

**VOLUME 8, NUMBER 3, DECEMBER 2003** 

## TRIPS from Doha to Cancún . . . to Ottawa: global developments in access to treatment and Canada's Bill C-56

In November 2003, Canada introduced legislation to amend the Patent Act so that manufacturers could obtain licences to make generic versions of patented pharmaceutical products for export to countries lacking sufficient capacity to produce their own. Bill C-56 aims to implement an August 2003 decision of the World Trade Organization (WTO) that relaxes its rules on pharmaceutical patents to allow this kind of measure. While the bill is a welcome development, it contains several serious flaws that will undermine the initiative and render it

largely meaningless. Civil society organizations, including the Canadian HIV/AIDS Legal Network, have called on the Canadian government to remedy the flaws before Bill C-56 is enacted. This article provides an overview of recent global developments leading up to Canada's initiative, as well as an analysis of Bill C-56 itself.

## Access to medicines and the World Trade Organization

#### The Doha Declaration

On 14 November 2001, at the WTO's Fourth Ministerial Conference in Doha, Qatar, member countries unanimously adopted a ministerial Declaration on the TRIPS Agreement and Public Health.<sup>1</sup> The Doha Declaration, as it came to be known, was made in response to criticisms from numerous developing countries and from civil society

cont'd on page 7



CANADIAN RÉSEAU HIV·AIDS JURIDIQUE LEGAL CANADIEN NETWORK VIH·SIDA

Published by the Canadian HIV/AIDS Legal Network. A project funded in part by Health Canada under the Canadian Strategy on HIV/AIDS.



### Inside

Warsaw Declaration on HIV/AIDS and injection drug use adopted	19
HIV-positive person who did not disclose status convicted of attempted aggravated assault	50
North America's first supervised injection site opens in Vancouver	24
Ontario court affirms that medical marijuana regulations are unconstitutional	53
UNGASS review: reports show little progress on human rights	34
New policy on methadone maintenance treatment in prisons established in Alberta	45
UK court denies prisoner with HIV early release	61

#### **CANADIAN HIV/AIDS POLICY & LAW REVIEW**

The Review is a summary of developments in HIV/AIDS policy and law in Canada and abroad. Its aim is to educate people about and inform them of policy and legal developments and to promote the exchange of information, ideas, and experiences. It is published every four months by the Canadian HIV/AIDS Legal Network.

Contributions are welcome and encouraged. Please contact us at the following address to discuss your article and to obtain a copy of our style guide:

> Canadian HIV/AIDS Policy & Law Review Canadian HIV/AIDS Legal Network 417 Saint-Pierre, Suite 408 Montréal, Québec H2Y 2M4 Tel: 514 397-6828 Fax: 514 397-8570 Email: info@aidslaw.ca

Managing Editor and Editor, Canadian News: David Garmaise, email: dgarmaise@rogers.com

Editor, International News: David Patterson,

email: dpatterson@aidslaw.ca

Editor, Global Access to Treatment: Richard Elliott, email: relliott@aidslaw.ca

Editor, HIV/AIDS in the Courts: Glenn Betteridge, email: gbetteridge@aidslaw.ca

Editor, HIV/AIDS in Prisons: Ralf Jürgens, email: ralfj@aidslaw.ca

Regular Correspondents, Canadian News:

#### Geographic

Tarel Quandt, British Columbia, email: tarelg@bcpwa.org Rebecca Scheer, Alberta, email: rscheer@aidscalgary.org Roger Procyk, Manitoba and Saskatchewan, email: rprocyk@ninecircles.ca Ruth Carey, Óntario, email: careyr@lao.on.ca Matthew Perry, Ontario, email: perrym@lao.on.ca Michel Morin, Québec, email: info@cocqsida.com Bill Downer, Newfoundland & Labrador, email: bdowner@acnl.net

#### Issue-Specific

Ian Culbert, Public Health, email: iculbert@cpha.ca Thomas Kerr, Illegal Drug-Use Issues, email: tkerr@aidslaw.ca Derek Thaczuk, Medical Marijuana Issues, email: derekt@pwatoronto.org

Copyeditors: Garry Bowers, Jean Dussault Translators: Roger Caron, Jean Dussault, Josée Dussault, Johanne Forget Typesetting: C & G Graphics, Montréal

© Canadian HIV/AIDS Legal Network 2003. We encourage the dissemination of the information contained in this Review and will grant permission to reprint material, provided that proper credit is given. The editors kindly request a copy of the publication in which material from the Review is used.

Circulation: 2000 ISSN 1195-5252

The publication of the Canadian HIV/AIDS Policy & Law Review is funded in part by Health Canada under the Canadian Strategy on HIV/AIDS.

The findings, interpretations, and views expressed in this publication are entirely those of the authors and do not necessarily reflect official policy or positions of Health Canada or the Canadian HIV/AIDS Legal Network.

Canadian HIV/AIDS Legal Network The Network is a charitable organization engaged in eduation, legal and ethical analysis, and policy development. We promote responses to HIV/AIDS that

- implement the International Guidelines on HIV/AIDS and Human Rights;
- · respect the rights of people with HIV/AIDS and of those affected by the disease;
- facilitate HIV prevention efforts;
- facilitate care, treatment, and support to people with HIV/AIDS;
- · minimize the adverse impact of HIV/AIDS on individuals and communities; and
- · address the social and economic factors that increase the vulnerability to HIV/AIDS and to human rights abuses.

We produce, and facilitate access to, accurate and up-to-date information and analysis on legal, ethical, and policy issues related to HIV/AIDS, in Canada and internationally. We consult, and give voice to, Network members and a wide range of participants, in particular communities of people with HIV/AIDS and those affected by HIV/AIDS, in identifying, analyzing, and addressing legal, ethical, and policy issues related to HIV/AIDS. We link people working on or concerned by these issues. We recognize the global implications of the epidemic and incorporate that perspective in our work.

The Network is based in Montréal. We welcome new members. For membership information, write to info@aidslaw.ca or visit our website at www.aidslaw.ca/AbouttheNetwork/membership.htm.



We would like to hear your views and opinions regarding the Review, its content and format. We also encourage comments on or responses to individual articles, and letters to the editor.

## CONTENTS

EDITORIAL	5
FEATURES	
TRIPS from Doha to Cancún to Ottawa: global developments in access to treatment and Canada's Bill C-56	I
Warsaw Declaration on HIV/AIDS and injection drug use adopted	19
The text of the Warsaw Declaration	21
CANADIAN NEWS	
North America's first supervised injection site opens in Vancouver	24
Ontario: People can now apply for forced HIV testing in certain situations	25
Many people in marginalized communities are not accessing antiretroviral therapy: BC study	27
Prison activist receives AIDS and human rights award	28
Ontario proposes to regulate viatical settlements	29
Survey reveals knowledge and attitudes of Canadians regarding HIV/AIDS	31
National school survey reveals gaps in knowledge of HIV/AIDS	32
INTERNATIONAL NEWS	
UNGASS review: reports show little progress on human rights	34
AIDS Law Project receives AIDS and human rights award	38
International Guidelines audit tool tested in Cambodia	39
Nigeria launches new AIDS policy	41
ABC approach not enough, reports show	42
New report profiles syringe access in California	43
HIV/AIDS IN PRISONS	
New policy on methadone maintenance treatment in prisons established in Alberta	45
Randomized controlled trial proves effectiveness of methadone	
maintenance treatment in prison	48
Australian discussion paper on prison needle exchange programs released	49
HIV/AIDS IN THE COURTS – CANADA	
HIV-positive person who did not disclose status convicted of attempted aggravated assault	50
Ontario court affirms that medical marijuana regulations are unconstitutional	53
Court strikes out latest action in contaminated blood litigation	56
HIV/AIDS IN THE COURTS – INTERNATIONAL	
HIV drug trademark case handed down in UK	58
UK:AIDS treatment main factor in decision to grant permission to appeal immigration decision	59
UK court denies appeal by woman who stabbed police officer	
with used needle	60
	cont'd

UK: Rape "aggravated" by knowledge of HIV and hepatitis B infection	60
UK court denies prisoner with HIV early release	61
UK: Hemophiliac wins access to recombinant factor VIII	62
UK: Precedent-setting criminal conviction for grievous bodily harm	62
LAW ESSAY CONTEST	
Canadian "medical necessity" and the right to health	63

## **EDITORIAL**

I consider AIDS to be nothing but a human rights issue. There is nothing about the pandemic that does not speak to human rights.

- Stephen Lewis<sup>1</sup>

As this issue goes to print, the second and final year of the World AIDS Campaign against stigma and discrimination is ending. But the work to reduce stigma and discrimination against people with HIV/AIDS and populations affected by HIV/AIDS is far from over. This is why the Canadian HIV/AIDS Legal Network is putting forward a Plan of Action for Canada.<sup>2</sup> A draft of the Plan of Action has been distributed widely for comments. The final plan will be launched early in 2004.

Why is it so important to reduce stigma and discrimination against people with HIV/AIDS and the many and diverse populations affected by the epidemic? Because stigma and discrimination prevent people from seeking HIV testing, counselling, and follow-up services. Because stigma and discrimination make it harder, if not impossible, for people to access information, prevention tools, health care, and social services. Because stigma and discrimination deprive people of their rights and dignity, isolate and oppress them, and threaten their health and well-being.<sup>3</sup>

We need to take action on several fronts.

First, *participation*. The people who experience stigma and discrimination are key to identifying where it happens, what it does, and how to stop it. We need to ensure that they are involved at every stage of research into the realities of their lives, and that they are involved at every stage of interventions designed to reduce the stigma and discrimination they experience.

Second, *public education*. We need to increase public awareness of stigma and discrimination toward people with HIV/AIDS and toward populations affected by the epidemic. Equally important, we need to communicate why such stigma and discrimination is harmful to individuals, to affected communities, and to Canadian society.

Third, *community action*. Action at the local level is crucial. We need to fund community organizations to make the one-to-one, peer-to-peer contact that helps to reduce fear and avoidance.<sup>4</sup> Recent surveys of attitudes in Canada, sponsored by Health Canada, shows that we have a way to go in this regard (see "Survey reveals knowledge and attitudes of Canadians regarding HIV/AIDS" and "National school survey reveals gaps in knowledge on HIV/AIDS" in Canadian News). We also need to provide adequate funds for community organizations to advocate for those who experience stigma, discrimination, or other barriers to services.

Fourth, *legal resources*. When people experience a violation of their rights as defined in Canadian law – which includes, but is not limited to, illegal discrimination – we need to provide more information to them about their options, and more support in seeking redress, should they choose to do so.

Fifth, *better practices in health, education, employment, and other sectors.* Studies have shown that some people are treated poorly or unfairly because of broader inequities or systemic barriers.<sup>5</sup> (See, in this regard, the disturbing results of a study of access to antiretroviral drugs in British Columbia,<sup>6</sup> as reported in "Many people in marginalized communities are not accessing antiretroviral therapy: BC study" in Canadian News.) We need to develop and promote practices in health care, social services, employment, and primary and secondary education that overcome such inequities and barriers. We also need to impress upon institutions in these sectors that they have legal obligations with regard to preventing and redressing indirect as well as direct discrimination.

Sixth, *international collaboration*. What we do in Canada can contribute to lowering stigma and discrimination in the world, and action around the world can help to lower stigma and discrimination in Canada. We need to support initiatives that link Canada's action with the world's, be that through increasing access to treatment, building capacity in organizations to advocate for human rights, or maintaining awareness in Canada of global issues.

On all these fronts, we need to get specific about the kinds of stigma and discrimination that different people with HIV/AIDS or people vulnerable to HIV infection experience. Silence, denial, rejection, and blame may be common to the experience of gay and bisexual men, women, people who use drugs, people from countries where HIV is endemic, Aboriginal people, and other populations living with or affected by HIV/AIDS. But the words that must be spoken and the actions that must be taken to undo homophobia or sexism or "addictophobia" or racism or other forms of prejudice are different.

This means that we must support networks of organizations that are in the best position to act or advocate for these different populations: gay and bisexual men, women, Aboriginal people, people who use drugs, youth, and people from countries where HIV is endemic. It also means that we must be sensitive to the intersections between these cultures, and tailor our efforts to the complex identities of people who are affected by multiple layers of stigma and discrimination.

This work cannot be limited to a two-year campaign. It cannot be achieved through short projects. It is work that has to be funded and sustained over many years. At the United Nations General Assembly Special Session on HIV/AIDS, all members of the United Nations, including Canada, agreed that by the year 2003 they should:

ensure the development and implementation of multisectoral national strategies and financing plans for combating

HIV/AIDS that address the epidemic in forthright terms; confront stigma, silence and denial; address gender and agebased dimensions of the epidemic; [and] eliminate discrimination and marginalization.<sup>7</sup>

One of the tests of Canada's commitment will be the future funding and priorities of the Canadian Strategy on HIV/AIDS. If the Strategy does not include plans to implement and finance action against stigma and discrimination in a sustained fashion over the next five years, Canada will have fallen short of its obligations. And the consequences will be lived in the infection, isolation, and oppression of yet more people with HIV/AIDS.

- Theodore de Bruyn

Theodore de Bruyn is a Senior Policy Analyst with the Canadian HIV/AIDS Legal Network. He can be reached at tdebruyn@cyberus.ca.

<sup>3</sup> See the literature cited in T de Bruyn. HIV-related stigma and discrimination – the epidemic continues. *Canadian Policy & Law Review* 2002; 7(1): 8-14.

<sup>6</sup> E Wood et al. Socioeconomic status, access to triple therapy, and survival from HIVdisease since 1996. AIDS 2002; 16(1): 2065-2072.

<sup>7</sup> United Nations General Assembly Special Session on HIV/AIDS. Declaration of Commitment on HIV/AIDS. Resolution A/Res/S-26/2, 27 June 2001, at para 37. Available at www.unaids.org/UNGASS/docs/AIDSDeclaration\_en.pdf.

<sup>&</sup>lt;sup>1</sup> From Mr Lewis's keynote address at the 2003 Annual General Meeting of the Canadian HIV/AIDS Legal Network, published in *Taking Action on Stigma and* Discrimination: Presentations Made on the Occasion of the Canadian HIV/AIDS Legal Network Annual General Meeting and Skills Building Workshops, Montréal (Québec) 12-14 September 2003. Available at www.aidslaw.cal/Maincontent/events/agm2003.htm.

 $<sup>^2</sup>$  See T de Bruyn's address at the closing plenary at the 2003 Annual General Meeting of the Canadian HIV/AIDS Legal Network, supra, note 1.

<sup>&</sup>lt;sup>4</sup> On the effectiveness of local programs involving one-to-one contact in reducing social distance toward people with schizophrenia, see H Stuart. Stigmatisation. Leçons tirées des programmes visant sa diminution. Santé mentale au Québec 2003; 18(1): 54-72.

<sup>&</sup>lt;sup>5</sup> See, eg, S Kellington et al. Listen Up! Women are Talking About... The social determinants of women's risk for HIV infection and illness in lower mainland British Columbia. Vancouver: Positive Women's Network, 1999, at 27-41; SJ Ship, L Norton. HIV/AIDS and Aboriginal women in Canada. In C Amaratunga, J Gahagan, eds. Striking to the Heart of the Matter: Selected Readings on Gender and HIV. Halifax: Atlantic Centre for Excellence in Women's Health, 2002, 47-63; B Ryan et al. Access to Care: Exploring the Health and Well-Being of Gay, Lesbian, Bisexual, and Two-Spirit People in Canada. Executive Summary. May 2000. Available at www.hc-sc.gc.ca/hppb/healthcare/pubs/circumstances/ partIII/.

## TRIPS from Doha to Cancún ... to Ottawa: global developments in access to treatment and Canada's Bill C-56

cont'd from page 1

organizations to the effect that WTO rules on intellectual property – specifically the rules on pharmaceutical patents – were impeding access to more affordable medicines. This is a matter of particular concern in developing countries that are facing HIV/ AIDS and other health problems and that are also burdened by widespread poverty, with few resources to spend on expensive patented drugs.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>2</sup> (TRIPS) requires all WTO countries to adopt certain minimum standards for protecting private intellectual property rights, including with respect to pharmaceutical inventions. Those rules create temporary monopolies over patented pharmaceuticals, meaning the company holding the patent can charge high(er) prices.

In the lead-up to the Ministerial Conference, and during the negotiations in Doha, critics pointed out that TRIPS was being interpreted and applied in a manner aimed at deterring governments from pursuing policies to decrease the price of medicines. The hypocrisy of developed countries at the WTO was starkly revealed by events following the terrorist attacks in the United States in September 2001. Five deaths from anthrax distributed through the mail caused concern about future bioterrorism and access to adequate supplies of ciprofloxacin, an antiobotic used to treat the disease. Both Canada and the US threatened to override Bayer's patent rights on the drug unless it supplied the desired quantities at a

reduced price. Yet developing countries such as South Africa and Brazil had been chastised for contemplating similar policies to deal with their HIV/AIDS epidemics and told that they were unacceptably undermining patent rights.<sup>3</sup>

The incident highlighted the double standard at play and fuelled developing countries' demands going into the Doha conference. The declaration that was eventually adopted is politically important because in bolsters efforts to balance protection of private patent rights with the public interest in affordable health care. The Doha Declaration is also significant because, under international law, it must guide future legal interpretations of TRIPS.<sup>4</sup>

Significantly, in the Doha Declaration, WTO members "recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."5 It is important to note that the three named diseases and other epidemics are identified as particularly serious illustrations of "public health problems." Contrary to suggestions by some countries and pharmaceutical companies after the Doha conference, the Declaration is not limited to covering only these particular problems.

In the Doha Declaration, WTO members also stated that:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.<sup>6</sup>

WTO members further recognized that this flexibility includes the right of each country "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."<sup>7</sup> A compulsory licence is an authorization granted to someone

Because it introduces competition into the market, a compulsory licence is one tool for bringing down the price of pharmaceutical products.

other than the patent owner, without the patent owner's consent, to use, make, sell, or import a patented product. Without this licence, a generic pharmaceutical company making its version of a patented product could be sued for patent infringement. TRIPS requires that when a compulsory licence is issued, the patent owner is entitled to "adequate remuneration" (to be defined under a country's own laws).<sup>8</sup> Because it introduces competition into the market, a compulsory licence is one tool for bringing down the price of patented medicines and other pharmaceutical products.

#### Limits on exports of generic pharmaceuticals: the Doha paragraph 6 problem

However, WTO members also recognized in the Doha Declaration (paragraph 6), that countries "with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." This is because a country that lacks its own capacity to make pharmaceuticals is not able to effectively give compulsory licences to domestic producers to make those products locally. This is the case with most developing countries. Compulsory licences could, however, still be used to authorize imports of generic pharmaceuticals made elsewhere. But, under TRIPS, countries that have the capacity to make generic pharmaceuticals - and could therefore be potential exporters - are usually restricted to using compulsory licensing "predominantly" for supplying their own domestic market.<sup>9</sup> This limits the possibility of generic pharmaceutical makers in one country getting compulsory licences authorizing them to produce cheaper products for export to other countries in need.

Having recognized the problem – which became known as the "Doha paragraph 6 problem" – WTO members committed to finding "an expeditious solution" by the end of 2002. Unfortunately, they were unable to meet this deadline.

#### From Doha to Cancún: negotiations on the Doha paragraph 6 problem

Over the course of the negotiations that followed the Doha Declaration, several countries - including Canada, the European Community (EC) countries, Japan, Australia, and Switzerland - joined with the US in trying to narrow the scope of any "solution." They sought to impose various conditions and restrictions that were at odds with the text and spirit of the Declaration, such as limiting which countries would be able to use it, and for which diseases, as well as imposing onerous obligations on any attempts to invoke it.<sup>10</sup> Those efforts were resisted by activists and by developing countries, with mixed results (as described below).

## Developed countries reject simple solution to problem

In addition to opposing these efforts to narrow the solution, non-governmental organizations (NGOs) also criticized the basic approach being pursued by the US, Canada, and other developed countries, which required a complicated reworking of Article 31 of TRIPS that would introduce unnecessary complexity into any solution, thereby hindering its possible usefulness. Instead, activists proposed that WTO members use the flexibility already found in another article to address the problem.

TRIPS Article 30 says that countries may create, in their own laws, "limited exceptions" to exclusive patent rights, as long as those exceptions "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." NGOs argued that WTO members should agree on an interpretation of Article 30 that would permit, as permissible exceptions to patent rights, all acts associated with producing a patented product that addresses health needs in another country where the product is either not patented or, if it is patented, a compulsory licence has been granted or government use has been made of that patent in accordance with the laws of that country. The NGOs argued that this would the simplest, easiest way to allow for speedy and effective use of compulsory licensing by countries needing to import cheaper medicines.11

The World Health Organization (WHO) also supported this approach.

As negotiations over the text of a solution dragged on, developed countries continued to propose various restrictions.

It released a paper setting out the features of a solution "which are desirable from a public health perspective," including broad coverage in terms of health problems and the range of medicines, simple and speedy legal procedures in the exporting and importing countries, and equality of opportunities for countries in need of medicines.<sup>12</sup> Based on this analysis, the WHO presented a statement to the WTO Council for TRIPS stating that

the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.

Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export patented medicines and other health technologies to address public health needs."<sup>13</sup>

However, in the negotiations that followed, the Article 30 approach was dismissed summarily by the US and some other developed countries. Although the EC had initially flirted with the approach, it also eventually favoured a solution based on Article 31. The idea of using Article 30 to solve the problem was eventually abandoned by WTO members, and attention focused on the details of a solution based on modifications to Article 31.<sup>14</sup>

## US, EC, and other developed countries push for narrow solution

As negotiations over the text of a solution dragged on into late 2002, developed countries continued to propose various restrictions. For example, Japan opposed the inclusion of vaccines in any solution. The US objected to a draft text that expressly said that the reference to "public health problems" in the Doha Declaration meant more than just HIV/AIDS, tuberculosis, malaria, and other epidemics. The US and the EC pushed for lists that would limit which countries could import generic pharmaceuticals, and also sought to limit the system so that only a handful of developing countries could be exporters of generic pharmaceuticals (thereby excluding the possibility of drawing upon the generic-drug-manufacturing capability in the developed world).

By December 2002, all WTO members except the US had approved a draft text of a solution. The US was unwilling to approve the text without the addition of a limited list of diseases for which compulsory licences could be used by developing countries to secure cheaper medicines. As one critic put it: "The US wants to have a global debate over the issue of the scope of disease. [The US President and Trade Representative] want to argue that the diseases their own children receive treatment for are off limits to poor children in poor countries. They cannot win this argument."15

Because of the US position, the WTO negotiations collapsed on 20 December 2002, with no solution reached by the WTO's own deadline. Further proposals were advanced in 2003 that perpetuated the double standard for developing countries. For example, in February 2003, the **TRIPS** Council Chairperson proposed to restrict the use of compulsory licensing for many developing countries to "national emergencies or other circumstances of extreme urgency." Activists pointed out that under TRIPS, wealthy countries are not required to declare the existence of an emergency to make use of compulsory licensing, so it would be unacceptable to require this of developing countries. Furthermore, it would be unsound public health policy to wait until a situation had become an "emergency" before being able to use compulsory licensing to import cheaper medicines.

With no resolution in sight, attention began to turn to the upcoming Fifth WTO Ministerial Conference, in September 2003 in Cancún, Mexico.

#### Solving the Doha paragraph 6 problem: the WTO decision of 30 August 2003

Finally, less than two weeks before the Cancún conference was to begin, the US agreed to join the consensus previously reached by all other WTO members in December 2002. On 30 August 2003, the General Council of the WTO unanimously adopted a decision on "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health."<sup>16</sup>

The decision is supposed to solve the difficulties faced by WTO members lacking sufficient pharmaceutical manufacturing capacity "in making effective use of compulsory licensing under the TRIPS Agreement." The decision takes the form of an "interim waiver" of TRIPS Article 31(f), the provision that restricts the use of compulsory licences to produce generic pharmaceuticals for export.

## Chairperson's statement: effort to narrow the August 30<sup>th</sup> decision

However, in the eight months following the breakdown of negotiations in December 2002, the US had succeeded in some of its efforts to narrow the scope of the August 30<sup>th</sup> decision. With the Cancún meeting approaching, the US turned its effort to obtaining a statement from the Chairperson of the General Council setting out WTO members' "shared understandings" of the August 30<sup>th</sup> decision. A "Chairperson's statement" was eventually adopted in conjunction with the text of the actual Council decision.17 The precise legal significance of such a statement remains unclear, although

under international law it would likely be of relevance in interpreting TRIPS and the text of the August 30<sup>th</sup> decision. The US tried to use the Chairperson's statement to attach imitations to the text of the actual decision.

#### Non-commercial motivation

For example, the US unsuccessfully pushed for a statement that the decision would not be used for "commercial gain" - an obvious attempt to limit the system to only government or public production of pharmaceuticals on charitable grounds, and to exclude any possibility of compulsory licences being granted to private generic companies. This proposal was rejected on the grounds that it would severely hamper the system's real effect, given that no private company would produce without the prospect of some commercial gain. In the end, the Chairperson's statement says that the system will "not be an instrument to pursue industrial or commercial policy objectives." It remains to be seen whether the US will use this "understanding" to undermine efforts at increasing the capacity of private, for-profit generic companies to manufacture products for export to importing countries using the new WTO system.

#### Eligible importing WTO members

The US and the EC also sought to establish lists of which countries would be eligible to use the system to import generic pharmaceuticals, based on data about the extent of their manufacturing capacity or level of income. These efforts were also rejected: the decision is clear that WTO members determine for themselves whether to use the system to import pharmaceuticals. In the case of "least-developed" countries, as defined by the United Nations, the decision deems them automatically to have insufficient pharmaceutical manufacturing capacity and therefore to be eligible to use the scheme in the August 30<sup>th</sup> decision to import generic pharmaceuticals. In the case of any other country belonging to the WTO, it must establish that its capacity is either nonexistent or currently insufficient to

The governments of some countries agreed to further restrictions on their sovereign rights to use compulsory licensing in order to placate the pharmaceutical industry and the US government.

meet its needs. However, the Chairperson's statement requires that the country notify the TRIPS Council in writing of how it reached this determination. It also says that any country can raise an issue regarding the interpretation or implementation of the decision for review at the TRIPS Council "with a view to taking appropriate action." This is not a requirement that the WTO approve the country's decision. However, this provision could be used by countries such as the US to pressure developing countries not to use the system to import generic pharmaceuticals.

Although it failed to establish a closed list of eligible and ineligible importing countries, the US was successful in getting specific WTO members to commit, on the record,

not to use the system as importers. According to the Chairperson's statement, 11 middle-income countries agreed to use compulsory licences to import pharmaceuticals only in situations of "national emergency or other circumstances of extreme urgency." 18 In addition, 10 Eastern European countries also committed to use compulsory licensing to import in emergency situations only, and to opt out of importing entirely once they join the European Union.19 Finally, 23 high-income countries committed to opt out of the system entirely, even if confronted with a national emergency for which their own domestic capacity to produce generic medicines is insufficient.<sup>20</sup> The governments of these countries have effectively agreed to further restrictions on their sovereign rights to use compulsory licensing - recognized in TRIPS and reaffirmed in the Doha Declaration - in order to placate the patent-protected pharmaceutical industry and the US government.

## Reaction to the August 30<sup>th</sup> decision

The August 30<sup>th</sup> decision and accompanying Chairperson's statement received a mixed reaction. The WHO said it was "encouraged" by the decision, but stressed that:

The agreement covers all medicines. Among the diseases that could be more effectively tackled as a result of this decision are AIDS, tuberculosis and malaria.... Given the urgency of the health needs in the poorest countries, the work to implement this agreement must proceed as quickly as possible. The full impact of the agreement will depend on how effectively it can be implemented in countries. For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers, when making purchasing decisions. WHO continues to urge Member States to consider using to the full the TRIPS flexibilities with regard to the protection of public health.<sup>21</sup>

A coalition of NGOs, including those most directly engaged in the WTO negotiations, issued a statement saying that although the deal was being described as a gift to the poor, it was "a gift bound in red tape."<sup>22</sup> They were critical of the unnecessary complexity of the system set out in the decision - such as requiring compulsory licences in both importing and exporting countries, and giving the WTO itself new authority to secondguess the decisions of sovereign countries to grant individual compulsory licences - and of other opportunities for the US and other wealthy countries to pressure developing countries into not issuing licences. However, like the WHO, they also urged every country to begin to use the TRIPS flexibilities and the August 30th decision to increase access to affordable medicines.

#### Implementing the August 30th decision: Canada's Bill C-56

Since the adoption of the Doha Declaration in November 2001, Canadian advocates<sup>23</sup> had been urging the Canadian government to make the necessary legislative changes to allow Canadian generic pharmaceutical manufacturers to supply developing countries. Like other NGOs active at the WTO, they argued that Canada should take advantage of the flexibility offered in TRIPS Article 30 to carve out "limited exceptions" to patent rights to allow generic exports.

The response had consistently been that action was unlikely until there was an outcome to the multilateral negotiations at the WTO on the Doha paragraph 6 issue. As men-

NGOs said that although the deal was being described as a gift to the poor, it was "a gift bound in red tape."

tioned above, the use of TRIPS Article 30 was not pursued in the WTO negotiations, where discussion focused instead on waiving and/or amending TRIPS Article 31(f).

