



FREE MARKET FOUNDATION

PO Box 4056 | Cramerview 2060
011 884 0270 | gailday@fmfsa.org

Free Market Foundation Submission on the National Health ACT

To: Committee 1 (Triple Challenges of Inequality, Poverty and Unemployment)
High Level Panel on the Assessment of Key Legislation

By: Free Market Foundation

1. The Free Market Foundation

The Free Market Foundation (FMF) is an independent non-profit public benefit organisation founded in 1975 to promote and foster an open society, the rule of law, personal liberty, and economic and press freedom as fundamental components of its advocacy of human rights and democracy based on classical liberal principles. It is financed by membership subscriptions, donations and sponsorships.

2. Introduction

Affordable and quality healthcare is innately important to overcoming the triple challenges of inequality, poverty, and unemployment in South Africa. Individuals spend substantial amounts of their money on their medical needs, meaning that in the case of the poor, they often lack access to healthcare completely or need to spend well over half of their income on it. It is with this in mind that it is of fundamental importance that the government not exacerbate the cost of healthcare, and allow competition in the market as to keep prices as low as they can possibly, and responsibly, be.

In terms of sections 36 to 40 of the National Health Act (61 of 2003) health agencies may not be established or substantially expanded without applying for and getting a 'certificate of need' from the Director-General of Health. Certificates of need are intended to match health services provided in a particular geographic area with the medical needs of the population in that area. It certainly amounts to an attempt by the government to centrally plan the healthcare market, which, despite the best of intentions, has and will lead to higher costs and monopolisation and harks back to an era of apartheid-style social planning

Because sections 36 to 40 of the Act have very little basis in rational economic thinking, we submit that they must be repealed in toto from the Act. Note: These sections were promulgated and then retracted by the Constitutional Court but they still remain in the Act.

3. Certificates of need are economically unfeasible

Section 36(1)(a) provides that new healthcare agencies, such as clinics or hospitals, cannot legally be established without a certificate. Section 36(1)(b) further provides that existing agencies cannot expand in terms of the amount of beds or technology they may acquire.

Logic dictates that these provisions, firstly, benefit existing large healthcare companies at the expense of small and emerging companies, because new health agencies must go through the process of applying and being approved for a certificate of need, which costs a substantial amount of money for startups. Secondly, the provisions hinder existing companies which have already proven their market sustainability and quality service to the public, from expanding. Therefore, the Act not only has the

effect of being a barrier to healthy competition, but also has the very perverted effect of denying healthcare at an existing facility (which seeks to expand its capacity), to untold numbers of South Africans.

Perhaps most troubling is that section 40 of the Act criminalises the act of providing healthcare.

Bear in mind that these provisions do not relate to standards of medical quality or health and safety regulation, but instead to a political desire to 'rationalise' the provision of healthcare. Our society is plagued by a lack of access to healthcare, and it is in this light that we believe it is neither morally nor economically justifiable to hold the threat of imprisonment over South Africans who seek to provide desperately needed services to their fellow countrymen.

4. Case study: the United States of America

Certificates of need are not a South African invention. In fact, they have been tried elsewhere, most notably in the United States of America. Certificates of need were mandated on the federal (national) level in America from 1972 onward, and were also adopted in various states. The United States has the highest health expenditure per capita in the world and a significant explanation for this, as will be demonstrated below is in large part due to the certificate of need laws that artificially cause prices to rise due to the effect that they have on blocking potential competition.

The United States federal government realises this error and repealed the certificate of need legislation in the early 1980s on the national level. Some states, however, have kept their certificate of need laws, which created the opportunity to compare states with, and without, such laws. Healthcare costs are 11% higher in the states which kept certificate of need laws than in those which did not.

The American Federal Trade Commission and Department of Justice said the following in a 2004 report: "The Agencies' experience and expertise has taught us that Certificate-of-Need laws impede the efficient performance of health care markets. By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They undercut consumer choice, stifle innovation, and weaken markets' ability to contain health care costs. Together, we support the repeal of such laws, as well as steps that reduce their scope."

South Africa should take heed of the American experience. It was not their context which necessitated the repeal of certificate of need laws, but rather the ordinary and widely-accepted principles of economics which apply just as much to South Africa as they do to the United States.

5. Conclusion

In light of the above, the FMF proposes that sections 36, 37, 38, 39, and 40 of the National Health Care Act be repealed in their entirety.

Attachments

1. National Health Act
2. Certificates of Need Constitutional Court Judgement
3. Article: Social engineering is not welcome
4. Free Market Foundation submission on MAKING HEALTHCARE AFFORDABLE



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- (b) in the case of a central hospital, determine the establishment of the hospital board and the management system of such central hospital.

Certificate of need

36. (1) A person may not—

- (a) establish, construct, modify or acquire a health establishment or health agency; 5
- (b) increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency;
- (c) provide prescribed health services; or
- (d) continue to operate a health establishment or health agency after the expiration of 24 months from the date this Act took effect, 10

without being in possession of a certificate of need.

(2) A person who wishes to obtain or renew a certificate of need must apply to the Director-General in the prescribed manner and must pay the prescribed application fee.

(3) Before the Director-General issues or renews a certificate of need, he or she must take into account— 15

- (a) the need to ensure consistency of health services development in terms of national, provincial and municipal planning;
- (b) the need to promote an equitable distribution and rationalisation of health services and health care resources, and the need to correct inequities based on racial, gender, economic and geographical factors; 20
- (c) the need to promote an appropriate mix of public and private health services;
- (d) the demographics and epidemiological characteristics of the population to be served;
- (e) the potential advantages and disadvantages for existing public and private health services and for any affected communities; 25
- (f) the need to protect or advance persons or categories of persons designated in terms of the Employment Equity Act, 1998 (Act No. 55 of 1998), within the emerging small, medium and micro-enterprise sector;
- (g) the potential benefits of research and development with respect to the improvement of health service delivery; 30
- (h) the need to ensure that ownership of facilities does not create perverse incentives for health service providers and health workers;
- (i) if applicable, the quality of health services rendered by the applicant in the past; 35
- (j) the probability of the financial sustainability of the health establishment or health agency;
- (k) the need to ensure the availability and appropriate utilisation of human resources and health technology;
- (l) whether the private health establishment is for profit or not; and 40
- (m) if applicable, compliance with the requirements of a certificate of non-compliance.

