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AIDS AND THE SCIENTIFIC GOVERNANCE OF MEDICINE IN SOUTH AFRICA

Nicoli Nattrass

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Nicoli Nattrass is the Director of the AIDS and Society Research Unit within the Centre for Social Science Research and a Professor in the School of Economics at the University of Cape Town.

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Abstract

South Africa's approach to AIDS has been shaped by persistent antipathy on the part of President Mbeki and his Health Minister towards antiretroviral therapy. This was framed initially by Mbeki's questioning of AIDS science and subsequently by direct resistance to implementing prevention and treatment programmes using antiretrovirals. Once that battle was lost in the courts and in the political arena, the Health Minister continued a war of attrition by portraying antiretrovirals as 'poison', supporting alternative untested therapies and undermining the scientific regulation of medicines. Two key scientific bodies, the Medicines Control Council (MCC) and the Medical Research Council (MRC) fall under the ambit of the national Department of Health. Although notionally independent, both have experienced political interference as a consequence of their scientific approach to AIDS. The MCC appears no longer able to respond to complaints if these are lodged against alternative therapists supported by the Health Minister, and its law enforcement personnel have been over-ruled by the Director General of Health.

Introduction

South Africa's strategy for combating AIDS has been shaped by a long-standing antipathy on the part of President Thabo Mbeki and his Health Minister, Dr Manto Tshabalala-Msimang, towards the use of antiretroviral therapy for AIDS prevention and treatment. In the early years of his Presidency (1999 to 2000), this was framed by his championing of a small group of AIDS denialists[1] who believe that HIV is harmless and that AIDS symptoms are caused by malnutrition and even antiretroviral therapy itself.[2] Since Mbeki's withdrawal in October 2000 from public commentary on the subject, Tshabalala-Msimang has

[1] AIDS denialists prefer to call themselves 'dissidents', but as this implies that they are engaged in a genuine scientific debate (which they are not), their alternative designation, 'AIDS denialists' will be used in this paper. For information on the errors and misrepresentations of science by AIDS denialists, see www.aidstruth.org.

[2] Heyward 2004.

taken his agenda forward by resisting the introduction of antiretrovirals for the prevention of mother-to-child transmission (PMTCT) until forced to do by the Constitutional Court,[3] and by resisting the introduction of highly active antiretroviral therapy (HAART) for AIDS-sick people until a cabinet revolt in late 2003 forced her to back down on this too. Nevertheless, she has continued to undermine the 'rollout' of HAART in the public sector, *inter alia* by supporting unproven alternative therapies and by describing antiretrovirals as 'poison'.

This paper argues that a key legacy of Mbeki's AIDS denialism has been the undermining of the scientific regulation of medicine in South Africa. It describes the conflicts which have arisen between Mbeki and his Health Minister on the one hand, and two quasi-independent scientific bodies on the other: The Medicines Control Council (MCC) which governs the registration of medicines, and the Medical Research Council (MRC), South Africa's parastatal medical and epidemiological research institute. Both bodies are located institutionally within the national Department of Health but are designed to operate without political interference. However, both have been subject to political pressure – the MCC more so than the MRC as its secretariat is staffed by civil servants working in the Department of Health, whereas the MRC employs its own personnel.

Historically, the scientific regulation of medicine in the advanced capitalist countries has been the outcome of defensive organisation by physicians to eliminate competition from 'quacks',[4] and of government intervention to protect the public from unsafe medicines.[5] However, this process neither eliminated the problem of medical charlatans, who continue to operate in the 'grey therapeutic zones' where regulatory authority is untested,[6] nor reduced public demand for alternative therapies to biomedicine. Indeed, from the 1960s onwards, there has been a growing 'new health mysticism' in its favour.[7]

But while 'holistic' alternative therapies have been contrasted favourably with impersonal and bureaucratic biomedical science,[8] the regulatory challenge remains: how to accommodate the demand for alternative healing strategies whilst simultaneously protecting the public against unsafe products and exploitation by fraudsters. As Porter warns, the new enthusiasm for alternative medicine may be no less 'medicalising' and risky than the orthodox medicine

[3] Heyward 2003.
[4] Porter 1989.
[5] Daennrich 2002; Young 1967.
[6] Young 1967, p. 391.
[7] Porter 1997, p. 709.
[8] Illich 1976.

being repudiated.[9] This is one of the reasons why regulatory systems, whilst seeking to be more accommodating of alternative therapies, continue to impose strict safety requirements on products claiming to be medicines. The European Union not only requires proof that a traditional medicine has been used as such for over thirty years, but insists that application for registration be accompanied by appropriate pharmaceutical tests.[10] In Australia complementary medicines fall into the low-risk component of the two-tier regulatory system, but only if they contain listed low-risk ingredients,[11] and in the United Kingdom, procedures are being put in place to improve the testing and safety of herbal remedies.[12]