## Renewed demand for patent law amendments

With the adoption of the WTO August 30<sup>th</sup> decision, advocates in Canada redoubled their efforts to get the Canadian government to act.

On 10 September 2003, the Canadian Generic Pharmaceutical Association (CGPA) wrote to the Honourable Pierre Pettigrew, then Minister for International Trade, requesting that the government change its patent laws to allow for the manufacture of generic versions of patented medicines for export.24 In Cancún at the WTO Ministerial Conference, a representative of Oxfam Canada supported the request, saying it was "one concrete way" Canada could make affordable medicines available to countries in need<sup>25</sup>

On 12 September 2003, the UN Special Envoy on HIV/AIDS in

Africa, Stephen Lewis, delivered a keynote address at the Annual General Meeting of the Canadian HIV/AIDS Legal Network in Montréal, in which he urged the government to amend the Patent Act immediately, as a step toward realizing the right to health of poor people in developing countries.<sup>26</sup> He reiterated the call a week later, on 20 September 2003, in Nairobi at the International Conference on AIDS and STDs in Africa, where his remarks were more widely reported.

On 23 September 2003, an opinion piece by the Canadian HIV/AIDS Legal Network in the *Globe and Mail*, Canada's leading national newspaper, declared that "there are no excuses left" and demanded an amendment to the Patent Act.<sup>27</sup> The same day, four national NGOs reiterated the request in a letter to Allan Rock, then Minister of Industry, and other government ministers.<sup>28</sup>

## Government announcement and reaction

On 25 September 2003, the government of Canada responded by announcing that it would amend Canadian patent law to implement the WTO decision.<sup>29</sup> The announcement received international attention. UNICEF welcomed the move, saying that it represented "the first major move by a major, industrialised country to overcome a key structural hurdle in getting life-saving medicines to people who desperately need them."<sup>30</sup>

In contrast, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the international lobby group for the patented pharmaceutical industry, declared that Stephen Lewis "is leading us all down the primrose path to a dead end," and said that Canada's initiative "won't solve a thing" and would be a "negative black eye for Canada" that will "very well affect the investment climate."<sup>31</sup> Harvey Bale, the IFPMA Director-General, suggested that it was more important to increase

The government of Canada's announcement that it would amend Canadian patent law to implement the WTO decision received international attention.

financial contributions to improve health-care infrastructure in developing countries (a request that Canadian activists had consistently made in conjunction with their request to amend patent laws).

Canadian civil society organizations welcomed the government's announcement.<sup>32</sup> But, concerned by certain remarks made by government ministers when announcing the planned amendment, they also called on the government not to restrict the amendment to specific diseases or emergencies. They pointed out that such an approach would represent a step backward from the consensus reflected in the August 30<sup>th</sup> decision, which does not impose such limitations.<sup>33</sup>

A few days after the government's announcement, Médecins Sans Frontières Canada, the Canadian HIV/AIDS Legal Network, Oxfam Canada, and the Canadian Auto Workers union held a joint press conference at which they were joined by Stephen Lewis. Speakers reiterated their support for the government initiative and urged it to act quickly. They said that the government must not backtrack on the WTO decision by unilaterally re-introducing restrictions such as those on the scope of health problems covered.<sup>34</sup> At the press conference, the Legal Network released a backgrounder, subsequently distributed to all Members of Parliament, making the case for an amendment to the Patent Act that fully reflects the scope of the August 30<sup>th</sup> decision.<sup>35</sup>

In conjunction with the press conference, over 70 NGOs from numerous countries (including China, Germany, Colombia, South Africa, the United Kingdom, Canada, Kenya, Thailand, the US, Nigeria, and Italy) signed a joint NGO statement supporting the initiative but calling on the government of Canada to ensure it did not compromise in fully implementing the August 30th decision.<sup>36</sup> The Treatment Action Campaign and the AIDS Law Project of South Africa also issued a joint statement.<sup>37</sup> The message from activists outside Canada was delivered to reporters at the press conference being held in Toronto.

The same day, the media reported that Paul Martin, a few months before assuming the office of Prime Minister, had expressed his support for the initiative.<sup>38</sup> Canada's **Research-Based Pharmaceutical** Companies (R<sub>x</sub>&D), the lobby group for Canadian companies producing patented pharmaceuticals, issued a news release saying it would "continue to work with the federal government to frame any legislative proposal to assist in humanitarian relief" but that it could not "comment further until a government decision is taken." The R<sub>x</sub>&D release also stated that the August 30th decision

"relates to the provision of generic medicines to treat HIV/AIDS and other life-threatening diseases such as tuberculosis and malaria."<sup>39</sup> The Canadian HIV/AIDS Legal Network criticized this statement as a misleadingly narrow characterization of the WTO decision.

## Ongoing advocacy and consultation

Following the government's announcement, a handful of Canadian civil society organizations engaged in extensive discussions with government officials from five departments, with the objective of ensuring that the government fully implemented the WTO decision, in all its flexibility.

However, by mid October, concern was growing among NGOs that the government had made no public commitment to reflect the full scope of the Doha Declaration and the August 30<sup>th</sup> decision in the amendment, and no commitment to refrain from restricting the amendment to specific diseases or to emergency situations. On 16 October 2003, the media reported that indeed it was the government's intention to impose these sorts of restrictions.<sup>40</sup> The same day, five organizations issued a joint open letter to the ministers of Industry and of International Trade, asking the government to publicly state its position on five key questions, including these restrictions.<sup>41</sup> The letter was circulated to the media, to other NGOs and to key parliamentarians, and was posted on the web along with other key documents on the campaign for a patent law amendment.

Additional initiatives followed soon after. Over 20 Canadian civil society organizations and over 100 individual Canadians signed a statement urging the Canadian government to quickly amend the Patent Act and not to compromise its initiative by limiting it to specific diseases or to countries facing emergencies.<sup>42</sup> In short order, similar statements were signed by over 100 physicians, health professionals, and medical students in Canada and internationally.<sup>43</sup>

In the House of Commons, Members of Parliament from the New

News reports kept the issue before the public and opinion pieces continued to pressure the government to introduce sound legislation.

Democratic Party repeatedly demanded that the government move quickly to table legislation and not to limit it to specific diseases.<sup>44</sup> News reports<sup>45</sup> kept the issue before the public and opinion pieces<sup>46</sup> continued to pressure the government to introduce sound legislation. Activists from various countries contacted the government, including through its diplomatic representatives abroad, to demand that it not impose unnecessary and unjustified restrictions on the amendment.<sup>47</sup>

Activists also demanded that the US not use intellectual property rules under the North American Free Trade Agreement (NAFTA) to block Canada's initiative – particularly since those rules are identical in key respects to the provisions in TRIPS that had just been addressed, by consensus, in the August 30<sup>th</sup> decision.<sup>48</sup> On 7 October 2003, following a meeting in Montréal of trade ministers from the three NAFTA countries, the US Trade Representative and the Mexican economy minister stated that they would not oppose the initiative.<sup>49</sup> Some uncertainty about the US position remained; a "senior Canadian official" was reported as saying that it "was understood" that "in keeping with the WTO deal, [exports] would be for treating only AIDS, tuberculosis, malaria and other public health emergencies."<sup>50</sup> However, activists decided to take the US statement at face value as an agreement not to use NAFTA to block a full implementation by Canada of the August 30<sup>th</sup> decision.

## Bill C-56: legislation tabled, but flawed

After further meetings with patented and generic pharmaceutical companies and with NGOs, the government introduced Bill C-56 in the House of Commons on 6 November 2003.<sup>51</sup> The bill proposes to amend the Patent Act to provide for the issuance of compulsory licences allowing generic pharmaceutical manufacturers to make generic versions of patented pharmaceuticals for export to countries that lack their own manufacturing capacity and that use the WTO August 30th system to import generics. (The bill does not affect patent holders' monopolies in the Canadian market.)

### Introduction of legislation welcomed

With this bill, Canada became the first country to take steps to implement the August 30<sup>th</sup> decision. Bill C-56 was welcomed by the WHO, which said that: "If replicated in other exporting countries, such a decision, coupled with increased efforts to improve global health infrastructure and service delivery could be a major step in closing the treatment gap for millions of people who cannot afford the essential medicines they need."<sup>52</sup> The UN Special Rapporteur on the right to health also welcomed the initiative, noting that governments have a responsibility under international human rights law to provide international assistance and cooperation in realizing human rights. He urged that any legislative and policy amendments fully reflect the spirit and scope of the Doha Declaration, along with concurrent obligations under human rights law.<sup>53</sup>

Canadian civil society organizations also applauded the introduction of the legislation. They welcomed the fact that Bill C-56 does not contain any restricted list of diseases or health conditions for which compulsory licensing may be used to obtain pharmaceuticals, and the fact that the bill does not limit the use of compulsory licences to supplying countries facing an emergency or other circumstances of extreme urgency.

In addition, the organizations welcomed the fact that Bill C-56 specifies a low royalty rate of "two percent of the value of the pharmaceutical products exported under the authorization."<sup>54</sup> This reflects the fact that the ultimate objective is to make it possible for generic manufacturers, likely to be operating on small profit margins on contracts with developing countries, to supply products that are ultimately priced very cheaply for those countries.

#### Flaws in Bill C-56

However, several serious concerns remain about the legislation. Canadian civil society organizations strongly support the objective of allowing compulsory licensing for exporting lower-cost generic pharmaceutical products to countries in need. But the flaws in Bill C-56, as it is currently drafted, will undermine this objective. Therefore, the legislation needs to be changed in several key respects before it is enacted, and civil society organizations have called upon the government to "fix the bill."<sup>55</sup> Four key flaws are discussed below.<sup>56</sup>

#### Provisions permitting anticompetitive action by patent holders to block licences for generic manufacturers

As introduced in Parliament, Bill C-56 creates an unnecessary and undesirable opportunity for Canadian patent holders to engage in anti-competitive action to block generic manufacturers from obtaining licences to produce and export pharmaceuticals. Bill C-56 sets out a process whereby a generic manufacturer wishing to produce a patent-protected product for export must notify the Commissioner of Patents of its intent to apply for a compulsory licence. The notice must set out the name of the product, the quantity to be produced, the country to which it is to be exported, and the terms and conditions of the contract between the generic manufacturer and the government of the country in question.

The notice must also include either a declaration that the product is not patented in the destination country or, if it is patented there, a written statement from the country that it has granted or intends to grant a compulsory licence in accordance with Article 31 of TRIPS. If the importing country belongs to the WTO, the document submitted must be the written notice that the country has provided to the TRIPS Council, in accordance with the August 30th decision. The notice must then be sent to the holder of the Canadian patent for the product, and the patent holder then has 30 days to decide how to respond. One of the options open to the patent holder is to voluntarily give the generic manufacturer a licence to make the product for export as set out in the notice it has filed, in exchange for the twopercent royalty set by the bill.<sup>57</sup>

However, under Bill C-56, the patent holder is also given another choice, one not required by TRIPS. The patent holder is granted the right to take over contracts negotiated by generic pharmaceutical manufacturers with developing-country governments.<sup>58</sup> In order to do so, the patent-holding company must meet the terms of the contract negotiated by the generic manufacturer with the developing-country purchaser. Under this scenario, then, not only does the patent holder get to assume the would-be competitor's contract, but also (a) the patent holder has no obligation to negotiate the terms of a voluntary licence for the generic manufacturer, and (b) the Commissioner of Patents is prevented from issuing a compulsory licence to the generic company. The result is that no licence, either voluntary or compulsory, is obtained by the generic manufacturer.

Initially, in a few cases, this process could secure a lower price on a particular medicine for a developing country that has negotiated a contract with a generic manufacturer. However, generic manufacturers would quickly lose any incentive to negotiate such contracts in the first place. The company holding the patent would be able to repeatedly block the generic manufacturer from obtaining the licence needed to make the product and fulfil the contract. In short order, there would be no potential competition from generic manufacturers and there would be no reason for the brand-name company holding the patent to lower its prices. As the association representing Canada's generic drug industry pointed out, "if generic pharmaceutical

manufacturers spend time and money arranging the details of an agreement only to have the brand company that holds the patent take over that agreement, they will quickly realize the futility of trying to make the agreement work."<sup>59</sup>

Furthermore, under Bill C-56, a generic manufacturer could obtain a licence for a maximum of two years.<sup>60</sup> This will likely operate as a further disincentive to generic manufacturers, as they will be unable to supply the pharmaceuticals for a significant period of time and achieve the economies of scale necessary to keep prices low but still make a small profit. Furthermore, it means that the company owning the Canadian patent will have another opportunity, after only two years, to "scoop" a contract from a generic manufacturer and block a new licence. This might be a particularly attractive move for the patentowning company in a case where the generic manufacturer's initial contract, perhaps in conjunction with an increase in a country's funds for purchasing medicines, has led to an increased market for the product.

These provisions in Bill C-56 will frustrate the stated objective of implementing the August 30<sup>th</sup> decision. That decision is aimed at enabling countries lacking pharmaceutical manufacturing capacity to make effective use of compulsory licensing to obtain less expensive pharmaceutical products. Giving Canadian patent holders another means of blocking generic companies from getting licences runs directly counter to this objective. As well, these provisions go beyond what Canada is required to do under TRIPS.

Under Article 31(b) of TRIPS, before a compulsory licence is issued there must first be an effort to negotiate a voluntary licence with the patent holder on "reasonable commercial terms and conditions."<sup>61</sup> If those negotiations do not succeed "within a reasonable period of time," a compulsory licence may be issued by the appropriate authority, which then fixes the "adequate remuneration" to be paid to the patent holder. Either way, however, the generic producer may obtain a licence and the patent holder receives some compensation.

Currently, Canada's Bill C-56 would create an added benefit for patent holders: by taking over a contract negotiated by a generic manufacturer, the patent holder can block the generic manufacturer from obtaining any licence at all, whether voluntary or compulsory. In this way, the bill goes beyond Canada's obligations under TRIPS to protect intellectual property rights, to the detriment of efforts to respond to public health problems in developing countries.

## (2) Limited list of pharmaceutical products

Bill C-56 also includes a limited list of pharmaceutical products for which a compulsory licence may be obtained.<sup>62</sup> The list consists of those products on the WHO Model List of Essential Medicines that are patented in Canada (as of the date of Bill C-56's introduction in the House of Commons). Bill C-56 also states that the Cabinet of the government of Canada may authorize the addition (or removal) of any other "patented product that may be used to address public health problems," and that the Cabinet may establish an "advisory committee" to advise it on products to be added to (or removed from) the approved list.63

The list in Bill C-56 is flawed because it contains a very limited number of products. For example, eight of the antiretroviral drugs (ARVs) used to treat HIV/AIDS currently approved for sale, and patented, in Canada are not included on the list of products for which a compulsory licence may be obtained. Nor are combination formulations such as Trizivir and Combivir. Both products contain the drug lamivudine (3TC), which is one of the most commonly prescribed ARVs, but is not included in Bill C-56.

Formulations of several drugs in a single pill, with a simpler dosing regimen, can be of particular benefit in settings where support systems and health-care infrastructure are less than ideal, a factor to be considered in scaling up access to ARVs in many parts of the developing world. As part of its recently launched "3 by 5" initiative, which aims to get ARV treatment to three million people living with HIV/AIDS in the developing world by 2005, the WHO has added three generic versions of fixed-dose combinations for first-line treatment to its list of medicines meeting WHO standards of quality, safety, and efficacy.<sup>64</sup> Two of the drugs in those combinations - lamivudine and nevirapine are not covered by the list found in Bill C-56.

Civil society organizations have questioned the need for any list. A limited list of products would represent a step backward from the August 30<sup>th</sup> decision, in which all WTO members endorsed an approach that is not restricted to specific medicines or other products. Furthermore, requiring approval by Canada's Cabinet for the addition of a product to the list puts the Canadian government in the position of gatekeeper over developing countries' access to lower-cost Canadian generic pharmaceuticals, and introduces further delay. In addition, having a political body such as the Cabinet making these determinations opens the door to lobbying by patent holders to prevent a given product from being listed.

Civil society organizations have put forward proposals to improve aspects of the bill.

Civil society organizations have therefore put forward proposals to improve this aspect of the bill. The objective is to ensure that the Canadian legislation respects the right of sovereign nations to determine for themselves which problems warrant the use of compulsory licensing to obtain less expensive pharmaceutical products.

#### (3) Denial of benefit to some countries that are not WTO members

Under the current scheme proposed in Bill C-56, all least-developed countries may benefit from the export of generic pharmaceutical products from Canada, whether or not they belong to the WTO.65 However, in the case of countries that are not least-developed countries, Bill C-56 only recognizes countries that are WTO members. Countries that do not belong to the WTO are unable to benefit from the possibility of importing generic pharmaceuticals from Canada. This includes several countries facing numerous public health problems including serious HIV/AIDS epidemics in some cases – with limited

resources, high levels of poverty, and low levels of access to medicines.<sup>66</sup> There is no sound basis for excluding such countries from potentially benefiting under this legislation. A developing country should not have to be a member of the WTO to be able to import lower-cost medicines from Canadian suppliers.

### (4) No provision for NGOs to procure generic medicines

Currently, Bill C-56 only contemplates that a government, or an "agent of that government," could enter into a contract with a Canadian generic manufacturer to purchase a pharmaceutical product. NGOs and other private-sector entities providing treatment in a developing country are not "agents" of government, and so may not be covered by the bill. Assurances from government drafters notwithstanding, it would be a stretch to interpret the phrase "agent of that government" as encompassing non-government organizations. Yet NGOs are often an important provider of health care in many developing countries, and in humanitarian crises. It would be unwise to require NGOs to be designated as government agents in order to be able to obtain necessary medical supplies for the patients they treat. It would also introduce further delays and provide another opportunity for governments, particularly if they have poor relations with NGOs, to play politics with the lives and health of people needing treatment.

There is nothing in the August 30<sup>th</sup> decision that limits the use of the system to governments and their agents, nor is this required under TRIPS. This limitation should be removed, and the bill should expressly provide for generic manufacturers contracting directly with NGOs to supply lowercost pharmaceuticals.

#### The future of Bill C-56 and the August 30<sup>th</sup> decision

Bill C-56 was introduced in the House of Commons on 6 November 2003. The following day was expected to be the last sitting day before that session of Parliament was prorogued (ie, terminated) by outgoing Prime Minister Jean Chrétien, in anticipation of the election of a new leader of the Liberal Party who would also assume the office of Prime Minister. The House Leader of the Liberal Party secured all-party agreement to pass the legislation quickly through all three required readings before prorogation. However, concerned about the serious flaws in the bill, civil society organizations mobilized on 6 and 7 November and contacted both the governing Liberal Party and other parties in the House of Commons. They urged that the bill not be passed in its current, flawed form, but rather that it be sent to committee for further discussion and debate so that it could be improved.<sup>67</sup> As a result, the government decided to not seek third and final reading of Bill C-56 immediately,<sup>68</sup> a decision supported by the New Democratic Party. Instead, the bill passed through first and second readings, and was sent to the House of Commons Standing Committee on Industry, Science and Technology for further consideration.69

When outgoing Prime Minister Chrétien prorogued Parliament on 12 November 2003, Bill C-56 died on the order paper. Two days later, Canadian activists gathered outside the Metro Convention Centre in downtown Toronto where the governing Liberal Party was holding its national convention to confirm the election of Paul Martin as new party leader and as new Prime Minister of Canada. Wearing costumes and using props, they played a game of "street hockey for global health" to dramatize their demand that Martin fix Bill C-56 and pass it quickly.<sup>70</sup> Activists also distributed leaflets with the message to party delegates inside the Convention Centre, and did media interviews.

At the time of writing, it had been reported that incoming Prime Minister Paul Martin planned to re-introduce the bill in the next session of Parliament in early 2004. Given previous all-party support for the bill, it was anticipated that the bill would be reinstated at the same stage it had reached in the previous session, meaning that the process would resume with Standing Committee hearings. Paul Martin was also reported as having acknowledged that there are "shortcomings" in Bill C-56 as tabled.<sup>71</sup> Canadian activists continue to call on Martin and the government to "fix the bill" and ensure that it is passed quickly in the next session of Parliament.72

Advocacy also remains critical at the WTO. The August 30th decision states that the Council for TRIPS will, by the end of 2003, start preparing a more permanent amendment to the TRIPS Agreement, to replace the interim waiver, with a view to adopting that amendment by mid-2004. Once an amendment is adopted and takes effect in any given WTO member country, the August 30<sup>th</sup> decision, and any waivers it grants, will end for that country.73 NGOs have called for WTO member countries "to draft an amendment to the TRIPS that simplifies and clarifies the procedures and removes unnecessary obstacles to the export of medicines to address public health problems."74

Canadian activists will also need to ensure that the process of securing a more permanent solution at the WTO will not be used to undermine Bill C-56 and, similarly, that any negative features in Bill C-56 are not used as a bad precedent to argue for a weakened permanent solution at the WTO.

#### Conclusion

Beyond amending patent laws to facilitate access to lower-cost pharmaceuticals, many other steps must be taken to mount an effective global response to the HIV/AIDS pandemic and other health challenges - including mobilizing the resources necessary for purchasing pharmaceuticals, strengthening health-care systems where they are currently lacking, and demonstrating strong political leadership to overcome the stigma and discrimination that still undermine HIV prevention efforts and keep people from accessing HIV testing and care, treatment, and support.

But Bill C-56 is an important initiative. It is symbolically important, because a developed country implementing the August 30th decision - if it is done correctly and in good faith helps further bolster the political feasibility of other developing countries also using policy options such as compulsory licensing to secure less expensive pharmaceuticals. And, if it eventually leads to Canadian generic manufacturers supplying products at significantly lower prices than might otherwise be available to patients in developing countries, then it will also be of great practical benefit. It remains to be seen whether the promise will be realized.

#### - Richard Elliott

Richard Elliott is Director of Legal Research & Policy with the Canadian HIV/AIDS Legal Network and a founding member of the Global Treatment Access Group, an affiliation of Canadian civil society organizations collaborating to realize the human right to health. He can be reached at relliott@ aidslaw.ca.

The text of Bill C-56 and additional information and updates about the Canadian patent law amendment can be found at www.aidslaw.ca, as can various documents from Canadian NGOs relating to the patent law amendment and other aspects of global access to treatment. Texts of WTO documents can be found via www.wto.org. Many detailed documents about the WTO negotiations over TRIPS and public health can be found on the website of the Consumer Project Technology at www.cptech.org.

<sup>2</sup> Annex IC to the Agreement Establishing the World Trade Organization, 14 April 1994.

<sup>3</sup> For a summary of these cases, see: A Kleinsmidt. Pharmaceutical companies abandon case against South Africa: victory for people with HIV/AIDS. *Canadian HIVIAIDS Policy & Law Review* 2001; 6(1/2): 75-76; R Elliott. US files WTO complaints against Brazil over requirement for "local working" of patents. *Canadian HIVIAIDS Policy & Law Review* 2000; 5(4): 28. Many key documents from these cases may be found on the websites of the Treatment Action Campaign (www.tac.org.za) and the Consumer Project on Technology (www.cptech.org).

<sup>4</sup> Pursuant to Article 31(3) of the 1969 Vienna Convention on the Law of Treaties, any interpretation of the TRIPS Agreement must take into account the Doha Declaration as either a "subsequent agreement" between WTO members regarding the interpretation of TRIPS or the application of its provisions, or as a "subsequent practice" in the application of TRIPS that establishes WTO members' agreement regarding its interpretation, or both. Under WTO law, these Vienna Convention rules for interpreting treaties have been recognized as rules of customary international law as well. This means the rules bind all countries, not just those countries that have ratified the Vienna Convention.

<sup>5</sup> Doha Declaration, supra, note | at para |.

<sup>7</sup> Ibid. at para 5(b).

<sup>8</sup> TRIPS, supra, note 2 at Article 31(h).

 $^9$  lbid. at Article 31 (f). Note that this restriction does not apply where a compulsory licence is issued to remedy a practice that a court or administrative process has found to be "anti-competitive":TRIPS Article 31 (k).

<sup>10</sup> For a summary of post-Doha negotiations, see R Elliott. WTO: failure to meet deadline on Doha commitments regarding access to generic drugs. *Canadian HIVIAIDS Policy & Law Review* 2003; 8(1): 38-40; and R Elliott, MH Bonin, C Devine. Patents, International Trade Law & Access to Essential Medicines (3<sup>rd</sup> ed). Canadian HIV/AIDS Legal Network & Médecins Sans Frontières: Reneging on Doha: an MSF analysis of recent attempts to restrict developing countries' use of compulsory licensing to a set list of diseases, May 2003; and Doha Derailed: A Progress Report on TRIPS and Access to Medicines – MSF Briefing for the 5<sup>th</sup> WTO Ministerial Conference, Cancún 2003 (available via www.msf.org).; and Prof. Fred Abbott. Canada and the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Slides from presentation on Parliament Hill, sponsored by North-South Institute, 21 October 2003 (available via www.aidslaw.ca).

<sup>11</sup> Letter to TRIPS Council on Paragraph 6, from Consumer Project on Technology, Médecins Sans Frontières, Oxfam International, Health Gap Coalition, Third World Network and Essential Action, 28 January 2002.

<sup>12</sup> Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Health Economics and Drugs, EDM Series No. 12, WHO/EDM/PAR/2002.3 (June 2002).

<sup>13</sup> Statement by the representative of the World Health Organization, WTO Council for TRIPS, 17 September 2002.

I<sup>4</sup> It should be noted, however, that the text of the solution finally adopted in August 2003 expressly says that the decision is "without prejudice to the rights, obligations and flexibilities" that WTO members have under other provisions in the TRIPS Agreement. Therefore it remains legally open for WTO members to experiment with measures under Article 30 that could be used to increase access to affordable pharmaceuticals, including through export – although any WTO member doing so would likely face considerable pressure from one or more of the more powerful developed countries in the WTO.

<sup>15</sup> James Love, Consumer Project on Technology. CPTech statement on collapse of Doha paragraph 6 negotiations, 20 December 2002.

<sup>16</sup> "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health": Decision of the General Council of 30 August 2003, WTO Doc. IP/C/W/405.

<sup>17</sup> General Council Chairperson's statement, 30 August 2003.

<sup>18</sup> Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

<sup>19</sup> Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia.

<sup>20</sup> Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States.

<sup>21</sup> Statement of the World Health Organization on WTO access to medicines decision, Geneva, I September 2003.

<sup>22</sup> Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A "Gift" Bound in Red Tape, 10 September 2003.

<sup>23</sup> Members of the Global Treatment Access Group (GTAG) had repeatedly urged this action by the government. The GTAG is a working group of Canadian civil society organizations undertaking joint efforts to realize the human right to health globally, with a particular focus on access to comprehensive care, treatment, and support for people with HIV/AIDS and other health needs in developing countries. More information about GTAG is available via www.aidslaw.ca.

<sup>24</sup> Letter from Canadian Generic Pharmaceutical Association to Hon. Pierre Pettigrew, 10 September 2003; S Chase. Generic drug makers seek export rights. *Globe and Mail*, 11 September 2003: B1, B6;T Cohen. Drug companies ask Canada to change laws. Associated Press, 12 September 2003.

<sup>&</sup>lt;sup>1</sup> Declaration on the TRIPS Agreement and Public Health. Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2. For a summary and commentary on the Declaration, see R Elliott. WTO Ministerial Conference adopts Declaration on TRIPS and Public Health. *Canadian HIVIAIDS Policy & Law Review* 2002; 6(3): 50-52.

<sup>&</sup>lt;sup>6</sup> Ibid. at para 4.

<sup>25</sup> S Chase. Generic drug makers seek export rights. *Globe and Mail*, 11 September 2003: B1, B6.

<sup>26</sup> CBC National News, CBC Radio, 13 September 2003.

<sup>27</sup> R Elliott. Canada can carry much more. *Globe and Mail*, 23 September 2003: A23.

<sup>28</sup> Letter from Canadian HIV/AIDS Legal Network, Médecins Sans Frontières Canada, Oxfam Canada and Interagency Coalition on AIDS and Development to Hon. Allan Rock, 23 September 2003.

<sup>29</sup> H Scoffield, S Chase. Ottawa heeds call on AIDS. Globe and Mail, 26 September 2003: A1, A9; D Fagan, H Scoffield, S Chase. Ottawa scrambles to meet AIDS-drug pledge: a key initiative shapes up in public view and the government rushes to keep up. *Globe and Mail*, 4 October 2003: A20.

<sup>30</sup> UNICEF hails Canada's move to expand access to AIDS drugs. Media release, 29 September 2003.

<sup>31</sup> S Chase, D Fagan. Drug companies balk at Ottawa's plan. *Globe and Mail*, 27 September 2003.

<sup>32</sup> Eg. National Union of Public and General Employees. AIDS in Africa: good news at last on generic drugs, NUPGE welcomes announcement but wants to see the legislation. Press release, 26 September 2003.

<sup>33</sup> Canadian HIV/AIDS Legal Network. Press release: Export of generic medicines to developing countries: amendment to Patent Act must benefit as many as possible, urge Canadian organizations, 26 September 2003; Médecins Sans Frontières Canada. Press release: MSF supports federal decision but says it's not enough, 26 September 2003.