(4) The Director-General may investigate any issue relating to an application for the issue or renewal of a certificate of need and may call for such further information as may be necessary in order to make a decision upon a particular application. 45

(5) The Director-General may issue or renew a certificate of need subject to—

- (a) compliance by the holder with national operational norms and standards for health establishments and health agencies, as the case may be; and
- (b) any condition regarding— 50
 - (i) the nature, type or quantum of services to be provided by the health establishment or health agency;
 - (ii) human resources and diagnostic and therapeutic equipment and the deployment of human resources or the use of such equipment;

- (iii) public private partnerships;
 - (iv) types of training to be provided by the health establishment or health agency; and
 - (v) any criterion contemplated in subsection (3).
- (6) The Director-General may withdraw a certificate of need— 5
- (a) on the recommendation of the Office of Standards Compliance in terms of section 79(7)(b);
 - (b) if the continued operation of the health establishment or the health agency, as the case may be, or the activities of a health care provider or health worker working within the health establishment, constitute a serious risk to public health; 10
 - (c) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, is unable or unwilling to comply with minimum operational norms and standards necessary for the health and safety of users; or 15
 - (d) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, persistently violates the constitutional rights of users or obstructs the State in fulfilling its obligations to progressively realise the constitutional right of access to health services. 20
- (7) If the Director-General refuses an application for a certificate of need or withdraws a certificate of need the Director-General must within a reasonable time give the applicant or holder, as the case may be, written reasons for such refusal or withdrawal.

Duration of certificate of need 25

37. A certificate of need is valid for a prescribed period, but such prescribed period may not exceed 20 years.

Appeal to Minister against Director-General's decision

38. (1) Any person aggrieved by a decision of the Director-General in terms of section 36 may appeal in writing to the Minister against such decision. 30
- (2) Such appeal must—
- (a) be lodged within 60 days from the date on which written reasons for the decision were given by the Director-General or such later date as the Minister permits; and
 - (b) set out the grounds of appeal. 35
- (3) After considering the grounds of appeal and the Director-General's reasons for the decision, the Minister must as soon as practicable—
- (a) confirm, set aside or vary the decision; or
 - (b) substitute any other decision for the decision of the Director-General.
- (4) The Minister must within a reasonable time after reaching a decision give the appellant written reasons for such decision. 40

Regulations relating to certificates of need

39. (1) The Minister may, after consultation with the National Health Council, make regulations relating to—
- (a) the requirements for the issuing or renewal of a certificate of need; 45
 - (b) the requirements for a certificate of need for health establishments and health agencies existing at the time of commencement of this Act;
 - (c) the requirements for a certificate of need for health establishments and health agencies coming into being after the commencement of this Act; and

- (d) any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies.
- (2) Regulations made under subsection (1)—
 - (a) must ensure the equitable distribution and rationalisation of health, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities; 5
 - (b) may prescribe the fees payable in respect of applications for the issuing and renewal of certificates of need;
 - (c) must prescribe the formats and procedures to be used in applications for the issuing and renewal of certificates of need, and the information that must be submitted with such applications; 10
 - (d) must ensure and promote access to health services and the optimal utilisation of health care resources, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities;
 - (e) must ensure compliance with the provisions of this Act and national operational norms and standards for the delivery of health services; 15
 - (f) must seek to avoid or prohibit business practices or perverse incentives which adversely affect the costs or quality of health services or the access of users to health services;
 - (g) must avoid or prohibit practices, schemes or arrangements by health care providers or health establishments that directly or indirectly conflict with, violate or undermine good ethical and professional practice; and 20
 - (h) must ensure that the quality of health services provided by health establishments and health agencies conforms to the prescribed norms and standards.

Offences and penalties in respect of certificate of need

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40. (1) Any person who performs any act contemplated in section 36(1) without a certificate of need required in terms of that section is guilty of an offence.

(2) Any person convicted of an offence in terms of subsection (1) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

30

Provision of health services at public health establishments

41. (1) The Minister, in respect of a central hospital, and the relevant member of the Executive Council, in respect of all other public health establishments within the province in question, may—

- (a) determine the range of health services that may be provided at the relevant public health establishment; 35
- (b) prescribe the procedures and criteria for admission to and referral from a public health establishment or group of public health establishments;
- (c) subject to subsection (2), prescribe schedules of fees, including penalties for not following the procedures contemplated in paragraph (b), for— 40
 - (i) different categories of users;
 - (ii) various forms of treatment; and
 - (iii) various categories of public health establishments; and
- (d) in consultation with the relevant Treasury, determine the proportion of revenue generated by a particular public health establishment classified as a hospital that may be retained by that hospital, and how those funds may be used. 45

(2) When determining a schedule of fees, the fee for a particular service may not be varied in respect of users who are not ordinarily resident in a province.



CONSTITUTIONAL COURT OF SOUTH AFRICA

Case CCT 201/14

In the matter between:

PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA First Applicant

MINISTER IN THE PRESIDENCY Second Applicant

DIRECTOR-GENERAL IN THE PRESIDENCY Third Applicant

MINISTER OF HEALTH Fourth Applicant

**DIRECTOR-GENERAL OF
THE DEPARTMENT OF HEALTH** Fifth Applicant

and

SOUTH AFRICAN DENTAL ASSOCIATION First Respondent

HOSPITAL ASSOCIATION OF SOUTH AFRICA Second Respondent

Neutral citation: *President of the Republic of South Africa and Others v South African Dental Association and Another* [2015] ZACC 2

Coram: Mogoeng CJ, Moseneke DCJ, Cameron J, Froneman J, Khampepe J, Leeuw AJ, Madlanga J, Nkabinde J, Tshiqi AJ, Van der Westhuizen J and Zondo J

Decided on: 27 January 2015

Summary: Section 167(6) of the Constitution — direct access — application to declare invalid and set aside President's Proclamation — review of exercise of public power

ORDER

On application for direct access:

1. Direct access is granted.
2. Proclamation 21 of 2014 is declared invalid and set aside.
3. There is no order as to costs.

JUDGMENT

THE COURT:

Introduction

[1] This is an application for direct access in terms of section 167(6)(a) of the Constitution.¹ The matter concerns the premature promulgation of a

¹ Section 167(6) provides:

“National legislation or the rules of the Constitutional Court must allow a person, when it is in the interests of justice and with leave of the Constitutional Court—

- (a) to bring a matter directly to the Constitutional Court; or
- (b) to appeal directly to the Constitutional Court from any other court.”

