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Unethical Promotion and Testing of Medicines on Humans

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A Judicial Investigation into the Presidency and Health Ministry and criminal proceedings against Christine Qunta are necessary.

SUMMARY

"34. (1) A person desiring to initiate or conduct a clinical trial in respect of an unregistered medicine, a new indication or new dosage regimen of a registered medicine or substance, shall apply to the Council on a form determined by the Council for authority to conduct such a clinical trial?.

?(5) No person shall conduct clinical trials referred to in subregulation (1) without the authorisation of the Council.?

Government Notice R510 in Government Gazette 24727, General Regulation of the Medicines and Related Substances Control Act 101 of 1965

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THE OFFICE OF THE PRESIDENCY, THE PRESIDENT AND VIRODENE

1. There is prima facie evidence that illegal and unethical experiments were conducted on people living with HIV/AIDS with a toxic and unregistered substance named Virodene.

2. The aim of the experimentation was commercial benefit.

3. Virodene P058 is a derivative of the toxic, potentially lethal industrial solvent N, N dimethylformamide (DMF). It has never been registered with a medicines regulatory authority of any state in the world.

4. There is evidence that the Office of the Presidency, President Mbeki and Minister of Health Manto Tshabalala-Msimang were involved in these trials after the Medicines Control Council and the University of Pretoria ruled them unethical and in contravention of the law.

5. State support for AIDS denialism and pseudo-science emanating from the President and the Minister of Health over the last decade has led to unnecessary and preventable loss of life.

6. Therefore, the Treatment Action Campaign (TAC) calls for the appointment of a judicial commission of inquiry. The mandate of the inquiry into unlawful experimentation on human subjects should include examinations of:

6.1. the extent of the involvement of the President, officials in the Presidency, the Health Minister or any other senior office bearers in government;

6.2. the extent of involvement by private South African citizens, organisations (public and private) in experimentation on people in South Africa and other African countries;

6.3. the legal steps that should be taken against officials of the South African government, private citizens and organisations; and

6.4. the degree to which the Presidency and the Health Ministry have been involved in undermining the independence of the Medicines Control Council required by the Constitution and Parliament to prevent unlawful human experimentation and to regulate medicine safety, efficacy and quality in the public interest.

CHRISTINE QUNTA, ATTORNEY, PRESIDENTIAL ADVISOR AND AIDS PROFITEER

1. There is prima facie evidence that Christine Qunta, a practising attorney, is an investor and director in a company that profiteers from selling untested and unregistered cures and treatments for AIDS.

2. Qunta was also appointed at the ?instance of the Presidency? by Manto Tshabalala-Msimang to ?The Presidential Task Team on African Traditional Medicines in South Africa? on 11 October 2006. 1 Other members of the Task Team include Professor Herbert Vilakazi, the promoter of Ubhejane another untested remedy for HIV/AIDS, and Professor Anthony Mbewu previously associated with Matthias Rath. 2

3. While we accept that everyone is entitled to legal representation, Qunta Inc, the legal firm, has earned tens of thousands of rands in fees profiteering from the unethical, unscrupulous and unlawful activities of Matthias Rath, the vitamin salesman. She and her law firm have not merely represented Rath, they have pro-actively defended his activities in the media.

4. Until 15 September 2007, the public was not aware that Qunta is ?an investor and director? of the company Comforter?s Healing Gift (CHG) which markets its fake HIV/AIDS cure as ?Ancient African Wisdom?.

5. CHG ?s chief marketer and the head of Qunta?s company, Freddie Isaacs from Uitenhage has styled himself a prophet and is a known confidence-trickster.

6. Their company sells an unknown substance that they have patented.

7. Qunta claims that ?until tests were completed? the product should be described as a nutritional supplement. However, there is evidence that the product is actually sold as a treatment for AIDS. They have learnt from Rath to try and disguise their ?medicines? as food while profiteering from the desperate and dying poor.

8. The TAC calls on the Law Society and the Directorate of Public Prosecutions to start disbarment and criminal proceedings against Christine Qunta. These bodies have to ask the following questions:

8.1. As a lawyer has she intentionally subverted section 20 of the Medicines Act to sell untested medicines to desperate and dying people?

8.2. What scientific and medical qualifications does she have to make claims about the nutritional or medicinal properties of untested substances?

8.3. On whose scientific or clinical advice do her companies rely?

8.4. Has she used her position and connection with the Presidency and Health Minister to promote untested remedies?

8.5. Did she disclose her conflicts of interest to the President and Health Minister?

9. The sale of untested remedies by her company is more than enough evidence to start disbarment proceedings on whether she is a fit and proper person to be an attorney. However, a further question arises to protect the public, can an entrepreneur whose company sells untested remedies protect consumer interests? Or, is her real agenda on the Presidential Task Team on African Traditional Medicines an attempt to undermine the imperatives of the Medicines Act that requires regulation in the public interest based on stringent tests for safety, efficacy and quality of medicines.