In some respects, Tshabalala-Msimang's attempts to promote alternative therapies are part of the global trend towards more diverse regulatory structures. It also resonates with post-colonial attempts to reclaim a greater role for traditional medicine. But in South Africa's case, there are no established 'traditional' treatments for AIDS. Instead, the alternative medical market is characterised by a diverse cast of characters all peddling cures which have not been scientifically tested. South Africa's Health Minister has yet to put in place a regulatory system that can guarantee the safety of these alternative products. Instead, she has undermined the independence of the MCC and has ridden rough-shod over existing safety procedures in her support of purveyors of untested substances.

The Virodene saga

The first confrontation between Mbeki and the scientific governance of medicine occurred in 1997 when he was Deputy President. This so-called 'Virodene saga' began in January 1997 when University of Pretoria scientists 'Ziggie' and Olga Visser informed the Health Minister (then Nkosazana Dlamini-Zuma) about an unofficial trial they were conducting on AIDS patients using a freezing solution (dimethylformamide) dubbed 'Virodene'. They claimed that their results were promising but that 'the AIDS Establishment' was blocking their research because it threatened the profits of large pharmaceutical companies.[13] The Health Minister responded by inviting the Vissers (and some of their patients) to a cabinet meeting.

[9] Porter 1997, p. 708.
[10] EMA 2006.
[11] TGA 2006.
[12] MHPRA 2004.
[13] Myburgh 2005.

Writing in the African National Congress (ANC) magazine, *Mayibuye*, Mbeki described what a 'privilege' it was 'to hear the moving testimonies of AIDS sufferers who had been treated with Virodene, with seemingly very encouraging results'.[14] After giving the Vissers a standing ovation, the Cabinet took a decision to help them win approval for a scientific drug trial and to 'support the Virodene research up to the completion of the MCC process'.[15]

The MCC operates through a network of committees drawing on independent scientists, usually based in universities, to manage the registration of medicines and ongoing assurance of the quality of medicines on the market. As part of its work, the MCC evaluates clinical trial protocols and assesses the evidence from such trials when submitted as part of a dossier for drug registration. To Mbeki's evident dismay (1998), the MCC refused the Vissers permission to continue their trial.

Conflict subsequently escalated between the Health Minister and the MCC over Virodene and a range of other issues relating to her emerging plans to restructure the MCC.[16] The Health Minister set up a 'review team', widely seen as working on her behalf for political ends,[17] which recommended that an entirely new structure be created.[18] She subsequently suspended the Registrar of Medicines and his deputy (an action that was subsequently overturned by an arbitration hearing of the Commission for Conciliation, Mediation and Arbitration[19]). Ironically, the new MCC, which was regarded as more sympathetic to the Health Minister's concerns[20] continued to deny the Vissers permission to conduct Virodene trials. It also acted quickly to shut down an operation offering experimental 'oxytherapy' (that is, injecting ozone into people's blood vessels) to AIDS patients even though the Health Minister was reportedly about to visit it.[21]

South Africa's high-level attempt to 'fast-track' a supposed miracle AIDS drug has distinct echoes with a similar saga in Kenya. After initial trials (later revealed to be faulty), Kenyan scientists announced in 1990 that they had discovered that alpha interferon was a cure for AIDS. President Moi formed a company to promote the product, which he named 'Kemron', branding those who expressed doubts as unpatriotic.[22] Kemron was subsequently promoted

[14] Mbeki 1998.
[15] *ibid*.
[16] Folb 1998; Gray *et al* 2002.
[17] Sidley 1998a, p. 1037.
[18] Dukes *et al* 1998, pp. 2-3.
[19] Gray *et al* 2002, p. 40.
[20] Sidley 1998b, p. 1696.
[21] Sidley 1998b, p. 1969.
[22] Hyden and Lanegran 1993.

among African-Americans in the United States as a potential cure that was being ignored because it posed competition for antiretrovirals.[23] Despite a number of studies showing that alpha interferon was ineffective against AIDS, the Federal Drug Administration (FDA) in the United States was eventually prevailed upon to allow a clinical trial of Kemron in 1997, but this was subsequently terminated because of poor recruitment into the trial.[24] By that time the effectiveness of HAART had been well established and AIDS patients were unwilling to experiment with dubious alternatives.

