TREATMENT INFORMATION GROUP
thinking about AIDS drugs
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18 December 2007

Dr M E Tshabalala-Msimang
Minister of Health
Private Bag X828
Pretoria

And to cc list for information

Dear Dr Tshabalala-Msimang

AZT IN PREGANCY

I refer to your Department's media statement on the 1st, announcing that 'Dual therapy for Prevention of Mother to Child Transmission of HIV should be implemented from the beginning of next year'.

I haven't seen the 'draft treatment guidelines' currently being considered by the National Health Council, but 'Dual therapy' in this context conventionally means giving AZT or a similar nucleoside analogue drug to pregnant women and their babies in combination with nevirapine.

You'll recall President Mbeki's warning about AZT nine years ago at the National Council of Provinces on 28 October 1999:

> There … exists a large volume of scientific literature alleging that, among other things, the toxicity of this drug is such that it is in fact a danger to health. These are matters of great concern to the government as it would be irresponsible for us not to heed the dire warnings which medical researchers have been making.

As you correctly observed to journalists outside Parliament immediately afterwards (I quote a SAPA report), there was indeed:

> a body of scientific research and information which indicated that AZT was a dangerous drug, and had not been designed for the treatment of HIV/AIDS. Because it was unable to target only the human immunodeficiency virus when it went to work in the body, it further weakened the immune system. There was also a danger that ... mothers taking the drug might produce children with disabilities. Tshabalala-Msimang said her ministry would not like to look back ten or fifteen years down the line and find it had exposed the vast majority of historically disadvantaged people in South Africa to a dangerous drug.

Two weeks later, on 16 November, you elaborated in Parliament:

> AZT is a drug that was developed for use in chemotherapy for cancer patients. It was, however, never used in cancer patients because it was regarded as too toxic to use. Tests have clearly shown that rats that were exposed to … AZT [in the womb during gestation], developed vaginal cancer. This is a very serious finding. Other toxicological data exists with respect to AZT, including damage to nerves, muscles and bone marrow. All of this data needs to be assessed very thoroughly. As the Minister of Health I have a responsibility for ensuring that South Africans get appropriate and affordable healthcare. This responsibility extends to ensuring that no healthcare intervention has a long-term negative effect on people.

You need no reminding that the Medicines Control Council provided you with such disgracefully ignorant and inadequate 'assess[ments] … [of] this data' that you turned to the Cochrane Centre, which then did no better.

Some of your well-informed statements on AZT, supported by citations from the medical literature, are included in the enclosed introductory leaflet *Why do President Mbeki and Dr Tshabalala-Msimang warn against the use of ARV drugs like AZT?*

In the several years since 1999 when you and President Mbeki first expressed your concerns about AZT, particularly in regard to its harmful effects on unborn and newly born children, scores more research reports have been published confirming your worst apprehensions.

This literature is canvassed in depth in a series of letters my group wrote to the Medicines Control Council, gathered in a compendium under the title

Poisoning our Children: AZT in Pregnancy. It can be downloaded free from our group's website mentioned in our letterhead.

A few reports in this regard are included in the enclosed leaflet: *Why do Zackie Achmat, Nathan Geffen and Mark Heywood want pregnant African women and their babies to be given AZT? What AZT does to unborn and newly born children.*

According to the media statement, the new 'draft treatment guidelines' were developed on account of concerns about the 'limited effect and drug resistance associated with … single drug nevirapine'.

The problems with giving newborn babies, mostly African, even a single dose of nevirapine after birth are considerably graver than this.

Official audits of HIVNET 012, the Ugandan study preceding nevirapine's conditional approval in this country by the MCC, found a very high incidence of unreported serious adverse events and many deaths among African babies exposed to this exceptionally toxic drug. This is detailed in my book *The trouble with nevirapine*, which can be downloaded free at my group's website.

