Acta Tropica 112S (2009) S76–S79

Contents lists available at ScienceDirect

Acta Tropica

journal homepage: www.elsevier.com/locate/actatropica

Using the courts to challenge irrational health research policies and administrative decisions

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ARTICLE INFO

Article history:
Available online 8 August 2009

Keywords:
Court
Legal
Unethical research
Judiciary

ABSTRACT

While the judiciary has previously adjudicated on research-related matters, with several landmark cases having been heard in North America, the use of the judiciary in research-related matters in the developing world is relatively rare. Even rarer, both in developed and developing countries, is public-interest litigation in the health research context. South Africa is proving to be a trail-blazer in this respect. This work outlines three landmark South African cases where irrational, discriminatory, and arguably unethical decisions of government authorities pertaining to research were successfully challenged in the courts. The experience of South Africa demonstrates that while the courts should not generally interfere in the affairs of science, they can be a useful mechanism to reverse irrational ideology-driven science policy and decision-making.

Published by Elsevier B.V.

1. Introduction

While the judiciary has previously adjudicated on research-related matters, with several landmark cases having been heard in North America, (Halushka, 1965; Kus, 1995; Lenahan, 2004; Weiss, 1989) the use of the judiciary in research-related matters in the developing world is relatively rare. Even rarer, both in developed and developing countries, is public-interest litigation in the health research context. South Africa is proving to be a trail-blazer in this respect. To date, two such landmark cases already having been heard. What makes these cases particularly unusual is that, unlike the aforementioned cases in North America, none of the cases centered on the infringement of a particular research participant's rights. Nor was either matter brought by aggrieved research participants. Instead one centered on the rights of thousands of women who were being denied the standard of care provided to participants in an operational research study. The second centered on the failure of authorities to act against a researcher who was openly conducting an illegal and arguably invalid clinical trial. Both cases were brought by civil society organizations. A further South African case where judicial intervention occurred in the research realm was brought by scientists whose research was being unreasonably stonewalled by authorities. In all three cases, ideology rather than science seemingly underpinned the decision-making of authorities. This work outlines these landmark cases and argues that while the courts should not generally intervene in matters of science, the experience of South Africa demonstrates that they can be a useful mechanism to reverse irrational ideology-driven science policy and decision-making.

2. Case 1: challenging an irrational government policy to conduct redundant research when efficacy evidence already exists

South Africa's Constitution is arguably the most liberal constitution in the world. Aside from being the first Constitution in the world to prohibit discrimination on the grounds of, amongst others, sexual orientation, it is also one of the world's few Constitutions that contain provisions governing research. In this regard the South African Bill of Rights explicitly recognizes a person's right to academic freedom and freedom of scientific research (Section 16(1)(d)) and a person's right not to be subjected to medical or scientific experiments without informed consent (Section 12(2)(c)). Ironically, these constitutional rights were not central to challenging the South African government's decision to conduct operational research on a HIV drug when sufficient evidence already existed on the subject matter. Rather, the constitutionally enshrined right to health, was.

Frustrated by the South African government's apathy and lethargy in managing the country's HIV/AIDS crisis, a civil society

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0001-706X/$ – see front matter Published by Elsevier B.V.
doi:10.1016/j.actatropica.2009.07.035

AIDS advocacy group, the Treatment Action Campaign (TAC), brought an action against the South African government to compel it to provide to pregnant mothers the drug Nevirapine, a HIV anti-retroviral agent used to prevent mother-to-child transmission of HIV. The TAC based its case on, amongst other factors, the mother and child's right to health, which is enshrined in the South African Constitution (Section 27). The matter culminated in the landmark 2002 Constitutional Court case, *Minister of Health and Others v. Treatment Action Campaign and Others* (Minister of Health and Others). While the efficacy of providing Nevirapine to pregnant mothers in reducing mother-to-child transmission of HIV had, by then, long been demonstrated in clinical trials, the government had restricted the provision of Nevirapine to just 18 test sites, claiming, in essence, it needed to conduct operational research to assess the feasibility of employing the drug. The TAC demanded that this program be instituted nationwide so that mothers and children everywhere could benefit from the drug (Singh et al., 2007).