The link between Virodene and AIDS denialism

According to Myburgh (2005), it was the Vissers who, in March 1999, alerted Mbeki to a debate between Anthony Brink (a South African AIDS denialist with no training in medical science) and Dr. Des Martin (president of the Southern African HIV/AIDS Clinicians Society) in the *The Citizen*. In his article 'AZT: A medicine from hell', Brink defended the Health Minister's decision not to make AZT (Zidovudine) available for PMTCT, comparing her to the FDA's Francis Kelsey who saved the USA from thalidomide by delaying the drug's approval.[25] He asserted that AZT was so toxic that prescribing it 'was akin to napalm-bombing a school to kill some roof-rats'. Professor Martin responded by pointing out that HAART had resulted in a 40 per cent decline in US AIDS mortality between 1995 and 1997, and that AZT has been shown to cut maternal transmission by 67 per cent. He agreed that the toxicity of AZT was a 'very real issue' requiring constant vigilance on the part of clinicians. However, its benefits for PMTCT rendered the drug in his view, 'a medicine from heaven'.

In some respects, this 'debate' rehearsed the often emotional clash of perspectives over AZT in the United States during the early 1990s.[26] However, by 1999, the anti-AZT position had been relegated to fringe websites by the therapeutic success of its use in combination therapy (HAART) and by its proven success in PMTCT. The consensus in both activist and scientific communities was that the benefits of AZT outweighed the risks.

A small group of AIDS denialists have, however, in the face of substantive criticism and evidence to the contrary, been arguing for nearly two decades that AZT is a cause of, rather than a treatment for, AIDS. These denialists have no credibility in the scientific community. As far back as 1995, an investigation by *Science* concluded that none of the claims made by the leading denialist, Peter

[23] Noel 1998; Wakefield 2000.
[24] Goldstein 1997.
[25] Brink 2000.
[26] Epstein 1996.

Duesberg (a professor of molecular and cell biology at the University of California), stood up to scrutiny.[27] In 1998, the journal *Genetica* published an article by Duesberg and Rasnick (1998) summarising their key claims, but followed this immediately with a point by point refutation.[28]

According to Bialy, the Duesberg and Rasnick article had a major impression on Mbeki.[29] This suggests that either Mbeki was not aware of the rebuttal by Galea and Chermann, or if he was, that he rejected it along with the many substantial arguments available at the time that HIV causes AIDS[30] as being part of the existing corrupt scientific establishment. One of the hallmarks of AIDS denialist discourse is the assumption that the entire cannon of established science on AIDS is faulty and hence that *none* of its conclusions can be trusted.

Mbeki's challenging of orthodox science

By the time Mbeki became President in June 1999, it would appear that he had already immersed himself in the AIDS denialist literature and was in close contact with Brink, Rasnick and Duesberg.[31] Mbeki launched his first broadside when he addressed the National Council of Provinces in October 1999. He reported that AZT was toxic and formally asked the Health Minister to find out 'where the truth lies'. This process culminated in the setting up of the Presidential AIDS Advisory Panel the following year, comprising both AIDS denialists and orthodox scientists. Mbeki also urged council members 'to access the huge volume of literature on this matter available on the internet'.[32]

The notion that government ministers should educate themselves about the science of AIDS through internet research was a less-than-subtle shot across the bows of the scientific community. It implied a belief that 'the truth might be on the internet, free of "Western" or US self-interested censorship'[33] rather than in the pages of peer-reviewed academic journals. As such, it demonstrated a clear disregard for the authority and credibility of established scientific expertise.

In his opening address at the first meeting of the Presidential AIDS Advisory Panel in May 2000, Mbeki (2000) describes his process of self-education in disarming detail:

[27] Cohen 1994.
[28] Galea and Chermann 1998.
[29] Bialy 2004, p. 182.
[30] For example, NIAID 1995.
[31] Brink 2000; Bialy 2004.
[32] Mbeki 1999.
[33] Sheckels 2004, p. 72.

> I faced this difficult problem of reading all these complicated things that you scientists write about, in this language I don't understand. So I ploughed through lots and lots of documentation, with dictionaries all around me in case there were words that seemed difficult to understand. I would phone the Minister of Health and say, 'Minister, what does this word mean?' And she would explain. I am somewhat embarrassed to say that I discovered that there had been a controversy around these matters for quite some time. I honestly didn't know. I was a bit comforted later when I checked with a number of our Ministers and found that they were as ignorant as I, so I wasn't quite alone.[34]

This is strongly reminiscent of the way that AIDS activists in the USA came to grips with the science of their disease through self-education.[35] But unlike these AIDS activists, Mbeki was head of state. Why did he not instead seek the advice of South Africa's internationally recognised medical scientists – including for example, Professor Malegapuru Makgoba, an immunologist and head of the MRC? The MRC has a large body of research scientists any number of which would have been up to the task. However, by this stage, it appears that Mbeki had already developed a strong distrust of the scientific establishment, and was poised to argue with orthodox scientists rather than seek their advice.