In view of the focus of the 'process of consultation with experts and stakeholders', namely to 'try and address this challenge' of 'limited effect and drug resistance associated with … single drug nevirapine', it seems unlikely that due attention was given during the 'process of consultation' to the proven serious harm that AZT has been shown in dozens of research reports to cause unborn and newly born children.

This is because since the thalidomide disaster it's universally considered unconscionable to expose a pregnant woman to any drug known to harm the baby she's carrying. And it's equally unacceptable to treat a baby with a harmful drug that may seriously injure and possibly kill it. I enclose a copy of a press statement in this regard recently issued by my group on the 30th anniversary of the beginning of the thalidomide disaster, entitled *October 1957: Thalidomide and pregnancy; October 2007: AZT and pregnancy; Another tragedy of countless children killed and maimed foretold*.

In the interests of a generation of children, born to mostly poor African mothers, I implore you as a key member of the NHC to direct that an oral hearing be held at which I might present and be questioned on the medical

research data that I've collected on how AZT and other nucleoside analogue drugs harm unborn and newly born children before the NHC accepts the new 'draft treatment guidelines' supporting their use.

You'll recall that although I'm a lawyer, a member of the MCC mentioned to you having been struck by the 'impressive detail' of my submissions concerning the foetal and neonatal toxicity of AZT, of which the MCC had been 'unaware', he said. The leading, most rigorous critics of AZT as an AIDS drug, Papadopulos-Eleopulos and her colleagues in Perth, Western Australia, have remarked to me: 'Clearly your knowledge-base in this subject extends far beyond ours.' In recognition of my expertise on the clinical and molecular pharmacology of AZT and nevirapine, which I've been studying for more than a decade, the scientists awarded me an honorary co-authorship credit of their 2001 monograph *Mother to child transmission of HIV and its prevention by AZT and nevirapine: A critical analysis of the evidence*. It can be downloaded from our website.

Section 6(1)(c) of the National Health Act 61 of 2003 requires that people should 'have full knowledge' of the 'risks' and 'consequences generally associated with each option' offered them by medical practitioners. Obviously, no pregnant African woman would consent to exposing her baby to AZT (or similar) were she told of the proven 'risks' and 'consequences generally associated with' the drug, namely that

> Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death

and

> Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system

as my group summarized the research in the *Mail&Guardian* on 22 November 2004 – a drug so toxic, especially to unborn children, that even its inventor Professor Richard Beltz disavowed it in an email to me on 11 May 2000:

> you are justified in sounding a warning against the long-term therapeutic use of AZT, or its use in pregnant women, because of its

> demonstrated toxicity and side effects. Unfortunately, the devastating effects of AZT emerged only after the final level of experiments were well underway, that is, the experiments which consisted of giving AZT to large numbers of human patients over a long period of time. Your effort is a worthy one … I hope you succeed in convincing your government not to make AZT available.

I appreciate that you have been under enormous pressure by the pharmaceutical industry and its local agents to provide AZT and similar drugs to pregnant African women and their babies, and that South African National AIDS Council deputy chairperson Mark Heywood's AIDS Law Project acting on behalf of his and Zackie Achmat's Treatment Action Campaign menaced you with legal action in October, but it's unimaginable that apprised of all the facts any judge would rule the government's reluctance to poison African babies with AZT unreasonable. And certainly no African judge.

Please act to avert this impending tragedy.

Yours sincerely

ADV ANTHONY BRINK

CHAIRMAN: TREATMENT INFORMATION GROUP

CC: President Thabo Mbeki; Department of Health Director-General Thamsanqa Mseleku; Department of Health Deputy Director-General Nthari Matsau; NHC members; all Provincial Health MECs; South African Local Government Association; South African Military Health Services; SANAC chairperson Deputy President Phumzile Mlambo-Ngcuka; SANAC deputy chairperson Mark Heywood; Parliamentary Health Portfolio Committee chairperson James Ngculu and all other members; Medical Research Council president Professor Anthony Mbewu; other interested parties, media, and online at www.tig.org.za