Rule 18 of the Rules of the Constitutional Court provides:

- “(1) An application for direct access as contemplated in section 167(6)(a) of the Constitution shall be brought on notice of motion, which shall be supported by an affidavit, which shall set forth the facts upon which the applicant relies for relief.
- (2) An application in terms of subrule (1) shall be lodged with the Registrar and served on all parties with a direct or substantial interest in the relief claimed and shall set out—
 - (a) the grounds on which it is contended that it is in the interests of justice that an order for direct access be granted;

proclamation bringing certain sections of the National Health Act² into operation.

[2] The President, the Minister in the Presidency, the Director-General in the Presidency, the Minister of Health and the Director-General of the Department of Health (the applicants) maintain that the President's decision to bring the provisions into operation was made in error and was therefore irrational in law. They seek an order declaring the Proclamation³ invalid and setting it aside. The South African Dental Association (SADA) and the Hospital Association of South Africa (HASA) are cited as respondents in this matter. They support the relief sought by the President. Indeed, it was SADA who brought the alarming situation that necessitates this application to the attention of the Presidency.

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- (b) the nature of the relief sought and the grounds upon which such relief is based;
 - (c) whether the matter can be dealt with by the Court without the hearing of oral evidence and, if it cannot,
 - (d) how such evidence should be adduced and conflicts of fact resolved.
 - (3) Any person or party wishing to oppose the application shall, within 10 days after the lodging of such application, notify the applicant and the Registrar in writing of his or her intention to oppose.
 - (4) After such notice of intention to oppose has been received by the Registrar or where the time for the lodging of such notice has expired, the matter shall be disposed of in accordance with directions given by the Chief Justice, which may include—
 - (a) a direction calling upon the respondents to make written submissions to the Court within a specified time as to whether or not direct access should be granted; or
 - (b) a direction indicating that no written submissions or affidavits need be filed.
 - (5) Applications for direct access may be dealt with summarily, without hearing oral or written argument other than that contained in the application itself: Provided that where the respondent has indicated his or her intention to oppose in terms of subrule (3), an application for direct access shall be granted only after the provisions of subrule (4)(a) have been complied with.”

² 61 of 2003.

³ Proclamation by the President of the Republic of South Africa 21 of 2014: Commencement of Certain Sections of the National Health Act 61 of 2003, GN 21 GG 37501, 31 March 2014 (Proclamation).

Factual and legal background

[3] On 21 March 2014 the President signed the Proclamation pursuant to section 94 of the National Health Act.⁴ As its only purpose, the Proclamation brought sections 36, 37, 38, 39 and 40 of the National Health Act into operation on 1 April 2014. Taken together, these sections criminalise providing health services without holding a certificate of need. The National Health Act authorises the Minister of Health (the Minister) to prescribe regulations regarding applications for, and the granting of, certificates of need.⁵ These regulations are not yet in place.

[4] The consequence is that health service providers in South Africa are currently engaging in criminal conduct, as no individual or entity that provides health services is in a position to obtain the required certificate of need as long as the regulations have not taken effect.

⁴ Section 94 provides that the National Health Act “takes effect on a date fixed by the President by proclamation in the Gazette”. See also section 81 of the Constitution.

⁵ Section 1 defines “health services” as—

- “(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;
- (b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;
- (c) medical treatment contemplated in section 35(2)(e) of the Constitution; and
- (d) municipal health services.”

Section 36(1) proscribes the provision of health services absent the certificate of need. Subsection 2 thereof directs applications for this certificate to the Director-General “in the prescribed manner” subject to a “prescribed fee”. Section 37 provides that a certificate of need will be valid for a “prescribed period”. And most importantly, section 39(1) authorises the Minister to prescribe, through regulations, the requirements for the issuing of a certificate of need to individuals and various categories of entities. Section 39(2) empowers the Minister, also through regulations, to prescribe fees and other processes in relation to the application for certificates of need. Lastly, section 40 makes non-compliance with section 36(1) a criminal offence accompanied by criminal sanctions. It follows that section 40 of the Act is currently enforceable against all health service providers.

[5] The President approached this Court directly to rectify this.⁶ He submits that the regulations, which do not yet exist, form an essential part of the legislative scheme.

[6] He submits that the untimely effect of the Proclamation was unintentional since it was promulgated in error. According to the President, he acted in good faith when he determined a date for the statutory provisions to take effect, but was led astray by his advisors' mistaken counsel. Had he been aware of the correct position, namely that the necessary regulations were still pending, he would have selected a later date. Thus the Proclamation should be reversed to allow the consultative process to run its course. Since the provision of health services is now proscribed, the issuing of the Proclamation was objectively irrational as a matter of law.

[7] The President also maintains that the Proclamation is at odds with sections 1, 7, 8, 11, 27, 28 and 195 of the Constitution.⁷ Accordingly, he asks this Court to declare the Proclamation invalid in terms of section 172(1)(a) of the Constitution.⁸

[8] SADA and HASA agree that this Court is the proper forum to grant the relief and that the Proclamation should be declared invalid and set aside.

Direct access

⁶ The third applicant, the Director-General in the Presidency, deposed to the founding affidavit to the application for direct access on behalf of the President and the other applicants. As the President is the first applicant, this judgment will refer to the President when it is detailing the submissions of the applicants.

⁷ Section 1(c) of the Constitution provides for the supremacy of the Constitution and the rule of law. Section 7(2) provides that the state must respect, protect, promote and fulfil the rights in the Bill of Rights. Section 8 provides that the Bill of Rights is applicable to all branches of government. Section 11 guarantees everyone the right to life. Sections 27 and 28 enshrine the right to access to health care for adults and the right to basic health care for children. Section 195 sets out the basic values and principles governing public administration including transparency and accountability.

⁸ Section 172(1)(a) provides: "When deciding a constitutional matter within its power, a court . . . must declare that any law or conduct that is inconsistent with the Constitution is invalid to the extent of its inconsistency".

[9] This Court is generally reluctant to sit as a court of first and final instance.⁹

Direct access is granted only if it is in the interests of justice to do so.¹⁰ In determining whether direct access is in the interests of justice, a range of factors is relevant, including—

“the importance of the constitutional issue raised and the desirability of obtaining an urgent ruling of this Court on that issue, whether any dispute of fact may arise in the case, the possibility of obtaining relief in another court, and time and costs that may be saved by coming directly to this Court.”¹¹

[10] The matter raises an issue of constitutional importance – the provision of health services. The provisions brought into force by the Proclamation contemplate a legislative scheme detailed in regulations that are non-existent and consequently criminalise the provision of health services. There are no disputes of fact or contested legal averments that necessitate the matter first being heard by the High Court and the Supreme Court of Appeal. This Court is the only court that can finally and effectively dispose of it.¹² The legislative process required for Parliament to address the consequences of this Proclamation would be lengthy and burdensome and may fail to expeditiously address the precarious position that the health services industry finds itself in.¹³ There is no reason to believe that this

⁹ *Brink v Kitshoff NO* [1996] ZACC 9; 1996 (4) SA 197 (CC); 1996 (6) BCLR 752 (CC) at para 14.