<sup>34</sup> Médecins Sans Frontières Canada & Canadian HIV/AIDS Legal Network. Press release: Save Lives Now: Amend Without Delay – Amending Canada's Patent Act to allow exports of generic medicines, I October 2003; H Scoffield, P Knox. Big drug companies embrace AIDS Jan. Globe and Mail, 2 October 2003: A1, A4; Canada to be first G-7 country to allow export of generic HIV/AIDS drugs. BRIDGES Weekly Trade News Digest 2003; 7(32): I October 2003; A Silversides. "No turning back" on cheap AIDS drugs for poor nations, UN vows. Canadian Medical Association Journal 2003; 169(10): 1067 (11 November 2003).

<sup>35</sup> Canadian HIV/AIDS Legal Network. Protecting Global Health & Human Rights: Why and How the Patent Act Should Be Amended to Allow Generic Drug Exports to Developing Countries. October 2003.

<sup>36</sup> Joint NGO Statement on Canada's Efforts to Amend the Patent Act to Increase Access to Generic Medicines (October 2003).

<sup>37</sup> South Africa's Treatment Action Campaign (TAC) and AIDS Law Project (ALP) Welcome Canada's Commitment to Ensuring Access to Medicines, I October 2003.

<sup>38</sup> H Scoffield. Martin endorses AIDS plan. *Globe and Mail*, I October 2003: A1, A5.

<sup>39</sup> Canada's Research-Based Pharmaceutical Companies. News release: Partnership for developing countries, I October 2003.

<sup>40</sup> S Chase, H Scoffield. Ottawa leans toward limits on cheap-drug distribution. *Globe and Mail*, 16 October 2003: A9.

<sup>41</sup> Canadian HIV/AIDS Legal Network, MSF Canada, Oxfam Canada, Canadian Labour Congress & Interagency Coalition on AIDS and Development. Amending the Patent Act to Authorize Exports of Generic Medicines to Developing Countries: An Open Letter to the Government of Canada, 16 October 2003.

<sup>42</sup> Medicines for All: Don't Compromise Health in Amending the Patent Act (October 2003). <sup>43</sup> The Need for Affordable Medicines in the Developing World:The Patent Act and Exports of Generic Pharmaceuticals. Statements by Canadian and international physicians, and by Canadian and international health organizations and professionals (October 2003).

<sup>44</sup> Eg, question by Svend Robinson (Burnaby-Douglas, NDP) to Minister for International Trade, 23 October 2003; question by Bill Blaikie (Winnipeg-Transcona, NDP) to Prime Minister, 28 October 2003.

<sup>45</sup> Eg, H Scoffield. Lewis urges Ottawa to table legislation on AIDS medicine. *Globe and Mail*, 25 October 2003: A5; R Trichur: Africa: Can Canada help save it from AIDS? [Halifax] *Chronicle-Herald*, 30 October 2003: A10.

<sup>46</sup> Editorial. Canada targets AIDS. Toronto Star, 4 October 2003; D Morley. We led on AIDS. Why hang back now? Globe and Mail, 24 October 2003: A17; J Dussault. Sauver des millions de vies – La Loi sur les brevets doit être amendée, Le gouvernment du Canada ne doit surtout pas s'arrêter à mi-chemin. Le Devoir, 24 October 2003; R Elliott. Canada has an opportunity to show real leadership on "big pharma." Hill Times, 27 October 2003.

<sup>47</sup> Health GAP (Global Access Project) Action Alert. Progress on Access to Affordable Medicines in Jeopardy: Will Canada Give in to Pharmaceutical Industry Pressure?, 20 October 2003.

<sup>48</sup> Eg, R Weissman, Essential Information. Briefing Note: NAFTA issues in the context of the Canadian implementation of the paragraph 6 agreement, 7 October 2003. See also: H Scoffield, S Chase. Canada to seek assent on AIDS drug plan. *Globe and Mail*, 7 October 2003: A11.

<sup>49</sup> P White. US, Mexico support Canada on generic drug aid. *Reuters*, 7 October; S Chase, H Scoffield. Mexico, US back export of cheaper AIDS drugs. *Globe and Mail*, 8 October 2003; A4.

<sup>50</sup> Chase & Scoffield, ibid.

<sup>51</sup> Department of Foreign Affairs and International Trade. News release: Government of Canada introduces legislative changes to enable export of much-needed, lowercost pharmaceutical products to developing countries; A Dunfield. PM introduces bill to allow cheaper drugs for poor nations. *Globe and Mail*, 6 November 2003; New Democratic Party of Canada. Media release: New Democrats committed to the Lewis legacy, 6 November 2003.

<sup>52</sup> Statement of the World Health Organization on Canada's proposed legislative changes for medicines, Geneva, 7 November 2003.

<sup>53</sup> UN Press Release: UN rights expert welcomes Canadian initiative on access to low-cost drugs in developing countries, 7 November 2003.

#### <sup>54</sup> Bill C-56, s 21.08.

<sup>55</sup> Canadian HIV/AIDS Legal Network. Media release: Canada can set global precedent with Patent Act changes, but flaws in legislation could undermine potential benefit, 6 November 2003; Oxfam Canada & Oxfam Québec. Media release: Generic medicines for poor countries - Oxfam urges quick action on patent amendment, calls for changes, 6 November 2003; Canadian Council for International Cooperation. Media release: Canada helps world's poorest and sickest, NGOs congratulate government for access to essential medicines commitment, 6 November 2003; MSF Canada. Media release: Canadian Patent Act Amendment - Medicines for All? Not Yet, 6 November 2003. See also: R Elliott. Flirting with flawed patent law amendment, Canada may undermine welcome "access to medicines" initiative. BRIDGES Monthly Review, November 2003, Year 7, No 8, at 21-22 (available at www.ictsd.org/monthly/bridges/ BRIDGES7-8.pdf).

<sup>56</sup> See also: Canadian HIV/AIDS Legal Network.

Amendment to Canada's Patent Act to authorize export of generic pharmaceuticals: Update – 10 November 2003.

#### <sup>57</sup> Bill C-56, s 21.08.

<sup>58</sup> Bill C-56, ss 21.04(6)(a) and 21.04(7)(a), s 21.05(5).

<sup>59</sup> CGPA. News release: Generic industry welcomes introduction of access to generic medicines bill, Details of full legal and regulatory package will determine practical effect, 6 November 2003.

#### <sup>60</sup> Bill C-56, s 21.09.

<sup>61</sup> Note that this requirement to first negotiate for a voluntary licence may be waived in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use":TRIPS Article 31 (b).

<sup>62</sup> Bill C-56, Schedule I.

63 Bill C-56, s 21.03(1)(a).

<sup>64</sup> World Health Organization. Media release: WHO adds new fixed dose combinations to its list of quality products for AIDS treatment – Key component of 3 by 5 strategy, I December 2003.

<sup>65</sup> The UN recognizes 49 countries as "least-developed countries." Of these, all have been included in Bill C-56, with the exception of Myanmar (a WTO member), which omission arises because of the lack of diplomatic relations between the military dictatorship in that country and Canada. This omission needs to be corrected; patients needing affordable medicines should not be further penalized for the misfortune of living under a dictatorship.

<sup>66</sup> Some of the excluded countries are Viet Nam, Russian Federation, Belarus, Algeria, Serbia and Montenegro, Kazakhstan, East Timor, Ukraine, Azerbaijan, Uzbekistan, and Tajikistan, among others.

<sup>67</sup> Canadian HIV/AIDS Legal Network. Media release: Bill C-56 on medicines for developing countries is flawed, House of Commons should amend bill and get it right, 7 November 2003.

<sup>68</sup> S Chase. Poor-nation drug bill: Liberals table it, but admit it's not ready. *Globe and Mail*, 7 November 2003: A3; Committee to work AIDS bill into shape. *Globe and Mail*, 8 November 2003: A16.

 $^{69}$  For a transcript of debates and questions on Bill C-56 in the House of Commons, and information about the status of the bill, see the website of the Parliament of Canada at www.parl.gc.ca.

<sup>70</sup> MSF, Canadian HIV/AIDS Legal Network, World Vision & CAP-AIDS. Media relase: Street Hockey for Global Health – Canadian activists dramatize call on new Prime Minister to pass legislation allowing cheaper medicines for developing countries, 14 November 2003.

<sup>71</sup> S Rubec. Money tight, Martin warns. London Free Press, 16 November 2003: 5; S Rubec. Martin set to trim fat, PM-to-be lays out agenda in election-style book. Toronto Sun, 16 November 2003: 3; S Rubec. Paul plans tight ship: newly crowned Grit leader pleads fiscal poverty. Winnipeg Sun, 16 November 2003: A8.

<sup>72</sup> Eg. statement from Canadian HIV/AIDS Legal Network in "The Fight Against HIV/AIDS Must Continue," joint media release from seven national Canadian organizations responding to HIV/AIDS to mark World AIDS Day, 29 November 2003.

<sup>73</sup> Decision of the General Council of 30 August 2003, supra, note 16 at para 11.

<sup>74</sup> Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines, supra, note 22.

## Warsaw Declaration on HIV/AIDS and injection drug use adopted

Explosive epidemics of HIV among injection drug users are occurring in both developing and developed countries. Globally, it is estimated that 10 percent of HIV infections are attributable to injection drug use,<sup>1</sup> but this proportion is increasing, and is much higher in many countries. Effective interventions exist to prevent the spread of HIV among injection drug users, but in most countries they are being adopted too slowly, or not at all. On 14 November 2003, the Warsaw Declaration: A Framework for Effective Action on HIV/ADS and Injection Drug Use, was adopted at the 2<sup>nd</sup> International Policy Dialogue on HIV/AIDS. Its purpose is to provide a framework for – finally – "mounting an effective response that will slow and eventually stop the HIV/AIDS epidemic among injecting drug users worldwide."<sup>2</sup>

The Policy Dialogue was hosted by the government of Poland, and sponsored by the Joint United Nations Programme on HIV/AIDS (UNAIDS), Health Canada, the Open Society Institute, and the Canadian International Development Agency. Invited participants included people responsible for HIV/AIDS and people responsible for injection drug use (IDU) from transitional countries such as Poland, Tajikistan, and Ukraine; from developing countries such as Brazil, Indonesia, and Thailand; from industrialized countries such as Canada, Switzerland, and the United Kingdom; and from four international agencies - the World Health Organization (WHO), UNAIDS, the United Nations Office on Drugs and Crime, and the United Nations Development Program. A few nongovernmental organizations (the Dutch National Interest Group of Drug Users, the Canadian HIV/AIDS Legal Network, and the Monar Krakow Drugs Project) also participated.

Background papers prepared for the meeting provided a synthesis of the international epidemiology and burden of disease of IDU and HIV/AIDS, and of the evidence base for development of policies and programs to reduce the risks, harms, and costs of IDU and HIV/AIDS. The papers show that IDU, a risk factor for acquiring HIV infection through the sharing of injection equipment, is now a global phenomenon. According to the WHO, 134 countries, regions, or territories reported IDU in 1999, and of these 114 (84 percent) reported HIV among injection drug users. In 1992, by comparison, 80 countries reported IDU, with 52 (65 percent) reporting HIV among injection drug users.<sup>3</sup> In other words, HIV epidemics around the world are increasingly being fuelled by the diffusion of IDU. IDU is the major mode of HIV transmission in Eastern and Western Europe, Central Asia, East Asia, North Africa, the Middle East, North America, and parts of South America. The most affected regions to date

HIV epidemics around the world are increasingly being fuelled by the diffusion of injection drug use.

have been Southern and Eastern Europe, Central Asia, East Asia, North America, and Latin America. Explosive epidemics have occurred among injection drug users in each of these regions.<sup>4</sup>

The papers also show that different types of interventions to reduce the risks, harms, and costs of HIV/AIDS and injection drug use are in place in various regions of the world. Some have been proven effective, based on existing empirical evidence, while others have showed promise. But hardly anywhere are these interventions implemented quickly enough or scaled up appropriately. As a result, crucial opportunities to slow the HIV and hepatitis C epidemics are being lost, and the enormous financial and human costs continue to build around the globe.

Participants at the Policy Dialogue concluded that "continued failure to act can no longer be blamed on the absence of effective policies, programmes, interventions or resources," and called for increased political commitment.<sup>5</sup>

The Warsaw Declaration, reproduced below, should be used by governments worldwide as a framework for effective action on HIV/AIDS and IDU; and by community advocates as an additional tool to hold governments accountable for their failure to act. Ralf Jürgens is the Executive Director of the Canadian HIV/AIDS Legal Network. He was one of three NGO representatives at the Policy Dialogue. Ralf can be reached at ralfj@aidslaw.ca.

<sup>1</sup> Drug Abuse & HIVIAIDS: A Devastating Combination. Geneva: United Nations International Drug Control Programme and Joint Programme on HIV/AIDS, 2000.

<sup>2</sup> The Warsaw Declaration: A Framework for Effective Action on HIV/AIDS and Injecting Drug Use. Warsaw: 2<sup>nd</sup> International Policy Dialogue on HIV/AIDS, 2003.

<sup>3</sup> J Rehm , B Fischer, E Haydon (eds). Reducing the Risks, Harms and Costs of HIV/AIDS and Injection Drug Use: A Synthesis of the Evidence Base for Development of Policies and Programs. 2<sup>nd</sup> International Policy Dialogue on HIV/AIDS, Conference Paper 4. Ottawa: Health Canada (International Affairs Directorate), 2003, at 5.

<sup>4</sup> D Riley. An Overview of Harm Reduction Programs and Policies around the World – Rationale, Key Features and Examples of Best Practice. 2<sup>nd</sup> International Policy Dialogue on HIV/AIDS, Conference Paper 3. Ottawa: Health Canada (International Affairs Directorate), 2003, at 4.

<sup>5</sup> Supra, note 2.

– Ralf Jürgens

## The Warsaw Declaration: A Framework for Effective Action on HIV/AIDS and Injecting Drug Use

2<sup>nd</sup> International Policy Dialogue on HIV/AIDS

Held in Warsaw, Poland

November 12-14, 2003

The Policy Dialogue was hosted by the Government of Poland and sponsored by UNAIDS, Health Canada, The Open Society Institute, and the Canadian International Development Agency.

#### **Preamble:**

Two decades after the AIDS epidemic was first recognized, the spread of HIV infection through injecting drug use is an increasingly serious public health problem in many countries and regions of the world. Abundant, high-quality evidence of effective, safe and cost-effective harm reduction strategies exists, yet in many countries, the implementation of such strategies is still "too little and too late."

Continued failure to act can no longer be blamed on the absence of effective policies, programmes, interventions or resources. Political and social commitment, including commitment of the necessary resources, is what will make the difference between success and failure.

#### **Purpose:**

The purpose of this declaration is to provide a framework for mounting an effective response that will slow and eventually stop the HIV/AIDS epidemic among injecting drug users worldwide.

#### **Context:**

The HIV/AIDS pandemic constitutes an unprecedented global crisis, and HIV continues to spread worldwide. At

the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in 2001, all member states of the United Nations adopted a Declaration of Commitment that sets goals and targets for an expanded response to the epidemic. Included are commitments related to reducing HIV transmission among identifiable groups at highest risk (such as injecting drug users) through the provision of a wide range of programmes, including information, education and communication aimed at reducing risk-taking behaviour; expanded access to essential commodities including male and female condoms and sterile injecting equipment; and harm reduction efforts related to drug use.<sup>1</sup> The Declaration also calls on countries to enact, strengthen or enforce laws and regulations that protect against discrimination of people living with HIV/AIDS and members of vulnerable groups.

Transmission of HIV through the injection of drugs and the subsequent development of HIV-related illness in injecting drug users are significant contributors to increased morbidity, premature mortality, health care costs, economic losses and social disruption in industrialized, transitional and developing countries. In some countries, injecting drug use accounts for over half of all HIV transmissions. Worldwide, an estimated ten per cent of HIV/ AIDS is attributed to injecting drug use, and this proportion is progressively increasing. In addition to the costs and negative consequences for injecting drug users, the potential for injecting drug use to play a pivotal role in the dissemination of HIV to the general population in some regions of the world, especially Central and Eastern Europe and Central, South and South-East Asia, is of concern.

Different types of interventions to reduce the risks, harms and costs of HIV/AIDS and injecting drug use are in place in various regions of the world. Some are promising, while others have already been proven effective, based on existing empirical evidence. Both should be part of comprehensive programmes of HIV/AIDS prevention, care, treatment and support designed to address HIV/ AIDS and injecting drug use.

All of the prevention strategies needed to reduce the HIV infection rate among injecting drug users are entirely consistent with the international drug treaties,<sup>2,3</sup> have been endorsed by the UN General Assembly, the World Health Assembly, and several high-level UN Commissions, and are included in the operational plans of the World Health Organization (WHO) and the UN Office on Drugs and Crime (UNODC).

Decisive policy action at the regional and national levels is needed as the basis for an effective response to HIV/AIDS and injecting drug use. Such a response will also help to address the spread and consequences of hepatitis C. The following guiding principles and policy objectives are intended as the foundation for such policy action. They flow from and build upon the UNGASS Declaration of Commitment, the UNAIDS Global Strategy Framework on HIV/AIDS, the WHO Global Health Sector Strategy on HIV/AIDS, and the global priorities outlined in the UNAIDS Report from the XIV International AIDS Conference, Barcelona 2002. They are also informed by specially commissioned papers reviewing the evidence on reducing the risks, harms and costs of HIV/AIDS and injecting drug use and proposing policy approaches.<sup>4</sup>

#### **Guiding Principles:**

1. Pragmatic Focus. The need for an urgent response requires that the scope of policy action be clearly defined and pragmatically focused on factors that reduce the immediate risks and harms of HIV transmitted through injecting drug use. The challenging issue of overall prevention and control of drug use must be balanced by a primary and immediate focus on reducing HIV transmission through injecting drug use. Harmonization of drug policies and strategies with HIV/AIDS policies is essential in order to achieve this balance. The harm reduction framework provides for a continuum of approaches, ranging from needle exchange programs and substitution therapies to abstinence from drugs.

- 2. Intersectoral Action. Effective policy action must involve many sectors, recognizing the health factors, the legal framework and law enforcement practices, and the cultural, social and economic environments in which HIV/AIDS and injecting drug use emerge.
- 3. Comprehensive Response. The most effective policy response will include objectives and interventions that comprehensively address the range of factors that contribute to the risks, harms and costs of HIV/AIDS and injecting drug use. This will include actions to reduce the risk of infection, to reduce vulnerability to infection created by factors such as stigma, discrimination and social exclusion, to ensure equitable access to HIV/AIDS treatment and care (including antiretroviral therapy), to reduce the negative impact of HIV on those infected and affected, as well as their communities, and to evaluate interventions.
- 4. Broad Involvement. Input about policy objectives and actions to accomplish them should involve all levels of government, civil society organizations in sectors concerned with HIV/AIDS and injecting drug use, including non-governmental and community-based organizations, people living with HIV/AIDS, previous and current injecting drug users, researchers and professional organizations. To this end, responses should incorporate specific strategies for engagement and community development with this vulnerable population.
- 5. Evidence Based. Policy development must be informed by empirical evidence about reducing the risks, harms and costs of HIV/AIDS and injecting drug use.
- 6. Awareness and Advocacy. Informed individuals and groups, including people living with HIV/AIDS and injecting drug users, have key roles to play in stimulating and facilitating decisive policy action, recognizing that individuals working in the health, social services and law enforcement fields, other key interest groups and the general public need accurate information about

the risks, costs and harms of HIV/AIDS and injecting drug use, and effective responses to these issues.

#### **Policy Objectives:**

- 1. Protect the health and well-being of injecting drug users, their families and their broader communities by achieving control of HIV infection associated with injecting drug use.
- 2. Improve the health and social conditions of injecting drug users, in order to reduce their vulnerability to HIV/AIDS, and improve their capacity and support for adopting safer injecting practices, reducing injection frequency or entering drug dependence treatment programmes.
- 3. Reduce HIV transmission among those who inject drugs through strategies which decrease the use of contaminated injecting equipment and increase the adoption of safer injecting practices; and are delivered through sustained high-coverage programmes of information, education and communication aimed at reducing risk-taking behaviour; expanded access to sterile injecting equipment; and increased availability of a range of drug dependence treatment services, including substitution treatment and rehabilitation programmes.
- 4. Reduce the proportion of the population of drug users who inject drugs, through access to appropriate and effective education, information to promote changes in the route of administration, and prevention and treatment programmes related to both HIV/AIDS and injecting drug use.
- 5. Ensure that injecting drug users in the highest risk and most marginalized situations, including those in penal institutions and among those engaging in sex work, have equal access to HIV/AIDS and injecting drug use risk reduction, prevention, care, treatment and support opportunities that address their unique needs.
- 6. Reduce transmission of HIV between injecting drug users and their sexual partners, with a particular focus on injecting drug users who engage in sex work or whose partners engage in sex work.

- 7. Reduce mother-to-child transmission among current and former drug using women who have HIV infection and are pregnant, as well as among pregnant partners of HIV-positive male drug users, who decide to carry their pregnancies to term.
- 8. Provide access to comprehensive HIV/AIDS treatment and care, including antiretroviral treatment for injecting drug users who have HIV/AIDS.
- 9. Ensure that drug control laws and their interpretation and enforcement are complementary to HIV/AIDS strategies and do not hinder HIV/AIDS prevention measures among injecting drug users, increase the risk of HIV infection faced by drug users, or hinder drug users' access to care, treatment and support.
- 10. Increase empirical evidence to guide the development and delivery of policies and interventions addressing HIV and injecting drug use, including actions to fill major gaps in the evidence base and to address the varying needs and priorities of developing, transitional and industrialized countries.

Note: The following notes are part of the Warsaw Declaration and have therefore not been edited to conform with the house style of the Canadian HIV/AIDS Legal Network.

<sup>I</sup> The principles of 'harm reduction' as defined in documents published by the UN Office of Drugs and Crime, the World Health Organization, and the Joint United Nations Programme on HIV/AIDS refer to activities aimed at reducing the health and social consequences of injecting drug use: reaching out to injecting drug users, discouraging the sharing of contaminated injecting equipment by providing sterile injecting equipment and disinfectant materials, and providing a range of drug dependence treatment including substitution treatment. These principles, which are part of the principles for preventing HIV infection among drug users compiled by the World Health Organization in isolation from overall national drug strategies or national AIDS programmes. They are, however, valuable in guiding national policies and programmes as regards the specific goal of reducing HIV transmission among injecting drug users.

<sup>2</sup> These treaties are: The 1961 Single Convention on Narcotic Drugs; the 1971 Convention on Psychotropic Substances; and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

<sup>3</sup> See also "Impact and Implications of the International Drug Control Treaties on IDU and HIV/AIDS prevention and Policy", by Robin Room, in *Reducing the Risks, Harms and Costs of HIV/AIDS and Injecting drug use: A Synthesis of the Evidence Base for Development of Policies and Programs* (Conference Paper #4), Jurgen Rehm, Benedikt Fischer, Emma Haydon, eds.

<sup>&</sup>lt;sup>4</sup> Developing and Implementing National Policies on HIVIAIDS and Injecting drug use: A Framework and Guide for Action (Conference Paper #2), Diane McAmmond. An Overview of Harm Reduction Programs and Policies Around the World: Rationale, Key Features and Examples of Best Practice., (Conference Paper #3), Diane Riley. Reducing the Risks, Harms and Costs of HIVIAIDS and Injecting drug use: A Synthesis of the Evidence Base for Development of Policies and Programs (Conference Paper #4), Jurgen Rehm, Benedikt Fischer, Emma Haydon, eds.

## **CANADIAN NEWS**

This section provides brief reports of developments in legislation, policy, and advocacy related to HIV/AIDS in Canada. (Cases before the courts or human rights tribunals in Canada are covered in the section on HIV in the Courts – Canada.) The coverage is based on information provided by Canadian correspondents or obtained through scans of Canadian media. Regular correspondents are listed on page 2; information about occasional correspondents is provided with their contribution. Address correspondence to David Garmaise, the editor of Canadian News, at dgarmaise@rogers.com.

# North America's first supervised injection site opens in Vancouver

The number of injection drug users frequenting the long-awaited supervised injection site in the Downtown Eastside has steadily increased since the site opened in September 2003. However, there are concerns about the restrictions imposed by Health Canada and about the activities of the Vancouver Police.

On 15 September 2003, the Vancouver Coastal Health Authority formally launched North America's first legally sanctioned supervised injection site (SIS). The long-awaited project was unveiled at an elaborate media gathering. The doors were officially opened to local injection drug users six days later. The SIS is operated in partnership with the Portland Hotel Society. Health Canada has provided legal sanction for the site through a section 56 exemption under the Controlled Drugs and Substances Act.<sup>1</sup>

The 12-seat SIS is operating 18 hours a day (10 am–4 am), seven days

a week, and is staffed at all times by a manager, two nurses, and an addiction counsellor. Two members of the drugusing community are also present on each shift to greet and orient users to the site, and to provide peer support. The people using the site first register in a reception area, and are then led to an injecting room where they are provided with sterile injecting equipment and supervision throughout the injection process. After injecting, the users proceed to a post-injection or "chillout" room where they can rest and access other services, including primary care for wounds and abscesses, addiction counselling, and referrals to

other health and social services.

The SIS is expected to cost approximately \$2 million dollars a year to operate. The British Columbia Ministry of Health provided the operating funds for the first year and also provided \$1.2 million for renovations. Funding for the second year of operation has not yet been secured. Health Canada is providing \$1.5 million over three years for the scientific evaluation of the SIS, which will be conducted by the British Columbia Centre for Excellence in HIV/AIDS. Headed by Canadian HIV/AIDS Legal Network board member Dr Evan Wood and by Dr Mark Tyndall,

the evaluation will include process, outcome, and cost-effectiveness components.

On the first day of operation, staff at the SIS supervised 39 injections. Within a week, the daily number of supervised injections increased to 150. Since then, the number of visits to the injection room has increased fairly steadily, peaking at 529 on 29 October 2003.<sup>2</sup> At full capacity, a 12seat SIS operating 18 hours a day should be able to accommodate at least 648 injections a day. In a neighbourhood with an estimated 4700 injection drug users, a well-designed SIS could easily be overwhelmed by the demand.

While the opening of Vancouver's SIS represents a significant development in harm-reduction policy and practice in Canada, there are some lingering concerns regarding the specific SIS model that has been implemented. Three days before the opening of the SIS, a study published in the *Canadian Medical Association Journal* demonstrated the potentially adverse impacts of newly established Health Canada SIS restrictions and Vancouver police activities on uptake

of the Vancouver SIS by local injection drug users. The Health Canada restrictions included mandatory registration at the SIS, and prohibitions against user-assisted injection and the sharing of drugs within the site. While 92 percent of active users surveyed initially expressed a willingness to use the SIS, when the Health Canada restrictions were introduced, willingness dropped to 31 percent. When study participants were asked if they would use the SIS if police were stationed near the SIS, willingness dropped to 22 percent. Unfortunately, reports from Vancouver suggest that Vancouver police have maintained a presence near the site, and have continued their practice of parking police cruisers near the entrance of the SIS and other health services for injection drug users.

Concerns regarding Health Canada's restrictions were echoed in statements made by Libby Davies, the Member of Parliament for Vancouver East. Ms Davies urged Health Canada "to adopt the most minimal rules necessary for safety and health. Any attempts made to impose rigid rules and procedures will jeopardize the very purpose of a low threshold service to users."<sup>3</sup>

Activists, drug users, and many others have fought long and hard to establish the Vancouver SIS. While many people will celebrate this development, others will cautiously observe the progress of the SIS over the next year to see how well the site is accepted by local users, including those most at risk for illness and death. It is unclear whether the muchanticipated benefits of the SIS will be realized, given the current Health Canada restrictions and the activities of the Vancouver police. Only time and rigorous evaluation will determine if North America's first legally sanctioned SIS will succeed in reducing the severe drug-related harms that have plagued the Downtown Eastside for decades.

- Thomas Kerr

### Ontario: People can now apply for forced HIV testing in certain situations

Ontario has finally issued a regulation to accompany its controversial "blood samples" legislation, passed in 2001. As a result, in certain circumstances, a person in Ontario can now seek an order to require another person to be tested for HIV, hepatitis B (HBV), and hepatitis C (HCV). However, the regulation contains a number of restrictions on the ability to apply for such an order.

On 1 September 2003, a regulation came into effect in Ontario that accompanies the government's "blood samples" legislation. As a result, it is now possible, in certain situations, for individuals who think they may have

<sup>&</sup>lt;sup>1</sup> See T Kerr: Supervised injection sites: Health Canada approves Vancouver pilot sites, but concerns remain. *Canadian HIV/AIDS Policy & Law Review* 2003; 8(2): 18-20.

 $<sup>^{\</sup>rm 2}$  The number of injections supervised at the SIS is reported via www.vch.ca.

