Canadian HIV/AIDS Policy & Law Newsletter

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Canadian HIV/AIDS Policy & Law Newsletter

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TESTING & CONFIDENTIALITY

HIV Testing and Confidentiality Issues Re-examined

As part of their Joint Project on Legal and Ethical Issues Raised by HIV/AIDS, the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society have produced a *Discussion Paper* on HIV testing and confidentiality.[1] The Paper re-examines the broad social, legal, and medical consensus regarding the appropriate use of the HIV test and its results in light of new developments, including the availability of new treatments; the approval and marketing, in the United States, of the first HIV home testing kits; and the shifting demographics of the epidemic.

In the coming months the Project will solicit comments on the Discussion Paper from a broad range of individuals and organizations, organize a national workshop on the issues, and publish a final report in the spring of 1997.[2]

This issue of the *Newsletter* briefly revisits the history of HIV testing in Canada and reviews some of the new developments. It includes two articles on home testing for HIV: one argues for a cautious approach to the approval of such testing in Canada;[3] the other, written from a US perspective, argues that barring the licensure of home collection testing would be an unwarranted act of paternalistic and unwise public policy.[4]

History: Development of a Canadian Consensus[5]

Since the HIV antibody test was first made widely available in 1985, a great deal has been written on the question of the appropriate legal and ethical use of the test. In Canada, both the National Advisory Committee on AIDS[6] and the Law Reform Commission of Ontario[7] have written extensive and detailed reports. Both reports reached similar conclusions. Most importantly, both recommended that HIV testing only be done in a professional health-care setting with the specific, informed consent of the individuals being tested, and that the results remain either anonymous or confidential in all but the most

exceptional circumstances.

Although there had been calls for the widespread mandatory or routine testing of certain groups or populations, such as gay men, sex workers, pregnant women, hospital patients, and health-care workers, and for the mandatory reporting of the test results to public health authorities in all cases, both reports rejected such an approach. The reports recognized the significant impact a finding of HIV infection could have for a patient and concluded that the common law doctrine of informed consent required the specific, informed consent of each patient before an HIV test could be lawfully administered. Thus, they ruled out any practice of "routine" testing of certain populations without their specific consent. Both reports also concluded that a mandatory testing scheme would not further any particular public health objective. They noted that HIV was unlike other infectious diseases, where a testing and treatment regime might significantly reduce the spread of infection, because there were no effective treatments to cure HIV infection or significantly reduce the infectivity of persons with HIV. Moreover, the reports noted that a mandatory testing scheme would have the effect of driving away from the health-care system the persons most at risk of HIV infection and most in need of prevention education.

New Developments

Thus, a broad social, legal, and medical consensus developed regarding the appropriate use of the HIV test. This consensus has, however, recently come under increasing stress due to at least three developments.

New Treatments

First, new treatments have been developed that hold out hope that the progression of HIV infection can be slowed or even halted in some persons living with HIV, and that the infectivity of persons with HIV can be significantly reduced, thus reducing the risk of transmission to others. These new treatments can also significantly reduce the risk of perinatal transmission and, if administered very shortly after exposure to HIV, can reduce the risk of seroconversion.[8] Availability of these new treatments has raised the question of whether in some cases a more aggressive, and even mandatory, testing and treatment program might effectively prevent the further spread of HIV infection.

Home HIV Testing Kits

A second development has been the proposed introduction of home HIV testing kits. Such kits raise the possibility that HIV testing might become widely and easily available outside the health-care setting. The current model of HIV testing is closely directed by a health-care professional and involves (or should involve) intensive counselling and support. Should this model be changed, making HIV testing available outside a health-care setting, and with a minimum of professional assistance?

Shifting Demographics

A third development is the shifting demographics of HIV infection. Early in the epidemic, the vast majority of persons affected were those who had engaged in some readily identifiable high-risk activity, such as unprotected sex between men and sharing of drug injection equipment. Among those at higher risk, it was widely accepted that the most effective prevention method was education to reduce high-risk behaviour, and not any scheme of mandatory testing. However, the epidemic has increasingly moved beyond persons engaging in readily identifiable high-risk activity. In particular, the number of women infected with HIV continues to increase, and many of these women have become infected as a result of sexual relations with a male who had engaged in high-risk behaviour without informing his sexual partner. These women may have had no particular reason to believe that they were at risk of HIV infection, and as a result may not have taken any precautions.

This raises the question of whether more aggressive public health measures may be warranted, including mandatory reporting and partner notification. The consensus to date has largely concluded that the confidentiality of HIV testing results should be maintained in most cases, and partner notification could only be rarely useful. However, as treatments improve, holding out the hope, among other things, that the risk of perinatal transmission may be reduced, it may appear that a more aggressive testing and reporting policy, particularly in relation to persons who may not otherwise be aware that they are at any risk of HIV infection, is appropriate.

Re-examination of the Consensus

What is clear is that the previous consensus regarding HIV testing and confidentiality can no longer be assumed. New technological developments and the shifting demographics of the epidemic call for a re-examination of this consensus. These developments are examined in the *Discussion Paper*, along with their implications for HIV testing and confidentiality.