¹⁰ *Zondi v MEC for Traditional and Local Government Affairs and Others* [2004] ZACC 19; 2005 (3) SA 589 (CC); 2005 (4) BCLR 347 (CC) at para 12.

¹¹ *Id.*

¹² Section 172(2)(a) of the Constitution provides that the—

“Supreme Court of Appeal, the High Court of South Africa or a court of similar status may make an order concerning the constitutional validity of an Act of Parliament, a provincial Act or any conduct of the President, but an order of constitutional invalidity has no force unless it is confirmed by the Constitutional Court.” (Emphasis added.)

¹³ In *Pharmaceutical Manufacturers Association of SA and Another: In re Ex Parte President of the Republic of South Africa and Others* [2000] ZACC 1; 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC) (*Pharmaceutical Manufacturers*) this Court noted at para 91:

“The President is answerable to Parliament and Parliament has the power to correct the decision. But Parliament was not in session at the time because of the pending general election, and considerable cost and inconvenience would have been occasioned by calling

Court's intervention would upset the legislative process or programme or infringe the separation of powers. The impugned provisions are intended to come into force only once the regulations are in place. It is in the interests of justice that application for direct access be granted.

Merits

[11] At stake is the exercise of public power in accordance with the Constitution and the rule of law.¹⁴ The President's issuing of the Proclamation bringing into operation sections 36 to 40 of the National Health Act, before the issuing of regulations that are essential to the operation of these sections, has led to an untenable and unintended situation. Health service providers are practising without a certificate of need. And that certificate cannot be issued without the promulgation of the necessary regulations. This renders the provision of health services unlawful. Though, it seems, no criminal prosecutions have been brought, the position is clearly undesirable. South African health service providers may be inhibited or discouraged from providing an essential service at the risk of criminal sanction for doing so.

[12] The Proclamation was issued in error and the President submits that this exercise of his public power was *bona fide* but irrational. He is unable to withdraw the Proclamation because the date for its commencement has long since passed.¹⁵ There is no mechanism contained in the National Health Act

Parliament together on the eve of the election for the sole purpose of reversing the President's decision. The fact that another course might possibly have been open to the applicants in the present case does not mean that the President's decision was not justiciable. There might be cases in which a court would decline to intervene in matters that are properly matters to be dealt with by the Legislature, but this is not such a case."

A similar impediment to Parliamentary involvement was not present in this case. However, the Court did not find that only Parliament may be called upon to address issues such as these. In this case, the Court is satisfied that the facts justify judicial review.

¹⁴ Id at para 20.

¹⁵ *Kruger v President of Republic of South Africa and Others* [2008] ZACC 17; 2009 (1) SA 417 (CC); 2009 (3) BCLR 268 (CC) at para 61. In addition, this Court held at para 63 that—

itself to remedy the consequences of the Proclamation. Even though the Proclamation was issued in error, it remains in force and has legal effect. It is an inevitable consequence of the rule of law that the Proclamation may not be ignored until it is set aside.¹⁶ This Court is therefore called upon to consider and set aside the Proclamation.¹⁷

[13] In *Pharmaceutical Manufacturers* this Court held that the President's decision to bring an Act into force is reviewable and the standard is that of rationality.¹⁸ This Court stated:

"It is a requirement of the rule of law that the exercise of public power by the Executive and other functionaries should not be arbitrary. Decisions must be rationally related to the purpose for which the power was given, otherwise they are in effect arbitrary and inconsistent with this requirement. It follows that in order to pass constitutional scrutiny the exercise of public power by the Executive and other functionaries must, at least, comply with this requirement. If it does not, it falls short

"the President could lawfully have withdrawn the First Proclamation once he had realised his mistake as long as he did so in unambiguous terms, and before 31 July 2006. It would impose an undue burden on the President to have required him to apply to court to have the incorrect proclamation set aside even when the proclamation had not yet come into force."

¹⁶ *MEC for Health, Eastern Cape and Another v Kirland Investments (Pty) Ltd t/a Eye & Lazer Institute* [2014] ZACC 6; 2014 (3) SA 481 (CC); 2014 (5) BCLR 547 (CC) (*Kirland*) at para 103. See also *Oudekraal Estates (Pty) Ltd v City of Cape Town and Others* [2004] ZASCA 48; 2004 (6) SA 222 (SCA).

¹⁷ See also *Kirland* id at para 90, where this Court held that the appropriate remedy was judicial review.

¹⁸ This Court held at para 79:

"This is one of those difficult cases. The power is derived from legislation and is close to the administrative process. In my view, however, the decision to bring the law into operation did not constitute administrative action. When he purported to exercise the power the President was neither making the law, nor administering it. Parliament had made the law, and the Executive would administer it once it had been brought into force. The power vested in the President thus lies between the law-making process and the administrative process. The exercise of that power requires a political judgment as to when the legislation should be brought into force, a decision that is necessarily antecedent to the implementation of the legislation which comes into force only when the power is exercised. In substance the exercise of the power is closer to the legislative process than the administrative process. If regard is had to the nature and subject-matter of the power, and the considerations referred to above, it would be wrong to characterise the President's decision to bring the law into operation as administrative action within the meaning of item 23(2)(b) of the Sixth Schedule of the Constitution. It was, however, the exercise of public power which had to be carried out lawfully and consistently with the provisions of the Constitution insofar as they may be applicable to the exercise of such power." (Footnote omitted.)

of the standards demanded by our Constitution for such action.”¹⁹ (Footnote omitted.)

[14] This Court must therefore determine whether the President’s decision is rationally related to the purpose for which the power was given. This is an objective enquiry, unaffected by any good intentions the President may have had.²⁰

[15] The purpose of the President’s power to bring portions of the National Health Act into operation is to achieve an orderly and expeditious implementation of a national regulatory scheme for health services.²¹ Clearly the decision to issue the Proclamation before there was any mechanism in place to address applications for certificates of need, thereby rendering the provision of health services a criminal offence, was not rationally connected to this purpose (or any other governmental objective).