<sup>&</sup>lt;sup>3</sup> Open letter written for the opening of the SIS, dated 15 September 2003. On file with the author:

been exposed to the bodily fluids of another person to apply to the local Medical Officer of Health (MOH) for an order to force this person to be tested for HIV, HBV, and HCV.<sup>1</sup>

In 2001, the Ontario government amended the province's public health legislation, the Health Protection and Promotion Act<sup>2</sup> (HPPA), in order to grant MOHs the power to issue orders requiring people to submit to testing for certain bloodborne viruses in some circumstances.<sup>3</sup> Those amendments were contained in Bill 105, "An Act to amend the Health Protection and Promotion Act to require the taking of blood samples to protect victims of crime, emergency service workers, good Samaritans and other persons."4 Although Bill 105 received royal assent on 14 December 2001, the government delayed proclaiming it into force while it consulted on the content of any accompanying regulations. Bill 105 was finally proclaimed on 1 May 2003 and was made operational with the release of the regulation<sup>5</sup> on 1 September  $2003.^{6}$ 

Under the regulation, a person who wants to obtain an order must file his or her application in the required form within seven days of being exposed to the bodily substances of a person who refuses to be tested voluntarily.<sup>7</sup> The only people who can make such applications are: (a) victims of crime who were exposed to the bodily substance as a result of the crime; and (b) people who were exposed to the bodily substance while providing emergency health care or emergency first aid. It had been expected that the regulation would create additional classes of potential applicants, so that police officers, correctional workers, and firefighters would also be able to

apply for an order. This expectation was based on the fact that Bill 105 explicitly stated that one of the classes of potential applicants would be persons exposed to another person's bodily fluids while performing certain jobs, and the fact that those jobs were to be prescribed by regulation.<sup>8</sup> However, the regulation that was filed contains no such prescribed jobs or functions. This is an interesting omission, given that the main proponents of Bill 105 were groups such as the Police Association of Ontario.<sup>9</sup>

The statutory test that must be met before an order can be issued is that the local MOH must be of the opinion, on reasonable and probable grounds, that the order is necessary to decrease or eliminate the risk to the health of the applicant.<sup>10</sup> Under the regulation, applicants must file two forms with the MOH: (a) an application form containing information about the applicant, the "respondent" (the person against whom the testing order is sought), and the exposure; and (b) a physician report form.<sup>11</sup> The application form must be sworn before a commissioner of oaths.

One of the interesting provisions in the regulation states that physicians asked to complete the physician report form cannot do so unless they order baseline testing of the applicant.<sup>12</sup> This mandatory requirement for baseline testing of the applicant is curious because it appears to conflict with s 22.1(3) of the HPPA. That section states that a physician making a physician report has the discretion to require the applicant to submit to baseline testing, but is not required to do so. According to the regulation, the applicant is required to file the results of his or her baseline testing to the MOH within five

days of receiving the results, although the MOH is entitled to make a decision on the application prior to receiving said results.<sup>13</sup> If the MOH finds out after making an order that the applicant's baseline test results

The regulation contains some procedural requirements that give respondents additional protections and rights.

indicate that the applicant was positive at the time of the exposure, the MOH is required to rescind the order so that the respondent is not unnecessarily tested.<sup>14</sup>

The regulation also created procedural requirements that give respondents some additional protections and rights (over and above what is contained in the HPPA). For example, when an application is received, the MOH is required to direct a health professional to contact the respondent to talk about whether or not the respondent will volunteer for testing (which would eliminate the need for an order). The regulation requires that the conversations with the respondent be kept secret from the MOH making the decision, so that the MOH is not influenced in any way by what the respondent says.<sup>15</sup> Furthermore, when the MOH decides to hold a hearing on the application, the respondent has the opportunity to file a report setting out why an order for testing might put the respondent's health or life in danger, and providing any other information that the respondent thinks is relevant.<sup>16</sup> Finally, although an applicant whose application is denied by the local MOH can appeal to the

Chief Medical Officer of Health, the applicant has no further right of review or appeal, and no any right to an oral hearing. (In contrast, the respondent, the health-care professional who draws the blood sample, and the laboratory doing the testing, all have a right of appeal to the Health Services Appeal and Review Board, as well as a further right to appeal to the Divisional Court.)<sup>17</sup>

In September 2003, the Ontario Medical Association (OMA) sent an information circular to physicians in Ontario about the new physician report forms.<sup>18</sup> The circular warns physicians that there is a "high threshold of knowledge required to complete the form" and that there is a possibility that choosing to complete the form may result in the physician being involved as a witness in legal proceedings. Physicians are clearly told that they have the discretion to refuse to complete the physician report form. One of the reasons for the OMA's caution is that the HPPA states that a physician completing a physician report must be "informed in respect of matters related to occupational and environmental health and all protocols and standards of practice

in respect of blood-borne pathogens."<sup>19</sup>

In an effort to help physicians become familiar with the protocols and standards of practice in respect of bloodborne pathogens, the Ministry of Health and Long-Term Care has posted on its website a list of readings and references for physicians. Included in those references is the Canadian HIV/AIDS Legal Network's documents on occupational exposures to HIV, HCV, and HBV,<sup>20</sup> which include statements to the effect that compulsory testing orders like those permissible under Bill 105 are unethical and unjustified.<sup>21</sup> One reasonable conclusion to draw from the responses of both the OMA and the Ministry to Bill 105 is that neither is particularly enthusiastic about compulsory testing orders.

- Ruth Carey

<sup>2</sup> RSO 1990, c H.7, as amended.

<sup>3</sup> See R Carey. Ontario adopts "blood samples" legislation; and T de Bruyn, R Elliott. Compulsory HIV testing after an occupation exposure. *Canadian HIVIAIDS Policy & Law Review* 2002; 6(3): 39-40 and 1, 24-31 respectively.

<sup>4</sup> SO 2001, c 30.

<sup>5</sup> The regulation is available at www.elaws.gov.on.ca/DBLaws/Regs/English/030166\_e.htm.

/

<sup>6</sup> Ontario Gazette 136-20, 17 May 2003, at 577.

<sup>7</sup> Supra, note 4 at s 4(1).

 $^{8}\,\text{This}$  provision can now be found in s 22.1 (2)(a)(iii) of the HPPA.

<sup>9</sup> See de Bruyn & Elliott, supra, note 3 at 25.

<sup>10</sup> HPPA, supra, note 2 at s 22.1(2)(f)

<sup>11</sup> These forms are now available from both the Ontario government at www.health.gov.on.ca/english/public/forms/ form\_menus/pubh\_fm.html and the Ontario Medical Association at www.oma.org/phealth/hea\_main.htm.

<sup>12</sup> O Reg 166/03, subsection 5(1). Baseline testing refers to the initial testing for HIV/HCV and HBV that a person would normally undergo immediately after he or she is exposed to a possible source of infection. This testing is done to find out if the exposed person is already infected with one of the subject viruses at the time of the exposure in question. If he or she does test positive, then follow-up testing is not required, treatment can begin immediately, and the exposure in question is ruled out as a possible source of the person's infection.

<sup>13</sup> Ibid at ss 5(3) and 5(2) respectively.

<sup>14</sup> Ibid at s 5(6).

<sup>15</sup> Ibid at s 6.

<sup>16</sup> Ibid at s 10 and Form 3 – Respondent Report. However, the "hearings" contemplated by the regulation are paper hearings and the parties are not permitted to lead oral evidence.

 $^{17}$  lbid at s 16; and HPPA, supra, note 2 at ss 44(1) and 46(1).

<sup>18</sup> Available at www.oma.org/phealth/vol8n37.htm.

<sup>19</sup> HPPA, supra, note 2 at s 22.1(1), emphasis added.

<sup>20</sup> See the Ministry's website at

www.health.gov.on.ca/english/providers/project/bill\_105/ 105\_phys.html. There are extensive resources available on this site about both Bill 105 and the health management of exposures to HIV, HCV, and HBV.

<sup>21</sup> See, eg,T de Bruyn. Testing of Persons Believed to Be the Source of an Occupational Exposure to HBV, HCV, or HIV: A Backgrounder. Canadian HIV/AIDS Legal Network, 2001, at 43, available at www.aidslaw.ca/Maincontent/issues/ testing/e-compulsorytesting/toc.htm.

## Many people in marginalized communities are not accessing antiretroviral therapy: BC study

A study in British Columbia has found that high AIDS death rates persist because of a lack of, or only marginal access to, antiretroviral therapy among certain populations. The solution, the researchers say, is to develop novel health-care interventions and expand illegal-drug treatment programs. One of every three people who die of AIDS in British Columbia has never been treated with antiretroviral drugs. Aboriginal persons, women, poor people, and people residing in the

<sup>&</sup>lt;sup>I</sup> O Reg 166/03, s 2.

Downtown Eastside were over-represented in this group. These are the findings of a study conducted by a team of researchers at the B.C. Centre for Excellence in HIV/AIDS.<sup>1</sup> The researchers examined 1239 deaths attributed to AIDS during the period from January 1995 to December 2001. Antiretroviral cocktails were available throughout that period. In BC, these drugs are provided free of charge through the Centre.

The study also found that among the people who did access antiretrovirals, 54 percent did not take them consistently. Inconsistent use of antiretrovirals can reduce the efficiency of the drugs and lead to resistance. Those who did not take the drugs consistently were more likely to be Aboriginal persons, women, and poor people. Among the 81 Aboriginal persons in the study who accessed therapy, 77 percent did not take them consistently. Among the 90 women in the study who accessed therapy, 64 percent did not take them consistently. Dr Julio Montaner, one of the researchers, said that while economic barriers to accessing antiretrovirals have been removed, significant cultural and practical barriers remain.<sup>2</sup>

The researchers concluded that interventions aimed at improving access to antiretrovirals among HIVinfected Aboriginal persons, women, lower-income persons, and injection drug users are an urgent priority. They suggested that strategies to improve access and adherence could include better access to illegal-drug treatment programs, directly observed therapy programs, access to medical services without appointments, and on-site pharmacies at medical clinics. The researchers emphasized that further study is required to identify appropriate strategies.

The researchers stated that although their study was limited to British Columbia, it is likely that similar problems exist in other parts of Canada and the developed world.

– David Garmaise

## Prison activist receives AIDS and human rights award

Laurence Stocking, the recipient of the 2<sup>nd</sup> Annual Canadian Award for Action on HIV/AIDS and Human Rights, fought for the rights of prisoners to access HIV and hepatitis C (HCV) prevention and treatment programs.

Deceased Canadian prison activist Laurence Stocking has received the 2<sup>nd</sup> Annual Canadian Award for Action on HIV/AIDS and Human Rights. The award was formally presented by the Canadian HIV/AIDS Legal Network and Human Rights Watch to Stocking's mother and daughter at the Annual General Meeting of the Legal Network in Montréal, Québec, in September 2003.<sup>1</sup>

While incarcerated at Joyceville Institution in Kingston, Ontario, Stocking fought tirelessly for the rights of prisoners to stay free from HIV and HCV. These diseases are 10 to 70 times more common among prisoners than among the general public. Stocking raised awareness of the diseases and was an outspoken critic of Correctional Services Canada for its failure to provide prevention measures and adequate care to prisoners living with HIV.

Stocking's accomplishments ranged from peer counselling and organizing health-care seminars with outside agencies for prisoners, to playing a significant role in the production of two prisoner-produced videos on hepatitis, tattooing, and harm reduction. He was also instrumental in helping organize two published studies on the seroprevalence of HIV and hepatitis, and the risks associated with the contraction of these diseases, within prison.

"It is clear that prisons offer little to protect inmates from the risk of HIV infection, said Dr Mary Pearson, who worked as a physician at Joyceville while Stocking was there.<sup>2</sup> "For an inmate to speak out in a system such as this is both exceptional

<sup>&</sup>lt;sup>I</sup> E Wood et al. Prevalence and correlates of untreated human immunodeficiency virus type I infection among persons who have died in the era of modern antiretroviral therapy. *Journal of Infectious Diseases* 2003; 188: 1164-1170.

<sup>&</sup>lt;sup>2</sup> A Picard. Neediest lack access to drugs for AIDS: study. *Globe and Mail.* Online edition, 14 October 2003.

and dangerous," Pearson said. "To me, it speaks to Laurence's terrific and unbelievable courage and perseverance, and his ability to act despite the fact that he knew his actions were likely to result directly in danger to himself."<sup>3</sup>

After several media interviews in which he talked openly about the growing HIV/AIDS crisis in Canadian prisons, Stocking was involuntarily transferred to Kingston's Millhaven Penitentiary. Four months later, in November 1998, he died. A coroner's inquest ruled that his death resulted from an accidental drug overdose, but others have blamed delays in responding to calls for medical help.

The first Canadian Award for Action on HIV/AIDS and Human Rights was presented in 2002 to the Vancouver Area Network of Drug Users.<sup>4</sup>

– David Garmaise

infected and affected. The awards are co-sponsored by the International Harm Reduction Program, the Hilda Mullen Foundation, and Mark Gallop. Additional information about the awards and about the 2003 recipients is available at www.aidslaw.ca/Maincontent/awards.htm.

<sup>2</sup> Canadian HIV/AIDS Legal Network and Human Rights Watch. Canadian prisoner and AIDS Law Project of South Africa receive human rights awards. Press release. 12 September 2003. Available at http:// aidslaw.ca/Media/press-releases/e-press-sept1203.pdf.

<sup>3</sup> Canadian HIV/AIDS Legal Network. Taking Action on Stigma and Discrimination: Presentations Made on the Occasion of the Canadian HIV/AIDS Legal Network Annual General Meeting and Skills Building Workshops, 12-14 September 2003, Montréal. Available via www.aidslaw.ca/Maincontent/events/agm2003.htm.

<sup>4</sup> See T Kerr; T Haig, The 1<sup>st</sup> Annual Awards for Action on HIV/AIDS and Human Rights. *Canadian HIV/AIDS Policy and Law Review* 2002; 7(2/3): 1, 20-23.

## Ontario proposes to regulate viatical settlements

Proposed new regulations would allow any company to apply for a licence to trade in viatical settlements in Ontario. Currently, only insurance companies can engage in this practice.

Under proposed new regulations governing viatical settlements in Ontario, any company fulfilling the licensing criteria would be able to trade in viatical settlements. Currently, only licensed insurance companies are permitted to engage in this trade, and they are able to operate in an unregulated fashion.

The proposed regulations have been completed by the Financial Services Commission of Ontario (FSCO), the body responsible for overseeing the insurance industry in the province.<sup>1</sup> The draft regulations have been submitted for comments by "interested parties." If enacted, they will be the first regulations in Canada to specifically address viaticals.

Viatical settlements are an insurance and investment option that arose primarily in response to the AIDS epidemic.<sup>2</sup> These settlements typically involve a terminally ill individual with a short life expectancy (a viator) selling his or her life insurance policy to a third party who eventually receives the benefits upon the death of the insured. The amount the viator receives is less than the face value of the policy, with the size of the discount depending on the life expectancy of the viator. The purchaser of the policy either retains it and waits for the death of the viator, or resells it to one or more downstream investors. Although viaticals have been marketed in Canada, the viatical business is much larger in the United States.

The Ontario Insurance Act<sup>3</sup> is the legislation that currently permits insurance companies to engage in the viatical trade. The Red Tape Reduction Act, 2000,<sup>4</sup> which has been passed by the Ontario Legislature but has not yet been proclaimed, bestows on the FSCO the authority to open up the viatical trade to other companies and to make regulations. Proclamation of this legislation has been postponed pending the development of the regulations.

Under the draft regulations, in order for a transaction to qualify as a viatical settlement, an Ontario physician would have to certify that the insured has a catastrophic illness and a maximum life expectancy of two years. Companies wishing to engage in the viatical trade would need to be licensed. To obtain a licence, companies would have to maintain a minimum level of assets in order to meet

<sup>&</sup>lt;sup>I</sup> Each year the Canadian HIV/AIDS Legal Network and Human Rights Watch present awards to one Canadian and one international individual or organization to highlight outstanding work done to decrease vulnerability to HIV/AIDS and to protect the rights and dignity of those

the claims of creditors. Specific conditions would have to be met regarding disclosure to viators, including:

- revelation of any conflicts of interest;
- a description of how viatical settlement contracts operate;
- provision of contact information for the company; and
- encouragement to seek independent legal and financial advice.

Tying profitability to the early death of another human being strikes many people as inherently distasteful.

Viators would also have to be informed of the availability of alternatives such as accelerated death benefits, whereby the insurer itself advances payments to the terminally ill person from the value of the life insurance policy. In addition, a viator would enjoy a rescission period after the contract is signed during which the viator could void the transaction.

Companies applying for licences to engage in the viatical settlement business would need to submit, as part of their application, a description of the means by which they intend to prevent and combat fraud. Penalties for violations would include restitution, as well as fines of up to \$100,000 for a first offence and \$200,000 for further offences.

The original submission period for comments on the draft regulations was slated to end in August 2001. However, the FSCO has not yet finalized the regulation.<sup>5</sup> Development of a regulatory regime for viaticals was listed among the top priorities of the FSCO in its annual statements for both 2002 and 2003.<sup>6</sup>

## Concerns about viatical settlements

Under viatical settlements, the sooner the insured dies, the greater the returns for the investor, a fact that has caused these settlements to be viewed negatively by many. Tying profitability to the early death of another human being strikes many people as inherently distasteful. A further salient concern is that terminally ill policyholders will be in a position of vulnerability when transacting with viatical settlement providers (VSPs). The acute emotional duress and potential desperate need for funding that may arise in such circumstances could facilitate unconscionable dealings.

The proliferation of viatical settlements south of the border has been characterized by instances of fraud not only by VSPs and brokers,<sup>7</sup> but also by terminally ill viators. Misconduct at various stages of viaticals transactions has culminated in lost investments, bankrupt VSPs, and numerous arrests and convictions.8 For example, American Benefits and Financial Federated Title and Trust are two related Florida companies that accepted \$115 million from 3000 investors, using only \$6 million of the funding to acquire life insurance policies and pocketing the remainder.<sup>9</sup> The founder of Financial Federated was sentenced to 55 years in prison.<sup>10</sup>

Despite the potential for abuse, however, it should be acknowledged that viatical settlements do provide a valuable option to terminally ill persons for dealing with financial hardships related to their failing health. Properly and ethically implemented, they are instruments that can improve the welfare of all parties involved, making the best of regrettable circumstances.

-Andy Rich

Andy Rich is a graduate of the Faculty of Law at the University of Toronto. He can be contacted at andyrich@siliconinvestor. com.

For a critical evaluation of the regulation and further background information on viaticals, see A Rich. Viatical settlements: the visceral reaction, the existing market, and a framework for regulation (forthcoming in *Queens Law Journal*).

<sup>2</sup> See, eg, CM Ostrom. AIDS crisis gives birth to "death futures" industry. *Journal of Commerce*, 7 March 1994.

<sup>3</sup> RSO 1990, c l.8, s 115.

<sup>4</sup> SO 2000, c 26, Schedule G.

<sup>5</sup> The text accompanying the draft regulation invited the mailing of submissions to the following address: Chief Executive Officer and Superintendent of Financial Services, 5160 Yonge Street, Box 85, North York, Ontario, M29 6L9.

<sup>6</sup> See FSCO. Statement of Priorities, June 2003, at 8, available at www.ontarioinsurance.com/FSCO\_UW\_ MainEngine.nsf()/(71 L828fe9d5067a85256d0800517e07/ \$FILE/SOP-Jan2003.pdf; and, FSCO. Statement of Priorities, June 2002, available at http://fsco.gov.on.ca/ FSCO\_UW\_MainEngine.nsf()/67e62f7a6aaf993885256b eb004a8f8e/\$FILE/FSCO%20Statement%20of%20Priorit ies.pdf.

<sup>7</sup> See T Walsh. "Death future" swindle charge. Boston Herald, 23 October 2000: O27; and R Trigaux. Court closes Clearwater company. St. Petersburg Times, 3 May 1995: I.E.

<sup>8</sup> See Associated Press. Insurance exec sentenced for viatical fraud scheme. *Miami Herald*, 17 July 2003: 7B; and D DuPont. Future First execs jailed. *Miami Herald*. 3 May 2003: 3C.

<sup>9</sup> See H Huntley, Florida viatical dealer indicted. St. Petersburg Times. 11 September 1999: I.E; and US Securities and Exchange Commission. Litigation Release No. 16546, 9 May 2000, available at www.sec.gov/ litigation/litreleases/lr16546.htm; and US Securities and Exchange Commission. Securities Exchange Act of 1934 Release No. 46173, 9 July 2002, available at www.sec.gov/litigation/admin/34-46173.htm.

<sup>10</sup> See H Huntley.Viatical scam prison term: 55 years. St. Petersburg Times, 12 December 2000: I.E.

<sup>&</sup>lt;sup>I</sup> For a description of the regulations, see Financial Services Commission of Ontario. Viatical Settlements in Ontario: Key Elements of a Proposed Regulatory System – Consultation Draft. 13 July 2001. Available at www.ontarioinsurance.com/FSCO\_UW\_MainEngine.nsf/ 0/cd6a9a1e9d4b725085256a8b0054aff6/%24FILE/ viatical-en.pdf.

## Survey reveals knowledge and attitudes of Canadians regarding HIV/AIDS

According to a national survey, almost two out of every three Canadians think the federal government should be spending more to fight HIV/AIDS. The survey also found that: (a) although most Canadians know a lot about HIV/AIDS, there are some significant gaps in their knowledge; and (b) although most Canadians think HIV/AIDS is a serious problem, the vast majority do not consider themselves to be at risk for HIV infection. Few Canadians blame people for contracting HIV through sex or drug use, but many Canadians are still uncomfortable associating with people with HIV/AIDS in certain settings.

In March 2003, Health Canada sponsored a survey of the knowledge and attitudes of Canadians regarding HIV/AIDS.<sup>1</sup> The survey, which was conducted by Ekos Research Associates, asked questions about HIV transmission, perceptions of risk, sexual activity, recent HIV tests, sources of information, attitudes toward people with HIV/AIDS, and support for government involvement in HIV/AIDS.

The survey found that most Canadians think that HIV/AIDS is at least as serious a problem as it was five or ten years ago, if not more so. Almost two-thirds of respondents believe that the federal government should be spending more to fight the epidemic. Despite the fact that most Canadians see HIV/AIDS as a serious issue, less than one in ten classify themselves as being at moderate or high risk for contracting the disease.

Although the survey found that most Canadians were generally very knowledgeable about HIV/AIDS, only six in ten understand that HIV/AIDS is a fatal disease, and nearly one in five erroneously believe that HIV can be cured if treated early. (A study of Canadian youth in schools showed similar results; see following article.) Furthermore, while most people knew that HIV can be transmitted through sexual intercourse, less than half knew that it can also be transmitted by sharing needles. According to the survey, just over one in four Canadians say that they have been tested for HIV.

## Attitudes toward people living with HIV/AIDS

The findings of the survey with respect to the attitudes of Canadians toward people living with HIV/AIDS were mixed. Almost 85 percent of respondents said that they could be friends with someone who has HIV/AIDS, and only one in ten believe that people who are infected with HIV through sex or drug use have gotten what they deserve.<sup>2</sup> But when asked how comfortable they would be with a person with HIV/AIDS in different scenarios, the story is different:

• About 70 percent of Canadians would be somewhat or very comfortable working in an office where someone developed HIV/AIDS, or shopping in a grocery store where they discovered that the owner had HIV/AIDS.<sup>3</sup>

- Only 55 percent of Canadians would be somewhat or very comfortable if their child was attending school where one of the students was known to have HIV/AIDS.<sup>4</sup>
- About 40 percent of Canadians would be somewhat or very comfortable if a close friend or relative were dating someone with HIV/AIDS.
- Only a little over half of Canadians think that people with HIV/AIDS should be allowed to serve the public in positions such as dentists or cooks.

There are demographic variations in these attitudes. Canadians over the age of 65 and those born outside of Canada were less comfortable with the various scenarios in the survey. For all of the scenarios, *except* the one about a close friend or relative dating someone with HIV/AIDS, comfort levels increase with education and income. Women are somewhat more likely to demonstrate a high level of comfort than men (38 percent versus 31 percent).

The survey suggests that a combination of knowledge about HIV/ AIDS and contact with people living with HIV/AIDS helps to reduce

stigma and increase support for people affected by the epidemic. Four in ten Canadians know or have known someone with HIV/AIDS. They are more likely to believe that HIV/AIDS is a serious problem, to rate their knowledge of HIV/AIDS as high, and to be comfortable with HIV/AIDS. They are less likely to distance themselves from the issue. While some people became more cautious and spend less time with a person after they discover that he or she has HIV/AIDS, about as many became more supportive of the person. Those who rate their knowledge as high, and those who actually know more about HIV/AIDS, are less likely to reduce the time they

spend with the person.

Efforts to reduce stigma associated with schizophrenia may hold some important lessons in this regard. A recent review of programs in Canada, Australia, and the United Kingdom suggests that local programs that encourage one-to-one contact with people with schizophrenia are more effective in reducing social distance than broad public education campaigns.<sup>5</sup> We need to understand better the relationships between knowledge, personal contact, and social distance in order to ensure that programs to reduce stigma against people with HIV/AIDS are effective.

- Theodore de Bruyn and David Garmaise

<sup>I</sup> Ekos Research Associates. HIV/AIDS – An Attitudinal Survey. Final Report. 24 June 2003. An executive summary is available at www.hc-sc.gc.ca/hppb/hiv\_aids/pdf/ execsum\_e.pdf. For a copy of the full report, contact Shannon Brunton Stephens at Shannon\_Brunton\_ Stephens@hc-sc.gc.ca.

<sup>2</sup> In contrast, surveys conducted during the 1990s in the United States found that more than one in four respondents blamed people who have contracted HIV through sex or drug use. See GM Herek et al. HIVrelated stigma and knowledge in the United States: prevalence and trends, 1991-1999. *American Journal of Public Health* 2002; 92(3): 371-377.

<sup>3</sup> This percentage is somewhat less than in the United States. See Herek et al, ibid at 372.

<sup>4</sup> This percentage is considerably less than in the United States, where around 70 percent would be somewhat or very comfortable. See Herek et al, ibid at 373.

<sup>5</sup> H Stuart. Stigmatisation. Leçons tirées des programmes visant sa diminution. *Santé mentale au Québec* 2003; 18(1): 54-72.

## National school survey reveals gaps in knowledge of HIV/AIDS

A national survey conducted in 2002 concluded that the sexual knowledge of Canadian students was lower then than it was in 1989 (when the last such study was conducted). The study also found that attitudes toward people living with HIV/AIDS had improved somewhat over the same period. However, the study identified some disturbing trends with respect to bullying. The study's authors call for a greater focus on students' sexual health.

A survey conducted in Canadian schools indicates that there are still serious gaps in young people's knowledge of HIV/AIDS. The Canadian Youth, Sexual Health and HIV/AIDS Study<sup>1</sup> surveyed more than 11,000 students across the country in grades 7, 9, and 11 during the 2002 school year. The study, which was conducted by the Council of Ministers of Education, Canada, an organization established by provincial and territorial ministers of education, was funded by Health Canada. The study was carried out by researchers at Queen's University, the University of Alberta, Acadia University, and Université Laval. The study was designed to provide a contemporary picture of the sexual behaviour of adolescents. This was the first national study of its kind since the Canadian Youth and AIDS Study in 1989.

The 2002 study found that students

generally exhibited lower levels of sexual knowledge than those who participated in the 1989 study. In the 2002 study, two-thirds of grade 7 students and half of grade 9 students did not know that there is no cure for HIV/AIDS. Almost two-thirds of grade 9 students and almost half of grade 11 students thought that there was a vaccine available to prevent HIV infection. Only 40 percent of grade 11 students knew that Vaseline is not a good lubricant.

Although most of the students who participated in the 2002 study said that school provides an important source of sexual and HIV/AIDS information, over half of grade 7 students and about a third of grade 9 and 11 students reported that they had received either none or only one or two hours of instruction about HIV/AIDS over the previous two years.

With respect to attitudes toward people living with HIV/AIDS, the findings were mixed. Just over one in 10 of the respondents in the 2002 study said they could not be friends with a person living with HIV/AIDS, while less than one in 10 thought people living with HIV/AIDS got what they deserved. (This is a slight improvement from the attitudes exhibited at the time of the 1989 study.) However, only about four in 10 respondents in the 2002 study thought that people living with HIV/AIDS should be allowed to serve the public. (This was nevertheless an improvement over the 1989 study where just over three in 10 agreed with this statement.)

High-risk behaviour is significantly linked to anti-social behaviour. The 2002 study identified some disturbing trends with respect to bullying, which is one form of anti-social behaviour. The study found that in the two months that preceded the survey:

- almost half the males and about one-third of the females reported that they had bullied another student;
- between one-quarter and onethird of the students reported that they had been made fun of at least once because of the way they look or talk;
- about one-third of the students said that rumours or mean lies had been spread about them; and
- about one-quarter of the students said that they had experienced

sexual jokes, comments, or gestures.

The researchers concluded that the study's findings reinforce the need for a comprehensive focus on students' sexual health. They argued that the focus should go beyond examining the knowledge, attitudes, and behaviour of youth, and explore: (a) the contexts in which they engage in sexual activities; and (b) the belief systems that inform both positive and negative actions. The authors asserted that there is a continuing need to ensure that sexual health services are targeted toward the people who need them most. Finally, the authors stated that policymakers and implementers across Canada within local, regional, provincial, territorial, and national governments need to take the lead in ensuring that Canadian adolescents have access to education, information, services, and communities that will enable them to develop into sexually healthy adults.

– David Garmaise

<sup>&</sup>lt;sup>1</sup> Council of Ministers of Education, Canada. Canadian Youth, Sexual Health and HIV/AIDS Study: Factors influencing knowledge, attitudes and behaviours. 2003. Available at www.cmec.ca/publications/aids/.