Conclusion

After careful analysis, the Paper concludes that, while the new technologies and treatments have raised – and will continue to raise – new challenges, the principle of testing only with the specific, informed consent of the subject, and the confidentiality of the results in all but the most exceptional circumstances, must remain the predominant model. It is this model that will ensure that the maximum number of persons with HIV seek testing and treatment; in turn, this will not only ensure that persons with HIV are provided with optimal care, but also significantly further the public health objective of reducing the spread of HIV infection.

For more information and/or a copy of the *Discussion Paper*, contact the Project at (514) 987–3000 ext 6937#; fax: (514) 987–3422; e-mail: info@aidslaw.ca. Members of the Network and/or CAS may obtain one complimentary copy. For non-members, rates are as follows: Canada: Can$12; US: US$12; overseas: US$15. The *Discussion Paper* is also available on the Internet at http://www.aidslaw.ca/

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ENDNOTES

[1] M Palles, R Jürgens. *HIV Testing and Confidentiality*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1996.

[2] For more details, see R Jürgens. Project Begins Work on Testing and Confidentiality Issues. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 3.

[3] See, infra, M Palles and R Jürgens. Home Testing for HIV: Potential Benefits and Pitfalls.

[4] R Bayer et al, infra. Testing for HIV Infection at Home.

[5] The following section is taken, in large part, from W Flanagan. Comment on the Discussion Paper on HIV Testing and Confidentiality. Toronto, 10 October 1996.

[6] M Somerville, N Gilmore. Human Immunodeficiency Virus Antibody Testing in Canada. A Report Submitted to and Approved by the National Advisory Committee on AIDS. Montréal: McGill Centre for Medicine, Ethics and Law, 1988. See also National Advisory Committee on AIDS. Human Immunodeficiency Virus Antibody Testing in Canada. Recommendations of the National Advisory Committee on AIDS. *Canada Diseases Weekly Report* 1989; 15(8): 37-43.

[7] Ontario Law Reform Commission. *Report on Testing for AIDS*. Toronto: The Commission, 1992.

[8] Update: Provisional Public Health Service Recommendations for Chemoprophylaxis after Occupational Exposure to HIV. *Morbidity and Mortality Weekly Report* 1996; 45(22): 468-472.

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Compassionate Access to Investigational Therapies

From December 1995 to May 1996, the House of Commons Sub-Committee on HIV/AIDS organized a series of National Round Tables on the issue of compassionate access to investigational therapies. In October 1996, it released a report containing eight recommendations aimed at ensuring "a more liberalized form of compassionate access that is acceptable to all those concerned."[1]

Introduction

The House of Commons Sub-Committee on HIV/AIDS was established by the Standing Committee on Health in November 1994, and directed to

> study the spread of HIV and the prevention, treatment and support of persons infected or affected by HIV/AIDS, with special attention being given to the role of poverty and discrimination on the aforementioned matters.

The first action taken by the Sub-Committee was to study the effectiveness of Canada's National AIDS Strategy. During its examination of the Strategy, the Sub-Committee heard that one of the most immediate and pressing concerns of people with AIDS and, indeed, of anyone with a life-threatening illness, is the issue of access to experimental drugs. The normal process of drug development, testing, evaluation and approval can take five to ten years, time that people with a terminal condition simply do not have.

The Sub-Committee decided to address the issue of compassionate access to experimental drugs by hosting a series of National Round Tables.

- At the opening Round Table on 6 December 1995, "the human face of catastrophic illness was presented when the Sub-Committee heard from advocacy groups and the victims of cancer, amyotrophic lateral sclerosis, multiple sclerosis and AIDS."[2] In addition, primary-care physicians, nurses and representatives of Canada's pharmaceutical industry attended this Round Table.

- At the second Round Table, Canada's drug regulatory process and a proposed Special Access Program (SAP) were examined.

- At the third Round Table, the ethical and legal considerations surrounding expanded access were discussed by Canadian experts in the fields of bioethics and medical law.

- At the fourth session, the issue of responsibility (government leadership, financial responsibility, and the responsibilities of physicians, patients, insurance companies and pharmaceutical manufacturers) was addressed.

- The final Round Table, on 1 May 1996, was attended by national organizations: the Canadian Cancer

Society, Canadian AIDS Society, Canadian Haemophilia Society, Canadian HIV Trails Network, National Council on Bioethics in Human Research, AIDS Action Now!, Pharmaceutical Manufacturers Association of Canada, and Health Canada. These groups reviewed the proceedings of the previous sessions, attempted to clarify unresolved issues, establish common ground, and provide the Sub-Committee with suggestions and recommendations for action.

As stated in the Sub-Committee's Report, the "challenge given to the Sub-Committee was to determine if it is possible to protect the drug research system and the needs of the general public without sacrificing people who are already ill.[3]

Compassionate Access[4]

Compassionate access to experimental drugs, while important in the context of many diseases, has become a real issue of empowerment for people living with HIV/AIDS. It has been argued that people who are approaching the final stages of an incurable illness and are therefore "catastrophically ill" should have the right to take whatever experimental drug is available. This has been qualified as a "catastrophic right." A catastrophic right, which has never been legally sanctioned or recognized, is based on the idea that an experimental treatment is in fact the only hope for people who are terminally ill. In such cases, the potential benefits more easily outweigh the risks involved in taking a non-approved drug or undergoing a novel treatment, such as exposure to potentially severe side effects and in some cases even death.

