institution, or support such research financially".[60] In terms of section 81(3) of the NHB, however, the Health Research Committee is tasked with determining what health research is to be carried out by public health authorities, as well as developing and applying "an integrated national strategy for health research". Clearly, the scope of the MRC's research will be affected by decisions of the Health Research Committee, a body whose composition does not necessarily include any representation from the MRC.

Second, section 84 of the NHB sets up the National Health Ethics Council, the functions of which include the "setting of norms and standards for conducting research on human and animals, including clinical trials".[61] This clearly conflicts with section 17(2) of the MRC Act, which empowers the MRC to "determine ethical directives which shall be followed in … research [on] or experimentation [with humans, animals or human or animal material]." While the National Health Ethics Council's composition will include a representative of the MCC, it will not necessarily include a representative from the MRC.

[59] Section 4(1)(a)(i).
[60] Section 4(1)(a)(ii). Section 4 sets out additional functions, duties and powers of the MRC relating to research.
[61] Section 84(3)(c).

Finally, section 17 of the MRC Act empowers the MRC to "regulate and control research on or experimentation with humans, animals or human or animal material performed by—

(a) employees of the MRC; or

(b) persons performing such research or experimentation for or on behalf of the MRC, or with research aid by the MRC."

The effect of section 83 of the NHB, which gives the Minister the power to determine whether research on human subjects may be carried out, will be to erode the power of the MRC to regulate and control its research functions.

The objects of the MRC, as set out in section 3 of the MRC Act, are primarily, "through research, development and technology transfer, to promote the improvement of the health and the quality of life of the population of the Republic". Removing three of its key functions, as set out above, while simultaneously excluding the MRC from the decision-making authorities tasked with such functions, severely compromises its independence as well as its ability to realise its objects. It is difficult to understand what justification can be advanced for such action.

While recognising the need for the Essential National Health Research Committee and the National Health Ethics Council, the ALP, Consortium and TAC recommend that the MRC's jurisdiction be extended, and that these bodies are regulated in terms of the MRC Act. This would require an amendment to the MRC Act, with sections 81 to 85 of the NHB forming the substance of such an amendment.

Health Ethics Committees

Section 85(2)(a) of the NHB empowers health ethics committees to review research proposals and protocols to ensure that research conducted at all health establishments promotes certain goals. The omission of "disease treatment" from the list of health goals is cause for alarm. As the provision stands, it unjustifiably violates the right of access to health care services in section 27 of the Constitution, as well as the right to academic freedom and freedom of scientific research in section 16(1)(d). In the result, we recommend the following formulation for subsection (2)(a):

> "reviewing research proposals and protocols to ensure that research conducted will promote health, prevent disease and disability, and treat and cure disease".

Further, health ethics committees are not required or even empowered to receive the results (whether complete or partial) of all research conducted on human subjects. This severely limits the efficient and effective functioning of both health ethics committees and the National Health Ethics Council, for without information relating to these results, there is no mechanism for updating, re-evaluating and setting appropriate ethical guidelines, norms and standards. In the result, we recommend that a subsection (c) be added to section 85(2), reading as follows:

> "(c) receiving the results (whether complete or partial) of all research conducted on human subjects falling within the jurisdiction of the Health Ethics Committee."

National Health Information System Committee

Unlike the other bodies established by the Bill, the composition of the National Health Information System Committee (Information System Committee) is not defined. All that the Bill requires is that the members of the Information System Committee be

appointed by the Minister, "with the concurrence" of the NHA.[62] Given that the Information System Committee's main role is "the investigation and making of recommendations when requested to do so by the [NHA] on any matter relating to the development, implementation and review of the national health system",[63] and the constitutional obligations of the Legislature to promote, protect and fulfil the rights entrenched in the Bill of Rights,[64] it is not appropriate for the Bill to be silent on such issues.

Chapter 10: health officers and compliance procedures

Functions of health officers

Section 91 authorises a health officer to enforce compliance with *any* other law. Such powers are clearly too broad and thereby both inappropriate and unconstitutional. It is our submission that the reach of a health officer's monitoring and enforcement functions must be restricted to ensuring compliance with the NHB and other *health* legislation.