# **INTERNATIONAL NEWS**

This section provides brief reports on developments in HIV/AIDSrelated law and policy outside Canada. We welcome information about new developments for future issues of the *Review*. Address correspondence to David Garmaise, Managing Editor of the *Review*, at dgarmaise@rogers.com.

## UNGASS review: reports show little progress on human rights

Reports tabled at the second annual United Nations General Assembly debate on the implementation of the Declaration of Commitment on HIV/AIDS suggest that not a lot of progress has been achieved and that many countries will not meet the commitments listed in the Declaration for the year 2003. The one-day session was overshadowed by the fight against terrorism. NGO participation was minimal.

The world must look on this epidemic as a colossal risk that threatens humanity and demands a safety strategy on a world scale. That is one of the most striking examples of the need to coordinate our political guidelines and to take concrete measures, not unilaterally but in solidarity. The international political agenda, while concerned – and understandably so – with the fight against armed terrorism, cannot forget this other source of terror for the large number of people who, every single day, are killed or reduced to misery and pain by the HIV/AIDS epidemic. <sup>1</sup>

#### United Nations General Assembly

On 22 September 2003, the United Nations (UN) General Assembly commenced its 58<sup>th</sup> session at the

UN headquarters in New York with a discussion of the status of, and the response to, the global AIDS epidemic. In particular, the meeting sought to review the global progress in implementing the promises set out in the resolution of the 2001 UN General Assembly Special Session (UNGASS) on HIV/AIDS, known as the Declaration of Commitment on HIV/AIDS.<sup>2</sup>

This meeting was especially important because the 2002 session of the General Assembly devoted to the issue did not consider it in any depth, and because 2003 is the year in which the first time-bound targets set out in the Declaration of Commitment fall due. In the General Assembly, the day was taken up with short speeches from heads of state and national representatives (over 130 were listed to speak when the morning session opened). Meanwhile, parallel events, some open to NGO delegates, were conducted in other parts of the UN building.

The timing of the meeting was auspicious, as the following day the General Assembly was set to debate international terrorism. The agenda for that day included an address by United States President George W Bush, which may have accounted for the relatively large number of heads of state attending the meeting on HIV/AIDS. Unfortunately, media attention appeared distracted by the terrorism agenda - including the bomb attack outside the UN building in Baghdad on the morning the General Assembly session on HIV/AIDS opened.

A review of the morning's statements to the General Assembly by the heads of state and other national representatives revealed few concrete national achievements since 2001.<sup>3</sup> While many representatives noted the importance of access to treatment, the central importance of engaging people living with HIV/AIDS and vulnerable groups in the national response received scant attention. Many speakers welcomed the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria and the consequent mobilization of resources. Encouragingly, the Minister of Health of Mexico noted that its Congress had passed a law prohibiting all forms of discrimination, including discrimination relating to sexual orientation and health conditions in general and discrimination against people living with HIV/AIDS in particular. However, few others mentioned the Declaration of Commitment, let alone took the trouble to note whether their own nations were likely to meet the 2003

targets. The day continued pro forma, with short speeches continuing well into the evening.

Civil society must be held accountable for its failure to demand greater engagement in the events.

#### **NGO** participation

Unlike at the 2001 General Assembly Special Session, there was hardly any useful role for NGOs at the 58th session in September 2003. The fact that NGOs were largely absent can be partly attributed to poor communications between the Joint United Nations Programme on HIV/AIDS (UNAIDS) Secretariat and the NGOs officially accredited to the UN through the Economic and Social Council (ECOSOC). It can also be partly attributed, and this is perhaps of more fundamental concern, to an apparent lack of engagement by ECOSOC-accredited NGOs in working on HIV/AIDS at the UN level.

The day before the 58<sup>th</sup> session commenced, UNAIDS, working with the African Services Committee, convened a meeting of NGOs at UNICEF House to brief them on the high-level session and related issues. Peter Piot, UNAIDS Executive Director, noted that although there were expected to be over 20 heads of state attending the meeting, heads of state from Asian countries were notably absent. Paolo Teixera, recently appointed head of the HIV/AIDS, TB and Malaria Unit at the World Health Organization (WHO), presented the emergency plan to treat three million people in developing countries by 2005. He noted the challenges involved and spoke frankly of the need for civil society support in this endeavor. Jim Kim, Special Advisor to the WHO Secretary-General, also spoke and took questions from the NGOs present.

The meeting was poorly attended by NGOs, although it was an excellent opportunity for NGO representatives to meet key UN leaders in an informal setting and to question them on key aspects of the UN response and the UNGASS process itself. The UNAIDS Secretariat had failed to use the Conference of NGOs (CONGO) network to publicize the meeting and hence engage hundreds of the NGOs most active in the UN system on HIV/AIDS and related issues such as women, children, peace, and development. Nonetheless, the meeting was advertised through other channels, so civil society must also be held accountable for its failure to demand greater engagement in the events.

Unlike the 2001 Special Session, there was no provision at the 58th session for civil society representatives to address the General Assembly during the debate on HIV/AIDS. In order to include the voices of civil society in the events of the day, a separate event, an "informal interactive panel," was convened in the afternoon.<sup>4</sup> Fifteen representatives of international, national, or community organizations (including those representing and working for people living with HIV/AIDS) and the private sector (including pharmaceutical companies) were invited. The event, chaired by the Secretary-General, was very formal. While the panel was asked to reflect on a number of key questions, most speakers read prepared speeches which appeared to bear little relation

to either the questions posed or what had been said before. Three NGO representatives had the opportunity to speak. It is hard to assess the value and impact of the panel session, although a UN press release on the panel issued the same day usefully noted that combating stigma, civil society participation, and resource mobilization were identified by the panelists as keys to reversing the spread of HIV/AIDS.

The US government still maintains its travel ban on short-term visitors with HIV/AIDS. In 2001, a complicated and unsatisfactory temporary waiver system was belatedly introduced to allow the entry of "aliens" living with HIV/AIDS to attend the Special Session. No such arrangements were advertised for the 58<sup>th</sup> session, so this likely discouraged meaningful NGO participation in the event from outside the US.

In response to the above, the CONGO Deputy President, Leslie Wright, has proposed the formation of an HIV/AIDS Committee to bring together CONGO members (ie, UNaccredited NGOs) to work together to ensure that HIV/AIDS is addressed squarely by the UN system.<sup>5</sup> CONGO already has committees of members focusing on issues such as human rights, women, children, and development. The HIV/AIDS Committee would presumably include not only the CONGO member organizations with an HIV/AIDS mandate, currently the International Council of AIDS Service Organizations and the Canadian HIV/AIDS Legal Network, but also organizations working on HIV/AIDS-related issues such as women's and children's rights, health, and development. One task for such a committee would be to work toward meaningful engagement of NGOs and civil society at future such meetings.

This should include promoting the inclusion of civil society representatives and people living with HIV/ AIDS in national delegations.<sup>6</sup>

#### Country reports on the implementation of the Declaration of Commitment

Monitoring the implementation of the UNGASS commitments is key to the expanded global response to HIV/ AIDS, and UNAIDS has developed

"Fewer than one in four people at risk of infection are able to obtain basic information regarding HIV/AIDS."

core indicators by which to measure the implementation of these commitments.<sup>7</sup> The practice has evolved that every year the Secretary-General requests UN members to report by around May on steps taken to implement their UNGASS commitments, and these responses are compiled into a short report to the General Assembly that is debated sometime in September. It should be kept in mind, therefore, that the information in the 2003 reports relates mostly to the country situations in 2002 and early 2003.

The Secretary-General's report to the 58<sup>th</sup> session, based on responses obtained from 100 UN member states, noted soberly that:

Despite the growth in political commitment and resources for HIV/AIDS, globally it is estimated that: (a) Fewer than one in four people at risk of infection are able to obtain basic informa-

tion regarding HIV/AIDS; (b) Only one in nine people seeking to know their HIV serostatus have access to voluntary counseling and testing services; (c) Less than one in 20 pregnant women presenting for antenatal care are able to access services to prevent mother-to-child transmission of the virus; (d) Less than 5 per cent of those who could benefit from anti-retroviral treatment are currently able to access such treatment; (e) In the majority of countries where the sharing of equipment among injecting drug users is a major mode of HIV transmission, coverage for prevention and treatment programmes for drug users is under 5 per cent.<sup>8</sup>

The report tempers the catalogue of failure and inaction with some good news, notably in the areas of political commitment, access to essential services, and resource mobilization. However, noting that "several" UN member states risk falling short of the commitments for 2003 agreed to in the Declaration (in fact, the vast majority will fail at some level to meet these commitments), the report urges countries to immediately assess their national policies and accelerate the development and implementation of the policies necessary to both meet their commitments and stem the spread and impact of HIV/AIDS.9

In 2003, UNAIDS took the bold step of putting every national government report on its website. By doing so, UNAIDS has empowered national and international organizations worldwide to review governments' annual official submissions to the UN on their implementation of the UNGASS commitments. While the information presented is very useful, about 80 countries (ie, more than two in five) did not file reports, including many of the countries where human rights are least respected and people are most vulnerable to HIV/AIDS.

### UNAIDS report analyzing the global situation and country reports

In 2003, UNAIDS issued a report containing a detailed analysis of the over 100 country reports it received on the implementation of the Declaration of Commitment.<sup>10</sup> The UNAIDS report also draws on other sources to provide further information and analysis of global trends.

The UNAIDS report continues the unfortunate approach adopted in the Declaration of Commitment of assigning human rights as a sub-component of the national response, rather than viewing all aspects of the epidemic from a rights-based perspective. Hence, the section on human rights addresses discrimination and prevention, but not care and support (which is addressed in a separate section).

Regarding laws and regulations that protect people living with HIV/AIDS from discrimination, the UNAIDS report notes that only 62 percent of countries responding to the survey stated they have legal measures in place to protect people living with HIV/AIDS from discrimination. This may overstate the official commitment to eradicate HIV-related stigma and discrimination: some countries rely on general anti-discrimination provisions, while awareness may be low and enforcement inadequate.

The situation appears even worse for vulnerable populations, with only about one-third of country respondents indicating that measures to prohibit discrimination were in place. Even this figure seems high: the UNAIDS report does not indicate which vulnerable groups countries were claiming to protect. The UNAIDS report notes that officially sanctioned discrimination continues in many parts of the world, and that punitive legislative frameworks continue to impede access to

Only about one-third of country respondents indicated that measures to prohibit discrimination against vulnerable populations were in place.

treatment and services. The report lists countries where progress has apparently been made, citing Benin, Côte d'Ivoire, and Senegal for their work with sex workers, and Brazil for outlawing discrimination on the basis of sexual orientation.

Consistent with UN style, the UNAIDS report does not name and shame countries that have made little or no progress. Much of the value of the monitoring and reporting will emerge in subsequent years, because the indicators developed by UNAIDS will be used not only to compare countries and regions, but also to monitor the national response over time.

Yet the UNAIDS report can only be as good as the data on which it is based and, as Roseman and Gruskin have noted, the indicators developed by UNAIDS are inadequate. Human rights-sensitive indicators should be established for each section of the Declaration, and the rights to non-discrimination, equality, and participation should be given explicit attention in relation to the monitoring and evaluation of all HIV/AIDS-related efforts.<sup>11</sup> Further, the accuracy and completeness of country reports cannot be taken for granted, particularly as competition for Global Fund grants increases and countries must be increasingly ranked in terms of their suitability for funding. Civil society involvement in, and monitoring of, country reports is one way of encouraging governments to keep the reporting accurate and complete.

### Looking to the future

When the idea of a UN Special Session on HIV/AIDS was first proposed by the French government, there was much skepticism about the value of yet another large and costly international meeting at a time when the focus of attention was increasingly directed to country-level activities. The UNGASS Declaration of Commitment will only have value if it results in substantial improvement in responses to HIV/AIDS in countries and communities most vulnerable and affected.

The Declaration provides civil society with opportunities for advocacy on substantive issues such as law and policy reform, care and treatment, and stigma. Since 2001, civil society has promoted the Declaration at the global, regional, and national level. For example, the International Council of AIDS Service Organizations has produced advocacy tools to assist communities to use the Declaration to achieve change,<sup>12</sup> and the Asia Pacific Council of AIDS Service Organizations has produced a training workshop module to help community-based organizations to advocate for better responses to HIV and AIDS.13

Although the Declaration of Commitment reflects the Millennium Development Goal to combat HIV/ AIDS, malaria, and other diseases,<sup>14</sup> for the most part HIV/AIDS issues remained outside the mainstream debates on women, children, human rights, population, and development during the 1990s. This cannot continue. We must now consider how HIV/AIDS issues can be better mainstreamed into these other important and related agendas.

In 2004, the General Assembly will again debate HIV/AIDS, and will decide when to hold its 2005 session on HIV/AIDS and what format to use for that event. At issue is whether a separate event will be held, or whether it will in some way be incorporated into the other major reviews of that year. There would be definite advantages, from the civil society point of view at least, if the meeting could be scheduled around related meetings, such as the proposed 5<sup>th</sup> High Level UN Conference on Women. In the interim, UNAIDS should review and strengthen its UNGASS human rights indicators, and work with countries to make the implementation of the UNGASS commitments on human rights a larger priority.

– David Patterson

David Patterson is a health, law, and human rights consultant based in Montréal. He can be reached at david.patterson@videotron.ca.

<sup>2</sup> Information and documentation is available via the UNAIDS website at www.unaids.org/en/events/ un+special+session+on+hiv\_aids.asp.

<sup>3</sup> Official Record, General Assembly, 58<sup>th</sup> session, 3<sup>rd</sup> plenary meeting, 22 September 2003 (A/58/PV.3).

<sup>4</sup> Resolution 57/299, 20 December 2002.

<sup>5</sup> For further information, contact Leslie Wright at congovp@yahoo.com.

<sup>6</sup> As in 2001, the Canadian delegation included civil society representation, and a person living with HIV/AIDS.

<sup>7</sup> Monitoring the Declaration of Commitment on HIV/AIDS: Guidelines on Construction of Core Indicators, UNAIDS, 2002. See also M Roseman, S Gruskin. The UNGASS Declaration of Commitment on HIV/AIDS: one year later: *Canadian HIV/AIDS Policy & Law Review* 2003; 8(1):1, 7-14.

<sup>8</sup> Progress towards implementation of the Declaration of Commitment on HIV/AIDS: Report of the Secretary-General. UNGA 58<sup>th</sup> session, A/58/184. Available at www.unaids.org/en/events/un+special+session+on+hiv\_ aids/follow+up+to+the+2001+un+special+session+on+ hiv\_aids+-+september+2003.asp.

<sup>9</sup> For regional initiatives in the Caribbean, see: Caribbean nations hold first training workshop on AIDS laws and policies. *Canadian HIV/AIDS Policy & Law Review* 2003; 8(2): 33-34.

<sup>10</sup> Progress Report on the Global Response to the HIV/AIDS Epidemic, 2003 (Follow up to the 2001 United Nations General Assembly Special Session on HIV/AIDS). UNAIDS, 2003. See supra, note 8, for the website link.

<sup>11</sup> Roseman & Gruskin, supra, note 7 at 12.

<sup>12</sup> Advocacy Guide to the Declaration of Commitment on HIVIAIDS (English, French, Spanish); Update on the Declaration of Commitment on HIVIAIDS. International Council of AIDS Service Organizations. Available in English, French, Spanish via www.icaso.org.

<sup>13</sup> Making UNGASS Work, Asia Pacific Council of AIDS Service Organizations. Undated. Available via www. apcaso.org.

<sup>14</sup> In September 2000, at the United Nations Millennium Summit, world leaders agreed to a set of time-bound and measurable goals and targets for combating poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. Placed at the heart of the global agenda, they are now called the Millennium Development Goals (MDGs). See www.un.org/ millenniumgoals.

# AIDS Law Project receives AIDS and human rights award

The AIDS Law Project, the recipient of the 2<sup>nd</sup> Annual International Award for Action on HIV/AIDS and Human Rights, has been at the forefront of the struggle for human rights for people living with HIV/AIDS in South Africa. It has played a major role in convincing the South African government to implement a national HIV treatment plan.

The AIDS Law Project, South Africa (ALP) has received the 2<sup>nd</sup> International Award for Action on HIV/AIDS and Human Rights. The award was formally presented by the Canadian HIV/AIDS Legal Network and Human Rights Watch at the Annual General Meeting of the Legal Network in Montréal, Québec, in September 2003.<sup>1</sup>

The ALP has been on the frontlines of the battle for the rights of people with AIDS in South Africa to access antiretroviral drugs. It co-founded the Treatment Action Campaign (TAC), which is chaired by Zackie Achmat, a former ALP director. The ALP and TAC led a coalition that took the South African government to court in 2002, and that resulted in a ruling requiring the provision of antiretroviral drugs to pregnant women for the prevention of mother-to-child HIV transmission. TAC and the ALP were also lead players in the grassroots movement that led to the recent announcement by the South African government that it would roll out an antiretroviral treatment plan for the public sector, after years of resisting the very idea of treatment for AIDS.

<sup>&</sup>lt;sup>1</sup> His Excellency Mr Jorge Fernando Branco de Sampaio, President of the Portuguese Republic, 22 September 2003. Address to the United Nations General Assembly on 22 September 2003.

"The work of the ALP and the Treatment Action Campaign together has galvanized and inspired the global treatment access movement," said Joanne Csete, director of the HIV/ AIDS Program at Human Rights Watch.<sup>2</sup>

The ALP also does critical work day in and day out, work such as helping people living with HIV/ AIDS fight discrimination; helping women who face domestic violence and sexual abuse bring complaints against the perpetrators of these acts; helping women and children who survive sexual violence obtain drugs to prevent HIV transmission; helping dying patients ensure that their children will be able to inherit property; and dealing with the discrimination and persecution of gay and bisexual men and lesbians.

"[The] ALP's outstanding leadership addresses both the AIDS epidemic and the epidemic of human rights abuse that fuels AIDS in Africa and other parts of the world," Csete said . "[The] ALP won't rest until people with AIDS in South Africa and those at risk can live in dignity."<sup>3</sup>

In accepting the award, Liesl Gerntholz, Head of the Legal Unit of the ALP, said that the announcement of the antiretroviral treatment plan has given treatment activists hope for the first time in a long time. However, she said that with these new developments will come new challenges, and that the ALP has to start examining more closely issues around stigma and discrimination and the impact they will have on people's ability to access treatments. For example, Gerntholz said, the increasing number of orphans raises issues of legal guardianship and who can give consent for the children to be tested for HIV and to receive treatment. As well, she said that if an antiretroviral registry were established to assist in the monitoring of treatment, privacy and confidentiality issues would be raised.<sup>4</sup>

The first International Award for Action on HIV/AIDS and Human Rights was presented in 2002 to Dr Wan Yanhai, a Chinese physician and activist.<sup>5</sup>

– David Garmaise

<sup>2</sup> Taking Action on Stigma and Discrimination: Presentations Made on the Occasion of the Canadian HIV/AIDS Legal Network Annual General Meeting and Skills Building Workshops, 12-14 September 2003, Montréal. P. 16. Available at www.aidslaw.ca/Maincontent/events/ agm2003.htm.

<sup>3</sup> Canadian HIV/AIDS Legal Network and Human Rights Watch. Canadian prisoner and AIDS Law Project of South Africa receive human rights awards. Press release, 12 September 2003. Available at http://aidslaw. ca/Media/press-releases/e-press-sept1203.pdf.

<sup>5</sup> See T Kerr, T Haig, The 1<sup>st</sup> Annual Awards for Action on HIV/AIDS and Human Rights. *Canadian HIV/AIDS Policy & Law Review* 2002; 7(2/3): 1, 20-3.

### International Guidelines audit tool tested in Cambodia

Until mid-2003, the audit tool developed at the Australian National University to measure compliance with the International Guidelines on HIV/AIDS and Human Rights had not been tested in a developing country. This article describes the process and preliminary findings from the application of the audit in Cambodia. Of particular interest was the willingness of the Cambodian government to permit the audit, as well as the publication and dissemination of the results.

In July 2003, Dr Helen Watchirs from the Research School of Social Sciences at the Australian National University, and the author conducted an audit of the Cambodian legal system against the standards contained in the International Guidelines on HIV/AIDS and Human Rights.<sup>1</sup> They used an audit tool developed several years ago by Dr Watchirs.<sup>2</sup> The tool is designed to identify features of the legal system that assist or hinder the effectiveness of a country's response to HIV/AIDS, and indicate where reforms are needed.

In addition to conducting an audit of the legal system, Dr Watchirs also

<sup>&</sup>lt;sup>I</sup> Each year the Canadian HIV/AIDS Legal Network and Human Rights Watch present awards to one Canadian and one international individual or organization to highlight outstanding work done to decrease vulnerability to HIV/AIDS and to protect the rights and dignity of those infected and affected. The awards are co-sponsored by the International Harm Reduction Program, the Hilda Mullen Foundation, and Mark Gallop. Additional information about the awards and the 2003 recipients is available at www.aidslaw.ca/Maincontent/Jawards.htm.

<sup>&</sup>lt;sup>4</sup> Supra, note 2 at 19-20.

worked with The POLICY Project to develop a new version of the audit tool. Dr Watchirs had developed and applied an audit tool in several state and territory jurisdictions in Australia, in collaboration with the Australian Federation of AIDS Organisations. However, it became apparent that there was a need for a different version of the audit tool that recognized the realities of constraints in resource-poor settings, and the need for the progressive realization of rights.

Dr Watchirs wrote a draft audit report on the Cambodian legal system, using the new version of the audit questionnaire. Consultations were held in Cambodia through a series of face-to-face meetings with key informants, and through a daylong meeting in July 2003. This meeting was attended by 26 people representing the National AIDS Authority, government ministries and authorities, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the International Labour Organization, the Cambodian Human Rights and HIV/AIDS Network, the Network of Sex Worker Projects, and other stakeholders. The opening address to the meeting was given by His Excellency Professor Ly Po, Secretary of State, and Vice Chairman of the National AIDS Authority.

At the consultations and the oneday meeting, information was sought on the accuracy of the legal research in the draft audit report, how the Cambodian legal system operates in practice (and, in particular, where there are gaps between law and practice), and the relevance of the audit questionnaire: was it asking the right questions about the Cambodian legal system, and the impact of the legal system on Cambodia's response to HIV/AIDS? These issues are determined in part by the content of the International Guidelines, but also by the characteristics of the epidemic and the legal system in the jurisdiction being audited.

### **Preliminary findings**

Some of the preliminary findings from the audit are as follows:

- Although there are strong statements regarding the human rights of people living with HIV/AIDS in Cambodia's laws on the prevention and control of HIV/AIDS, such as the rights of non-discrimination and confidentiality, there is no agency with responsibility for monitoring and enforcing respect for these rights.
- Pre-employment HIV screening of workers, although prohibited by law, is occurring, and workers who test positive are refused employment.
- Although the sex industry is illegal, health and safety standards are to some extent regulated for one sector of the industry (brothels) by the Cambodian government through its 100% Condom Use Program (CUP). The CUP involves significant breaches of sex workers' human rights, which breaches are objectionable per se, and may also undermine program integrity.
- Sex between men is not criminalized but it is highly stigmatized. Sentinel HIV surveillance suggests that the HIV prevalence rate in men who have sex with men is more than four times higher than the prevalence rate in the general population.
- There are restrictions on the rights to freedom of movement

and assembly of vulnerable populations. An example of this was the refusal of the Cambodian government to issue a permit for a planned march to the National Assembly in May 2003 to commemorate victims of domestic violence.

- Patent legislation enacted in preparation for Cambodia's ascension to full membership of the World Trade Organization (WTO) will facilitate access to antiretroviral treatment in Cambodia, because it enables Cambodia to take advantage of all of the special provisions for least-developed countries contained in the Declaration on TRIPS and Public Health.<sup>3</sup>
- The most important issues for Cambodian prisoners are overcrowding, access to medical treatment, and access to food and water. This is an area where the gap between developed and developing countries was particularly obvious. The audit tool needs to reflect these differences if it is to be useful for developing countries. Issues that the audit tool examined in Australia - such as mandatory HIV testing, segregation of HIV-positive prisoners, denial of privileges to HIV-positive prisoners, access to condoms and sterile injecting equipment, and protection from rape and other forms of sexual violence are less relevant where the conditions in which prisoners are accommodated are so poor that their main priority is to avoid death from malnutrition or infectious diseases such as tuberculosis.
- The legal requirement to obtain voluntary and informed written

consent to HIV testing is breached in hospitals, where secret testing of patients occurs. Although there is a scheme that requires health-care facilities performing HIV testing to be accredited by the government, it is essentially voluntary because there are no penalties for noncompliance.

In addition to disseminating the findings of the audit, The POLICY Project Cambodia will develop a law reform advocacy agenda based on these findings. The POLICY Project will also disseminate information about the new version of the audit tool and the audit process in order to encourage their use in other countries.

– Chris Ward

Chris Ward is Senior Technical Advisor on HIV/AIDS and Human Rights for The POLICY Project Cambodia. He can be reached at cward@bigpond.com.kh. Further information can also be obtained from Helen Watchirs at watchirs@ coombs.anu.edu.au. on HIV/AIDS. HIV/AIDS and Human Rights: International Guidelines. Second International Consultation on HIV/AIDS and Human Rights, Geneva, 23-25 September 1996. New York and Geneva: United Nations, 1998. Available at www.unhchr.ch/hiv/ guidelines.htm.

<sup>2</sup> See H Watchirs. Measuring legal implementation of the International Guidelines on HIV/AIDS and Human Rights. *Canadian HIV/AIDS Policy & Law Review* 2001; 6(1/2): 29-31; also: Legislative initiatives in the Asia Pacific region. *Canadian HIV/AIDS Policy & Law Review* 2002; 7(2/3):44-45; also: Australian workshop puts auditing in perspective: regulatory tool, moribund remedy, or democratic champion? *Canadian HIV/AIDS Policy & Law Review* 2003; 8(1):36-37.

<sup>3</sup> The Declaration, which was adopted at the WTO Ministerial Conference in Doha in November 2001, deals with access to affordable medicines. Available at www.wto.org/english/thewto\_e/minist\_e/min01\_e/ mindecl\_trips\_e.htm. See also: R Elliott. WTO Ministerial Conference adopts Declaration on TRIPS and Public Health. *Canadian HIV/AIDS Policy & Law Review* 2002; 6(3): 50-52.

### **Nigeria launches new AIDS policy**

A new national policy on HIV/AIDS in Nigeria prohibits mandatory HIV/AIDS testing and addresses a number of other human rights and ethical issues. Activists welcome the new policy, but they point out that it is not legally enforceable. What is needed, they say, is for the government to introduce anti-discrimination legislation.

In August 2003, President Obasanjo of Nigeria launched a new national policy on HIV/AIDS. The former policy was considered outdated and not in conformity with recent developments on HIV/AIDS in the country. There are believed to be about 3.5 million people living with HIV/AIDS in Nigeria. Many of these people are subjected to various forms of human rights violations. The new policy contains important provisions to address the human rights and ethical issues raised by the epidemic in the workplace, health-care institutions, and the community as whole.

Some of the provisions of the new policy relate to the prohibition of

mandatory HIV/AIDS testing for any reason. The policy further states that testing will only be carried out with the informed consent of the patient. The policy provides generally that no one shall be discriminated against by reason of his or her HIV status and, in particular, makes it unlawful for health-care workers to refuse medical attention to anyone on the basis of his or her HIV/AIDS status.

The policy recognizes the importance of preventive programs on HIV/AIDS, and also emphasizes that caring for people already infected is equally important. The policy states that any clinical research on HIV/ AIDS should be done in accordance with international rules and standards, and that the human rights of trial subjects shall be respected.

According to the new policy, the federal government will do all that is possible to ensure the enactment of appropriate legislation on HIV/AIDS in the country. The policy recognizes the need for anti-discrimination legislation to protect the rights of people living with HIV/AIDS. The policy also contains provisions on voluntary testing and counselling (VTC), and recognizes the importance of VTC in curbing the spread of HIV/AIDS. It recommends the establishment of VTC centres across the country, which people should be encouraged to

<sup>&</sup>lt;sup>1</sup> Office of the United Nations High Commissioner for Human Rights and the Joint United Nations Programme

visit to ascertain their HIV status.

The new policy replaces the 1997 policy on HIV/AIDS in Nigeria. While activists have commended the new policy, they have reminded the government that a policy is merely a guideline that is not legally enforceable. They have said that the government should, without delay, enact anti-discrimination legislation in Nigeria to address the stigma and discrimination that people living with HIV/AIDS encounter daily across the country. Ebenezer Durojaye is a staff attorney at the Center for the Right to Health, Lagos, Nigeria. He can be reached at ebenezer1170@yahoo.com or crhaids@yahoo.com.

– Ebenezer Durojaye

# ABC approach not enough, reports show

Reports released recently by Human Rights Watch reveal that many women in Africa remain extremely vulnerable to HIV infection because of the violence practised against them, and because of legal systems that do not take the issue of violence seriously or that discriminate against women.