Compassionate access to new drugs can also be important when a new drug has been developed, and preliminary results of studies in Canada and elsewhere show great promise. Drug approval takes time, and people who are "catastrophically ill" want to be able to benefit from new life-prolonging drugs. The Drugs Directorate has, under the ordinary review process, a priority review policy for drugs that are intended to treat immediately life-threatening conditions. The AIDS drug 3TC, for example, was approved in five months rather than the average 17 months for an ordinary review. But for many people, five months can still be too long. They might want to benefit from newly developed drugs that are not yet approved.

Obtaining Experimental Drugs

In Canada, there are currently two major ways of obtaining experimental drugs:

- through participation in clinical trials; and
- through the Emergency Drug Release Program (EDRP).

Further, an individual may legally import a drug and self- medicate.

Clinical Trials

Many - not to say most - of the people living with HIV/AIDS participate at one time or another in a clinical trial in which novel therapies or drugs are tested. In these trials, novel therapy is compared to standard treatment or to placebo. Volunteers are assigned to one of these groups. The trials are most often double-blind, which means that neither the patients nor their physician know who is receiving the new drug. In some trials an "open arm" is added to the study, in which people who did not fulfil the selection criteria or did not participate for other reasons in the blind trial can receive the experimental treatment. It is only in open-arm trials that people are sure to receive the experimental drug. This has, in the past, led to delay in the conduct of trials, when people only wanted to be included in the open arm of a study. Research participants are also sometimes switched from the double-blind study to the open arm before the end of a trial. When the health of participants in a study is suddenly deteriorating, the drug they are taking will be unblinded and if they were receiving the standard drug they can be switched to the open arm of the study. In such cases, the novel drug might be the only hope.

Offering the new drug to people in an open arm is often done for compassionate reasons. Pharmaceutical companies are legally not obliged, however, to organize an open arm. A moral argument can be made that companies should offer the novel treatment to research participants once the trial is over, if the treatment has shown its effectiveness. Research participants have assisted in the testing of this drug. They were normally not paid for doing so and were exposed to

risks. In return, one could argue, pharmaceutical companies owe them assistance once the trial is over.

The Emergency Drug Release Program

In a clinical trial, participants generally are not sure whether or not they are receiving the new drug. This is not so under the EDRP. The EDRP has been established by Health Canada to allow physicians to treat people with life-threatening conditions when there is no standard treatment or when no standard drugs are available in Canada. This procedure has been used mainly in emergency cases, for treating rare diseases for which no approved drug is available in Canada. In the context of HIV/AIDS, the system has been invoked to allow patients to obtain compassionate access to promising experimental drugs that are still being tested.

The procedure for the EDRP is as follows: a physician can send a request for an emergency drug release to the Drug Directorate of Health Canada, explaining the medical urgency and data on drug efficacy and safety. The Drug Directorate then contacts the manufacturer to authorize release and sends a letter of authorization to the physician. Manufacturers are free to authorize release of the drug or not.

A Special Access Program

To respond better to the growing demand for both emergency access and compassionate access through the EDRP, the Drugs Directorate proposed to introduce a new program, the Special Access Program (SAP). This SAP would consist of two separate procedures:

- an emergency release procedure; and
- release of a drug that could maintain or extend quality of life.

In the first case, physicians would be allowed to directly contact the manufacturer when a patient is in a life-threatening situation and the release of a drug seems essential. The Drugs Directorate would have to be informed within 48 hours by the manufacturer. In the second case, the manufacturer would have to request an authorization from the Directorate to release a drug to a maximum of 50 patients. The Drug Directorate could refuse a request but would have to justify such refusal. It could also recommend establishing a clinical trial instead of allowing special access. The manufacturer would have to provide detailed information about the drug, potential side effects, dosage, etc. Data on adverse effects would have to be maintained by the manufacturer and a system of reporting would be introduced. For every new group of 50 prescriptions, a new authorization would have to be requested.

This new program would be less time-consuming for both the administration and the physicians involved and would therefore allow patients to have earlier access to experimental drugs.

Ethical and Legal Issues Raised by the SAP

The participants in the discussion were asked to comment on the social, ethical and legal issues raised by this new program. Questions were raised as to the danger that this program would turn into a pre-marketing program for non-approved drugs:

- that people with HIV/AIDS, while relying on preliminary results of studies, could be exposed to serious harm even if they were in the final stages of the disease;
- that the conduct of good clinical trials could be hampered;
- that pharmaceutical companies would conduct trials elsewhere to avoid requests for free compassionate access to drugs; and
- that the liability of the government could increase.

Several proposals were made to render the procedure safer and to promote access to new drugs. It was suggested that

pharmaceutical companies should be obliged to justify their decision not to provide compassionate access. It would seem reasonable, for example, to refuse compassionate access if scarcity of the product or the financial burdens would make it impossible for a company to organize a clinical trial at the same time. Some also argued that local Research Ethics Boards should be involved in the procedure; they should approve requests for compassionate access made under the SAP by individual physicians and pharmaceutical companies. Conditional approval of drugs was also mentioned as an option. Under such conditional approval, further reports on the efficacy and safety of the drug could lead to final approval or withdrawal of the drug.

