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TAC Electronic Newsletter

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TAC & SAMA v. Rath & Government of South Africa

What is the case about?

On 26 April 2007 the Treatment Action Campaign and South African Medical Association go to the Cape High Court to seek relief against the pharmaceutical proprietor Matthias Rath and several of his employees and associates, as well as the Government of South Africa, represented by the Minister of Health.

TAC and SAMA have asked the court to interdict Rath and several of his associates from:

- Distributing unregistered medicines
- Conducting an unauthorised clinical trial
- Making false claims about multivitamins in advertisements

These appear to be in breach of the Medicines and Related Substances Act 101 of 1965 (Medicines Act), its subsequent amendments and its regulations. We are pursuing this interdict because we believe Rath and his associates ran a clinical trial in Khayelitsha using unregistered multivitamins, which included a schedule 2 substance called N-acetylcysteine, and published advertisements claiming that multivitamins reverse the course of AIDS. He and his agents also prescribed multivitamins as a treatment for AIDS in their health facilities in various parts of the country including Kwazulu-Natal and Eastern Cape. TAC and, independently of us, several journalists have documented several alleged deaths that occurred on Rath's trial.

TAC and SAMA have also asked the court to find that the state has failed to investigate these allegations against Rath and to therefore order it to take reasonable measures from stopping the above activities. We are requesting a structural interdict, which means the state would have to report back to the court on how it has carried out the court's order.

TAC's rejected offer of a settlement to the state

Last year, the TAC met with the Deputy-President and we agreed that negotiations would be entered to settle with the state (only the state, not Rath) in this case. We wrote to the Acting Minister of Health on 22 March offering a settlement on the terms described in the attached letter. There was no answer from the state. Instead, the state attorneys sent a submission in support of an application by Rath to file a late 2,000 page affidavit clearly designed to delay proceedings. We sent a letter to the Deputy-President on Monday requesting her to intervene. In addition, we have directly approached members of the Health Department, but there has been no reciprocation.

We believe our case against the state is extremely strong. We offered a settlement to try to avoid the conflict of the last few years and because we believed the Ministry of Health would now have a new approach to the science of HIV and take action against people who break the Medicines Act. It is in the state's interest to settle this case, because such a settlement will likely avoid it much embarrassment and stop the undermining of the Medicines Act. It is therefore disappointing that the state has chosen conflict over settlement. TAC will mobilise extensively for this case.

Rath's attempt to delay proceedings

About a month ago, Rath filed an approximately 2,000 page affidavit, virtually doubling the court record. The affidavit contains conspiracy theories and is mostly irrelevant to this case. More importantly, it is over a year late and comes without warning long after our responding affidavit was filed and the matter was set down. We believe it is an attempt to delay and confuse proceedings. Rath has filed what is called an application for condonation, which is a request to the court to allow his affidavit to be filed. The application contains strange allegations as to why the affidavit is late. We have opposed this late application. However, we have informed Rath's attorneys that if Rath agrees to the interdict until the court case is decided then we will not oppose it being filed. We have not yet had a response to this offer.

Why is this case important?

Numerous charlatans across the country distribute unregistered and unproven medicines for the treatment of AIDS. The state, with very few exceptions, has failed to act against these life-threatening unscrupulous business practices. TAC hopes this case will set a strong precedent for acting against others who sell unproven remedies to people with HIV, including Zeblon Gwala (who sells Ubhejane), Tine van der Maas (who claims her garlic concoction treats AIDS) and Steven Leivers (who sells the unproven product Secomet).

The Constitution guarantees the right to psychological and bodily integrity (Section 12) and the right to access health care services (Section 27).The state, especially the Department of Health's Law Enforcement Unit and the Medicines Control Council, have a duty to ensure that medicines sold to the public are safe, effective and of high quality. The state is failing to meet its constitutional duties. It is also failing to enforce the Medicines Act.

This case is also about the damage caused by AIDS denialists. The Rath respondents claim that HIV does not exist (Anthony Brink), that it does not cause AIDS (David Rasnick) or that the risks of antiretrovirals outweigh their benefits (all of them). One of the respondents in the case is David Rasnick, an American AIDS denialist who sat on President Mbeki's commission on the cause of AIDS in 2000. He is also a close colleague of Peter Duesberg, a discredited and dishonest scientist who leads many of the AIDS denialists.

Rath and other AIDS denialists use rhetoric about natural medicines and conspiracy theories about the pharmaceutical industry to disguise their ignorance of science and that they themselves are extremely profitable members of the pharmaceutical industry. They are guilty of far worse than the members of the industry that they usually malign.

Additional notes about the case

(1) Selling unregistered medicines

Andrew Gray, an expert in pharmacology who sits on one of the Medicine Control Council sub-committees, explains in an affidavit before the court that Rath sells unregistered medicines that should be registered. No expert testimony has been offered by either Rath or the state to contradict this.

Rath and his associates have distributed their high dose multivitamin products to people with AIDS, claiming that these products will treat their disease. Whether or not he distributes them for free, South African law considers this to be selling. All vitamins sold as medicines since 2002 have to be registered. Rath's vitamins are not registered. We contend that he is therefore selling unregistered medicines. This is illegal in the Medicines Act.

(2) Unauthorised clinical trials

Professor Leslie London, an expert in public health and medical ethics, explains in an affidavit before the court that Rath has conducted an unauthorised clinical trial. No expert testimony, either by the state or Rath, contradicts this.

Rath and his associates have apparently conducted experiments on people in South Africa without authority from the MCC. They have repeatedly published advertisements that they have conducted a "/clinical pilot study/" in Khayelitsha, Cape Town, and that the goal of the study was "/to show that a combination of micronutrients can reverse the course of AIDS, even in its advanced stage." /These have appeared in the New York Times, the International Herald Tribune, the Mercury, the Namibian and as pamphlets across South Africa.

TAC's court papers contain testimony of people who visited Rath's health facilities. They had blood taken from them and photos taken of them semi-naked.

No person may conduct a clinical trial on humans without permission of the Medicines Control Council. We contend that Rath is conducting illegal clinical trials.

(3) False and unauthorised statements that the Rath medicines are effective in treating or preventing AIDS

Dr Francois Venter, the President of the Southern African HIV Clinicians Society and an expert in the science of HIV/AIDS, explains in his affidavit before the court that there is no evidence that vitamins reverse the course of AIDS. The available evidence shows only that a particular combination in a particular dose delays the onset of AIDS in a specific group of patients. Neither the state nor Rath has put forward expert testimony contradicting Dr Venter.

Rath and his associates have made numerous claims in advertisements that vitamins can reverse the course of AIDS, even in its advanced stage. This is illegal.

For further information, see Wrongs of Rath

[END OF TAC v. RATH AND STATE]

Tenofovir registered

The Medicines Control Council has registered tenofovir and the combination pill tenofovir/FTC. See this TAC fact sheet on tenofovir. This is an important step forward for providing better medicines to people with HIV. However, the prices at which Aspen Pharmacare is selling these medicines is far too high. They are selling tenofovir at R199.29 (incl. VAT) per patient per month and the combination pill of tenofovir and FTC at R329.89 (incl. VAT) per patient per month. This is higher than the price at which patients were previously accessing it under Section 21 Authorisation!

Tenofovir is not patented in South Africa and we urge other companies to apply to register tenofovir so that competition drives the price down.

We also urge the Department of Health to revise the antiretroviral treatment guidelines to include tenofovir so that it becomes available in the public health system.

[END OF TENOFOVIR STATEMENT]

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