In January 2000, Dr Michael Cherry (a zoologist from the University of Stellenbosch and, *inter alia*, correspondent for *Nature*) published a newspaper article quoting Makgoba as saying that he had 'read nothing in the scientific or medical literature that indicates that AZT should not be provided to people'.[36] Mbeki promptly sent both Cherry and Makgoba a recent paper by Papadopulos-Eleopulos *et al* (1999) arguing that because the prevailing scientific understanding of the way that AZT worked was (in her view) inadequate, whereas its toxic effects were demonstrable, the drug should not be prescribed.

Makgoba responded to Mbeki, providing detailed counter-arguments.[37] He subsequently complained about Mbeki's enthusiastic embrace of Virodene without any scientific evidence and his apparent support for 'pseudo-science' on AIDS.[38] Makgoba's approach was thus to reassert the authority and integrity of the scientific community, and to tell Mbeki to 'leave science to the scientists'. Cherry's approach was less confrontational. After consulting with several specialists, he replied by arguing that Papadopulos-Eleopulos *et al* had presented no original research, had based their case against AZT on a very selective (and dated) set of references (thereby ignoring the best available science on the effectiveness of AZT), and had failed to weigh the costs of the drug (toxicity)

[34] Mbeki 2000.
[35] Epstein 1996, pp. 229-30.
[36] Cherry 2000.
[37] Cohen 2000, p. 590.
[38] Makgoba 2000, p. 1171.

against the benefits of MTCTP.[39] Mbeki forwarded these comments to Papadopulos-Eleopulos, who wrote a response, which Mbeki passed on to Cherry, to which Cherry responded once more, as did she.

This correspondence, the latter part of which is publicly available on one of the AIDS denialist websites,[40] is a typical example of the way in which AIDS denialists counter the conventional science on AIDS. In her response to every reference that Cherry made to the scientific literature, Papadopulos-Eleopulos asserted that none of it amounted to sufficient 'proof', in her view, of the efficacy of AZT. When he pointed out that AZT in combination with other antiretroviral drugs has been shown to reduce the viral load in patients, she responded, not by disputing the evidence, but by arguing that in terms of her understanding of virology, AZT could not possibly be effective. When Cherry observed that studies had shown that HAART had resulted in a large drop in mortality and morbidity, she responded by complaining about its side effects. Cherry pointed out that the authors of one of the articles she referred to in support of her 'AZT is toxic' argument had themselves concluded that the side effects should not be regarded as a reason not to use AZT for MTCTP. She responded by saying that those authors had no choice but to add this qualification to their work in order to get it published.

It is hard to know what anyone who is not a medical scientist could make of their 'debate'. The issues are clouded by complex medical terminology, by what appears to be interminable quibbling over what can or cannot be learned from existing studies, and by apparent rival understandings of virology, immunology and pharmacology. Ultimately, the issue of who to believe boils down to credibility and scientific authority. As Epstein puts it, 'Since no one can "know" all or even a fraction of the corpus of scientific knowledge through direct experience, science is made possible through the allocation of trust'.[41] Trust, in turn, rests on the reputation of experts, which in turn derives from their being able to publish in peer reviewed journals. In this regard, most reasonable non-specialists will opt to trust mainstream science on the assumption that the scientific cannon rests on the best available information and that when existing theory is shown to be incorrect by new evidence, theories change. While it is of course true that scientific advance is often shaped by commercial interests, that people with an intellectual or material stake in an existing paradigm may resist the implications of new evidence as long as possible,[42] and that the construction of scientific fact is a contested social process,[43] revolutions in scientific thinking

[39] Personal correspondence with Dr Michael Cherry.
[40] See www.tig.org.za.
[41] Epstein 1996, p. 15.
[42] Kuhn 1962.
[43] Epstein 1996.

are ultimately achieved through persuasion. Unfortunately, what characterises *all* exchanges between AIDS denialists and orthodox scientists on AIDS is an impenetrable persuasive barrier resulting from an extraordinary tenacity on the part of the dissidents to resist counter evidence[44] and by their pervasive mistrust of the integrity and credibility of orthodox scientists.