The Report: Issues and Recommendations

The Sub-Committee's Report analyzes these proposals in depth and contains sections on the concept of catastrophic rights; access to unapproved drugs; the case for compassionate access; concerns surrounding compassionate access; consensus on the need for compassionate access; proposed mechanisms to compel or encourage compassionate access to investigational therapies; ethical aspects; the role of Health Canada in making new therapies available; liability; and responsibility.

Eight recommendations are made:

1. The Sub-Committee recommends that the Governor in Council make whatever changes are necessary to the regulations of the Food and Drugs Act in order to require that pre-investigational new drug submissions and investigational new drug submissions include a statement of the pharmaceutical manufacturer's intention with respect to the compassionate provision of the investigational agent(s).

2. The Sub-Committee recommends that Health Canada, in cooperation with representatives of the Pharmaceutical Manufacturers Association of Canada and treatment activist groups, develop compassionate access guidelines. These guidelines are to include, but not necessarily be limited to, criteria to judge whether a pharmaceutical manufacturer's offer of compassionate access to an investigational therapy is fair and reasonable; and provisions to accommodate the flexible nature of consumer demand and the availability of an investigational therapy. These guidelines should be developed in all due haste and be available for decision-making purposes no later than 1 June 1997.

3. When a pharmaceutical manufacturer, in the absence of a clinical trial in Canada, establishes a compassionate access program to provide Canadian patients with an experimental therapy, the Sub-Committee recommends that the Drugs Directorate of Health Canada conduct the evaluation of the new drug submission for that therapy as expeditiously as possible.

4. The Sub-Committee recommends that the Governor in Council amend the regulations of the Food and Drugs Act that pertain to the Emergency Drug Release Program to give Health Canada the authority to require pharmaceutical manufacturers to account for a refusal to provide compassionate access to a therapy not approved for sale in Canada.

5. The Sub-Committee recommends that Health Canada review and strengthen the mandate of the National Council on Bioethics in Human Research to clearly establish the objective of promoting harmonized national standards of ethics in research involving humans.

6. The Sub-Committee recommends that Health Canada move with all due haste to put into effect, no later than 1 June 1997, a conditional approval process for drugs designed to treat life-threatening illnesses.

7. The Sub-Committee recommends that the Government of Canada study the future direction of drug regulation in Canada. This study should investigate, but not necessarily be limited to, the costbenefits of the present system, the advisability of phasing out the Canadian system, the efficiency and effectiveness of the new drug evaluation system in the European Community, and the possibility of applying this model to NAFTA partners.

8. The Sub-Committee recommends that the federal Minister of Health propose to the Conference of

Ministers of Health the establishment of a consultative mechanism to facilitate the timely adoption of new drugs on provincial formularies.

Follow-Up

The Committee has asked that the government table a comprehensive response to these recommendations and the Report.

The following two texts were presented at one of the round tables organized by the Sub-Committee. In the next issue of the *Newsletter*, we will publish an analysis of and commentary on the Report and its recommendations.

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ENDNOTES

[1] House of Commons Canada. *Compassionate Access to Investigational Therapies. Second Report of the Standing Committee on Health - First Report of the Sub-Committee on HIV/AIDS*. Ottawa: The House, October 1996 (Second Session, 35th Parliament), with reference to House of Commons, Minutes of Proceedings and Evidence of the Sub-Committee on HIV/AIDS of the Standing Committee on Health, Meeting No 19, 6 December 1995, at 2.

[2] Ibid.

[3] Ibid, with reference to Meeting No 19, 6 December 1995, at 8-12.

[4] The following sections were written by Trudo Lemmens.

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HIV/AIDS and Aboriginal Communities: Problems of Jurisdiction and Discrimination: A Review

Little discussion or research can be found on legal issues raised by HIV/AIDS in aboriginal communities in Canada. A paper prepared by Stefan Matiation for the 2-Spirited People of the First Nations on the subject is therefore a most welcome contribution.[1]

The paper explores the impact of HIV/AIDS on aboriginal communities and identifies two legal obstacles that such communities face in coming to grips with HIV/AIDS:

- the lack of political and legal power to develop and deliver HIV/AIDS-related health services to aboriginal peoples; and

- deficiencies in human rights legislation as a source of protection for aboriginal people who have HIV/AIDS.

According to the paper, it is difficult to determine the rate of HIV infection among aboriginal peoples. At the time the paper was written (April 1995), the estimate was at least 1000 people who *know* they are living with HIV/AIDS; the figure for those who actually have HIV/AIDS is higher.[2] Because the highest rates of infection are among adolescents and young adults – the persons who in aboriginal communities will be in the position to determine the future of aboriginal peoples in the next century – the paper contends that the rapidly increasing rate of HIV/AIDS infection poses a very serious threat to aboriginal peoples in Canada.

HIV and Aboriginal Peoples

The paper begins with a general discussion of HIV, and then goes on to describe the effects of the Canadian health system on aboriginal peoples. In the author's view, the Canadian health system has ignored aboriginal needs and imposed a colonial structure that does not recognize their unique cultural values. Despite recent initiatives by Canadian governments, aboriginal peoples, on average, continue to live under worse health conditions than other Canadians. For example,

- infant mortality rates among Inuit and registered Indian populations are more than twice as high as those in the rest of society; and

- the rate of sexually transmitted diseases among aboriginal peoples is estimated to be four to ten times higher than the Canadian average.