[16] This mirrors the finding of this Court in *Pharmaceutical Manufacturers*. There, the President had prematurely brought into operation an Act regulating the manufacture and sale of medicines before the appropriate regulatory infrastructure was in place.²²

[17] Accordingly, the President’s decision was irrational and therefore invalid. The Proclamation must be set aside.

¹⁹ *Pharmaceutical Manufacturers* above n 13 at para 85.

²⁰ *Id* at para 86.

²¹ In terms of section 79(1) of the Constitution:

“The President must either assent to and sign a Bill passed in terms of [Chapter 4 of the Constitution] or, if the President has reservations about the constitutionality of the Bill, refer it back to the National Assembly for reconsideration.”

In terms of section 81:

“A Bill assented to and signed by the President becomes an Act of Parliament, must be published promptly, and takes effect when published or on a date determined in terms of the Act.”

²² *Pharmaceutical Manufacturers* above n 13 at para 87.

Order

[18] The following order is made:

1. Direct access is granted.
2. Proclamation 21 of 2014 is declared invalid and set aside.
3. There is no order as to costs.

For the Applicants:

State Attorney, Cape Town.

For the Respondents:

Werksmans Attorneys.

Attachment to Free Market Foundation submission on the National Health Act

Social engineering is not welcome

The Department of Health must be applauded. Because of it, the president's office has withdrawn the promulgation of provisions requiring all health establishments, including GPs, to obtain a Certificate of Need (CON) from the department by April 2016. Without a CON, public and private sector facilities would not have been able to build, establish, modify or acquire a health establishment or health agency.

A CON would also have been required by any health establishment or health agency seeking to increase the number of beds or to acquire any new technology. Existing health establishments and health agencies would have needed to obtain a CON just to continue to operate.

The intended purpose of the CON purports to be control of the kind of services that may be offered in any particular area. In other words, it is an attempt to match health services offered with the needs of the population on a geographical basis. This is neither feasible nor economically justifiable.

Regrettably, this draconian piece of legislation seems only to have been 'shelved' because, as deputy director-general for regulation and compliance Anban Pillay said, "One needs to give parties sufficient time to engage with the regulations".

The USA has a CON system for medical facilities. It does not, however, go so far as to apply apartheid-style planning on where people may live and work. The US adopted its CON laws in 1974. The stated reason at the time was to prevent duplication and resulting costs. Compared to the rest of the world, the US has the highest health expenditure per capita (measured in constant prices on a purchasing power parity basis). This is largely due to the fact that the CON legislation is having the opposite effect to the act's stated purpose. It is causing prices to increase because it blocks potential competition and creates monopolies and cartels.

In 1982, the US federal government acknowledged the failure of the CON laws to reduce health care costs and repealed the national health planning requirements. Since then, fourteen states have eliminated their CON laws. Thirty-six states, on the other hand, intensified their CON laws under the premise that too much supply drives up cost. A curious stand for them to adopt because a fundamental tenet of economics, widely accepted by all but a few fringe economists (usually with special interests), is that increased competition leads to lower prices.

This is backed up by US data which demonstrates that health care costs are 11% higher in CON states than in non-CON states. Specifically, the price in CON states averages \$7,230 per capita compared to \$6,526 in non-CON states. Further, a study by Conover and Sloan in the *Journal of Health Politics, Policy, and Law* states, "CON programs result in a slight (2 percent) reduction in bed supply but higher costs per day and per admission, along with higher hospital profits".

According to a 2004 Federal Trade Commission (FTC) and Department of Justice (DOJ) joint report, "The Agencies' experience and expertise has taught us that Certificate-of-Need laws impede the efficient performance of health care markets. By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They undercut

consumer choice, stifle innovation, and weaken markets' ability to contain health care costs. Together, we support the repeal of such laws, as well as steps that reduce their scope."

Because of the time and expense involved in obtaining a CON for medical personnel and facilities, and other long, complicated bureaucratic procedures that delay the introduction of new medical technologies, CON legislation stifles competition and increases the cost of healthcare. And the only way these costs can be recovered is from the people they are supposed to protect – the patients.

CONs are a Soviet-style form of social engineering. They have no place in a democratic state. Dictating to people involved even remotely in the healthcare industry where they may or may not work harks back to an apartheid-style form of social planning. This is not welcome - especially after so many South Africans fought so long and hard for their freedoms.

South Africa is in a desperate struggle to improve access to quality healthcare. To pin our hopes on big-bang healthcare reforms such as the proposed National Health Insurance scheme or the introduction of draconian pieces of legislation such as the proposed CON laws is false optimism. South African policy makers should rather seek out ways to increase competition in the market and remove the barriers that currently constrain efficient functioning of the market.

Jasson Urbach
Director, FMF Health Policy Unit



FREE MARKET FOUNDATION

PO Box 4056 | Cramerview 2060
011 884 0270 | gailday@fmfsa.org

Free Market Foundation submission on MAKING HEALTHCARE AFFORDABLE

To: Committee 1 (Triple Challenges of Inequality, Poverty and Unemployment)
High Level Panel on the Assessment of Key Legislation

By: Free Market Foundation

1. The Free Market Foundation

The Free Market Foundation (FMF) is an independent non-profit public benefit organisation founded in 1975 to promote and foster an open society, the rule of law, personal liberty, and economic and press freedom as fundamental components of its advocacy of human rights and democracy based on classical liberal principles. It is financed by membership subscriptions, donations and sponsorships.

2. Overview

Please note: The bullet points below are supported by attached documentation.

- If South Africa wants better health outcomes, it must have economic growth. It is intuitive that there is a strong relationship between income and health, not least because greater wealth buys greater access to the basic determinants of health: nutrition, better accommodation and sanitation.
- This relationship was confirmed by a seminal 1996 study by economists Lant Pritchett and Lawrence Summers, who showed the dramatic effect that increases in incomes can have on health. Pritchett and Summers found a strong causative effect of income on infant mortality and demonstrated that, if the developing world's growth rate had been 1.5 percentage points higher in the 1980s, half a million infant deaths would have been averted.
- The FMF maintains that the private supply of competitive health-care services and the incremental extension of private funding is the most effective method of supplying high quality health care to the entire South African population.
- Government should not be in the business of providing healthcare to all South Africans. Rather, government should devote its limited health budget to the supply of services to the indigent, to purchase an increasing percentage of those services from private providers, and to allow and encourage the rapid growth of the private healthcare sector, enabling it to provide services to an increasing percentage of the population.
- The FMF contends that public healthcare is not in fact cheaper than private healthcare and that this assertion misdirects public policy in the healthcare arena.
- Given the revealed preferences of South Africans, to access private medical facilities whenever possible, reforms should focus on enrolling more individuals in private medical schemes. This will reduce the burden on public sector healthcare facilities and free up scarce taxpayer resources so that the government can focus on purchasing the best available care from privately competing healthcare providers.
- Far from marginalising medical schemes, government should be promoting their proliferation because regular, small, fixed payments to a medical scheme make intuitive sense, as opposed to the rare but devastating high out-of-pocket payments required when illness strikes.