It was thus entirely predictable that Mbeki's Presidential AIDS Panel was not going to achieve any consensus on AIDS science or AIDS policy: ignoring the evidence presented by scientists showing that HIV-infected babies succumbed rapidly to AIDS and that antiretroviral treatment reduced HIV transmission substantially,[45] the denialists argued that 'AIDS would disappear instantaneously if all HIV testing was outlawed and the use of antiretroviral drugs was terminated'.[46]

Whether Mbeki was simply naïve in assuming that any other outcome was possible, or whether he was simply using the panel as a means of boosting the authority of the AIDS denialists and as a delaying tactic in the battle over antiretroviral therapy, will never be known. What we do know, is that the panel served as a means for Mbeki and the Health Minister to portray AIDS science and policy formation as deeply contested, and contestable. This, in turn, provided them with the space to resist the introduction of AZT and other antiretrovirals on the grounds that 'more research was needed' into their toxicity and effectiveness. For example, in a news conference in February 2000, the Health Minister revealed that she had turned down two reports from the MCC concluding that the benefits of AZT outweighed the risks on the grounds that more information was needed about toxicity. This suggests that the Health Minister believed that she knew better than the MCC about weighing up the risks and benefits of AZT – an extraordinary assumption of authority on her part over that of the scientists represented on the MCC.

For Mbeki, the established scientific cannon is merely a viewpoint, and not one which government should give particular priority to. In a letter he wrote to Tony Leon, the leader of the parliamentary opposition, this view is spelled out very clearly:

> The idea that as the executive, we should take decisions we can defend simply because views have been expressed by scientist-economists, scientist-agriculturalists, scientist-environmentalists, scientists-pedagogues, scientist-soldiers, scientist-health workers, scientists-communicators is absurd in the

[44] See also Maddox 1993.
[45] PAAPR 2001, pp. 22, 33.
[46] *ibid*, pp. 15, 79, 83.

> extreme. It is sad that you feel compelled to sink to such absurdity, simply to promote the sale of AZT.[47]

Despite their efforts, Mbeki and his Health Minister were unable to win what Gramsci would call the 'war of position' they were fighting over AIDS science, and by implication, over the authority of the scientific community to shape AIDS policy. They were ridiculed in the mainstream media and ran into increasing opposition within their own ranks and from allies like the Congress of South African Trade Unions.[48] Last ditch attempts by Mbeki to swing internal support behind him by telling the ANC caucus that the CIA (working with the large drug companies) was part of the conspiracy to promote the view that HIV causes AIDS[49] could not unite his own party behind him. In mid-October he announced his withdrawal from the public debate on AIDS science.

Political interference with the MRC

This 'withdrawal' from the debate was, however, far from total. In September 2001, he crossed swords once again with the head of the MRC, Professor Makgoba. Mbeki suggested, on the basis of 1995 figures he found on the internet, that as only 2.2 per cent of recorded deaths were listed as AIDS deaths, the government's social and health priorities should be revisited.[50] At this time, it was common knowledge in academic circles that an MRC cause-of-death study[51] had come to diametrically opposite conclusions, but was being embargoed by government. The following month, this study was leaked to the media. It showed that death rates had increased substantially in the population especially for young people and that this was consistent with the results of demographic modelling of the impact of AIDS.[52] The Department of Health responded by putting out a joint statement with Statistics South Africa (South Africa's official statistics body) saying that the 'MRC research is not absolutely definitive and its mortality rates are estimates rather than exact calculations because they rest on various assumptions'.[53] This resulted in a tense exchange between Statistics South Africa and the MRC researchers who argued that Statistics South Africa had misunderstood and misrepresented their findings. Individual members of the MRC were placed under political pressure to

[47] Letters tabled in Parliament, 5 October 2000.
[48] Van der Vliet 2004.
[49] Barrell 2000.
[50] Van der Vliet 2004, p. 66.
[51] Dorrington *et al* 2001.
[52] *ibid.*
[53] DOH 2001.

disassociate themselves from the report and Makgoba was put under pressure to withdraw it, which he refused to do.[54]

Interviewed shortly before his tenure came to an end at the MRC in August 2002, Makgoba observed that the cause-of-death study was 'a ground-breaking report in a country where denials rule the day'.[55] He went on to complain about the great pressure on the MRC to 'toe the party line and become the trusted scientific voice that justifies unscientific findings or pseudo-scientific ideas', saying that this approach has 'never worked successfully anywhere where excellent science is being done'.

