#### Health and human rights

# AIDS: patent rights versus patient's rights

After the discovery of combination antiretroviral therapies that could transform HIV infection from a death sentence to a chronic disease, the use of such combinations spread widely in more-developed countries, and AIDS-related mortality in Europe and the

US dropped by more than 70%. In less-developed countries—home to 95% of people living with HIV—the past 4 years have been starkly different, characterised more by death and societal disruption than by

media. Please refer to the printed journal.

Campaigners in Thailand, 1999

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hope and treatment. Access to AIDS drugs in less-developed countries took centre stage at the International AIDS conference in Durban, South Africa last month (July 9–14).

To propose that all people with AIDS in less-developed countries should immediately be given combination antiretroviral therapy is not realistic. In the poorest countries enormous efforts are necessary to even offer the most basic treatment of opportunistic infections. An adequate health structure and trained and committed staff are also needed. But to conclude that the focus should therfore be on activities such as prevention<sup>2</sup> is simply to abandon about 30 million people with HIV/AIDS in poor countries.

Issues of cost-effectiveness are also invoked: preventing vertical transmission would be cost-effective for a resource-poor country but life-long antiretroviral medication would not.3 In such circumstances the cost of the medicines-which should be the subject of debate—is instead set in stone. Moreover, without treatment there is no hope and so little reason to take an HIV test. We can expect that increasing access to treatment will reinforce prevention activities. Unfortunately, the high price of drugs often limits de facto any action or willingness to act.

And this high price—currently around \$US10 000 for a year's triple therapy—is difficult to justify. Zidovudine was first synthesised in 1964. Most of the research that showed the drug's effectiveness as an antiretroviral was done by the US National Institutes of Health.<sup>4</sup> Nevertheless, Glaxo Wellcome, having obtained the patent for zidovudine for the treatment of AIDS, brought the drug onto the market in 1987 as one of

the most expensive ever sold. 13 years later, the drug remains unaffordable for most people with AIDS. They will have to wait another 5 years before the patent expires.

The story is the same for most antiretrovirals: often discovered by

public laboratories, devel-oped in short time-frames in clinical trials supported by public funds, and then sold at a high price. Public re-search institutes have heavily funded anti-retroviral development, includ-

ing that for didanosine, abacavir, stavudine, zalcitabine, and the concept of protease inhibitors. Researchers com-paring the time-to-approval of AIDS drugs found that antiretrovirals were approved in an average of 44.6 months, close to half the industry-wide average of 87.4 months for the approval of drugs.4 Patents for didanosine, stavudine, and zalcitabine held by public authorities (www.fda.gov/cder/ob/default.htm; www.patents.ibm.com), but rights to commercialisation have been granted to private companies on an exclusive basis. Thus, the usual explanation proffered by industry to justify their high prices—that research and development is a long and expensive process—is extremely weak here. Nothing explains why companies charge so much except that they were initially put on the market in the USA, a rich country without price controls. Unfortunately for most of the world's 34 million people infected with HIV, pharmaceutical companies impose US prices on the rest of the world.

Donations and discounts do not address the issue of fair and equitable pricing. On May 11 five big pharmaceutical companies loudly announced that they would make substantial discounts on their AIDS drugs. The price cuts currently suggested (85%) are extremely modest in comparison to those already in place for vaccines and oral contraceptives. 3 months on, and details and commitments are still being discussed, but no medicines have reached patients.

The refusal or reticence of drug companies to substantially lower their prices in poor countries naturally attracts attention to their market monopolies granted through patents. Least-developed countries that are part of the World Trade Organisation (WTO) have until 2006 at the latest to

adopt intellectual property laws that enshrine 20 years of patent protection for medicines. Because this is not a retroactive agreement, generic sources of antiretrovirals exist from countries that did not respect patents before entering the WTO. In these countries, as is always the case when there is market competition rather than monopoly, the price comes down.

production The of generic antiretrovirals in India (zidovudine, stavudine, lamivudine, and nevirapine) and Thailand (zidovudine, stavudine, and didanosine) has increased access to treatment. Brazil has been able to afford to put 90 000 people with AIDS on combination therapy because generic competition has reduced prices of antiretrovirals by more than 70% during the past 5 years. Less-developed countries unable to produce antiretrovirals themselves could import them from Brazil, India, or Thailand (through compulsory licensing if they are patented), but usually come under pressure from intense pharmaceutical industry and western governments not to do so.

The gap between the prospects for people with AIDS living in the western world and those living in lessdeveloped countries makes the problem of access to AIDS treatments much more than a medical concern. This gap is also a social, economic, moral, and political issue. The question of AIDS treatment leads to a wider reflection of the balance between public and private interests, between patent rights and the rights of patients. Access to health care and to medical progress as a human right is a challenge that AIDS poses to humanity. It is no longer morally acceptable to debate if antiretrovirals should be provided. We should now concentrate on how quickly they can be provided.

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- 1 Palella FJ, Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. N Engl 7 Med 1999: 279: 853-60.
- 2 Ainsworth M, Teokul W. Breaking the silence: setting realistic priorities for AIDS control in less-developed countries. *Lancet* 2000; 356: 55–60.
- 3 Zwi K, Söderlund N, Schneider H. Cheaper antiretrovirals to treat AIDS in South Africa BM7 2000; 320: 1551–52.
- 4 Mitsuya H, Weinhold K, Yarchoan R, Bolognesi D, Broder S. Credit government scientist with developing anti-AIDS drug. The New York Times September 28, 1989.
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### Health workers at risk

Health workers around the world continue to face political obstacles in carrying out their work, according to an Amnesty International report published recently.1 Despite international human-rights standards and humanitarian laws protecting their status, in many countries pressure is placed on doctors, nurses, and other health workers to curtail their professional work, human-rights activities, or non-violent political activity. This pressure ranges from the denial of promotion, transfer to undesirable locations and dismissal, through to death threats or threats against family members, abduction and "disappearance", killing, and torture.