The general poor health of aboriginal communities (brought on by substandard housing, inadequate nutrition and lack of health services and information) is, according to the study, a significant health factor for HIV transmission in aboriginal communities in Canada.

The paper cites other contributing factors, such as the disproportionate incidence of sexual violence in aboriginal communities, low self-esteem manifested in high suicide rates among aboriginal peoples, discrimination by non-aboriginal persons and the presence of aboriginal people in such high-risk environments as urban centres and prisons. Because of these risk factors for HIV infection in the aboriginal populations, it is argued that only a comprehensive

"holistic" approach to HIV prevention among aboriginal peoples will work. But such an approach runs into the two legal obstacles mentioned above, obstacles that aggravate HIV/AIDS risks for aboriginal peoples.

Constitutional and Political Barriers to Dealing with HIV/AIDS in Aboriginal Communities

The paper outlines the legal structure within which aboriginal peoples live. Constitutional jurisdiction over "Indians" (as the word is found in the *Constitution Act, 1867*) is exclusively granted to the federal government. This term has been interpreted to cover only First Nations and Inuit peoples, not the Métis. The federal government has created more divisions among aboriginal peoples, because it has not legislated to the full extent of its powers. This leaves those aboriginal peoples living off-reserve in the provinces, as well as those not having "Indian status," in a policy vacuum.

It is in the health area where this policy vacuum causes the greatest difficulties for aboriginal persons living with HIV/AIDS. The federal and provincial governments share many areas of responsibility with respect to health. As a result, aboriginal peoples cannot deal with one level of government to obtain all needed funding or services. This jurisdictional gap is further complicated by legal divisions between status and non-status Indians, and between those living on and off reserves.

Such jurisdictional problems make funding sources for aboriginal peoples difficult to obtain, the paper explains. They force aboriginal organizations dealing with HIV/AIDS to compete for the limited funding available on a playing field already biased against them, and limit the scope of services to the funding source obtained (eg, only to reserve or status populations), away from where the need may be greater. Consequently, aboriginal peoples are often divided against themselves, labeled according to artificial legal definitions (such as "Indian" or "Métis," or status or non-status). Thus, damaging and inappropriate distinctions and divisions are created among aboriginal communities and are further exacerbated by the weaknesses in human rights protection for aboriginal peoples living with HIV/AIDS.

Human Rights Protection for Aboriginal People Living with HIV/AIDS

The paper argues that the jurisdictional problems concerning health service delivery also complicate human rights protection for aboriginal persons living with HIV/AIDS. Moreover, the federal government has not lived up to its responsibilities to aboriginal peoples and has particularly failed to adequately protect the human rights of aboriginal persons living with HIV/AIDS.

One gap in legal protection is due to a section of the *Canadian Human Rights Act*, section 67, which excepts the *Indian Act*. Two aboriginal women have taken human rights cases, one against the band, the other against the Department of Indian Affairs, only to find that the human rights tribunals had to rule that if a band or government decision or policy, no matter how prejudicial to the woman, is made in accordance with the *Indian Act*, human rights protection is unavailable under the federal statute.

Moreover, bands exercising by-law powers under the *Indian Act* have the power to legislate on community health matters on-reserve. A band might, therefore, force aboriginal persons living with HIV/AIDS to stay off a reserve or seek medical care off-reserve, without being subject to the strictures of the *Canadian Human Rights Act*. Of course, the Minister of Indian Affairs has the legal authority to disallow such discriminatory legislation, but such decision-making power is purely discretionary and does not provide aboriginal persons living with HIV/AIDS any legal guarantee. Neither do administrative law remedies that would oblige an aboriginal living with HIV/AIDS to seek redress through the courts. Nor is the Charter an attractive source of legal protection, because litigation invoking it is costly and the remedies that parties may seek are not always fully effective. The Charter, it should be remembered, is also a highly controversial legal instrument for aboriginal peoples to use, because it is seen by many aboriginal persons as potentially limiting their right of self-government.

It is therefore possible, according to the paper, that a "carefully worded" band by-law discouraging PWAs from remaining on the reserve or ordering certain behaviour under applicable provincial health legislation could be made. It then becomes important to assess whether human rights legislation as a source of protection is of any use for aboriginal persons living with HIV/AIDS.

The paper identifies four major flaws in human rights legislation:

- the long delays associated in taking cases through the human rights process, including the possibility of appeals, and the heavy caseload of human rights commissions, such as in Ontario;

- the alien nature of the Canadian justice system – according to the study, aboriginal peoples are underrepresented among human rights commission staff;

- difficulties experienced by human rights commissions in dealing with cases of deeply rooted systemic discrimination – a situation that most aboriginal peoples in Canada have to face; and

- legal problems in determining which level of government, federal or provincial, has jurisdiction over the issue (because of the split between status and non-status people, on-reserve or off-reserve, or whether First Nations, Inuit or Métis).