- Considering South Africa's relatively small tax base and thus limited available pool of revenue, and given our chronic levels of unemployment as well as our limited number of skilled healthcare personnel, the proposed National Health Insurance scheme is simply inappropriate for South Africa. Moreover, attempting to provide universal coverage is not a particularly good use of scarce resources since each additional rand committed to healthcare expenditure necessarily precludes funding for other objectives, which may be more efficiently utilised at the margin.
- The economic consultancy, Econex, has demonstrated that the proposed National Health Insurance scheme faces a R200 billion shortfall by 2025-26 – almost double the amount initially anticipated by the Department of Health.
- The FMF contends that in order to alleviate the chronic shortage of skilled medical personnel in South Africa, a short-term response would be to allow more skilled foreign health professionals to practise in South Africa. The majority of foreign doctors in South Africa work in rural areas – without them the rural system would be sure to collapse. Foreign doctors with the appropriate skills can alleviate the chronic shortages virtually overnight as opposed to training doctors in South Africa (or foreign nations that have completely different diseases profiles and often don't even speak the same languages).
- A longer-term strategy to alleviate the chronic staff shortages requires the government, and more specifically, the Department of Education, to relax the controls on tertiary education facilities, make entrance to these facilities less restrictive, and allow the private sector to provide a large percentage of tertiary medical education for doctors. If private education facilities are established they could operate on either a for-profit or non-profit basis and would have the potential to relieve a significant part of the burden currently faced by the public sector.

3. The FMF's alternative solutions to improved health care for all

- Encourage more private hospitals by deregulating the industry and eliminating Certificates of Need. **See FMF submission.**
- Remove price controls, which send mixed messages to the industry. **See FMF submission.**
- Zero rate VAT on all medicines being sold legally within South Africa. **See FMF submission.**
- Remove prescribed minimum benefits provisions. **See FMF submission.**
- Focus on funding the indigent ie finance health care for the poor – preferably via state-sponsored vouchers, which the indigent can spend where they choose.
- Reduce prices and increase health care quality through increased competition.
- Train more doctors and nurses (the number of doctors is limited to 1,300 a year; this number has remained the same since the 1970s despite increases in the population and the disease burden).
- Allow the private sector to train doctors and nurses.
- Encourage income-producing medical tourism.
- Retain skilled South Africans and attract others by removing the limit on skilled foreign doctors.
- Deregulate medical schemes so they can offer their clients exactly what they want.
- Deregulate pharmacies.
- Speed up registration of clinical trials.
- Give those who pay for their own health care a tax deduction.

Attachments

1. Article: Your life at stake: False assertions about hospital costs
2. Article: SA students flee Cuba, next time it will be Russia
3. Article: Streamlining drug approvals

Attachment to Free Market Foundation submission on Health OVERVIEW

Your life at stake: False assertions about hospital costs

Private medical schemes will no longer exist in a decade or so, predicted Health Minister Aaron Motsoaledi at a gathering of the National Editors' Forum in Cape Town. The reason was escalating costs, he said, and then went on to compare with anecdotal evidence the huge cost differences between public and private hospitals.

Private hospitals, for example, he said, charge up to R15,000 for a circumcision while township clinics charge only a "few rand". A private hospital charged R150,000 for a spinal decompression whereas the Steve Biko Academic Hospital in Pretoria charged only R30,000.

Well, for the ordinary, everyday, thinking South African, this anecdotal guide to the relative costs of public and private hospital treatment simply will not do.

Yes, it is true that private medical scheme rates are growing faster than other categories of medical expenses (and CPIX). However, this is not due to the logic of private medical care per se, it's due to the conditions forced on the medical scheme industry by the state. For example, they are not allowed to risk rate or exclude certain pre-existing conditions. They are forced to offer fairly generous minimum benefits to all. These measures very quickly raise costs to levels way above those that a private medical scheme would institute if left alone.

The comparative costs quoted by the Minister illustrate why science regards anecdotal evidence as useless. The examples don't compare like with like and were probably chosen to be maximally misleading. No doubt the circumcision example compares straightforward circumcisions involving normal foreskins, to the most complicated and expensive circumcision operation carried out in a private hospital. The same goes for the spinal decompression. For example, a procedure which puts in artificial discs and involves cutting through the abdomen and moving aside organs to insert expensive hardware is doubtless much more expensive than the more common practice of fusing the vertebrae without an abdominal invasion. And most unforgivably, the Minister was quoting what was charged to the patient (or their medical aid) and not the true cost of the procedure. On top of that, he simply omitted to include in his calculation the huge state subsidy that finances public health. The huge state subsidy financed by taxpayers' money. Does this possibly mean that all public health care is after all actually being funded by the private sector?

To do a fair comparison, we have to compare overall hospital costs per patient, after controlling for the following: differences in the reason for treatment (type of problem), the severity of the condition (number of days admission involved), the risks involved (extra procedures or expertise necessary to counter these), as well as the fact that at public hospitals patients do not have to pay VAT but at private hospitals patients do have the additional expense of funding government by paying this tax.

Innovative Medicines South Africa (IMSA) just happens to have conducted such a study. In a raw comparison, before introducing the controls mentioned above, it found, on average, that private hospital costs were 1.438 times more expensive than public hospital costs. This is the result of the sort of unadjusted, like versus unlike comparison that the Minister used to select his examples from.

However, after equating like for like, they found that private hospital costs were 1.053 times that of public hospital costs.

This figure doesn't take into consideration the differences in the quality of medical care and associated services, like food and bedding. A substantial number of public health doctors are interns, or freshly qualified and doing community service, rather than experienced doctors. Because private health pays more and is more likely to have patients who will sue if something goes wrong, it is more discerning of who it employs. That is why in private hospitals there are more experienced doctors and nurses with better skills on average who know that they are likely to be dismissed if they don't perform.