The era of the MRC standing up to government appears to have come to an end. Since the replacement of Makgoba with Anthony Mbewu, the MRC has had no further conflict with the government, but instead has had research discussions with, and has accepted payment (for 'workshops') from, the Rath Health Foundation, a multi-national enterprise which claims that its vitamins cure cancer and AIDS[56] and which is supported by the Health Minister (see below).[57]

Resisting and undermining the HAART rollout

Just as AIDS denialists resist epidemiological models of AIDS mortality, so too do they oppose the use of antiretrovirals. When the Health Minister lost her final court battle with the Treatment Action Campaign (TAC) over the introduction of PMTCT,[58] she complained bitterly about being forced to 'poison my people'.[59] She also resisted the introduction of HAART by pointing to its side-effects and to the complexity of administering it – but was defeated politically on this issue too. Faced with growing internal dissention and a civil disobedience campaign lead by the TAC, the cabinet announced in October 2003 that the government would be rolling out HAART in the public health sector.[60]

Butler (2005: 15-18) argues that this reassertion of cabinet authority over presidential authority was one of the positive impacts of AIDS on governance in South Africa. That this 'Cabinet revolt' was a blow to the Health Minister is clear. She was reportedly despondent and distanced herself from the decision, saying 'I am not the one making the decisions; the Cabinet decides

[54] Malan 2003.
[55] http://www.mrc.ac.za/mrcnews/aug2002/makgoba.htm.
[56] Geffen 2005.
[57] See *Mail & Guardian* 2006.
[58] Heyward 2003.
[59] Garrett 2001.
[60] Kindra 2003.

collectively.[61] However, as she remained firmly in the driving seat, her power to shape the rollout (or lack of it) remained substantial. Cabinet authority over policy is easily shipwrecked on the rocks of ministerial intransigence over implementation – especially when the minister concerned is acting under the protection of the President. She has interfered with the ability of provinces to raise money from the Global Fund,[62] presided over a very long antiretroviral drug procurement process (the TAC had to threaten her with legal action in March 2004 before she agreed to allow provinces to procure their own drugs using interim procurement procedures and the national drug tender was awarded only in March 2005) and she has failed to address adequately the human resources crisis in the health sector.[63]

One month after the Cabinet decision on antiretroviral treatment, the government released its 'Operational Plan' to have 54,004 people on treatment by March 2004.[64] However, it was only from late 2004 and into 2005 that the rollout gathered pace – a performance driven in no small measure by outside funding from the Global Fund and PEPFAR.[65]

Rather than actively supporting the rollout, the Health Minister constantly points to the side effects of antiretrovirals whilst highlighting the benefits of nutrition (notably garlic, lemon and olive oil), saying that patients must exercise 'choice' in their treatment strategies.[66] This has resulted in AIDS patients being reluctant to take antiretrovirals because they feared they were 'poisonous'.[67] She has also created the space for alternative remedies to compete with antiretrovirals even though their clinical effects are at best unproven.

Support for alternative (scientifically untested) remedies

As Ashforth has pointed out, in South Africa's era of AIDS, business for healers of all descriptions is booming.[68] This, in turn, has posed regulatory challenges for the MCC which has had to act against medical charlatans (such as the purveyors of 'oxytherapy') and self-styled 'traditional' healers like Siphiwe

[61] Quoted in Kindra 2003.
[62] Naimak 2006.
[63] Nattrass 2006.
[64] DOH 2003, p. 248.
[65] Nattrass 2006.
[66] For example, Cullinan 2005a.
[67] Cullinan 2005b; JCSMF 2006, p. 2.
[68] Ashforth 2005, p. 54.

Hadebe who made a fortune selling a fake AIDS cure 'umbimbi' made out of salt and 2 herbs.[69]

To add to the problems faced by the MCC in assuring the scientific regulation of medicine, the Health Minister appears to be providing both active and passive support for those providing alternative treatment to HAART. For example, in late 2003, the Health Minister sent an alternative therapist to Fana Khaba (a popular DJ for Johannesburg's youth radio station, Yfm) when he lay sick and dying of AIDS.[70] Having initially started taking antiretrovirals, Khaba discarded them after a week in favour of alternative remedies. These included taking *muti* from sangomas and courses of 'Amazing Grace' pills (manufactured by a white woman from Brakpan using 'supermarket ingredients') that cost R100 a course. When these did not work, Tshabalala-Msimang sent Tine van der Maas to the Khaba household.[71]

Van der Maas is a retired Dutch nurse who sells a nostrum called 'Africa's Solution' as an AIDS remedy and recommends that people fight HIV through diet rather than through antiretroviral therapy.[72] 'Africa's Solution' comes in liquid form and the label on the bottle (in the ruling ANC colours of gold, green and black) says that it contains *inter alia* vitamins and extract of African potato, olive green leaf and grapefruit seed. The bottle also advises patients to take 2 crushed cloves of garlic a day and to eat 1 cup of Pronutro (a South African cereal). Even though Khaba's CD4 count was 2 at the time (that is, his immune system was very seriously compromised), Van der Maas claimed that she could treat him, saying 'He doesn't want ARVs. I say to him it is not necessary'.[73] By this time, however, Khaba was simply too desperately ill to be treated by nutritional interventions alone, and he died three months later.