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BACKGROUND

On the weekend of 15-16 September 2007 several articles appeared in the Independent Group Newspapers and the Sunday Times alleging financial support of Virodene emanating from the Presidency and the sale of an untested remedy for the treatment of AIDS by a company of which Christine Qunta is co-director. 3 These two stories are not directly related, but they are further evidence of a continued support for AIDS pseudoscience by President Mbeki and those close to him since 1997.

This pseudoscience has at various times included actions and statements that question the causal link between HIV and AIDS, dispute the efficacy of antiretroviral medicines, cast doubt that there is a large HIV epidemic in South Africa and promote untested, even dangerous, medicines for the treatment of AIDS.

The consequences of this have been delayed and poor implementation of the mother-to-child transmission prevention and antiretroviral treatment programmes coupled with massive public confusion. This has caused hundreds of thousands of avoidable deaths and undermined the rule of law by allowing numerous charlatans to breach the Medicines Act with impunity. Therefore the TAC calls for the following:

* There should be a judicial investigation into the links between the presidency and the promotion or testing of Virodene, a poisonous industrial solvent that the country's medicines regulatory authority, the Medicines Control Council, determined should not be tested on humans. At best it appears someone in the Presidency acted unethically in 2000 and 2001. At worst, there is direct involvement of the President himself in corrupt, illegal actions with potentially deadly consequences for patients with HIV. If this is the case, Thabo Mbeki is unfit to hold public office. The public has a right to know what the truth is and a judicial investigation would resolve these concerns. If the President is innocent, he should welcome such an investigation.

* We further call for the people who have made the allegations about the Presidency's involvement in the funding of Virodene to come forward. Similar allegations have surfaced in the past, but those making the allegations hide behind anonymity making it extremely difficult to get to the bottom of this story.

* There should be disbarment and criminal proceedings against Christine Qunta because of her activities with the company Comforter?s Healing Gift, which has sold unregistered medicines for the treatment of AIDS to members of the public. Qunta's involvement in this company as well as her support of other AIDS pseudoscience render her an inappropriate choice for the SABC board, let alone its head.

Presidency?s Alleged Support for the Promotion and/or Testing of Virodene

On 15 and 16 September 2007 articles authored by Fiona Forde appeared in a number of prominent South African newspapers. They contain substantiated accusations that in 2000 and 2001 individuals connected with the Office of the Presidency channelled tens of millions of Rands towards the promotion, development, and clinical trial of Virodene P058, a full three years after the Medicines Control Council (MCC) suspended trials of the drug in South Africa and banned its further provision to patients.

In particular Ms. Forde?s articles make the following explicit claims:

* Throughout 2000 and into early 2001 approximately R40 million was handed over by representatives of the Presidency to Olga and Zigi Visser, the lead developers of Virodene. This money was regularly and routinely collected in briefcases containing US$100 notes directly from the Union Buildings as well as from the Johannesburg offices of an unnamed ANC-linked businessman.
* An unnamed source in the articles, stated to be a former insider within the Virodene research team, claims that the money received from the Presidency went towards ?researching, promoting and developing the drug? in South Africa and Tanzania. This claim is allegedly substantiated by hundreds of emails, letters and faxes handed over to the Weekend Argus.
* Between September 2000 and March 2001, during the period of time that the Presidency was diverting funds towards Virodene?s development, the Tanzanian People?s Defence Force conducted human trials of the drug on behalf of the Virodene research team.

The Tanzanian trials of Virodene were performed at two healthcare facilities, one a military hospital the other a private clinic, in Dar-es-Salaam. These trials were conducted on 64 HIV-positive men including retired military personnel as well as civilians.

In early 2001 South African Minister of Health Dr. Manto Tshabalala-Msimang, acting in her official capacity, visited Tanzania to carry out an inspection of the Virodene trials. This claim has previously been acknowledged by Dr. Tshabalala-Msimang herself and recently corroborated by staff from Lugalo Military Hospital in Dar-es-Salaam, one of the locations at which human testing of Virodene was carried out.

The Presidency has confirmed that it granted official authorisation for Dr. Tshabalala-Msimang?s Tanzanian trip in 2001 but it remains unclear whether or not this approval extended to the trial inspections.

Citing problems with the study?s ethical and scientific protocol, the Tanazanian trials of Virodene were suspended by Tanzania?s National Institute for Medical Research in March 2001, shortly after Dr. Tshabalala-Msimang?s inspection. The trials were apparently continued later that year.