Private medical care staff tend to have a better professional attitude than those in public health. Private hospitals have better equipment and are better able to maintain stocks of basic necessities like rubber gloves, syringes, swabs, etc. Patients at private hospitals are not subjected to common public hospital problems such as a lack of bedding or decent food.

The effect on outcome of quality differences is substantial. In "A Comparison of health outcomes in public versus private settings in low- and middle-income countries" Montagu et al report that risk of mortality in private health settings is 60 per cent of that in public health settings.

Private medical care is accused of "over-servicing" for profit. But, even if this is so, it isn't really making private hospital care any costlier than public hospital care. The main factor which leads many astray in their reasoning, including the Minister, is the huge state subsidisation of public hospitals.

Economist Mike Schüssler compiled statistics from independent sources such as Statistics South Africa, the National Treasury and the Council of Medical Schemes reports. He says that on average 100 per cent of the cost in private hospital care is borne by the client whereas only 2 per cent of the cost of public hospital care is charged to the client. If we fail to take all the relevant factors into account and only consider costs passed on to the client at private and public hospitals then average private hospital charges are 60 times public hospital charges.

Just because a public hospital client doesn't pay 98 per cent of the cost of their care, it doesn't mean this cost does not exist. But what it does mean is that someone else (a taxpayer) has to do the paying. The money still comes out of the economy. Channelling this payment via government, instead of it being paid directly to the hospital, no doubt involves a significant portion of those funds being diverted into government itself to cover administration and the like. In other words, the government funding figures will underestimate the actual cost of public hospitals to taxpayers, and therefore the true cost to the country. The IMSA relative cost equation above does not take into account this inefficient channelling of funds through government when estimating the relative cost to the economy of private and public hospitals.

Let's apply the 60 fold ratio of private to public hospital client charges to the Minister's anecdotal examples. If clients paid full costs in public hospitals, his "a few rand" for circumcision could become "more than a hundred rand, if not several hundred", and the costs of a spinal decompression operation could be as high as R1.8 million in public hospitals. Alternatively, if

private care was subsidised to the same extent and didn't pay VAT, a client could be charged as little as R250 for a private circumcision and R2,500 for a spinal decompression. This makes the Minister's case look quite bad.

Schüssler goes on to show that between 2000 and 2008 private hospital charges rose by 74 per cent and, while public hospital charges rose by only 12.8 per cent, the government funding cost per admission rose by an astounding 111.7 per cent. I estimate therefore that full public hospital costs rose by 108 per cent. That is 46 per cent faster than private hospital costs. The difference was especially marked between 2001 and 2006. For that period, the Council for Medical Schemes reports say that private costs per admission rose 22.1 per cent and public (full) costs per admission rose 57.7 per cent. Public hospital costs therefore rose 161 per cent faster than private hospital costs in that period. All of this is in spite of there being only a 0.5 per cent growth in public hospital admissions in the context of an 8.5 per cent growth in population between 2000 and 2008, and a 42 per cent mortality increase between 2000 and 2005. So, in the face of greater urgency, the ability of public health care to reach the poor actually declined by 7.4 per cent in this period.

In sum, reliable statistics show that private hospital care is at worst 5.3 per cent more expensive than public hospital care, but is likely to be significantly cheaper when quality of care and other services, as well as the inefficiency of the government funding channel, are taken into account. For example, if the 60 per cent private versus public health setting mortality rate applies to SA, the cost of saving a life is 36.8 per cent cheaper in private hospitals than in public hospitals. Furthermore, in terms of the cost to the economy at large, public hospital care has been, and is likely to continue, getting more expensive than private hospital care, at a rapid rate. Finally, public hospitals are getting worse, not better, at providing affordable health care to the poor.

A superficial glance at the costs to clients suggests that public health care is cheaper to provide than private care but when you look at the cost to the economy at large and the effectiveness of actually providing care, the opposite is clearly true.

In order to provide more health care at a lower price to the poor, government is undermining the myriad private efforts of South Africans to look after their own health. Less obviously, it is shifting a great proportion of the country's productive efforts away from other important purposes in order to provide a far from satisfactory form of health care.

The declining public admission rates per capita, in the context of high mortality, shows clearly that government's current healthcare policy actually leads to less care for the poor. Even if we were to accept that the health of the poor justifies a drop in overall utility, the anti-private pro-public path chosen by government is a failure. If government is serious about saving the lives of the poor, and improving welfare generally, it needs to take a different path.

Garth Zietsman
Statistician

Attachment to Free Market Foundation submission on Health OVERVIEW

SA students flee Cuba, next time it will be Russia

It came as no surprise that a group of South African medical students have fled Cuba to escape the horrendous conditions they were being subjected to in that country.

In 1996, the Department of Health dreamt up a programme to train doctors in Cuba to reduce the chronic shortage of skilled doctors in SA and avoid the supposedly high cost of training them here. Students, keen to study medicine but unable to get into any of SA's eight government-run medical schools went along with the plan.

Why should we not be surprised that they want to flee the country? Cuba is one of the world's most repressed countries with an economic freedom score of 28.5 out of 100 according to the Heritage Foundation's 2013 Index of Economic Freedom. It is second to last in the world ranking, one place better than North Korea. Cuba's socialist command economy lurches from one crisis to the next under a resolutely Communist economic policy. The average worker earns less than USD25 (R228) a month. Any move towards genuine political or economic freedom is rejected by the Castro regime.

According to SA's Minister of Health, Aaron Motsoaledi, "It costs R750,000 to train a South African medical student in Cuba, but double that to train them here." The problem that South African students going to Cuba have to study in Spanish, and on their return to South Africa have to relearn medical vocabulary in English seemed to be of minor importance.

But our healthcare problem is urgent, so Dr Motsoaledi says, "With the shortage we have got we want to send (them) to any part of the world. It's an advantage, of course, to send them to a country where the language is the same." So now the Minister is contemplating sending SA students to Russiawhere training is provided in English.

How soon will our students be fleeing from Russia? It also ranks poorly (139th) on the Heritage Foundation's Index of Economic Freedom, amongst the likes of Guinea-Bissau (138th) and Vietnam (140th) and slightly ahead of the Central African Republic, which is ranked 142nd.

What Minister Motsoaledi intentionally overlooks in his quest to send our students off to economically and politically repressed destinations is that our very own private sector has already shown a keen interest in training doctors right here in this country. A few years ago, when a private institution applied to establish a medical school in Midrand, Gauteng, it was turned down by government. This naturally quashed any interest by others contemplating the same move.