As a result, it should come as no surprise that human rights legislation is rarely resorted to by aboriginal peoples: for example, according to the Ontario Native Council on Justice, only 152 complaints were filed with the Ontario Human Rights Commission between 1981 and 1990.[3]

Solutions

The paper argues that these legal problems can be resolved by restructuring the relationship between First Nations people and the Canadian government, by repealing the *Indian Act*, and by promoting self-government agreements with aboriginal peoples. It endorses Ian Scott's view, expressed in a 1988 address he gave when he was the minister responsible for Native Affairs in the Ontario Liberal government, that both levels of government must recognize their distinct roles and responsibilities rather than fight over who has sole legal power. The federal government has a historic role to provide the needed political, economic and social support to aboriginal governments, and provincial governments have a responsibility to protect the equality rights of aboriginal peoples as aboriginal citizens and provide services accordingly.

Allocating roles and responsibilities in this way, according to the paper, would foster a better attitude toward the development of aboriginal communities as self-sustaining communities in Canada, and create a healthier relationship with non-aboriginal governments. A separate agency devoted to aboriginal human rights and including aboriginal persons living with HIV/AIDS should also be considered, which would improve the effectiveness of human rights remedies for aboriginal peoples. The paper advocates using the Charter and non-aboriginal human rights legislation to protect aboriginal peoples from discrimination by non-aboriginals. But it also argues that aboriginal governments must enact human rights guarantees for their own people. In this dual process, 2-Spirited People and aboriginal persons living with HIV/AIDS will have a major contribution to make.

The 2-Spirited People is a non-profit service organization for the aboriginal gay and lesbian community of Toronto. Starting as a social club, it has now become a focus for this community and for aboriginal persons living with HIV/AIDS generally. It has been active in expressing its concerns to the provincial government and in raising awareness among Toronto's aboriginal community about the issues of persons living with HIV/AIDS and their health care needs. For more information, contact the 2-Spirited People at 2 Carlton Street, Suite 1419, Toronto M5B 1J3. Tel: (416) 944-9300; fax: (416) 944-8381.

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ENDNOTES

[1] S Matiation. *HIV/AIDS and Aboriginal Communities: Problems of Jurisdiction and Discrimination*. Paper prepared for the 2-Spirited People of the First Nations, Toronto, 28 April 1995.

[2] See Health Canada. Information: HIV/AIDS and Aboriginal Peoples in Canada. March 1994, cited in Matiation, supra, note 1 at 91, n4.

[3] Ontario Native Council of Justice Report, at 3, cited in Matiation, supra, note 1 at 69, n 189.

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What Did We Learn? Legal and Ethical Issues at the Vancouver Conference

During the closing remarks at the Conference, one speaker noted that "we sometimes get the impression that everything that needed to be said about ... the issues raised by HIV/AIDS has already been said, but since no one paid attention when it was first said, we need to be saying it again." In many of the presentations that focused on legal and ethical issues raised by HIV/AIDS, this sense of bearing witness to past efforts attended the discussion of the present. Even as we learned of new developments, we were reminded of past accomplishments, struggles and, sadly, failures. This article will present an overview of these and other presentations of the XI International Conference on AIDS, held in Vancouver on 7-12 July 1996.

Vulnerable Populations

A number of presentations focused on projects designed to meet the particular needs of vulnerable populations and to ensure that legal information is, among other things, culturally accessible. Mexicans who immigrate to the United States were identified as one such vulnerable population. Many Mexican immigrants lack even basic information about the issues surrounding HIV/AIDS. Among this population, illegal aliens are at the greatest risk: the inability to access basic health care due to fears of deportation, compounded by the language barrier, puts them at greater risk of HIV infection. One presenter discussed a special program initiated in the United States to help PWA immigrants cope with the confusing and unfamiliar realities of their new country.[1] Another focused on the inception of a legal education program for Brazilian workers, which educates them about their rights in the workplace.[2] Finally, we heard of the successes enjoyed by a national French hotline that offers information on insurance and employment law.[3]

HIV/AIDS in Prisons

The issue of HIV/AIDS in prisons received some attention at the Conference, where it was the focus of one afternoon's session. The needle distribution project at the Hindelbank prison for women in Switzerland was presented,[4] as well as the pilot project on bleach distribution undertaken in a federal prison in British Columbia.[5] One speaker described an HIV/STD harm-reduction program in California that seeks to empower inmates, enabling them to make informed decisions about their health by encouraging, among other things, the sterilization of needles and tattooing equipment.[6]

Legislation

Several speakers provided overviews of their country's legislation as it related to one or more aspects of HIV infection. Two presentations discussed the impact of HIV/AIDS legislation in Russia, detailing how even basic human rights are violated. As it stands, Russian legislation promotes invasion of privacy and engenders the conditions necessary for various forms of discrimination. Furthermore, non-governmental organizations active in AIDS work receive little or no funding, and their valuable contributions are rarely given consideration. Much work remains to be done for this country to meet acceptable standards and to begin to address the needs of people living with HIV/AIDS. A recent initiative in Russia that focuses on improving access to health care, and training and sensitizing policymakers and health-care workers, offers some hope for the future.[7]

Highlights of this portion of the conference included a review of the laws and regulations affecting limitations on the sale and possession of syringes in the United States.[8] The review concluded by emphasizing how existing laws and regulations pose substantial barriers to public health efforts to decrease HIV transmission among injection drug users through criminalization of the sale and possession of syringes.