Representatives from both the Virodene research team as well as the Presidency have denied that there was any financial support given to Virodene?s development by the South African government . A spokesperson for the Presidency has, however, admitted that there was ?some kind of contact? between the Presidency and lead Virodene researcher Olga Visser.

Many of the points raised in Ms. Forde?s articles have been on public record for several years. Researcher James Myburgh has written a detailed 5 part synopsis on the Virodene scandal. 4 Details of the Tanzanian trials of Virodene were widely reported in South African and international media in 2001 and the studies are even cited in an executive brochure available for download on the website of Virodene Pharmaceutical Holdings (VPH, the company that manufactures Virodene P058). 5

Likewise, Minister of Health Tshabalala-Msimang?s inspection of those trials has also been previously commented on in media sources. Tshabalala-Msimang has formerly acknowledged the fact that she visited the clinics at which clinical testing of Virodene was taking place during her trip to Tanzania in 2001 but her office insisted that the link with Virodene was ?purely coincidental?.

The new information that Ms. Forde's articles contain is that the source of funding for Virodene?s promotion and development, including the Tanzanian trials, which has long been a matter of intense speculation. Virodene P058, a derivative of the toxic, potentially lethal industrial solvent N, N dimethylformamide (DMF), has never been registered with the pharmaceutical regulatory authority of any state in the world. The drug has failed clinical tests for safety and efficacy in South Africa, Great Britain and Germany. Rather than acting against HIV, several studies have shown that Virodene either has no effect on inhibiting the progression of HIV or that the drug may possibly even activate the virus.

Despite the fact that by the late 1990s Virodene was proven to be unsafe as an anti-AIDS drug, huge sums of money continued to be pumped into its development. Commenting on the Tanzanian studies, VPH shareholder Charles Fourie was quoted in September 2001 as saying that, ?the Vissers are being funded by someone and must have spent at least R10 million on these recent trials?.

Furthermore Mr. Fourie stated that Zigi Visser had contacted him ?from Tanzania just two weeks ago to offer to buy us all out for US$5 million?. The identity of Virodene?s mystery benefactor(s) has never been ascertained, having remained hidden even from fellow VPH shareholders. The evidence suggests, however, that Virodene?s primary sponsors are intimately connected to senior officials within the South African government and the ANC.

There is clear evidence that high-ranking members of the South African government and the ANC, including President Thabo Mbeki, were enthusiastic political patrons of Virodene. The presentation to cabinet given by Virodene?s research team in February 1997, an event arranged by then Deputy President Thabo Mbeki and former Minister of Health Nkosazana Dlamini-Zuma, was greeted with spontaneous applause from cabinet members and a ?favourable? response from Mbeki on possible state support for Virodene?s development.

Later, when the MCC suspended trials of Virodene in South Africa, Minister Dlamini-Zuma dismissed MCC chairperson Peter Folb and curtailed the MCCs regulatory powers in retribution. The ANC intervened on several occasions between 1997 and 1999 after the MCC continued to reject Virodene research protocols. The ruling party called on the council to accelerate the bureaucratic and investigative processes that would allow for the reinstatement of clinical trials of the drug in South Africa. During this period of time Deputy President Mbeki even personally arbitrated in an internal legal dispute between Virodene?s producers. The personal involvement of high-ranking ANC government officials such as Dlamini-Zuma and Mbeki in the Virodene saga suggests that the ruling party, for whatever reasons, had invested a sizeable political stake in furthering the drug?s development. Dr. Manto Tshabalala-Msimang?s 2001 inspection of Virodene trials in Tanzania serves as further proof of the political investment in Virodene research made by the ANC government.

Questions still remain however as to whether or not the ANC ever had a financial investment in Virodene P058. In early 1998 the Democratic Party released documents in its possession which indicated that the ANC stood to benefit from Virodene?s production. 6 These documents showed that the ruling party owned a 6% share in the Virodene company, though how the shares were acquired was never clarified. These allegations were denied by then Deputy-President Mbeki: ?Neither the ANC nor anyone in its leadership, whether working inside or outside government, has been or will be involved in any financial arrangement related to Virodene?.

Less than three months after Mbeki?s denial that the ANC was financially involved in any way in Virodene?s promotion or development, it emerged that a group of South African and Namibian investors led by ANC member and MK veteran Joshua Mxomalo purchased a 60% stake in Virodene. The new shareholders insisted that their identities remain secret, but according to media reports they included ?business people involved in primary health care- a central component of government policy?. 7 According to these same media reports, Mxomalo had been instrumental in arranging for ?Virodene?s founders to meet senior government officials, including Mbeki?. For his ?introductions? work Mxomalo had previously been ?given? a small stake in the Virodene company. But despite Mxomalo?s close links with Mbeki, a report released in May 1999 by Public Protector Selby Baqwa found that neither Mbeki nor Dlamini-Zuma had ever been involved in any financial or business transactions related to Virodene.