The "ABC" approach to HIV prevention - Abstinence, Be Faithful, Use Condoms - has attracted renewed attention in the last year as the United States (US) and other donors have committed greater resources to addressing the global AIDS epidemic. ABC, which discusses abstinence as well as condom use as effective means of HIV prevention, is often cited as one reason why Uganda showed some success in reducing HIV prevalence early in the epidemic. Now ABC is under attack as conservatives in the US government try to promote "abstinence only" approaches to HIV prevention. Senior members of the Bush administration have misleadingly referred to ABC as "the abstinence approach" or have argued that the secret behind Uganda's lower HIV transmission rates is abstinence. Anne Peterson, the director of global health for the US Agency for International Development (USAID), told the *Washington Times* in March 2003 that "the core of Uganda's success story is big A, big B and little c."<sup>1</sup>

The irony is that ABC is only the beginning of a comprehensive response to HIV. According to a recent Human Rights Watch report on HIV/AIDS in Uganda,<sup>2</sup> women who have access to condoms remain vulnerable to HIV/AIDS as a result of epidemic levels of domestic violence and a legal system that fails to take violence against women seriously. Many women say that they cannot refuse sex or negotiate safer sex for fear that their husbands will beat or rape them. Marital rape is not considered a crime in Uganda, and biased police and justice officials further undermine access to redress by sexual and domestic violence survivors. Fear of violence prevents women from obtaining HIV/AIDS information,

from testing for HIV infection, from receiving counselling, and from obtaining AIDS treatment.

Indeed, according to a multi-country report on gender and HIV/AIDS released by Human Rights Watch on World AIDS Day 2003,<sup>3</sup> African women who are married or in longterm unions, and who remain faithful to their husbands, are among those at highest risk of HIV infection. In Kenya, for example, unequal property rights upon separation or divorce discourage women from leaving violent marriages. In many cases, other forms of violence, such as abandonment or eviction (which are often accompanied by physical violence), hold even greater terror for economically dependent women who, confronted by a hostile social environment, ignore their husbands' adultery and acquiesce in their husbands' demands for unprotected sex.

African women and girls face violence and discrimination not only in marriage, but at all stages of life - as children in school or, as is increasingly the situation of girls affected by HIV/AIDS, out of school; as adults, in long-term unions where decisionmaking authority over sex is too rarely theirs, and where economic dependence and inequality under the law limit their options for redress; in widowhood, where gender discrimination is the rule rather than the exception for inheritance and control of property; and in war and civil conflict, where rape is used strategically

as a weapon. All these human rights abuses increase their vulnerability to HIV infection.

Governments must address these abuses as a central part of strategies to fight HIV/AIDS. Urgent action must be taken to reform laws and policies to improve protections against sexual and domestic violence, eliminate gender inequities in property and divorce rights, and ensure equal access to health and education services. This may not be as easy as ABC, but it is one lesson that must be learned quickly. Rebecca Schleifer is a researcher with the HIV/AIDS and Human Rights Program at Human Rights Watch. She can be reached at schleir@hrw.org.

<sup>2</sup> Human Rights Watch. Just Die Quietly: Domestic Violence and Women's Vulnerability to HIV in Uganda. August 2003. Available at www.hrw.org/reports/ 2003/uganda0803/.

<sup>3</sup> Human Rights Watch. Policy Paralysis: A Call for Action on HIV/AIDS-Related Human Rights Abuses Against Women and Girls in Africa. December 2003. Available via www.hrw.org/reports/2003/africa1203/.

– Rebecca Schleifer

## New report profiles syringe access in California

A case study conducted by Human Rights Watch in California reveals that counties have to declare a local health emergency if they want to set up a needle exchange program. Even where such programs have been established, police harrassment of the needle exchange clients is widespread.

For better or worse, the United States (US) is often looked to for leadership in preventing HIV/AIDS. The rapid spread of HIV/AIDS in the former Soviet Union and Eastern Europe, driven largely by a growing epidemic of injection drug use, has necessitated a search for models of how to prevent HIV transmission among injection drug users. Unlike much of the Commonwealth and western Europe, the US has shown little leadership on this issue. Programs that provide sterile syringes to injection drug users, such as needle exchange, remain relatively few in the US, totally unsupported by the federal government, and in many cases forbidden by state law.

In September 2003, Human Rights Watch (HRW) released a case study of sterile syringe programs in California.<sup>1</sup> California is typical of US states in that it prohibits the possession of syringes (sterile or used) as "drug paraphernalia." While some counties in California allow needle exchange programs, they are only permitted to do so if they declare a "local health emergency" due to a critical injectiondriven HIV/AIDS epidemic. Even in those counties that have made this declaration, possession of syringes remains a misdemeanor offence. This places injection drug users in a classic Catch-22 situation, whereby they have access to legal needle exchange programs in some counties, but state law forbids them from possessing syringes.

Interviews with nearly 70 injection drug users in California showed that police frequently use their discretion

<sup>&</sup>lt;sup>1</sup> T Carter: Uganda leads by example on AIDS; emphasis on abstinence or fidelity slashes infection rate. *Washington Times*, 13 March 2003: A13.

to stop, arrest, and search clients of legal needle exchange programs, and to confiscate their syringes. This is particularly true among injection drug users who experience constant encounters with the police: sex workers, probationers and parolees (who can be stopped and searched at any time), the homeless, and people in sparsely populated rural areas. Many injection drug users told the HRW that they feared using needle exchange services because they did not want to go to jail. "I'm more afraid of carrying syringes than sharing them," one said. Another, a homeless woman in San Francisco, said, "Getting needles is not a problem. Keeping them is the problem."

The situation in counties that have not legalized needle exchange is especially dire. Here, some injection drug users reported reusing syringes so many times they had become dulled beyond usefulness. While underground needle exchange services had been established in some cases, volunteers worked under the constant risk of arrest. In 2002, Sacramento County became the first jurisdiction in California to convict a lay syringe exchanger of unauthorized possession of hypodermic syringes. This volunteer is now on probation and faces a jail sentence if she continues to exchange needles. A similar case is pending in Lake County, a rural county just north of Sacramento.

Interference with needle exchange is a national problem in the US. Since 1988, the US government has refused to fund needle exchange program services, claiming that these programs encourage drug use. President George W Bush has described needle exchange as "an abdication."<sup>2</sup> Funding for needle exchange research has also come under attack as extreme members of the religious right have urged members of Congress to review grants to needle exchange researchers from the National Institutes of Health.<sup>3</sup>

– Jonathan Cohen

Jonathan Cohen is a researcher with the HIV/AIDS and Human Rights Program at Human Rights Watch. He can be reached at cohenj@hrw.org.

<sup>&</sup>lt;sup>1</sup> Human Rights Watch. Injecting Reason: Human Rights and HIV Prevention for Injection Drug Users: California: A Case Study. September 2003. Available at www. hrw.org/reports/2003/usa0903/.

<sup>&</sup>lt;sup>2</sup> Response of Governor George W. Bush to the AIDS Foundation of Chicago. Available at www.aidschicago. org/pdf/candidate\_gwb.pdf (accessed 17 November 2003).

<sup>&</sup>lt;sup>3</sup> See, for example, NIH questions researchers on AIDS grant. *Los Angeles Times*, 28 October 2003.

# **HIV/AIDS IN PRISONS**

This section of the Review addresses issues related to HIV/AIDS in prisons. For more information, contact Ralf Jürgens, Executive Director of the Canadian HIV/AIDS Legal Network, at ralfj@aidslaw.ca.

We begin with a report on an important, precedent-setting case in which, for the first time ever, a Canadian court has ordered that a prisoner be provided with methadone maintenance treatment (MMT) during his or her period of incarceration. We then summarize the results of an Australian study that has demonstrated that providing MMT in prisons not only has a positive impact on release outcome and on institutional behaviour (as previously shown by a Canadian study), but also reduces drug use and injection in prisons. Finally, we report on an Australian discussion paper on needle exchange in prisons. This will be the main focus of the section on HIV/AIDS in prisons of the next issue of the Review, which will contain an overview of prison needle exchange or distribution programs worldwide.

# New policy on methadone maintenance treatment in prisons established in Alberta

The right of a prisoner to access methadone maintenance treatment (MMT) while incarcerated in a correctional institution has recently been raised and examined in the Alberta Court of Queen's Bench case of Milton Cardinal v The Director of the Edmonton Remand Centre and the Director of the Fort Saskatchewan Correctional Centre.<sup>1</sup> This is a significant, precedent-setting case. For the first time, a Canadian court has ordered that a prisoner be provided with MMT during his or her period of incarceration. As a result of the case, and just before it was to proceed to trial, Alberta changed its policy and is now providing MMT to its provincial prisoners – at least when they had been receiving MMT prior to their incarceration.

Milton Cardinal was arrested and incarcerated in the Edmonton Remand Centre (ERC) in December 2002. It was estimated that Cardinal had been an inmate in the ERC more than 30 times. Cardinal had suffered from an addiction to opiate-based narcotics for over 20 years. Over the years, he had attempted various programs to treat his addiction but none of them were successful.

In May or June 2002, Cardinal applied to be placed on the MMT program offered by the Alberta Alcohol and Drug Abuse Commission (AADAC). The AADAC's attending physician quickly identified Cardinal as an appropriate candidate for the program based upon his personal history. Cardinal began to receive MMT immediately.

As of the time of Cardinal's incarceration, the standard policy of the ERC was not to provide MMT to prisoners. This policy was reflected in certain "standing orders" that were applied to all prisoners on a blanket basis and without any consideration as to their individual facts and circumstances. However, the ERC would permit inmates to continue to receive MMT from the AADAC for as long as the AADAC was willing to continue the treatment. The AADAC's policy was to allow MMT to continue in the ERC for 30 days. Beyond this period, the AADAC would not provide MMT because the prisoners could not be monitored and because the AADAC was not responsible for the medical treatment of prisoners under the care and control of the Director of the ERC.

Following the expiration of the 30-day period, all prisoners were placed on a "mandatory withdrawal" regimen. The prisoner's methadone was quickly reduced over a period of approximately 10 days, and the prisoner was provided with such substances as vitamin B, Librium (chlordiaxepoxide), clonidine, and chloral hydrate, which served to relieve withdrawal symptoms to a limited extent. There was no requirement that a prisoner be seen or examined by a physician prior to being placed in this program.

Cardinal was cut off methadone on 9 February 2003. As might be expected, his withdrawal from MMT was traumatizing and his physical and mental suffering was acute. Cardinal made repeated written requests to be seen by a physician, but all such requests were "screened out" by the ERC's nursing staff.

On 19 February 2003, Cardinal was sentenced to 10 months in a provincial correctional institution by

Judge AG Chrumka of the Provincial Court of Alberta for the offence of robbery contrary to s 344 of the Criminal Code. In imposing sentence, Judge Chrumka recommended that Cardinal be kept on the MMT program during the term of his sentence, though he was aware of the fact that it was not the policy of Alberta Corrections to provide such treatment. Following his sentencing, Cardinal was transferred to the Fort Saskatchewan Correctional Centre (the Fort) around 28 February 2003, and was not provided with MMT due to the absence of any such program at the Fort.

By Notice of Motion filed on 4 April 2003, Cardinal brought an application for habeas corpus seeking an order compelling the Director of the Fort to provide him with MMT. The Legal Aid Society of Alberta granted funding for this application.

On 2 May 2003, Cardinal brought a contested application in Special Chambers before Justice Ouellette of the Alberta Court of Queen's Bench seeking an interim mandatory injunction requiring the Director of the Fort to allow Cardinal to receive MMT as prescribed by a doctor at the Boyle McCauley Health Centre.

The Alberta government retained the services of a large private law firm to oppose the interim motion, and six lengthy affidavits were filed by Alberta. The Fort's physician deposed that there was no medical reason for Cardinal to be receiving MMT. He then stated on cross-examination that the prevention of relapse, and the provision of relief from the physical and psychological stress caused by the addiction, were both valid medical reasons to provide Cardinal with MMT. He also volunteered that MMT could be useful in relieving Cardinal's chronic pain.

Similarly, the Fort's health-care manager deposed that the Fort was not equipped to provide MMT to prisoners such as Cardinal. She then admitted on cross-examination that the Fort already administered such a program to its prisoners.

Two senior Edmonton-area Queen's Counsel appeared in court on behalf of Alberta and argued strenuously against Cardinal's interim application in an effort to prevent him from receiving his medical care. Justice Ouellette granted Cardinal's interim application. Justice Ouellette's hurried reasons were delivered orally on 2 May 2003. He stated:

The risk to Mr. Cardinal in not having methadone maintenance treatment program poses a far greater danger than if he were to receive the methadone maintenance treatment program. One the evidence that has been put before me that the sharing of needles and intravenous drug use can result in HIV, the risk becomes potentially life or death. I am not suggesting that that would be the end result if this treatment were not reinstated or put in place. However, it is clear that that could be one of the results of a relapse by Mr. Cardinal into drug use. Quite frankly, with the statement being agreed to, even by the doctor on behalf of the respondent, that there is a high probability of relapse, to do otherwise would be negligent, in my opinion, that is to say that there will not be irreparable harm in the event that methadone is not reinstated or that he is not granted the methadone maintenance program.

Cardinal was placed back on MMT, but continued to proceed to trial. Although he had obtained the primary relief he was after, Cardinal continued to seek a declaration that his Charter rights had been violated and an order pursuant to s 24(1) of the Charter reducing his sentence as a result of the suffering he had endured. His argument was based primarily upon s 7 of the Charter.<sup>2</sup> Additionally,

"That [denial of MMT] was wrong.... They have no right to torture your client, none whatsoever. It's almost like keeping food away from him, starving him. He needs this. It's a medical necessity. He's going to get it."

- Justice Feehan, Alberta Court of Queen's Bench

Cardinal relied upon sections 12 and 15 of the Charter. The trial was set to proceed on Monday, 23 June 2003, before Mr Justice Feehan.

Late on the afternoon of the Friday before trial, counsel for the Solicitor General of Alberta advised by letter that, by a fortunate coincidence, a new policy had just been brought into force. Henceforth, prisoners in Alberta's correctional institutions who had been receiving MMT prior to their incarceration would be permitted to continue treatment while incarcerated. Additionally, it was confirmed that Cardinal would continue to receive MMT for the remainder of his sentence, regardless of the outcome of the trial.

Notwithstanding the contents of this letter, Cardinal attempted to proceed with the trial seeking a declaration and reduction in sentence. Counsel for Alberta argued that the case had been rendered moot. Justice Feehan was inclined toward the latter view and stated as follows:

And that [denial of MMT] was wrong. That was wrong. They have no right to torture your client, none whatsoever. It's almost like keeping food away from him, starving him. He needs this. It's a medical necessity. He's going to get it.

Now what more do you want? You want me to say they're bad guys and we're going to punish them by letting him out of gaol. Why should I do that?

Following this comment, there was a somewhat heated exchange in which Justice Feehan indicated that he had no intention of reducing Cardinal's sentence as a result of the denial of MMT. Based upon this comment, Cardinal moved to have Justice Feehan recuse himself. The morning ended with Justice Feehan saying:

I'm not going to kick the government, I'm not going to kick the penitentiary people. I'm going to give you what he's prepared to offer in his letter, you've read it, and your man will be treated in – the way that is expressed so that you've won. You've got everything you want for your man.

What you want is a declaration that is going to make legal history and I'm telling you I'm not prepared to do that. So you want another judge, I'm going to give you another judge. I recuse myself.

Following these events, counsel for the parties agreed to settle Cardinal's habeas corpus application on the entry of a consent order signed by Justice FF Slatter containing the following conditions:

 The provision of methadone maintenance treatment to persons who suffer from opioid drug addiction constitutes the community standard of health care in the province of Alberta;

- 2. The Respondent, the Director of the Fort Saskatchewan Correctional Centre, shall continue methadone maintenance treatment to the Applicant for the remainder of his current sentence in accordance with the terms of the Order of Justice V.O. Ouellette of Friday, May 2nd, 2003; and
- 3. The Applicant shall have his taxable costs of this proceeding.

At the end of the day, as a result of the Cardinal case, Alberta is now providing MMT to its provincial prisoners – at least where they had been receiving MMT prior to their incarceration. Cardinal has now filed a civil claim seeking Charter s 24(1) damages for the suffering he endured as a consequence of his forced withdrawal from MMT.

- Nathan J Whitling

Nathan J Whitling, BComm, LLB, LLM is with the Edmonton law firm of Parlee McLaws LLP. He can be reached at nwhitling@parlee.com.

<sup>&</sup>lt;sup>1</sup> (Action No 021531397P1) (Alberta QB). Copies of the originating Notice of Motion, interim Notice of Motion, and interim order on file with the Canadian HIV/AIDS Legal Network. See also the article on the interim order: G Betteridge. Alberta court orders methadone maintenance therapy for prisoner on interim basis. *Canadian HIV/AIDS Policy & Law Review* 2003; 8(1): 53-54.

 <sup>&</sup>lt;sup>2</sup> As interpreted in such cases as R v Morgentaler, [1988]
I SCR 30; Rodriguez v British Columbia (Attorney General),
[1993] 3 SCR 519; and R v Parker (2000), 188 DLR (4th)
385 (Ont CA).

# Randomized controlled trial proves effectiveness of methadone maintenance treatment in prison

A study on methadone maintenance treatment (MMT) undertaken by the Correctional Service of Canada in 2001 demonstrated that MMT has a positive impact on release outcome and on institutional behaviour.<sup>1</sup> Now, a new study undertaken in an Australian prison system has demonstrated that MMT also reduces drug use and injection in prisons.<sup>2</sup> The implications of this study are far-reaching. They suggest that in all jurisdictions where community-based programs operate, prison-based methadone programs should be introduced or expanded.<sup>3</sup>

MMT reduces mortality, heroin consumption, criminality, HIV transmission, and re-incarceration among injection drug users in community settings.<sup>4</sup> But few studies have examined the effectiveness of MMT in prisons. In one study, injection drug users in MMT reported lower levels of injecting in prison than non-treated peers.<sup>5</sup> In Canada, an important study on MMT in federal correctional institutions demonstrated that MMT has a positive impact on release outcome and on institutional behaviour, but did not assess the impact of MMT on the health of inmates on MMT or, more specifically, on frequency of drug use or injection drug use.<sup>6</sup>

A recent study by Dolan et al, undertaken in prisons in New South Wales (NSW), Australia, has now done that, and has provided evidence of the effectiveness of prison MMT in reducing drug use and injection in prisons.

In 1997, there were 7957 prisoners in NSW prisons, of whom 685 received MMT. The prevalence of HIV and HCV among NSW male prisoners was less than one percent and approximately 30 percent, respectively. The aims of the Prison Methadone Program were to reduce drug injecting and prevent HIV and hepatitis transmission in prison. The study examined whether the program was achieving its aim.

In 1997, the waiting time for MMT in NSW prisons was approximately six months. All prisoners on the waiting list were asked to enter the study and, if assessed as suitable, they were either randomized into MMT immediately or experienced a four-month delay with guaranteed access after that period. Heroin use was measured by hair analysis and self report; drugs used and injected, and syringe sharing, were measured by self report. HCV and HIV incidence was measured by serology.

Of 593 eligible prisoners, 191 were randomized to MMT and 191 to control; 129 treated and 124 control subjects followed up at five months. Heroin use was significantly lower among treated than control subjects at follow-up. Treated subjects also reported lower levels of drug injecting and syringe sharing at follow-up.

No subject was found to be HIVpositive at baseline or follow-up, reflecting the very low HIV prevalence of about one percent among injection drug users in Australia. Approximately 70 percent of subjects were hepatitis antibody–positive at baseline, reflecting the very high HCV prevalence of over 50 percent among injection drug users in Australia. Predictors of HCV seroconversion were: being tattooed in prison, being more than 25 years old, and recent heroin injection. A limitation of the study was the short duration of follow-up. This, coupled with the high prevalence of HCV, precluded the possibility of detecting a difference in HCV incidence between groups.

Nevertheless, this study is significant and should have far-reaching implications. It has provided conclusive evidence that MMT reduces drug use and injection in prisons. As a result, MMT programs in Canadian prisons should be expanded (or introduced where they do not yet exist).

- Thomas Haig

<sup>3</sup> For an overview of provision of MMT in Canadian prisons, see R Lines. Action on HIV/AIDS in Prisons:Too Little, Too Late – A Report Card. Montréal: Canadian HIV/ AIDS Legal Network, 2002 (available at www.aidslaw.ca/ Maincontent/issues/prisons.htm).

<sup>4</sup> Dolan et al, supra, note 2, with many references.

<sup>5</sup> KA Dolan et al. Methadone maintenance reduces injecting in prison. *British Medical Journal* 1996; 312: 1162.

<sup>6</sup> Supra, note 1.

<sup>&</sup>lt;sup>1</sup> R Jürgens. Canada: study demonstrates positive effect of methadone treatment. In: HIV/AIDS in prisons: new developments. *Canadian HIV/AIDS Policy & Law Review* 2002; 6(3): 13-19, at 15-16, with reference to Correctional Service Canada. Research Report: Institutional Methadone Maintenance Treatment: Impact on Release Outcome and Institutional Behaviour. Ottawa: CSC Research Branch, September 2001.

<sup>&</sup>lt;sup>2</sup> KA Dolan et al. A randomised controlled trial of methadone maintenance treatment versus wait list control in an Australian prison system. *Drug and Alcohol Dependence* 2003; 72: 59-65.

# Australian discussion paper on prison needle exchange programs released

The Australian Injecting and Illicit Drug Users League (AIVL) recently released a discussion paper on prison-based needle exchange or distribution programs, expressing concern "about the gaps in service provision and neglect for the health and human rights of injecting and illicit drug users within the Australian prison systems."<sup>1</sup>

The discussion paper reviews prisonbased needle exchange programs (PNEPs) in Switzerland, Germany, Spain, and Moldova, and contains a set of guiding principles for PNEPs. In developing these principles, it was AIVL's aim to shift the debate about PNEPs "away from a debate about 'whether' we should have [such] programs to 'how' we should go about implementing them."<sup>2</sup> The guiding principles are:<sup>3</sup>

- 1. All stakeholders must be included in every stage of the development and implementation.
- 2. The PNEP should be made available to all prisoners.
- 3. Initiation to the service should be by way of all new prisoners having a blood borne virus kit placed in their cell.
- 4. The provision of needles and syringes must be through both vending machines and external non-governmental organization staff.
- 5. Vending machines need to be well placed, regularly stocked and protected from vandalism. Where possible, machines should also provide other resources such as soap and condoms to protect confidentiality.
- Staff operating the program should be from an external NGO who are less likely to gain person-

ally from prison culture and systems and should be managed directly by the prison's Governor.

- 7. In female prisons, the program staff should be women.
- Staff must be well trained and supervised and where possible should have drug-using experience and first-hand experience of prison culture.
- 9. Staff should rotate so that they cannot become entrenched in prison culture and attend regular team meetings to be able to debrief.
- 10. The service needs to be non-judgmental, accessible yet confidential and well monitored and evaluated.
- 11. A full range of injecting equipment needs to be made available within the program, as in the community. Other services should also be available such as referral to health services, drug treatment and peer education/support initiatives.
- 12. Equipment should be kept in a designated container and area within each cell.
- 13. All prison staff should undertake, as part of their induction, training program sessions that address all aspects of injection drug use and models of health promotion and human rights.

 Training should be offered on a regular basis and attitudes to prisoners (particularly injection drug users) should be monitored through staff appraisals.

#### The discussion paper concludes:

There is injecting equipment in Australian prisons today, it is an underground system and it is inadequate and dangerous.... AIVL believes that [PNEPs] can deliver real and tangible benefits for prisoners, prison staff, and the broader community. There is little doubt that prisons are central to the hepatitis C epidemic in Australia. The current situation in relation to hepatitis C in Australia is nothing short of a disgrace. [PNEPs] present the opportunity to make a positive contribution to stemming the transmission of hepatitis C, both within prisons and the wider community.<sup>4</sup>

– Thomas Haig

 $^{\rm 2}$  lbid at 5.

<sup>3</sup> Ibid at 7-10, 14.

<sup>4</sup> Ibid at 13.

<sup>&</sup>lt;sup>1</sup> Australian Injecting and Illicit Drug Users League. Discussion Paper: Prison-Based Syringe Exchange Programs (PSE Programs). Canberra: AIVL, 2003 (available via www.aivl.org.au/resources.html).

# HIV/AIDS IN THE COURTS - CANADA

This section presents a summary of Canadian court cases relating to HIV/AIDS or of significance to people with HIV/AIDS. It reports on criminal and civil cases. The coverage aims to be as complete as possible, and is based on searches of Canadian electronic legal databases and on reports in Canadian media. Readers are invited to bring cases to the attention of Glenn Betteridge, editor of this section, at gbetteridge@aidslaw.ca.

# HIV-positive person who did not disclose status convicted of attempted aggravated assault

On 18 September 2003, the Supreme Court of Canada released its unanimous decision in *Williams*.<sup>1</sup> This is the first case on the issue of criminal liability for HIV exposure decided by the court since its 1998 decision in the *Cuerrier* case.<sup>2</sup> *Williams* raised the issue of whether persons with HIV who have unprotected sexual intercourse without disclosing their status to a sexual partner who might already have been infected with the virus, can be convicted of aggravated assault or attempted aggravated assault. The Supreme Court decided that only a charge of attempted aggravated assault could stand. The decision is also significant because the Supreme Court's comments on two ancillary issues may lead to a significant extension of the criminal law related to HIV transmission or exposure.

Williams began an 18-month relationship in June 1991 with a woman who was eventually the complainant in the case. They had unprotected sex on numerous occasions. On 15 November 1991, Williams learned that he had recently tested positive for HIV. The complainant received a negative test result a few days later. However, the court acknowledged that at the time she was tested, Williams may have already infected her and she may have been in the "window period" between infection and seroconversion.

After Williams learned of his positive diagnosis, he did not disclose to his partner either that he had been tested for HIV or that he had tested positive. The relationship continued for another year and included unprotected sex. The evidence before the court showed that Williams had been counselled on three different occasions by two doctors and a nurse about HIV, its transmission, safer practices, and his duty to disclose his HIV status to sexual partners.

The relationship ended in November 1992. In April 1994, the complainant learned she was HIV-positive. It was accepted as fact that the complainant would never knowingly have had unprotected sex with Williams had she known he was HIV-positive. Williams conceded that he infected the complainant with HIV. The prosecution conceded that it is quite possible that Williams infected the complainant before learning of his HIV-positive status.

### Lower-court decisions

The Newfoundland trial court convicted Williams of aggravated assault and common nuisance.<sup>3</sup> The Court of Appeal of Newfoundland and Labrador upheld the conviction for common nuisance, but substituted the conviction for aggravated assault with a conviction for attempted aggravated assault.<sup>4</sup>

The Court of Appeal based its decision on the Supreme Court's decision in Cuerrier. In that case, the Supreme Court held that not disclosing one's HIV-positive status before unprotected vaginal or anal sex amounts to fraud, which makes a sexual partner's consent to sex legally invalid. Therefore, the Supreme Court said, such physical sexual contact amounts to an assault. Since the Cuerrier decision, HIV-positive people have had a legal duty to disclose their HIV infection before engaging in any activity that posed a "significant risk" of transmitting HIV. The Court of Appeal found that Williams breached this duty.

The court went on to analyze whether Williams was guilty of the offence of aggravated assault, which further requires that the assault "endanger the life of the complainant." It determined on the evidence that the complainant might already have been infected through unprotected sex with Williams before he

Since the *Cuerrier* decision, HIV-positive people have had a legal duty to disclose their status before engaging in any activity that posed a "significant risk" of transmitting HIV.

learned he was HIV-positive. The court therefore agreed that it could not be proven beyond a reasonable doubt that Williams's conduct, after learning he was HIV-positive, endangered her life through the risk of HIV infection. As a result, Williams was convicted of attempted aggravated assault, which carries a lesser penalty under the Criminal Code. The prosecution appealed this finding to the Supreme Court. Williams appealed the attempted aggravated assault conviction.

# The Supreme Court decision

The Supreme Court decided that Williams could only be convicted of attempted aggravated assault. It concluded that, based on the evidence, it was "likely" that the complainant was already infected with HIV through unprotected sex with Williams before he learned of his positive diagnosis. As a result, the prosecution could not prove beyond a reasonable doubt that Williams had endangered the complainant's life and, absent the aggravating factor of endangerment, he could not be convicted of aggravated assault. The Supreme Court found that Williams was guilty of an attempt to commit the offence. The Supreme Court reviewed the law on the crime of attempt, and found that in order to secure a conviction for an attempt the Crown is required to prove the accused intended to commit the crime in question and took legally sufficient steps toward its commission. Applying the relevant legal principles to the facts in *Williams*, the Court stated:

Failure to prove endangerment of life was fatal to the prosecution in this case of aggravated assault but it is not fatal to a conviction for attempted aggravated assault. Clearly, the respondent took more than preparatory steps [toward committing the offence of aggravated assault]. He did everything he could to achieve the infection of the complainant by repeated acts of intercourse for approximately one year between November 15, 1991 [the date of his diagnosis] and November 1992 when the relationship ended. The reasonable doubt about the timing of her actual infection was the product of circumstances quite extraneous to the respondent's post-November 15, 1991 conduct.5

Although not necessary to its decision about whether Williams could be convicted of aggravated assault or the attempt, the Supreme Court addressed the issue of criminal intent. Specifically, the court examined what awareness an HIV-positive person must have about his or her HIV status before it can be said that the person has committed fraud for the purposes of vitiating a sexual partner's consent. The court said that:

The critical date for establishing fraud to vitiate consent (*Criminal Code*, s. 265(3)(c)) is when the respondent had sufficient awareness of his HIV-positive status that he can be said to have acted "intentionally or recklessly, with knowledge of the facts constituting the offence, or with willful blindness toward them."<sup>6</sup>

With respect to the knowledge required to vitiate consent in the case of an HIV-positive person who has unprotected sexual intercourse without disclosing his or her status, the court stated:

Once an individual becomes *aware of the risk that he or she has contracted HIV*, and hence that his or her partner's consent has become an issue, but nevertheless persists in unprotected sex that creates a risk of further transmission without disclosure to his or her partner, recklessness is established.<sup>7</sup> [Emphasis added.]