In delivering its judgment, South Africa's Constitutional Court made it clear that it was not convinced that the South African government needed to assess the feasibility of introducing the intervention in a pilot study before doing so nationwide. The Court held that the government's policy was unreasonable in that it did not allow for the administration of Nevirapine elsewhere in the public health system when there was capacity to administer it and its use was medically indicated. It also deemed unreasonable the government's confinement of Nevirapine to research and training sites as this failed to address the needs of mothers and their newborn children who did not have access to these sites. The Court stated:

> The fact that the research and training sites will provide crucial data on which a comprehensive programme for mother-to-child transmission can be developed and, if financially feasible, implemented is clearly of importance to government and to the country. So too is ongoing research into safety, efficacy and resistance. This does not mean, however, that until the best programme has been formulated and the necessary funds and infrastructure provided for the implementation of that programme, Nevirapine must be withheld from mothers and children who do not have access to the research and training sites. Nor can it reasonably be withheld until medical research has been completed (Paragraph 69 of judgement).

The court held that although it was not possible for the government to make available a 'full package' of medical services to the general public, it had to reformulate its health policy bearing in mind its constitutional obligation (realizing the right to health). In recognizing that this did not mean that everyone could *immediately* claim access to such treatment, the court affirmed that this should be the ultimate goal. It found that every effort had to be made to do so as soon as reasonably possible. In making its order, the court held:

(a) Sections 27(1) and (2) of the Constitution [the right to health] require the government to devise and implement within its available resources a comprehensive and co-ordinated programme to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV.
(b) The programme to be realized progressively within available resources must include reasonable measures for counselling and testing pregnant women for HIV, counselling HIV-positive pregnant women on the options open to them to reduce the risk of mother-to-child transmission of HIV, and making appropriate treatment available to them for such purposes (Paragraph 135 of judgement).

This ruling is consistent with the Court's previous ruling on the right to housing (Government of RSA) wherein it held that any government program that excludes a significant segment of society cannot be reasonable. Although it took further pressure for the South African government to act on the judgment, as a result of this case the government's Nevirapine pilot study operational research was stopped and the drug was eventually made freely available to thousands of pregnant mothers at government treatment facilities throughout the country. The South African government had attempted to justify the pilot study on the basis of needing to monitor the feasibility of employing the drug in the public sector. Ironically, the government has since been accused of not adequately monitoring the success of the program, and of not doing enough to remedy disparities that exist between provinces in respect of access to the intervention and standard of care provided (Pao, 2006). That said, this case holds important lessons. From a constitutional perspective, this case centers on the right to health. From a research ethics perspective, however, this case centers both on the ethics of conducting redundant operational research and applicable standards of care. It demonstrates that ill-founded ideology-driven redundant and unreasonable operational research can be successfully challenged in court. Moreover, that the courts can order higher standards of care in state-driven pilot study sites to be administered beyond study sites if scientific evidence and resources support doing so.

3. Case 2: challenging a drug regulator's refusal to register and approve an ethically defensible and scientifically sound clinical trial

In 2003 pediatric HIV researchers at the University of KwaZulu-Natal (UKZN), Durban, South Africa, were awarded US$7.5 million dollars to conduct a double-blinded placebo trial on the anti-AIDS drug, Nevirapine. Currently, a once-off dose of Nevirapine is administered just before birth to reduce the chances of a child becoming infected with HIV during the birth process. The prevailing standard of care worldwide during the first 6-month period after birth was no treatment. The UKZN trial was designed to assess whether Nevirapine would have a protective effect over that 6-month period. According to the study design, only HIV-positive mothers who elected to breastfeed, despite the risk of mother-to-child transmission, would be enrolled in the trial. Half the newborns would be given Nevirapine and half a placebo for 6 months or until they stopped breastfeeding. The researchers would then monitor the children for signs of HIV infection until 18 months of age.

The researchers first applied for approval to South Africa's medicines regulatory authority, the Medicine Control Council, to conduct the trial, in November 2003. Despite the MCC's claimed turnaround time of 3–6 months, the application was eventually rejected only in December 2004. The MCC based its refusal to register the trial on its inclusion of a placebo arm, claiming doing so would be unethical as infants in the placebo arm of the trial would be exposed to HIV through breastfeeding. The MCC also doubted the efficacy of Nevirapine to prevent mother-to-baby transmission of HIV, questioning the findings of the landmark Ugandan study that led to its registration as an ARV drug for children. When the investigators took the MCC's decision on appeal to the MCC's independent Appeals Committee (a 3-person panel appointed by the Minister of Health), the Appeals Committee found in favor of the investigators in February 2006 and overturned the MCC's decision (David and Scott, 2007). Astoundingly, the MCC ignored that ruling and continued to refuse to approve the study. Both researchers and the MCC then turned to the courts for relief: the MCC for an order to deny the authority of the Appeal Committee, the investigators, to compel it. Following court orders issued in favor of the scientists, the MCC applied for leave to appeal those decisions.