If this recent news reports alleging the involvement of the Presidency in the promotion, distribution, development and clinical testing of Virodene P058 are accurate, they describe actions that are at best unethical, but quite possibly illegal.

Christine Qunta's Involvement in the Promotion of an Untested AIDS Medicine

Christine Qunta has been nominated to the South African Broadcasting Corporation (SABC) board and is expected to be selected by President Mbeki to head it. Her involvement in AIDS pseudoscience and in the activities of a company

profiteering on people with HIV renders her unsuitable for public office of any kind.

The Independent Group newspapers reported that a University of Rhodes student together with TAC activist Emma Baleka recently purchased two containers of pills and a bottle of black liquid manufactured by Comforter?s Healing Gift (CHG) from Uitenhage ?healer? Freddie Isaacs. Isaacs, who is co-director of CHG along with Christine Qunta and businessman Mashudu Ramano, purported that the pills and liquid were cures for AIDS. In a follow-up interview Isaacs confirmed that the CHG products are being marketed at outlets nationwide and that the idea for the AIDS cure ?came to him in a dream?. Isaacs? daughter has also suggested that the products could help diabetics.

The reports state that Ms. Qunta, a lawyer whose firm defends Matthias Rath, denied personal involvement in the marketing of CHG products as cures for AIDS. She is reported to claim that she plays no role in the day to day administration of the company. Qunta has stated that any comments made by Isaacs on the alleged healing properties of CHG?s products reflect Isaacs? own personal views and not those of the company. Apparently the products have been submitted to the MRC and the CSIR for testing and pending the results of those tests Qunta has stated that the products should be described as ?nutritional supplements?. Qunta asserts that she and Ramano had instructed Isaacs not to make any ?claims for the product until scientific tests were completed as this would be unethical?. Indeed, attributing false claims of healing effects to a scientifically unproven product is unethical and illegal.

Yet accompanying the article in the Saturday Argus (one of the Independent Group newspapers that broke the story) is a photograph of the CHG building in the Nelson Mandela Metropole. A nearby sign identifies the CHG building as a treatment centre and a sign on the building reads ?Our mission is to fight all AIDS-related illnesses.? Therefore the reported claim by Qunta that Isaacs is acting in his personal capacity and that she was unaware that the product is being sold as an AIDS treatment is implausible.

Furthermore, Qunta appears to misunderstand that proper testing of a product for efficacy against HIV requires Medicines Control Council approved phased clinical trials on people. Laboratory testing for efficacy against HIV is insufficient. Also, no testing in humans should begin unless there's scientific evidence that a medicine is likely to be safe and effective. No claims should be advertised about a medicine unless the medicine is registered with the Medicines Control Council for that claim.

Mr. Isaacs? sale of substances which he purported to be cures for HIV/AIDS to members of the public, substances whose therapeutic efficacy and safety have not been scientifically verified and whose registration has not been approved by the Medicines Control Council (MCC), constitutes a breach of the Medicines Act and is therefore in violation of the law. Isaacs has committed a criminal offence and the TAC demands that both he and Comforter?s Healing Gift face appropriate legal sanctions. Although she denies any personal wrongdoing, Qunta as co-director of CHG bears a professional responsibility for the illegal actions taken by fellow co-director Isaacs. The TAC will therefore lodge a complaint against Qunta with the Law Society and the Director of Public Prosecutions. We also demand that Qunta steps down from the SABC Board.

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Footnotes

1. Government Gazette, 11 October 2006. No. 29288.

2. See http://www.tac.org.za/nl20060615.html

3. See
http://www.iol.co.za/index.php?set_id=1&click_id=13&art_id=vn20070915081047136C406709
and
http://www.iol.co.za/index.php?set_id=1&click_id=125&art_id=vn20070915090457461C213058.

4. James Myburg's synopsis The Virodene Affair:

Part 1:
http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83156&sn=Detail
Part 2:
http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83179&sn=Detail
Part 3:
http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83213&sn=Detail
Part 4:
http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83231&sn=Detail
Part 5:
http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83253&sn=Detail

5. See
http://www.virodene.com/downloads/Virodene_Executive_Brouchure.pdf.
Interestingly, the executive brochure available on the VPH website
claims that the clinical trials of the drug conducted in Tanzania were
only completed in 2004.

6. Medicine for Beginners: How ANC burnt its fingers on AIDS solvent,
Sunday Times: 26 September 1999.

7. Virodene?s New Black Owners, Mail and Guardian: 19 June 1998.

- AIDS Denialism
- Manto Tshabalala-Msimang
- Thabo Mbeki

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