The Health Minister appears to have promoted Van der Maas's activities a lot more substantially than merely referring her to potential patients. She also arranged for Van der Maas to address a meeting of all the provincial health ministers, after which she was invited to conduct 'trials' with AIDS patients at various government hospitals and clinics.[74] The Health Minister has visited Van der Maas's 'research sites' in Natal more than once, and has appeared on Van der Maas's promotional videos.[75]

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[69] Smetherham 2003.
[70] McGregor 2005.
[71] McGregor 2005, p. 18.
[72] McGregor 2005, pp. 17-23.
[73] Quoted in McGregor 2005, p. 17.
[74] Cullinan 2005c.
[75] Geffen 2005.

It is unclear what was involved in Van der Maas's 'trials'. There is no indication that she applied for or obtained permission from the MCC to run them. She claims to have treated over 40,000 people, but has no records of these patients because a burglar allegedly urinated on them in 2002.[76] She is nevertheless confident that her patients are well, because 'If you don't hear from your patients, they are usually doing well. If it's not going well, they'll phone'.[77] The Health Minister has also allocated an advisor working in the Department of Health to assist and advise Van der Maas. When asked if they would be prepared to take part in a scientific study of the diet, the advisor said: 'We don't want to be tied up with scientists in the laboratory. But we would be prepared for the diet to be given to patients in an academic hospital where the benefits can be monitored by an independent neutral person'.[78]

This speaks volumes about the attitude of Department of Health officials towards scientists and scientific regulation: scientists are not neutral, and their testing procedures are inappropriate for non-orthodox remedies. This has distinct echoes with earlier attempts, e.g. the South African Medicines and Medical Devices Regulatory Authority Act that was passed in 1998 but repealed in 2002, to free traditional/complementary/alternative remedies from scientific regulation. But despite attempts to create alternative regulatory mechanisms for non-orthodox remedies, the Medicines and Related Substances Control Act of 1965, as amended in 1997 and 2002, endorsed the role of the MCC as scientific regulator of *all* medicines and related substances. According to the Act, a medicine:

> means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in –
>
> a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
>
> b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

This clearly includes all orthodox, complementary or traditional medicines (as is stressed by the MCC on its website[79]). The Minister's support for the by-passing of scientific testing of alternative AIDS remedies is thus in contravention with both the letter and spirit of the existing legislation.

[76] Brits 2005.
[77] *ibid*.
[78] Cullinan 2005c.
[79] www.mccza.org.za.

More worrying than even her involvement with Van der Maas is the Health Minister's support for the activities of Matthias Rath, a wealthy German entrepreneur. His multinational 'Rath Health Foundation' (which employs AIDS dissidents such as Brink, Rasnick and Mhlongo) sells multivitamins as alternative treatment for cancer and AIDS.[80] As part of its marketing strategy, the Rath Foundation engages in scare-mongering over antiretrovirals, saying that they are 'severely toxic' and 'attack the immune system of patients already suffering from immune deficiency'. Such misleading and aggressive advertising is a hallmark of Rath Foundation advertising world wide, and he has had a number of warnings and rulings against him by regulatory authorities in several countries.[81]

The Rath Foundation also appears to have conducted an unofficial 'trial' in Khayelitsha (Cape Town) outside of South Africa's regulatory structures and with the tacit (if not active) support of the Health Minister. This trial was conducted under the leadership of Sam Mhlongo (apparently a close friend of Mbeki's[82] and the only African scientist who was also an AIDS denialist that Mbeki could find to appoint to his Presidential AIDS Panel). This trial, involving the administering of extremely high doses of vitamins to people with HIV, failed to get approval from Mhlongo's home institution, the University of Limpopo's Medunsa campus, which identified 34 problems with the protocol, and was never presented to the MCC.[83] The results were subsequently published in newspaper advertisements posted in May 2005, claiming that his micronutrients reversed the course of AIDS (Geffen, 2006).[84] Rasnick and Mhlongo were then invited to present their findings to the National Health Council (a body comprising all the provincial ministers of health).[85]

Responding to question about Rath, the Health Minister told reporters:

> 'We cannot transplant models designed for scientific validation of allopathic medicine and apply it to other remedies. There is need for creativity to come up with relevant and pragmatic models to prove safety, quality and efficiency of complementary, alternative and African traditional medicines'.[86]

She claims that rather than undermining the government's position on AIDS, the Rath Foundation is in fact supporting it by providing vitamins and

[80] Geffen 2005.
[81] *ibid*.
[82] Cullinan 2005d.
[83] Cullinan and Thom 2006.
[84] Geffen 2006.
[85] Cullinan and Thom 2006.
[86] *ibid*.

micronutrients.[87] She told reporters that she would only distance herself from Rath 'if it can be demonstrated that the vitamin supplements that he is prescribing are poisonous for people infected with HIV'.[88]

A de-clawed MCC

Whereas in 2003, the MCC was quick to act against complaints about Hadebe's 'umbimbi' AIDS scam, the opposite has been the case with regard to the Rath Foundation. Despite a series of complaints by the TAC and others, no action has been taken against him. Finally, the TAC, together with the South African Medical Association, filed court papers on 29 November 2005 against the Minister of Health, Matthias Rath and several others including Brink, Rasnick and Mhlongo.