Two countries illustrate in sharp relief the problems faced by health professionals who are active in prodemocracy and human-rights movements. In Burma (Myanmar), doctors and nurses were active in demonstrations throughout the country in March 1988 calling for an end to 26 years of one-party military rule in Burma. The demonstrations continued until Sept 18, 1988, when military forces crushed opposition and imposed military control. Despite national elections in 1990—which were convincingly won by the opposition—the military government refused to accept the result and there were widespread arrests of opposition supporters. A number of those arrested were medical professionals, several of whom still remain in prison a decade after the elections. Among those arrested was Dr Daw Shwe Bo, sentenced to life imprisonment in July 1999 allegedly in connection with a march in support of the National League for Democracy to campaign for lowering of food prices and revision of civil servants' salaries. She had previously been forced to resign from her position as a medical officer.

By contrast, Turkey is a democracy and member of the Council of Europe. However, human-rights abuses are widespread, with an institutionalised use of torture and as a consequence of this is the continuing problem of

pressure on doctors to collude in the medical cover-up of torture.2 The Human Rights Foundation of Turkey, the Human Rights Association, and the Turkish Medical Association (TMA) have actively defended human rights and health workers at risk. In 1996 the TMA convened humanrights meetings in Istanbul and Adana to raise awareness among local medical practitioners of human-rights issues and professional ethics. The meeting in Adana gave rise to a 3-year collaboration between Turkish and foreign doctors which eventuated in the elaboration of a detailed protocol for the investigation of torture. This document, the Istanbul Protocol, was presented to the United Nations High Commissioner for Human Rights, Mary Robinson, in Geneva in August 1999. The TMA has also given support both to doctors under pressure from the authorities for their humanrights work and to those who have been ill-treated in custody.

What elements of medical practice do some governments regard as illegitimate or blatantly Prominent among these is the provision of medical treatment to opponents of the government. Doctors who are seen by the authorities as sympathetic to, providing treatment for, or failing to report members of opposition groups may be prosecuted. This happened in Peru in 1992 prompting international non-government organisations and professional delegations to visit the country in 1993 and 1994—and in Turkey where the arrest and prosecution of doctors during the past year has provoked international protest.

The reason for this international concern is obvious. Health professionals who may feel sympathy with a militant opposition group cannot by law be regarded as acting illegally, provided that such sympathy does not manifest itself in anything more than agreement with the goals of the organisation or support for the rights of its members. Providing medical care to armed opponents of the government should not in itself be a prosecutable offence since the most fundamental tenet of

medical ethics is that a person in need of medical care should receive such medical care irrespective of "age, disease, or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation or social standing.' In some cases, governments have framed charges against doctors precisely in terms of their "treating" an armed government opponent. Dr Zeki Uzun was acquitted in a Turkish court on May 23 on charges of "aiding an illegal organization" by knowingly treating two women who were allegedly members of the Kurdistan Workers Party. He was tortured after his arrest.

Failing to report the treatment of an alleged armed opposition figure is a more complex issue. Some countries have laws that require doctors to report to the police when patients have wounds caused by a weapon—presumably because such wounds may be indicative of a crime. A doctor wishing to maintain patient confidentiality, contrary to the requirement of such a law, would need to be prepared to justify that decision before a court. In some countries, obeying rules that require doctors to report on their patients could be so dangerous to the patient that it would be unethical for a doctor to routinely obey such laws. To do so could "make doctors accomplices to wrong-doing"4 by putting the patient at risk of torture or death.

What measures can be taken to protect health professionals facing human-rights abuses? The Istanbul Protocol represents one standard that doctors can cite in support of their insistence on carrying out proper medical examinations in torture cases. In a wider context, the World Medical Association has proposed, together with a consortium of human-rights bodies, the creation of a UN Special Rapporteur for the independence and integrity of health professionals. In the meantime, more protests by professional bodies and non-governmental would help those organisations professionals who attempt to put into action the dry words of international ethical and human-rights standards.

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- 1 Harming the healers: the violation of human rights of health professionals. (ACT 75/02/00). London: Amnesty, May 2000.
- 2 Physicians for Human Rights. Torture in Turkey and its unwilling accomplices. Boston: PHR, 1996.
- 3 Declaration of Geneva of the World Medical Association. Ferney-Voltaire, WMA, 1983.
- 4 Reyes H. Medical neutrality: confidentiality subject to national law: should doctors always comply? *Medisch Contact* 1996; 45: 1456–59.

## **UPDATE: Prof Veli Lök**

On June 13 Prof Veli Lök, an orthopaedic surgeon and human-rights defender from Turkey, known internationally for his work on the diagnosis, documentation, and treatment of torture victims, was sentenced in a Turkish court. He was given a 1 month prison term, but this was commuted to a fine and suspended providing he does not comment on certain political issues for 5 years. The International Rehabilitation Council for Torture Victims condemned the treatment of doctors in Turkey, saying "It is incomprehensible that torture could continue to be widely practised in Turkey and that doctors treating torture victims could themselves become targets for harassment." James Welsh (Amnesty International) added that those who work to end torture "should be protected and supported rather than prosecuted." SH
See: Wenzel T et al. Torture and the scientific community. Lancet 2000; 255: 1550.

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