Therefore, it appears that a person who is aware of the risk that he or she is HIV-positive has a legal duty to disclose this risk to his or her sexual partners before engaging in behaviours that carry a substantial risk of HIV transmission.

The Supreme Court also commented on the medical evidence that may be adduced in future cases related to sexual transmission or exposure to HIV, specifically in relation to the potential medical consequences of unprotected sex between HIV-infected partners.<sup>8</sup> Expert medical evidence before the court raised the possibility of harm resulting from re-infection with a potentially different strain of HIV. The Supreme Court cited with approval the Newfoundland and Laborador Court of Appeal's view that regardless of the fact that a complainant may already be HIV-positive, evidence might demonstrate that unprotected sexual intercourse with an HIV-positive person may still represent a significant risk to the complainant's life.

### Commentary

The *Williams* decision may lead to a significant extension of the criminal law, well beyond the court's decision in *Cuerrier*, and thus raises concerns

about the direction of Canadian criminal law with respect to conduct that risks transmitting HIV. On the question of intent, the court said that there was sufficient intent for a conviction on an assault charge if a person acts

The decision suggests that it is not just once persons receive a definitive diagnosis of HIV infection that they have a legal duty to disclose before having unprotected sex, but that there might be a duty to disclose if persons are aware of a risk that they might be HIV-positive.

"recklessly." The court's reference to reckless behaviour suggests that it is not just once persons receive a definitive diagnosis of HIV infection that they have a legal duty to disclose before having unprotected sex, but that there might be a duty to disclose even before this point if they become aware of a risk that they might be HIV-positive.

This could become a slippery slope as courts try to decide how to apply such a standard. When does a person become aware of a risk that he or she might be HIV-positive? What sort of past activities that might have carried a risk of HIV infection will mean that a person is aware of a risk of having contracted HIV? How significant a risk does it have to be before ignoring it becomes "reckless?" It remains to be seen how prosecutors and courts will interpret this statement by the Supreme Court in future cases.

This issue illustrates why the criminal law is not particularly helpful in responding to conduct that risks transmitting HIV. If the risk of criminal liability only exists once a person actually receives a positive test result, then this is a disincentive to getting tested for HIV, because someone who has not been tested can plead ignorance of his or her status. But if persons can be held criminally liable when they are aware of the risk that they might be infected with HIV, the criminal law may cover a potentially wide range of situations. Setting the standard for criminal intent as awareness of a risk of one's infection, rather than actual knowledge of HIV infection, is to invite an overly broad application of serious criminal penalties and could lead to undesirable invasions of privacy. The Supreme Court's comments effectively invite prosecutors and lower courts to scrutinize a person's past sexual and needle-use activities in search of risk-taking behaviour, and to ask whether that person was aware that such behaviour put them at risk of HIV infection.

The other way in which the criminal law may potentially be extended concerns situations involving sexual relations where both partners are HIVpositive, but either one or both have not disclosed their status before engaging in high-risk behaviour. In fact, the Supreme Court's comments on the issue of re-infection seem to invite prosecutors to charge and prosecute HIV-positive people who engage in sex that carries a significant risk of HIV transmission without first disclosing their status, even if their sexual partner was already HIV-positive.

- Richard Elliott and Glenn Betteridge

Richard Elliott is Director of Legal Research & Policy at the Canadian HIV/AIDS Legal

Network. He can be reached at relliott@aidslaw.ca. Glenn Betteridge is Senior Policy Analyst at the Network. He can be reached at gbetteridge@aidslaw.ca.

 $^2$  R v Cuerrier, [1998] 2 SCR 371. For an in-depth analysis of the decision, see R Elliott. After Cuerrier: Canadian

Criminal Law and the Non-Disclosure of HIV-Positive Status. Montréal: Canadian HIV/AIDS Legal Network, 1999. Available at www.aidslaw.ca/Maincontent/issues/ criminallaw.htm.

<sup>3</sup> R v Williams, [2000] NJ No 138 (SCTD) (QL) [conviction, 26 April 2000].

<sup>4</sup> R v Williams, 2001 NFCA 52, [2001] NJ No 274 (QL). For a summary and analysis of the decision of the Newfoundland and Labrador Court of Appeal, see R Elliott. Criminal law and HIV transmission/exposure: three new cases. Canadian HIV/AIDS Policy & Law Review 2002; 6(3): 64-66.

<sup>5</sup> Williams, supra, note 1 at para 64.

<sup>6</sup> Ibid at para 27.

<sup>7</sup> Ibid at para 28.

<sup>8</sup> Ibid at paras 67-70.

# Ontario court affirms that medical marijuana regulations are unconstitutional

On 7 October 2003, the Ontario Court of Appeal upheld the Ontario Superior Court of Justice decision in *Hitzig*, which found that the Marihuana Medical Access Regulations<sup>1</sup> (MMAR) represented an unconstitutional barrier to accessing a legal supply of marijuana for persons with a recognized medical need.<sup>2</sup> The Court of Appeal tailored its remedial order by striking down the second specialist test required for certain applicants, and eliminating the unconstitutional eligibility and supply provisions, rather than declaring unconstitutional the entire MMAR as the lower court had done. The court's declaration was made effective immediately, in order to maintain the prohibition for nonmedicinal possession of marijuana under section 4 of the Controlled Drugs and Substances Act<sup>3</sup> (CDSA), and to constitutionalize the medical exemption for marijuana possession created under the MMAR.

### Accessing medicinal marijuana – the evolving regime

The *Hitzig* appeal is the latest chapter in the story of the government's attempt to create a constitutionally viable framework in which persons with a recognized need for medicinal marijuana –such as people living with HIV/AIDS – can access the drug. Both the plaintiffs and the government had appealed the ruling by the Ontario Superior Court of Justice, which found the MMAR unconstitutional because they provided for neither a legal source nor a supply of medicinal marijuana.<sup>4</sup> That court declared the MMAR invalid, but suspended the declaration for six months in order to give the government time to create a legal source and supply of medicinal marijuana.

The government twice brought motions unsuccessfully to the Court of Appeal to stay the judgment of the Superior Court of Justice.<sup>5</sup> On 9 July 2003, the government put in place an interim policy in an attempt to render the MMAR constitutionally valid.<sup>6</sup>

### The parties' positions

At the Ontario Court of Appeal, persons seeking access to medical marijuana argued that the lower court erred in finding that the MMAR eligibility requirements did not infringe their section 7 Charter rights. They concentrated this aspect of their challenge on the requirement for some applicants to get specialist approval, arguing that specialists are less easy to access than general practitioners (especially in rural areas), that they do not know very much about the medicinal qualities of marijuana, and that many specialists are reluctant to get involved in the MMAR approval process. Finally, they argued that the specialist requirements are arbitrary and, therefore, contrary to the principles of fundamental justice because they do not support the government's interest in controlling the use of marijuana.

For its part, the government argued that it had no obligation to ensure a legal supply of marijuana because it is not an approved drug. It took the

<sup>&</sup>lt;sup>1</sup> R v Williams, [2003] SCJ No 41.

position that section 7 of the Charter obligates the government not to interfere with those rights only where interference would be inconsistent with the principles of fundamental justice. It said that there is no positive obligation on the government to ensure that section 7 Charter rights are protected by creating a legal supply of marijuana. In the alternative, the government argued that even if the regulations did interfere with the liberty or security interests, the MMAR's provisions relating to selfand designated-person cultivation and supply of marijuana negated any onus on the government to create a legal supply. The government also said that users of medicinal marijuana have established links with "unlicensed suppliers" (the black market) that provide a safe source of the drug. In conclusion, it argued that section 1 of the Charter excused the government if any section 7 violations did exist.7

# The Court of Appeal decision

In considering the supply issue, the Court of Appeal first asked if the MMAR represented a threshold violation of the applicants' section 7 Charter rights. The applicants had all demonstrated a need to use marijuana for medicinal purposes and, according to *Parker*,<sup>8</sup> were entitled to a constitutionally acceptable medical exemption. Accordingly, the Court of Appeal upheld the lower court's conclusions on the supply issue, and harshly criticized the MMAR for its failure to provide a logically and legally sound supply mechanism:

The premise underlying the MMAR, that seriously ill people ... can grow their own medicine, have a friend grow it, or get it on the black market, is puzzling.<sup>9</sup>

It is ironic, given the Government's reliance on this part of the black market to supply those whom the Government has determined should be allowed to use marihuana, that the police, another arm of the state, shut down these operations from time to time, presumably because they contravene the law.<sup>10</sup>

The court said that the requirement created by the medical exemption regime that some people resort to illegal channels for their marijuana infringed on their liberty interest, because it subjected them to potential criminal prosecution. It said also that the personal production licence and designated production licence (DPL) provisions were highly inadequate. In the first place, the court said, many people cannot produce their own marijuana due to the severity of their illnesses. In the second place, it said, the restrictions on designated persons – such as that they cannot be paid for their services, supply more than one permit holder, or combine their growing with more than two other designated producers - significantly reduced the effectiveness of the DPL system. The court also found that the MMAR's supply provisions impinged on human dignity by making some permit holders consort with criminals. Finally, it said, the limited access framework violated the security of the person interest because it severely constricted the right to make choices about bodily integrity.

Because compelling collective interests can override individual rights,<sup>11</sup> the court had to decide if the MMAR's violation of the liberty and security of the person interests were consistent with the principles of fundamental justice. Fundamental justice is "founded upon a belief in the dignity of the human person and the The court found that the MMAR's supply provisions impinged on human dignity by making some permit holders consort with criminals.

rule of law."12 The rule of law is a constitutional principle that subjects the state to the law and that promotes respect for the law.<sup>13</sup> The court found that the MMAR created a relationship between the government and the criminal underworld, because of the dependence on that world for supply. The court concluded that this could only discourage respect for the rule of law, with the added effect of infringing on human dignity by making seriously ill people consort with criminals. The court said that the result of the MMAR, therefore, was to infringe on both individual and collective interests. With respect to collective interests, it said, the government's obligation to promote public health and safety could not be fulfilled in a framework that so heavily relied on the black market.<sup>14</sup>

The court agreed with the lower court's conclusions that the government was right to require prescribing physicians to put limits on daily doses, to determine if marijuana was a suitable treatment method for individual applicants, and to require specialist support in some cases. It said that there was a "substantial and compelling interest" to ensure that doses were not above the necessary limits, that the medical nature of the issue required a doctor's prescription, and that specialists necessarily have more detailed knowledge in their fields than general practitioners and

should therefore be consulted in some cases.<sup>15</sup> The court found no evidence to conclude that barriers to applicants based on alleged specialist inaccessibility existed.

Where the court differed with the previous findings was on the requirement, in some cases, for the approval of a second specialist. The court found this requirement, which made the agreement of the second specialist with the first's diagnosis necessary, to be arbitrary, and therefore inconsistent with the principles of fundamental justice: "There is no rational connection between this requirement and the state objectives."<sup>16</sup>

### The remedy ordered

The Court of Appeal took a different approach than the lower court in setting out the appropriate remedies for the constitutional violations in the MMAR. Rather than declare the entire MMAR of no force or effect, it chose to strike out only the constitutionally offensive provisions. On the supply issue, it removed restrictions on DPL holders in order to make a legal supply more readily available. DPL holders may now be remunerated for their services, may grow for more than one person, and may combine their efforts with more than two other DPL holders. For future DPL holders who do not have a legal source to begin their cultivation, the court ruled that the government could provide a "first seed" from its research contractor, Prairie Plant Systems. The court concluded that these modifications, combined with the existence of some operating DPL holders, would provide people who required marijuana for medical purposes with a sufficiently large legal supply base. On the eligibility issue, the court struck down the second-specialist requirement.

The court did not to suspend its ruling, in order to immediately make

The court found no evidence to conclude that barriers to applicants based on alleged specialist inaccessibility existed.

available an effective alternative to the black market. It reasoned as follows:

Finally an order that is not suspended gives immediate recognition to the s. 7 rights of those whose serious illnesses necessitate that they use marihuana. Some of these people are terminally ill. To suspend our remedy if they may die in the meantime is, in our view, inconsistent with fundamental Charter values.<sup>17</sup>

Furthermore, because the ruling in Parker had decreed the prohibition against possession of marijuana invalid if the government could not come up with a constitutionally valid medical exemption, and because the MMAR regime did not adequately provide that exemption, the marijuana prohibition under section 4 of the CDSA had been of no force or effect since 31 July 2001. The Court's order, because it "has the result of constitutionalizing the medical exemption created by the Government,"18 rendered the marijuana prohibition in the CDSA constitutionally valid once again.

### Comment

Overall, the conclusions in *Hitzig* are positive for people living with HIV/AIDS who use marijuana for medical purposes, because they make access to a legal supply of medicinal marijuana safer and easier. A wider supply base will give permit holders a broader range of choice in deciding their source, which is important, given complaints relating to the quality and efficacy of the marijuana grown by Prairie Plant Systems.<sup>19</sup>

One major question raised by the decision, however, relates to the accessibility of medicinal marijuana. The case confirms that those with a demonstrated medical need have a constitutional right to use marijuana, and that there is a corresponding positive obligation on the government to ensure the availability of a legal supply. Nothing was said, however, about the implications of the prohibitively high costs of marijuana use. Therefore, serious concerns about access remain, especially given that poverty is a reality for many people living with HIV/AIDS.

Another potential barrier to access is the discomfort in much of the medical community about its role in the MMAR process. This concern was raised by the *Hitzig* applicants, but the court found "that a sufficient number of individual physicians" were authorizing the use of medicinal marijuana to negate arguments about the practical unavailability of medical exemptions.<sup>20</sup> Nonetheless, physicians' groups, such as the Canadian Medical Association, have been vociferously opposed to their role under the MMAR.<sup>21</sup> It will be important, therefore, to monitor the system's efficiency based on a continuing evaluation of doctor participation.

- Gordon Cruess

Gordon Cruess is a first-year student at the Faculty of Law, McGill University.

<sup>&</sup>lt;sup>I</sup> SOR/2001-227.

<sup>&</sup>lt;sup>2</sup> Hitzig v Canada, [2003] OJ No 3873 (CA) (QL)).

<sup>&</sup>lt;sup>3</sup> SC 1996, c 19 (CDSA).

<sup>4</sup> Hitzig v Canada, [2003] OJ No 12 (SCJ) (QL).

<sup>5</sup> Hitzig v Canada, [2003] OJ No 3117 (CA) (QL).

<sup>6</sup> The interim policy is available through Health Canada's Office of Cannabis Medical Access website at www. hc-sc.gc.ca/hecs-sesc/ocma/guides.htm.

<sup>7</sup> Section 1 of the Charter reads: "The Canadian Charter guarantees rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society." Here, the reasonable limits on the s 7 rights would be the government's obligation to society to protect against the proliferation of an illegal drug.

<sup>8</sup> R v Parker (2000), 49 OR (3d) 481 (CA).

<sup>9</sup> Ibid at para 88.

<sup>10</sup> Hitzig, supra, note 2 at para 23.

<sup>11</sup> Ibid at para 136.

<sup>12</sup> Ibid at para 128.The court is quoting Lamer J from the Reference re s. 94 (2) of the Motor Vehicle Act (British Columbia), [1985] 2 SCR 486 at 512.

<sup>13</sup> Ibid at para 129.

<sup>14</sup> Ibid at para 138.

<sup>15</sup> Ibid at para 153.

<sup>16</sup> Ibid at para 167.

<sup>17</sup> Ibid at para 175.

<sup>18</sup> Ibid at para 187.

<sup>19</sup> See, eg, D Beeby, Health Canada medical marijuana could be better, supplier agrees. *Canadian Press*, 18 September 2003. This article is available at http:// mediresource.sympatico.ca/health\_news\_detail.asp? channel\_id=28&news\_id=2310.

<sup>20</sup> Hitzig, supra, note 2 at para 156.

<sup>21</sup> See, eg, D Garmaise. Physicians dislike new medical marijuana regulations. *Canadian HIV/AIDS Policy and Law Review* 2002; 6(3): 34. See also the CMA's open letter to its members regarding the MMAR, 3 August 2001, available at www.cma.ca/cma/common/displayPage.do? pageld=/staticContent/HTML/N0/12/advocacy/news/ 2001/08-03d.htm.

## **Court strikes out latest action in contaminated blood litigation**

On 24 June 2003, the Federal Court of Canada – Trial Division struck out an action by three hemophiliacs infected with HIV through contaminated blood products.<sup>1</sup> The case arose out of the destruction of records by members of Canadian Blood Committee (CBC) in 1989. The defendants were the government of Canada and three government of Canada employees who worked at the CBC in 1989 and were alleged to have been involved in the destruction of records.

In 2001, the Ontario Court of Appeal overturned a lower-court decision that had found the Canadian Red Cross Society and the government of Canada liable in negligence for delays in taking steps to protect the plaintiffs from contracting HIV through blood products.<sup>2</sup> The court held that Canada, the province of Ontario, and their respective agencies were not liable for the infections, as it was not proven that the infections would have been prevented by implementing the new practices sooner.<sup>3</sup> On the issue of whether the government of Ontario was guilty of "spoliation" resulting from the destruction of records, the court upheld the trial judge's finding that there was no evidence that Ontario spoliated or destroyed evidence.<sup>4</sup> The plaintiffs had not alleged that Canada was liable for spoliation. The plaintiffs' application for leave to appeal the Ontario decision to the Supreme Court of Canada was denied on 5 September 2002, without reasons.<sup>5</sup>

A number of the plaintiffs from the original negligence action launched a \$2.4 million action in the Federal Court against the government of Canada and three former employees of the CBC over the destruction of blood system records. The plaintiffs alleged that but for the destruction of the materials, they would have been successful at the Ontario Court of Appeal. They sought damages equal to the award of damages made by the Ontario trial court. The defendants, both the government of Canada and the individuals, brought a motion to the Federal Court to strike out the plaintiffs' claim.

The Federal Court granted the motion to strike out the claim. It held that it had no jurisdiction to decide the claims against the individual defendants. As for the claim against the government of Canada, the court found that the issue had been dealt with by the Ontario Court of Appeal, that the plaintiffs' action amounted to an abuse of process, and that "however culpable the destruction of the CBC's records might have been, it caused none of the damages claimed by the Plaintiffs."<sup>6</sup>

- Collin Smith and Grant Holly

Collin Smith is a second-year student, and Grant Holly a first-year student, at the Faculty of Law, McGill University. <sup>I</sup> Leblanc v Canada, [2003] FCJ No 1005 (FCTD) (QL).

<sup>2</sup> Robb v St Joseph's Health Centre; Rintoul v St Joseph's Health Centre; Farrow v Canadian Red Cross Society [2001] OJ No 4605 (CA) (QL).

 $^3$  See R Elliott. Ontario appellate court overturns judgment for plaintiffs infected through tainted blood.

Canadian HIV/AIDS Policy & Law Review 2002; 6(3): 62-63.

<sup>4</sup> *Robb*, supra, note 2 at paras 206, 207.

 $^5$  Robb v St Joseph's Health Care Centre, [2002] SCCA No 44 (QL).

<sup>6</sup> Leblanc, supra, note | at para 45.

# HIV/AIDS IN THE COURTS - INTERNATIONAL

This section presents a summary of important international cases relating to HIV/AIDS or of significance to people living with HIV/AIDS. It reports on civil and criminal cases. Coverage is selective. Only important cases or cases that set a precedent are included, insofar as they come to the attention of the *Review*. Coverage of US cases is very selective, as reports of US cases are available in *AIDS Policy & Law* and in *Lesbian/Gay Law Notes*. Readers are invited to bring cases to the attention of Glenn Betteridge, editor of this section, at gbetteridge@ aidslaw.ca.

# HIV drug trademark case handed down in UK

A United Kingdom (UK) court has ruled that that the diversion to, and sale in, the UK of antiretroviral medications destined for Africa infringed the patents of Glaxo Group Ltd.<sup>1</sup>

In July 2003, the Chancery Division decided *Glaxo Group Ltd* v *Dowelhurst and another*, concerning the importation of antiretroviral medications. The claimant, a multinational pharmaceutical corporation, contended that the defendants had infringed trademarks held by the company on the HIV antiretroviral drugs Epivir, Combivir, and Trizivir by importing those products into the UK. The first defendant was a parallel importer of pharmaceuticals, and the second was the first defendant's majority shareholder and managing director.

Glaxo had originally arranged for shipments of the medications to go to French West Africa under a nonprofit humanitarian scheme. The scheme enabled HIV antiretrovirals to be made available to developing countries at cost or just above. In October 2002, it was revealed that a large quantity of these drugs designated for Africa was not reaching the intended consumers. A criminal investigation in Switzerland later uncovered that some of the drugs had been diverted by various intermediaries and brought into the UK by the defendants. Before the court, Glaxo contended that the defendants had infringed trademarks on the antiretrovirals by importing the medications into the UK, since they were never intended for or offered for sale on the European market by Glaxo. Glaxo sought an injunction to prevent any further importation. The defendants opposed the application. In the alternative, they suggested that if the injunction were to be granted by the court, it should not apply to drugs put on the market in the European Economic Area by Glaxo itself, with Glaxo's consent, or if the defendants had reasonable grounds for believing either of these circumstances.

The court found that there was no defence to Glaxo's claim for trademark infringement in relation to the medications originally destined for French West Africa, since Glaxo had not provided its consent to having the drugs re-exported to, and marketed in, Europe. As a result, the court granted an injunction against the parallel importer prohibiting the importation of the medications that had been intended for Africa. However, the court refused to grant a blanket prohibition preventing the defendants from importing Glaxo antiretrovirals into the UK. since Glaxo could not show any material injury or inconvenience as a result of such activities as long as it adopted measures that would allow parallel traders to identify and avoid medications intended for Africa.

#### – Jennifer Gold

Jennifer Gold, BCL/LLB (Candidate), is a student at the Faculty of Law, McGill University.

# UK: AIDS treatment main factor in decision to grant permission to appeal immigration decision

On 26 June 2003, the England and Wales Court of Appeal (Civil Division) granted an application for leave to appeal a decision of the Immigration Appeal Tribunal, which had overturned an adjudicator's decision to allow an HIV-positive citizen of Uganda to immigrate to the United Kingdom (UK).<sup>1</sup>

Rose Maureen Namazzi, a citizen of Uganda, sought leave to appeal a decision of the Immigration Appeal Tribunal. That tribunal had allowed an appeal by the Secretary of State against a determination of an adjudicator who granted Namazzi's appeal, on human rights grounds, of an earlier order refusing her entry to the UK. Namazzi's counsel argued that Namazzi is currently receiving sophisticated and intensive treatment in the UK, that that treatment is superior to what she would receive in her native country, and that there is considerable lag time between the availability of new drugs in the UK versus Uganda. In his judgment for the court, Lord Justice Pill recognized that Namazzi had received "sophisticated, prolonged and intensive treatment" in the UK. He also noted that AIDS is "a condition all too common throughout the world, in particular in Uganda, the country from which she came and to which she would be returned."

In granting leave to appeal, Lord Justice Pill referred to Article 3 of the European Convention on Human Rights, which prohibits torture or inhuman or degrading treatment or punishment. He relied on the decision of the European Court of Human Rights in *Pretty* v *United Kingdom*, in which the court recognized that "Article 3 has most commonly applied in the context in which the risk to the individual of being subjected to any of the prescribed forms of treatment emanated from intentionally inflicted acts of state agents or public authorities."<sup>2</sup> He also referred to the case of  $D \vee United Kingdom$ , for the principle that the court has the authority and flexibility to address the application of Article 3 as situations arise.

Lord Justice Pill cautioned that it is a "long step" to establish that medical facilities being inferior in another country may constitute a breach of Article 3 in requiring the departure of a person to her country of citizenship. He cited two conflicting cases on the matter. In the successful case, of D v United Kingdom, the court concluded that the applicant's removal would expose him to a serious risk of dying under "most distressing circumstances" and would thus constitute inhumane treatment. On this basis, Lord Justice Pill held that the issue of the application of Article 3 raised by Namazzi merited the attention of the court, and granted permission to appeal.

– Jennifer Gold

 $<sup>^{\</sup>rm I}$  Glaxo Group Ltd  $\vee$  Dowelhurst and another, [2003] All ER (D) 22 (Aug).

<sup>&</sup>lt;sup>1</sup> Namazzi v Secretary of State for the Home Department, [2003] EWJ No 3665, [2003] EWCA Civ 1018 (QL).

# UK court denies appeal by woman who stabbed police officer with used needle

On 2 September 2003, the England and Wales Court of Appeal (Criminal Division) denied the appeal against sentence by a woman living with hepatitis C who stabbed a police officer repeatedly with a used syringe while resisting arrest. 'The court confirmed the nine-year sentence.

The appellant, Gooding, participated in the robbery and assault of a 95year-old woman. When Gooding then tried to use stolen banking passbooks to withdraw and transfer funds, she was detained by police. She struggled and fled, and was chased by a police officer. When he tried to arrest her, she stabbed him repeatedly with a used syringe. During a police interview, Gooding revealed that she was hepatitis C-positive and expressed remorse for assaulting the officer. The police officer was admitted to hospital two days after the assault for a week of

intravenous antibiotics. Six months later he was tested to determine if he had contracted hepatitis C, hepatitis B, or HIV. During this period he underwent numerous blood tests and follow-up visits to the hospital. Although it was finally determined that he had not contracted any virus, the trial court heard evidence that his wife now "had great concern whenever he went out on duty."

At the Court of Appeal, Gooding argued that a combined sentence of nine years' incarceration for the burglary and the offence of wounding with intent was excessive. The court disagreed, stating that the intentional wounding with the syringe was "plainly a very serious offence ... it is possible that the police officer could have suffered even more than he did." The court also noted that the police officer had been left traumatized by the incident, and spent months not knowing whether or not he had been infected with hepatitis C or another disease.

– Jennifer Gold

# UK: Rape "aggravated" by knowledge of HIV and hepatitis B infection

On 22 August 2003, the England and Wales Court of Appeal (Criminal Division) refused an appeal by a 23-year-old man with HIV and hepatitis B who had been sentenced to four years' incarceration after pleading guilty to rape.<sup>1</sup>

The complainant was a young man who had been staying in a homeless hostel who fell asleep one night in car park after drinking with a friend. When he awoke he was face down with his pants down and with the applicant on top of him engaged in non-consensual intercourse. He was able to get away, but was "very distressed" about what had occurred.

The applicant appealed his sentence. The court denied the appeal,

<sup>&</sup>lt;sup>1</sup> R v Gooding, [2003] EWJ No 4623, [2003] EWCA Crim 2515 (QL).

referring to the fact that the case was especially serious in that the applicant knew he was HIV- and hepatitis B–positive. The court also referred to evidence that demonstrated that after learning of his attacker's medical conditions, the victim was extremely worried until he received negative test results three months later. The court stated that these facts "clearly aggravated the offence which was committed." <sup>I</sup> R. v ADC, [2003] EWJ No 4447, [2003] EWCA Crim 2455 (QL).

– Jennifer Gold

## UK court denies prisoner with HIV early release

On 19 August 2003, the England and Wales Court of Appeal (Criminal Division) denied an application by a man with HIV and hepatitis C to suspend his sentence of imprisonment due to his poor health.<sup>1</sup>

At trial, Jose Dionisio Guerra Veiga was convicted of robbery at knifepoint, and was sentenced to four-anda-half years' imprisonment. At the time of his appeal against sentence, he was incarcerated. Before the Court of Appeal, he relied on a medical report showing that he was in a "very poor state" of health, and argued that his sentence should be suspended as a result. In addition to suffering from HIV and hepatitis C infections, Veiga was addicted to crack cocaine. A physician's report stated that without effective antiretroviral therapy, it is unlikely Veiga would survive longer than six to twelve months. However, it was also noted that should he comply with his antiretroviral drug regimen, his prognosis might be significantly improved. While the physician's prognosis was that Veiga's condition was "poor," the physician conceded that it was "not possible to be precise" about the prognosis. A second report noted that Veiga had complained to a physician from an outside clinic that some of his supplies were late and that he had missed doses of medication while incarcerated.

The court stated that in appropriate circumstances a life-threatening illness may bring about exceptional circumstances that justify a suspended sentence. However, the court was not convinced that there was "any ground whatsoever" for viewing the sentence as inappropriate. The court also stated that while the treatment received by Veiga in prison was "by no means perfect," the chaotic lifestyle he led before his arrest gave no reason to believe that he would access treatment more regularly should his sentence be suspended. The court accordingly dismissed the appeal.

– Jennifer Gold

<sup>&</sup>lt;sup>I</sup> *R* v *Veiga*, [2003] EWJ No 4380, [2003] EWCA Crim 2420 (QL).