Educating Policymakers

Two presentations stressed the need to educate policymakers on issues related to HIV/AIDS. One such project in the United States involves some twenty legislators in a two-day workshop. Presentations by expert speakers, group discussions, and break-out sessions serve to provide policymakers with an accurate picture of the HIV pandemic.[9] A similar approach is used in Chile in an effort to combat discrimination experienced by people living with HIV. Through direct involvement with, and education of, policymakers, members of non-governmental organizations hope to promote more efficiently the rights of persons living with HIV.[10]

Legal Decisions

Few specific legal decisions were reported at the conference. We did hear, however, of the controversial response of politicians, the media, and the public to a New Zealand case very similar in nature to the Ssenyonga case in Canada.[11] Peter Mwai, an African immigrant to New Zealand, was charged with six HIV-related offences based on the fact that he was aware of his seropositive status, understood the implications of unprotected sex and, regardless, insisted on not wearing a condom during intercourse with his female partners.[12] The author of the poster presentation focused on the public outrage provoked by the case, and its political consequences, as politicians used the occasion to argue for mandatory HIV testing of immigrants and refugees.

Criminal Law and Public Health

Other sessions examined the issue of criminalization of HIV transmission, and public health measures to be taken when persons knowingly put others at risk of contracting HIV. Richard Elliott, author of *Criminal Law and HIV/AIDS: A Discussion Paper*, produced as part of the Joint Project on Legal and Ethical Issues Raised by HIV/AIDS in Canada, presented his research.[13] He argued that the criminalization of HIV transmission would harm rather than assist HIV prevention efforts. A variety of other approaches, involving public health measures, were identified as more appropriate alternatives – more effective, easier to implement, and more acceptable to persons living with HIV/AIDS – than the use of criminal law. The adoption of preventive rather than punitive approaches was successful in Washington state, where appropriate responses to people who are either unwilling or unable are designed and applied by specially trained public health workers.[14]

One presentation focused on the potential criminalization of perinatal transmission of HIV. The authors supported criminalization and advocated the establishment of guidelines for an eventual HIV-specific statute in California. In their opinion, such a statute would require knowledge, on the part of the mother, that she is HIV-positive, knowledge of a substantial risk of transmission, as well as a causal link between transmission and the infant's injury or death. The authors considered this "immediate" and "effective" deterrent not only feasible, but necessary.[15] On the issue of testing, one speaker adopted a view that was far more respectful of current ethical discourse. In reviewing the historical, legal and ethical principles that form a subtext to informed consent, the speaker concluded that most legislators and public health officials appropriately support universal counselling and voluntary testing as the approach most likely to facilitate family-based HIV-related care.[16]

HIV/AIDS and Human Rights

Throughout the Conference, much emphasis was put on the link between human rights violations and increased vulnerability to HIV transmission. For example, one author stressed the need for laws that regulate the cultural practices and distribution of marital property in Africa, in an effort to decrease the vulnerability of African women.[17] Integral to many of these presentations was the strong desire to create more efficient mechanisms for the documentation of human rights violations around the world.

Networks on HIV/AIDS, Law, and Ethics

Another commonality among speakers was the recognition that fragmentation undermines a strategic response to HIV/AIDS. Many presenters focused on their country's need to build networks of committed individuals and organizations. Others detailed their experiences in creating just such a committed coalition, able to address policy issues raised by HIV/AIDS in an effective manner. The experiences of persons already engaged in a community-based response to HIV/AIDS, as well as the experiences of those engaged in related fields – eg, women's rights organizations operating in countries in Asia, sub-Saharan Africa, Latin America and the Caribbean – serve to illustrate the importance of local and inclusive processes in decision-making.[18] In both Turkey and Columbia, legal and policy networks were tactically effective at handling the human rights violations experienced by people living with HIV/AIDS.[19] In Africa and Latin America, the collective efforts of lawyers, policymakers, people living with HIV/AIDS, and others, to promote the exchange of information and collective decision-making, led to significant successes. As one of the presenters noted, such a network in Latin America guarantees an appropriate response to discrimination and an effective form of support for persons living with HIV/AIDS.[20]

The Kenya Legal and Ethical Issues Network made a success of just such an approach. As part of a project in Nairobi, the Network initiated a massive public campaign to foster awareness of legal and ethical issues. Their effort to reduce discrimination in employment and health-care settings, as well as within families, netted positive results.[21] Closer to home, the Canadian HIV/AIDS Legal Network presented the results of its work.[22] The Network was established with the goal of developing resource and advocacy materials through a community- and consensus-building process; it was through a period of extensive consultation that we identified the priority legal and ethical issues that Canadians wanted us to address.

Goals

Our ultimate goal, as well as the goal of many of us working on legal and ethical raised by HIV/AIDS, might easily be summed up in the words of the Uganda AIDS Commission:

> The law and its practitioners can influence the success of HIV/AIDS policies and programmes. Law *can* be about positive cultural and social changes.[23]

- Bruno Guillot-Hurtubise

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ENDNOTES

[1] M Muniz-Martelon et al. Mexican migrant HIV issues problems and strategies. Abstract TU.D.246. XI International Conference on AIDS (the following notes refer to abstracts of the Conference).