It is unclear, precisely, what has been happening in the MCC as there is no annual reporting, minutes are secret and decision-making processes are very opaque. There are some indications that the MCC started an investigation, but that this stalled in late 2005 when the original investigator was removed from the case.[89] Furthermore, the Health Minister and her new Director General have sought to downplay the need for such an investigation on the grounds that his vitamins are 'complementary'[90] – even though he campaigns aggressively against HAART in order to promote his product.

However, some of Rath's vitamins contain scheduled substances – such as N-acetylcysteine – which need to be registered with the MCC. This was the reason why port health officials impounded a shipment of Rath products in June 2006. The shipment was eventually released after the personal involvement of Thami Mseleku, the Director General (DG) of Health – to the concern of law enforcement personnel working in the Department of Health. One of them told reporters:

> 'This is the second time it's happened. The consignment gets withheld because we have problems with the content of the tablets because it doesn't comply with the Medicines Act and then we're told to ignore our concerns and ignore the law we're supposed to enforce'.[91]

Professor Peter Eagles, the current chairperson of the MCC, commented that the Health Minister is entitled to delegate authority to the DG to over-rule the law

[87] Cullinan 2005d.
[88] Cullinan and Thom 2006.
[89] Cullinan and Thom 2006.
[90] *ibid.*
[91] Quoted in Joubert 2006.

enforcement officers, but that this means that the DG has to take 'full responsibility when something goes wrong'.[92]

The Health Minister appears to have finally succeeded in de-clawing the MCC which now appears incapable of responding to complaints against the illegal trials undertaken on AIDS patients, by Van der Maas and Rath. Whereas during the Virodene saga, Mbeki and the Health Minister respected the authority of the MCC to rule that the Vissers were not allowed to conduct trials, in the case of Rath and Van der Maas, the Health Minister has simply side-stepped the MCC. She has given Van der Maas access to AIDS patients in hospitals to run trials – none of which appear to have been presented to the MCC for permission – and she has refused to act on complaints against Rath, even going as far as over-ruling the Department of Health's law enforcement personnel. She appears to believe that it is only necessary to act against Rath if it can be shown that his vitamins are harmful. In other words, under her stewardship, the burden of proof has shifted from the purveyor of the remedy to those who raise doubts about the remedy. That all this undermines the scientific governance of medicine goes without saying.

Although the legislation clearly places all alleged remedies and cures under the ambit of medicines, the Minister of Health appears to be acting according to an alternative set of rules for 'traditional' or 'alternative' remedies – even to the point of supporting their distribution through the public health system without their ever having been tested scientifically. The most recent example of this is the distribution of a herbal product called 'ubhejane', through AIDS clinics in KwaZulu-Natal. Although one of the promoters of ubhejane (a retired sociologist and government health advisor) claimed that research at the University of KwaZulu-Natal had demonstrated its effectiveness,[93] the university subsequently released a statement (17 March 2006) denying this. When the opposition Democratic Alliance (DA) complained about the manufacture of 'fake cures' such as ubhejane by what it called 'backyard chemists', the Department of Health retorted that the DA was simply perpetuating racist stereotypes.[94]

The Department of Health is apparently in the process of formulating new legislation to regulate complementary/alternative/traditional remedies. According to a Departmental press release (18 March 2006), 'in finalising the regulation of these medicines, we are avoiding the pitfall of putting such products in the same regulatory environment as pharmaceutical drugs whose testing is very different'. While this, in principle, is consistent with international

[92] *ibid*.
[93] Vilakazi 2005, p. 7.
[94] DOH 2006.

attempts to accommodate alternative medicines, the devil will be in the details. Scientific research has shown that HAART reduces AIDS-related mortality[95] and that herbal remedies can interact adversely with HAART.[96] Unless safety and efficacy of alternative therapies for AIDS patients can be established – and it is unclear how this can be done outside of scientific regulation – the cost will be paid in human lives lost.

[95] Smit *et al* 2006.
[96] Mills *et al* 2003.

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