Entry and inspection with a warrant

The grounds upon which a magistrate may issue a warrant to a health inspector to enter and inspect any residential land or premises for ensuring compliance with the NHB, as set out in section 93(3), are unnecessarily broad. Merely having reasonable grounds for believing that there is non-compliance with the terms of the NHB or *any* other law does not necessarily justify a limitation of the right to privacy by a health officer. This is so for three reasons. First, the provision is not restricted to the enforcement of health laws. Second, it is difficult to understand how *any and all*

[62] Section 87(2).
[63] Section 87(3).
[64] *Dawood*, supra note 21 at para 48.

forms of non-compliance justify an entry and inspection. For example, a failure of the DG to compile an annual summary of national and provincial health care plans, as required by section 32(2) of the NHB, can in no way justify a search and inspection of the DG's home. Finally, section 93(3) does not require that a rational connection between the act of non-compliance and the need for entry and inspection be established. The ALP, Consortium and TAC submit that the provision can be saved only if it is redrafted to narrow the ambit of its reach, so as to ensure that a warrant for an entry and inspection is granted only where it will not result in the unjustifiable limitation of the right to privacy.

Entry and inspection without a warrant

Section 94(1) of the Bill permits a health officer "to enter into business land or premises to carry out an inspection … without a warrant of search, if in his or her opinion there is a reasonable belief that the provisions of [the Bill] are being, about to be or have been contravened." Ordinarily, a warrant is required for such an entry and inspection.

In *Mistry v Interim Medical and Dental Council of South Africa and Others*, the Constitutional Court held section 28(1) of the Medicines and Substances Control Act, 101 of 1965, to be inconsistent with the right to privacy in section 13 of the interim Constitution.[65] "The existence of safeguards to regulate the way in which the State officials may enter the private domains of ordinary citizens", it was held, "is one of

[65] 1998 (4) SA 1127 (CC). In short, section 28(1)'s powers of entry gave inspectors of medicines the right, "at all reasonable times … [to] enter upon any premises, place, vehicle, vessel or aircraft at or in which there is or is on reasonable grounds suspected to be any medicine or scheduled substance", without a warrant.

the features that distinguish a constitutional democracy from a police State."[66] In coming to the conclusion that the provision was unconstitutional, the Court found it to be "so wide and unrestricted in its reach as to authorise any inspector to enter any person's home simply on the basis that aspirins or cough mixture are or are reasonably suspected of being there."[67]

Section 94(1) of the draft Bill does not raise problematic concerns of this nature. Nevertheless, as even searches with a warrant constitute a limitation of the right to privacy,[68] any searches or inspections undertaken in the absence of a warrant must be closely scrutinised. Understood in this context, section 94(1)'s authorisation of entry and inspection without a warrant is problematic in three respects. First, such inspections raise similar concerns to those raised in relation to inspections conducted with a warrant. Second, that the inspector only need be of the *opinion* that "there is reasonable belief that the provisions of [the Bill] are being, about to be or have been contravened" does not offer sufficient protection to those whose grounds or premises are to be inspected. This can be remedied by requiring that the inspector have reason to believe that such activity is currently taking place or about to take place, which will go some way towards ensuring that sufficient protection is given without unduly interfering with the inspector's role.

Finally, while it may be justifiable to enter and inspect without a warrant if there is reason to believe that the delay caused by the need for obtaining a warrant may result

---

[66] Ibid at para 25.
[67] Ibid at para 28.
[68] See *Investigating Directorate: Serious Economic Offences and Others v* ***Hyundai*** *Motor Distributors (Pty) Ltd and Others: In re:* ***Hyundai*** *Motor Distributors (Pty) Ltd and Others v Smit NO and Others* 2001 (1) SA 545 (CC).

in evidence being destroyed, or other such circumstances of need, it does not necessarily follow that an entry without a warrant will be justifiable as long as reasonable grounds exist for believing that provisions of the Bill are being or have been contravened. In short, the inspector should be required to have reason to believe that the delay caused by obtaining a warrant will undermine the objects of the Bill. The NHB needs to set out objective criteria—such as irreparable harm or an imminent threat to public health—that would justify such a limitation of the right to privacy.

Chapter 11: Regulations

As currently drafted, the power granted to the Minister to issue regulations "on any matter in order to achieve the purpose of [the NHB]" remains unclear. The uncertainty regarding the extent of ministerial discretion relates to the form and nature of the regulations. In respect of certain express powers, such as the power to issue regulations on "[p]rocedure for determining policy contemplated in section 29(2)(a)", there is no uncertainty whatsoever. Such a power is quite clearly a power to determine procedures. Other express powers are not so certain, with it remaining unclear whether the power of the Minister is to determine results, or rather to determine the process by which—and the criteria in terms of which—such results are determined. Such ambiguities need to be clarified.

Conclusion

The ALP, Consortium and TAC look forward to the imminent tabling of a National Health Bill in Parliament. We are aware that the process of transforming the health care system in line with the dictates of the Constitution is both difficult and challenging, and that many of the provisions contained within the draft NHB need to

be implemented urgently. However, we remain convinced that the consultation process is not yet over. In this light, we express our support for an open and consultative legislative process, which includes comprehensive public Parliamentary hearings.

We thank you once again for this opportunity to make representations.