Apart from the language barrier, are foreign trained returning doctors adequately equipped to handle problems unique to SA? According to the economics consultancy group Econex, SA has a "quadruple burden of disease". As a result Econex states, "The types of in and out-patient treatment, medication, primary and other care needed in South Africa, are not like that of other countries. One implication is, for instance, that more hospital beds, and therefore medical as well as other staff, will be required in a country where there is such a high prevalence of HIV/AIDS, communicable diseases and also injuries".

It is not only more staff we require but also medical personnel. Personnel who gain an acute in-depth knowledge of prevailing local conditions that can be acquired only by obtaining training in this country.

The HIV/AIDS prevalence rate in Russia is 1 per cent. In Cuba, it is 0.1 per cent. In South Africa, it is 17.8 per cent. From this it should be obvious that we require local solutions to heal local problems.

In SA every year, thousands of potential candidates, even those who achieve distinctions in their matric examinations, are turned away because the number of positions available at SA's eight government run medical schools is limited to around 2,000 positions. This number is only fractionally higher than that which was set in the early 1970s, despite our rising disease burden and a population that has more than doubled.

An obvious short-term solution to the chronic shortage of skilled healthcare personnel in SA would be to allow foreign skilled healthcare personnel to practice here, without any restrictions on where they are allowed to work and for whom. A longer term solution would be for the Department of Education to relax the restrictions and allow the private sector to establish private medical schools so that thousands of SA's brightest students can pursue their dream of studying medicine. Whether these schools operate on a for-profit or non-profit basis, their establishment can only alleviate the burden.

South African private hospitals are well-established centres of excellence and world-renowned for their high levels of care. Privately run education facilities, if conducted in co-operation with private hospitals, have the potential to attract internationally recognised lecturers, which, in turn, will increase the available pool of knowledge as well as international students, who quite possibly will continue to work in SA.

Unlike government, the private sector has an immediate economic incentive to ensure that doctors who qualify at their institutions measure up to SA's high standards. Fears that they will not are unfounded.

Privately run medical schools will not solve the chronic doctor shortage overnight, but they will definitely assist the government's long-term efforts to increase the number of doctors practicing in SA.

Jasson Urbach
Director, FMF Health Policy Unit



STREAMLINING DRUG APPROVALS

by **Jasson Urbach**: Director Freemarket Foundation

Drug regulators worldwide are grappling with the problem of how to approve medicines quicker whilst still ensuring that drugs are safe to be released into the market.

Writing in the *New England Journal of Medicine*, Hamburg and Sharfstein note, "Critics concerned about haste point out, accurately, that drugs and other products are generally approved on the basis of relatively small studies and that safety problems often emerge when large populations are exposed to the products. Those worried about delay note, correctly, that people with life threatening diseases have no time to wait".

The harmonisation of drug regulators' activities is proving, increasingly, to be the answer to this apparent conundrum. For example, the European Medicines Agency (EMA) has demonstrated that a central drug agency that coordinates all drug approvals has the ability to reach a vast number of patients because there is only one application process and gives the applicants access to all 28 countries of the European Union.

Increased cooperation between major drug regulators has also been occurring. According to Lembit Rago, coordinator of quality assurance and safety of medicines at the World Health Organisation, "Even the big fish like the FDA and also EMA are increasingly exchanging views and cooperating".

This increased harmonisation is justified by the increased interdependence between nations and the desire for the latest developments to be made available to patients as quickly as possible. The benefits of emerging market economies cooperating with advanced country drug regulators are manifold. In addition to ensuring the safety and efficacy of drugs that are already on the market through an open and transparent communications channel, increased cooperation prevents duplication of efforts. This argument is particularly important for poor, developing countries such as South

Africa. The opportunity costs of investing vast resources into the duplication of efforts are staggering.

According to the Department of Health (DoH) Annual Report for 2012/2013, one of the key objectives of the sub-programme Pharmaceutical Trade and Product Regulation is to "Improve the registration of medicines and reduce the time to market by reducing the backlog on medicine registrations". Moreover, according to the Report, the DoH sets itself the target of registration timelines of "28 months for new chemical entities (NCEs) and 15 months for generics". The report, however, reveals that the average registration period for generics was 34 months and for NCEs 36 months. Thus, in an age of tremendous scientific and medical progress that offers new hope to South African patients, the regulator failed to approve both generic and NCEs in a timely manner, reporting a variance of 19 months for generic registrations and eight months for NCEs.

The DoH annual report cites a number of reasons for the variance. Firstly, "[The] lack of evaluators – in-house and external". Secondly, "Difficulty in recruiting evaluators at the remuneration rates paid". Finally, "Registration occurs at MCC meetings, which take place six times a year, based on peer-reviewed evaluators' reports received from five expert committees".

From this we can be led to believe that the staff and part-time assistants that support the MCC in the drug registration process are to blame. Not so. It is the system that is at fault. Consider the high profile case that included the HIV/AIDS treatment called Tenofovir. This particular drug was approved by the FDA in 2001. Only after much local public criticism did the MCC eventually register the drug in South Africa in 2007. This is just one example where the drug approval procedure for a drug already approved by stringent drug regulators in advanced countries has

caused pain and suffering amongst South Africa's sick and vulnerable.

There is a simple policy that, if adopted, will improve South African patients' access to the world's most innovative new medicines and vaccines, and thereby allow us to leapfrog up the developmental ladder. South Africa's medicines authority should identify a handful of reference regulatory agencies that it deems competent. For example, it may decide that the United States Food and Drug Administration (FDA), Health Canada, the United Kingdom's Medicines and Health Products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA) and the European Medicines Agency (EMA) are sufficiently stringent regulators.

If the application has yet to be approved by any of those regulatory authorities, then a full dossier must be submitted to the regulator for evaluation and a regulatory decision. If the application has been approved by one drug regulatory agency from the agreed reference basket, an abridged dossier may be submitted for an abridged evaluation and a regulatory decision. If the application has already been approved by two or more of the reference regulatory agencies, then a verification dossier may be submitted for evaluation, and the regulatory decision based on the assessment report provided by a reference regulatory agency.

The primary aim of this proposal is to reduce the time period for patients in South Africa to have access to the latest available technologies. Delaying access to proven, effective drugs results in direct pain and suffering. There are other factors that have a bearing on patient access to quality care and treatment in our country, but our ability to reform the current drug review process ranks among those most easily achieved—but only if South Africa's Minister of Health demonstrates the compassion and the foresight, and sufficient political will to see it through.