# UK: Hemophiliac wins access to recombinant factor VIII

On 17 July 2003, the England and Wales High Court granted a hemophiliac leave to appeal a decision to refuse to provide him with recombinant factor VIII, a treatment for hemophilia not derived from human blood.<sup>1</sup> The applicant had been infected with HIV and hepatitis B, C, and G through tainted blood products.

Peter Longstaff, a 45-year-old hemophiliac, sought to challenge the Department of Health guidelines of March 1998, which stipulated that only hemophilia patients aged 16 and under, not previously treated with plasma-based blood-clotting products, should receive synthetic recombinant factor VIII. Factor VIII is indicated for the control and prevention of hemorrhagic episodes. Longstaff had contracted hepatitis B, C, and G, and HIV as a result of receiving tainted blood products. In 2000, Longstaff refused any further treatment with factor VIII derived

from human blood plasma. He took the position that it was not possible to guarantee the safety of the product. He asked doctors to use synthetic recombinant factor VIII, which is not derived from human blood products, as this would decrease the risk of future infections. His physicians supported his request on the basis of clinical need.

The court granted permission to seek judicial review of the decision to deny Longstaff synthetic recombinant factor VIII. The court determined that he had an arguable case that should go to a full hearing. Due to his poor and deteriorating health, the court ordered an expedited hearing. Longstaff sought access to the synthetic treatment as an interim measure until his full case was decided. The court refused to grant the interim relief because the defendant agreed that recombinant factor VIII would be provided in the event of a life-threatening bleed, and because to grant such interim relief would be to pre-empt the substantive hearing.

– Jennifer Gold

# UK: Precedent-setting criminal conviction for grievous bodily harm

On 14 October 2003, the Inner London Crown Court found Mohammed Dica, an HIV-positive man, guilty on two counts of grievous bodily harm after he infected two individuals with HIV.<sup>1</sup> On separate occasions, Dica convinced two women to have unprotected sex by claiming he had had a vasectomy. The landmark ruling is the first successful prosecution in England and Wales for the sexual transmission of HIV. This case is also the first in the past 137 years to convict an individual of infecting someone else with a sexually transmitted disease. Dica claimed that both women knew of his condition prior to having engaged in sexual relations. Following the ruling, he announced that he would appeal based on jurisprudence indicating that there is no assault when sexual relations are consensual. On 3 November 2003, Dica was convicted to eight years in prison.<sup>2</sup> Grant Holly is a first-year student at the Faculty of Law, McGill University.

- Grant Holly

<sup>&</sup>lt;sup>1</sup> Longstaff v Newcastle Upon Tyne NHS Primary Care Trust, [2003] EWJ No 4415.

<sup>&</sup>lt;sup>1</sup> HIV carrier convicted in landmark ruling. *Guardian Unlimited* (14 October 2003), online at http://guardian.co.uk.

<sup>&</sup>lt;sup>2</sup> HIV-positive man sentenced to 8 years. *Chronicle Herald*, 4 November 2003: B12.

# LAW ESSAY CONTEST

In 2002/2003, the Canadian HIV/AIDS Legal Network held its first-ever nationwide essay contest for law students.<sup>1</sup> There were two topic areas: one Canadian issue, and one international issue as it relates to Canada. This year, all the entries were on the international topic – a case comment on the 2001 ruling of the High Court of South Africa that the government was in breach of its constitutional obligations to provide a comprehensive national program to prevent mother-to-child transmission of HIV, including making antiretroviral drugs available for this purpose. Contest entrants were asked to discuss the implications this ruling might have regarding the right to health in Canada. In this issue, we are publishing an edited version of the winning essay. The second-place essay will be included in a future issue of the *Review*.

# Canadian "medical necessity" and the right to health

In this article, Kathryn Garforth examines legal claims to health care in South Africa and Canada. Both countries face rising costs of health care that put a great strain on publicly funded systems, albeit in radically different contexts. Kathryn argues that despite these differences there are similarities in how litigants in South Africa and Canada have framed their claims to healthcare services, in how governments have responded, and in the factors courts have analyzed in reaching decisions. In South Africa, the leading case is *Treatment Action Campaign (TAC) et al* v *Minister of Health et al*,<sup>2</sup> a constitutional challenge, while in Canada the relevant jurisprudence concerns the interpretation of the concept of medical necessity, articulated for the most part in non-constitutional cases.

The International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>3</sup> recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.<sup>24</sup>

Signatories to the Convention are obliged to take steps to realize this right, with the recognition that the obligation will differ for different states depending on their available resources. Faced with limited funds, many governments argue that they are unable to take the steps required to achieve the full realization of the highest attainable standard for their population. Countries with a commitment to socialized medicine face a particularly difficult challenge as the rising costs of health care put great strain on publicly funded medical systems.

Both Canada and South Africa face this problem, albeit in different contexts. Canada is a wealthy country with a long history of socialized medicine. South Africa is a poorer state, emerging as a full-fledged democracy after a long history of apartheid. While the population sizes are not that dissimilar - about 44 million South Africans compared with about 32 million Canadians -South Africa does not have the infrastructure to properly serve the healthcare needs of many of its citizens. In addition, approximately 11 percent of the South African population is infected with HIV/AIDS, including 24 percent of pregnant women.5 HIV prevalence studies in Canada indicate an overall infection rate of 0.0016 percent and an infection rate among pregnant women of about 0.03-0.04 percent, although data for some provinces have not been updated for five or more years.<sup>6</sup> So while access to health care may be a life-or-death situation for individuals in each country, in many ways the stakes are much higher in South Africa.

Despite these differences, there are similarities. In particular, these revolve around how individuals have sought to ensure access to health care in both these countries and how governments have tried to avoid committing additional resources to the public medical systems. In South Africa, the central case is TAC v Minister of Health, while in Canada the relevant jurisprudence concerns the interpretation of the concept of medical necessity. Comparing the South African case with the Canadian cases, we see that the arguments relied on by litigants seeking state-funded health care are strikingly similar. Moreover, in deciding such cases, both South African and

Canadian courts have analyzed a number of factors, including the effectiveness of the treatment sought, whether or not the treatment represents an accepted standard of care in other jurisdictions, and the cost of the treatment.

### TAC v Minister of Health

The decision in TAC v Minister of Health revolved around two main issues: (1) the availability of the drug nevirapine in public hospitals; and (2) the creation and implementation by the South African government of a mother-to-child transmission (MTCT) program to prevent the transmission of HIV during childbirth. In July 2000, the manufacturer of nevirapine offered to supply the drug to the South African government free of charge for a period of five years.7 Despite studies demonstrating the effectiveness of the drug in preventing MTCT, the government chose to limit the availability of the drug to a small number of pilot projects and refused to make it generally available for use in public-sector hospitals where most poor women are treated.

The government also refused to create and implement an MTCT prevention program. It suggested it was waiting for further research results on the effectiveness of nevirapine before planning an implementation program. When the study was completed and the government still did not act, TAC, supported by the Save Our Babies Campaign and the Children's Rights Centre, initiated legal action.<sup>8</sup>

TAC challenged the government's decision, arguing that it violated a multitude of constitutional rights: the right of access to health care; the rights to equality, life, dignity, and

reproductive choice; and the rights of children.<sup>9</sup> TAC also argued that the failure amounted to a violation of the

TAC challenged the government's decision, arguing that it violated the right of access to health care, and the rights to equality, life, dignity, and reproductive choice.

duties of public officials and a violation of the rights of children below the age of six and of pregnant women to have access to free health services.<sup>10</sup> Finally, TAC challenged the government's approach, arguing that it violated international law and international obligations incurred by South Africa.<sup>11</sup>

This article will focus on the right of access to health care as set out in sections 27(1) and (2) of the Constitution of the Republic of South Africa, 1996.<sup>12</sup> Section 27 grants everyone a number of rights, including the right "to have access to … health care services, including reproductive health care" and obliges the state to "take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation" of these rights.<sup>13</sup>

TAC's arguments regarding the right of access to health care centred on two points, namely that this right as contained in the Constitution created both a positive obligation on the state to provide such access and a negative obligation to refrain from activities that would impinge on the right of access. In making these arguments, TAC set out to establish the effectiveness of antiretroviral drugs, including nevirapine, the role of antiretrovirals in internationally accepted standards of care, and the costs and benefits of nevirapine.

The government responded with three arguments. First, it disputed the safety and the efficacy of the drug, arguing that more testing was needed before it could conclude that it was safe to use nevirapine to prevent MTCT.14 Second, it argued that making nevirapine and an MTCT prevention program universally available was prohibitively expensive. It said that nevirapine would gradually be made available to the public as funds allowed.<sup>15</sup> Finally, it argued that the court would be making a policy decision if it granted the relief sought by TAC, something it had no authority to do.16

In his ruling, Justice Botha framed the issue as being one of whether "the steps taken by the ... respondents with regard to the prevention of MTCT of HIV by establishing 18 pilot sites and confining the dispensing of Nevirapine to those sites, can be considered to be in compliance with the obligation of the State in terms of section 27(2) [of the Constitution]."<sup>17</sup> He dismissed the government's argument that issuing an order would be a policy decision, finding that it was his role "to determine whether the steps taken by the respondents were, in the circumstances, reasonable."18 He then considered the existence and scope of the constitutional obligation of the government to make nevirapine available in public facilities outside the test sites.

Justice Botha largely agreed with TAC's arguments, and he followed the precedent set by *Government of the Republic of South Africa* v *Grootboom and Others*.<sup>19</sup> In that case, the Constitutional Court found that the government had both a posi-

"About one thing there must be no misunderstanding: a country-wide MTCT prevention programme is an ineluctable obligation of the State."

tive obligation to ensure the progressive realization of rights in the Constitution and a negative obligation to desist from actions that would impinge on the progressive realization of these rights. Although the right to housing was at stake in *Grootboom*, Justice Botha applied the same reasoning to section 27(2) of the Constitution and its obligations concerning the right of access to health care.

In applying the test from Grootboom, Justice Botha found "that the policy of the ... respondents in prohibiting the use of nevirapine outside the pilot sites in the public health sector is not reasonable and that it is an unjustifiable barrier to the progressive realisation of the right to health care. It is a breach of their negative obligation ... to desist from impairing the right to health care."20 Relying on the situation in the Western Cape, a South African province where nevirapine was publicly available, he determined that it was possible for the government to sustain prescription of nevirapine in the public sector. He said that the drug's wide availability in the Western Cape had not caused "chaos or disarray"21 and the manufacturer's offer to supply the drug free of charge meant that the costs of the medication were minimal to nonexistent. While Justice Botha did not cite international law, his perception of a negative obligation is consistent with interpretive comments from the United Nations Committee on Economic, Social and Cultural Rights in reference to the right to health.<sup>22</sup>

Finally, on the issue of the national implementation of an MTCT prevention program, Justice Botha used very forceful language to define the government's positive obligation: "About one thing there must be no misunderstanding: a country-wide MTCT prevention programme is an ineluctable obligation of the State."23 He agreed with TAC that a plan for national implementation did not exist and that the steps taken by the government could not be considered reasonable under section 27(2) of the Constitution. He recognized that the lack of resources was a difficulty, but stated that the availability of resources could only affect the pace of implementation of an MTCT prevention plan, not its existence. After finding the existence of both a negative obligation to avoid impairing the right to health care and a positive obligation to provide access to health care, Justice Botha ordered the South African government to make nevirapine available in public hospitals and "to plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV."24

# Canadian courts and medical necessity

Unlike South Africa, the Canadian Constitution does not contain an explicit right to health or health care. Individuals have attempted to use the Charter of Rights and Freedoms<sup>25</sup> to argue that the lack of public insurance for a particular treatment infringed their right to life or security of the person or constituted a prohibited form of discrimination.26 These cases largely focus on arguments about equality or about whether there is an economic component to the right to security of the person, rather than consider what constitutes a right to health or health care.<sup>27</sup> Some litigants have taken an alternative path in seeking access to health services, basing their arguments on the medical necessity of particular treatments.

In Canada, both federal and provincial governments administer the healthcare system. Federally, the Canada Health Act<sup>28</sup> governs the policy of the medicare system but does not explicitly grant Canadians a legal right to health care.<sup>29</sup> Rather, the Act sets out the criteria that the provincial health insurance programs must meet in order for them to receive full federal funding under the Federal-Provincial Fiscal Arrangements Act.<sup>30</sup> These criteria are the "famous five" of the Canadian healthcare system: public administration, comprehensiveness, universality, portability, and accessibility.31 Sections 8 through 12 of the Canada Health Act further define what a province must do to fulfill the five criteria. Section 9 addresses comprehensiveness and, when read in conjunction with the definition of hospital services in section 2, requires provinces to insure hospital services that are "medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability." The difficulty is that "medically necessary" is nowhere defined in the Canada Health Act.

The difficulty is that "medically necessary" is nowhere defined in the Canada Health Act.

Québec is the only province with a statutory right to health care.<sup>32</sup> It is circumscribed, however, by fiscal considerations.<sup>33</sup> Laws in the other Canadian provinces, much like the Canada Health Act, state that they will insure medically necessary treatments and services but, again, do not define what constitutes "medically necessary." According to the Canadian Bar Association Task Force on Health Care Reform, this amounts to:

an expressed or implied right to health insurance under provincial health insurance acts but this does not constitute a right to health care because there is no guarantee of content of health insurance (i.e., provinces may de-insure services as they choose.) Further, there is no guarantee of procedural fairness in how insured services are selected or delisted.<sup>34</sup>

Not content with an empty right to health insurance, some Canadians have gone further, pressing for some guaranteed content in their public health insurance to meet their specific medical needs. While individual Canadians do not have standing to sue under the Canada Health Act, they can and do bring actions against provincial authorities that argue that certain aspects of health care are medically necessary. The arguments both for and against medical necessity in Canadian case law contain loud echoes of the arguments in *TAC* v *Minister of Health*.

In Stein v Québec (Régie de l'Assurance-maladie),<sup>35</sup> the Régie de l'Assurance-maladie du Québec refused to pay for Barry Stein's outof-country medical expenses.36 Among other things, Stein wanted the Régie to pay for a device known as an Infusaid pump that had been implanted in him by a physician in New York. The Régie refused to pay for the pump, claiming it was an experimental treatment and not available in Canada.<sup>37</sup> In reviewing whether the pump was in fact experimental, the Québec Superior Court considered evidence from Stein's American surgeon that the pump is standard procedure in cancer centres in the US.<sup>38</sup> It also referred to the Régie's own doctor, who said the pump is not available in Canada because of its cost.<sup>39</sup> The fact that the pump had been effective in treating Stein also seemed to play a role in the court's decision.<sup>40</sup> In ordering the Régie to pay for Stein's surgery, the court implied that the treatment was medically necessary regardless of its cost.

In *Cameron* v *Nova Scotia* (*Attorney General*), Alexander Cameron and his wife Cheryl Smith turned to intracytoplasmic sperm injection (ICSI), a form of in vitro fertilization (IVF), after their other attempts to have a baby were unsuccessful.<sup>41</sup> When the province refused to cover the procedures under the Nova Scotia Health Services and Insurance Act,<sup>42</sup> the couple brought an action claiming, among other things, that the treatment was medically necessary and that the wording of the Regulations thus required it to be insured.<sup>43</sup> The action was dismissed at trial. On appeal, Justice Chipman reviewed the evidence of the medical experts, who agreed that IVF is a standard treatment and that ICSI is currently, or is becoming, the treatment of choice. The trial judge felt that "neither 'medically indicated' nor 'standard medical procedure' equates to 'medically required'"<sup>44</sup> and Justice Chipman refused to find this to be an error.<sup>45</sup> Justice Chipman also found cost to be a factor in why the province did not consider IVF and ICSI to be medically necessary:

I much prefer, however, the primary approach of Dr. Collins which simply was that in the scheme of things – in the order of priorities – these two procedures, having regard to costs, the limited success rate and the risks do not, at this time, rank sufficiently high to warrant payment for them from public funding.... I am satisfied that this is the real explanation why these procedures were considered not medically necessary.<sup>46</sup>

He went on to give his own interpretation of what must be considered in determining medical necessity:

Of necessity, what is or is not medically required must be judged by those placed in charge of the administration of the policy. The judgment call requires an appreciation not only of medical procedures, but the availability of funds to finance them.<sup>47</sup>

In sharp contrast to *Stein*, where the court ignored costs in determining medical necessity, the court in *Cameron* explicitly incorporated financial considerations into the definition of what it considered to be medically necessary. According to this interpretation, what is medically necessary treatment is not determined solely by a patient's condition but also takes into account the ability

of the province to pay for a given treatment.<sup>48</sup>

Finally, in *Auton (Guardian ad litem of)* v *British Columbia (Minister of Health)*,<sup>49</sup> a group of autistic children and their guardians brought an action against the BC government claiming, among other things, that the government's treatment programs for autistic children were insufficient.<sup>50</sup> The applicants sought coverage for early intensive applied behavioural analysis (ABA) techniques.

The child petitioners had each received Lovaas Autism Treatment, a form of ABA, which had cost their guardians between \$45,000 and \$60,000 a year per child.<sup>51</sup> At trial, the petitioners argued "that Lovaas Autism Treatment is a medically necessary service insofar as it significantly improves the condition of these children."52 In assessing medical necessity, the court weighed the scientific evidence for and against Lovaas Autism Treatment and concluded that the most effective therapies for autism are those based on ABA.<sup>53</sup> The court then examined the treatments provided by the BC government for autistic children, which, it concluded, were "positively discredited by one of the Crown's own expert witnesses."54 Finally, the court examined government-supported treatment for autism in other jurisdictions - Canadian, American, and British - and found that numerous other governments funded ABA therapies for autistic children.55 As a result, the court found ABA treatment generally, although not Lovaas Autism Treatment specifically, to be a medically necessary service.56

These cases point to the need for a three-pronged analysis in determining medical necessity: a review of the effectiveness of the treatment in question; a review of the services the government already insures for the malady in question; and a review of whether the treatment is standard in other jurisdictions. The court in *Cameron* also added a fourth element: cost.

A belief in the apparent effectiveness of the treatment played a role in Justice Botha's order that the government make nevirapine publicly available.

### Access to medically necessary services in Canada and South Africa: a comparison

How does the test for medical necessity articulated by Canadian courts relate to TAC v Minister of Health? It is, in fact, very similar to the arguments raised by TAC in its affidavit and largely adopted by Justice Botha. The effectiveness of nevirapine was an issue for both TAC and the South African government. Justice Botha commented on the apparent effectiveness of nevirapine and how its conditional registration with the national drug authority pointed to its being "safe and efficacious."57 As was the case in Stein and Auton, a belief in the apparent effectiveness of the treatment played a role in Justice Botha's order that the government make nevirapine publicly available.

The second element of the test concerns the services already insured by the South African government for treating HIV/AIDS. TAC made the point that nevirapine and information on MTCT was not available to women in public hospitals outside the 18 pilot project sites. Justice Botha found there to be "incontrovertible evidence that there is a residual or latent capacity in the public sector outside the 18 pilot sites to prescribe Nevirapine."<sup>58</sup> This is very similar to the situation in *Auton*, where the poor to non-existent nature of publicly insured services for autistic children was a factor in the court's decision ordering the government to pay for ABA treatments.

The third element of the test is the use of the treatment in other jurisdictions. In its affidavit, TAC did not so much review how standard the use of nevirapine or the implementation of an MTCT prevention program was in other countries, but instead focused on the recommendations of the World Health Organization. These recommendations included placing nevirapine on its Essential Drugs List and suggesting alternatives to breastfeeding for HIV-positive mothers. Justice Botha chose to focus on the experience in the Western Cape, where nevirapine is widely available. The experience there pointed to a more equitable access to treatment as well as a contribution to the progressive realization of the right to health.59

The final element of the test, used by both TAC and the South African government, was cost. Justice Botha did not state whether he thought that an MTCT prevention program would actually save money in the long term; rather, he believed cost was not a consideration in the progressive realization of the right to health care. Progress would have to be made and the resources would have to be found gradually. The cost issue was also considered in *Cameron*. But the approach taken by Justice Chipman in that case is in sharp contrast to that of Justice Botha in *TAC*. The former believed cost to have a role in determining medical necessity; the latter, while not phrasing his decision in the same terms, essentially believed cost not to be relevant in determining medical necessity and what constitutes a right to health care.

The decision in TAC v Minister of *Health* may help Canadian advocates enunciate claims to health and health care in the language of human rights. This could have numerous beneficial consequences, including pushing Canadian governments to realize commitments under the ICESCR, and helping courts to clearly define the substantial interest in health care at stake in cases like Stein. Cameron, and Auton. A commitment to insure what is medically necessary is vague and unclear; a commitment to insure services and treatments that contribute to the realization of a right to health should make it easier for the courts to appropriately judge the competing interests.

#### Conclusion

Traditionally, Canadian courts have not turned to their South African counterparts when seeking possible interpretations of Canadian law. That said, the South African Constitution contains many more specific rights – such as the right to health care – than does our Charter of Rights and Freedoms. As the South African courts interpret and apply these rights, they are increasingly likely to become a source of inspiration for other jurisdictions.

Although they are couched in different terms, the tests for determining what constitutes medical necessity, and when the right to health care is being impinged upon by the state, involve common considerations. What TAC v Minister of Health contributes to this discussion is that not only is there a right to health, and not only do governments have an obligation to progressively realize this right, but these same governments must also be sure not to stand in the way of the realization of this right. The acknowledgment of this negative obligation makes the right to health that much more forceful. A similar acknowledgment in the Canadian test for medical necessity has yet to arise, but if Canadian judges look to their South African counterparts, we may come that much closer to enunciating our own right to health here in Canada.

- Kathryn Garforth

Kathryn Garforth, BA, LLB, MES, graduated from Osgoode Hall Law School, York University, in 2003.

<sup>3</sup> 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976).

<sup>&</sup>lt;sup>1</sup> Details of the contest can be found at www.aidslaw.ca/Maincontent/lawessaycontest.htm.

<sup>&</sup>lt;sup>2</sup> Case No. 21182/2001, 14 December 2001, High Court of South Africa (Transvaal Provincial Division). Reported in 2002(4) BCLR 356 (T) ), 2001 SACLR LEXIS 123, and available via www.tac.org.za [hereinafter TAC v Minister of Health], cited to LEXIS, which has its own internal page numbering for the judgment, which numbering is used in the following notes. The Order of the High Court was varied on appeal to the Constitutional Court of South Africa, Case CCT 8/02, 5 July 2002, available at http://www.concourt.gov.za/files/tac/ tac.pdf. The Constitutional Court generally ordered the South African and state government to devise and implement within its available resources a comprehensive and co-ordinated program 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. For the full Order of the Court, see the decision at para 135.

<sup>&</sup>lt;sup>4</sup> Ibid at article 12(1).

<sup>&</sup>lt;sup>5</sup> Joint United Nations Programme on HIV/AIDS. Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections: South Africa. UNAIDS, 2002, at 2-3, online at www.unaids.org/hivaidsinfo/statistics/ fact\_sheets/pdfs/Southafrica\_en.pdf (accessed 2 December 2002).

<sup>6</sup> The overall HIV infection rate in Canada can be obtained by dividing the estimated number of HIVpositive people living in Canada (49,800 in 1999, according to Health Canada. HIV/AIDS Epi Update: Prevalent HIV Infections in Canada: Up to One-Third May Not Be Diagnosed. Ottawa, April 2003) by the population estimate for the same year (30,403,900 according to Statistics Canada, available at www.statcan.ca/english/Pgdb/demo02.htm). For the situation of pregnant women, see Health Canada. HIV/AIDS Epi Update: Perinatal Transmission of HIV. Ottawa, April 2003. The provincial range is from 1.9/10,000 (Ontario 1991-1992) to 8.7/10,000 (Newfoundland 1991-1993) and large metropolitan areas have higher rates (4.7/10,100 for Vancouver versus 3.4/10,000 for the rest of BC in 1994, and 15.3/10,000 for Montréal versus 5.2/10,000 for the province of Québec in 1990). However, even provinces without large metropolitan areas have significant rates (for example, 4.1/10,000 in New Brunswick for 1994-1996), and data from Manitoba suggest an increasing trend of HIV infection among women of childbearing age (from 0.7/10,000 in 1991 to 3.2/10,000 in 1994-1995). A study is currently underway in Ontario to update the HIV prevalence in pregnant women. Preliminary results indicate a prevalence of 3.7/10,000 among the approximately 72 percent of pregnant women who agreed to voluntary testing in the third quarter of 2002.

<sup>7</sup> TAC v Minister of Health, supra, note 2 at 15.

<sup>8</sup> All future references to TAC refer to the three applicants in the case.

<sup>9</sup> Constitution of the Republic of South Africa, 1996, Act 108 of 1996, ss 27, 9, 11, 10, 12(2), and 28 respectively.

<sup>10</sup> Ibid at s 195 and Government Notice 657; see also L Gerntholtz. Preventing mother-to-child transmission: landmark decision by South African court. *Canadian HIV/AIDS Policy & Law Review* 2002; 6(3): 1, 20-24.

11 Gernholtz, ibid.

<sup>12</sup> See supra, note 9.

<sup>13</sup> Section 27 reads:

27. (1) Everyone has the right to have access to:

a. health care services, including reproductive health care;

b. sufficient food and water; and

c. social security, including, if they are unable to support themselves and their dependants, appropriate social assistance. (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3) No one may be refused emergency medical treatment.

 $^{14}\,$  TAC v Minister of Health, supra, note 2 at 24-25.

<sup>15</sup> Ibid at 26-27.

- <sup>16</sup> Ibid at 56.
- <sup>17</sup> Ibid at 64.
- <sup>18</sup> Ibid at 67.
- 19 2001(1) SA 46 (CC).

<sup>20</sup> TAC v Minister of Health, supra, note 2 at 59.

<sup>21</sup> Ibid at 77.

<sup>22</sup> UN Committee on Economic, Social and Cultural Rights. General Comment 14: The Right to the Highest Attainable Standard of Health (Art. 12). 4 July 2000, UN Doc. E/C, 12/2000/4.

 $^{23}$  TAC v Minister of Health, supra, note 2 at 83.

<sup>24</sup> Ibid at 86.

<sup>25</sup> Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11 (hereinafter "Charter").

<sup>26</sup> Sections 7 and 15.

<sup>27</sup> See, eg, Brown v British Columbia (Minister of Health) (1990), 66 DLR (4<sup>th</sup>) 444 where a section 7 argument for provincially funded access to AIDS medication was dismissed. See, eg, *Eldridge* v British Columbia (Attorney General), [1997] 3 SCR 624 for a successful s I 5 argument for access to health services and *Cameron*, infra, note 41, for an unsuccessful s I 5 argument.

<sup>28</sup> RSC 1985, c C-6.

<sup>29</sup> RA Stradiotto, JI Boudreau. Resource allocation and accountability in health care. *Health Law Canada* 2000; 20: 40, online at 2000 CHL LEXIS 2 at 3 [cited to I EXIS].

<sup>30</sup> Supra, note 28, s 2 definition of "cash contribution;" s 4. The Federal-Provincial Fiscal Arrangements Act is RSC 1985, c F-8.

<sup>31</sup> Supra, note 28, at s 7.

 $^{\rm 32}$  Health Services and Social Services Act, RSQ, c S-4.2, s 5.

<sup>33</sup> Ibid at s 13.

<sup>34</sup> What's Law Got to do With It? Health Care Reform in Canada. Ottawa: The Canadian Bar Association, 1994, quoted in *Cameron*, infra, note 41 at para 79.

<sup>35</sup> [1999] QJ No 2724 (QL).

<sup>36</sup> Ibid at paras I-3.

<sup>37</sup> Ibid at para 27. Experimental treatments are not considered to be medically necessary. This creates an incentive for cash-strapped provincial health insurance plans to label expensive new treatments as experimental in order to avoid having to pay for them. See M Somerville. The Ethical Canary: Science, Society and the Human Spirit. Toronto: Penguin Books, 2001, at 228.

<sup>38</sup> Supra, note 35 at para 40.

<sup>39</sup> Ibid.

<sup>40</sup> Ibid at para 43.

<sup>41</sup> [1999] NSJ No 297 (QL), leave to appeal to SCC refused [1999] SCCA No 531 (QL).

<sup>42</sup> RSNS 1989, c 20.

<sup>43</sup> Supra, note 41 at paras 28, 70.

<sup>44</sup> Ibid at para 41.

<sup>45</sup> Ibid at para 90.

<sup>46</sup> Ibid at para 87.

<sup>47</sup> Ibid at para 101.

<sup>48</sup> Somerville, supra, note 37 at 233-234.

<sup>49</sup> [2000] BCJ No 1547 (QL) (aff'd Auton (Guardian ad litem of) v British Columbia (Attorney General) [2002] BCJ No 2258 (QL).

<sup>50</sup> Ibid at para 8.

<sup>51</sup> Ibid at para 24.

<sup>52</sup> Ibid at para 29.

<sup>53</sup> Ibid at paras 51-52.
<sup>54</sup> Ibid at para 66.

- <sup>55</sup> Ibid at paras 69-83.
- <sup>56</sup> Ibid at para 102.

<sup>57</sup> TAC v Minister of Health, supra, note 2 at 73.

<sup>58</sup> Ibid at 75.

<sup>59</sup> Ibid at 77.