[2] MA Menezes. "Conquests": Legal advice to workers living with HIV/AIDS. TH.D.4947.

[3] M Shulz. SIDA INFO DROIT: a French national helpline on legal issues concerning AIDS. TH.D.4950.

[4] F Wasserfallen et al. AIDS prevention programme including needle distribution for female prisoners: the Hindelbank pilot project. MO.D.362.

[5] TL Nichol. Bleach kit distribution pilot project in a Canadian federal institution. WE.D.356.

[6] S Cozza. HIV/STD Harm reduction program for the incarcerated. Pub.D.1410.

[7] N Nedzelski et al. Problems of AIDS Legislation in Russia. TH.D.4944; and J Stachowiak et al. Human rights and Health in Russia project. TH.D.4946.

[8] Z Lazzarini et al. Limitations on the sale and possession of syringes; results of a national survey of laws and regulations. MO.D.364.

[9]LM LaChanse et al. Educating state legislators: the roundtable method. TH.C.4546.

[10] JL Palma-Gandara et al. Law project on AIDS: making state representatives, policy makers and other organizations involved in the issue aware of sero+ organization standpoint. TH.D.4939.

[11] For a summary of the Ssenyonga case, see B Guillot-Hurtubise. Criminal Law and HIV/AIDS: A Review of Cases (Part II). *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(2): 5-7 at 6.

[12] H Worth. Out of Africa; AIDS, race and social policy in the Peter Mwai affair. TU.D. 2907.

[13] R Elliott et al. Criminal law, public health laws, and HIV/AIDS. WE.D.494.

[14]FT Chaffe et al. Seattle-King county public health program for "behaviours endangering public health". WE.D.231.

[15] V Panossian et al. Criminalizing the perinatal transmission of HIV. Pub.D.1399.

[16] EB Cooper. Mandatory HIV testing of pregnant/delivering women and newborns: a legal, ethical and pragmatic assessment. WE.D.491.

[17] YK Nsubuga et al. The cultural, legal and ethical issues in the wake of HIV/AIDS: which way for the African women. WE.D.492.

[18] DW Patterson et al. Legal and ethical networking: enabling a community response to the HIV epidemic. WE.D.3895.

[19] S Ilkay et al. AIDS as a public policy problem; the paradigmatic significance of the Turkish case. WE.D.230 and HMD Ardila et al. Development of national network of human rights and HIV/AIDS in Columbia. Pub.D.1398.

[20] E Carrasco. Latin America and the Caribbean network on HR, ethics, law and HIV/AIDS: LACCASO/ACSI. Pub.D.1472; and CSA Mbengue. The African regional network on ethics, law and HIV: a collective commitment to promote human rights within the epidemic. Pub.D.1400.

[21]D Odhiambo. Legal education and awareness: a panacea for discrimination. TH.D.4943.

[22] R Jürgens et al. Promoting legal and policy responses to HIV/AIDS that respect human rights. WE.D.490.

[23] YK Nsubuga et al, supra, note 17.

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AIDS AND HUMAN RIGHTS

AIDS, Human Rights, and NAFTA: Challenges and Opportunities

Migration, both temporary and permanent, legal and illegal, from Mexico to the United States and Canada has been an ongoing phenomena for as long as can be remembered.

Reasons for Migration

Why would a person leave behind their land, relatives and ties? The answer is simple: most people migrate from South to North looking for better living conditions, better income or better opportunities for themselves and their families. Most migrants are simply hoping to reduce their own social vulnerabilities, and to find a situation that would make it possible for them and their families to enjoy the benefits of a decent job, food, education, and health care, as well as the other kinds of social and personal satisfaction they were unable to find in their country of origin. In short, migrants are looking for ways to protect their rights: economic, social and cultural.

Civil Rights

Though the social rights and overall situation of migrants often improves, it comes at a high cost in terms of their civil rights. Migrants are commonly stigmatized, and become victims of abuse solely on the basis of their ethnic or national origin.

NAFTA

The North American Free Trade Agreement (NAFTA), a trade pact between Canada, Mexico and the United States, went into effect in January of 1994. It was hoped that the Agreement would stimulate trade, investment and commerce among member countries. Mexico saw NAFTA as an opportunity to improve the economic well-being of its citizens. Over the life of NAFTA, there have been many achievements and many disappointments – for instance, no one could have predicted the economic crisis that hit Mexico in late 1994, throwing many free-trade efforts off-balance. However, one of NAFTA's major problems is its lack of a social component. Our nations have hoped to achieve economic integration without considering social integration, which creates major pressures among their citizens, as economic and societal disparities increase. NAFTA lacks a parallel social rights agreement between Canada, Mexico and the United States, one that would be similar to those that co-exist with other commercial agreements, such as European Union or Mercosur.

Vulnerability of Migrants

The particular vulnerability of migrants is the result of a complex interaction between pre-existing vulnerabilities – those derived from poverty in the country of origin – and new vulnerabilities related to social exclusion in the country that the person has migrated to. Not infrequently, the social rights of migrants are impinged upon with proposals like the recent immigration laws enacted by the United States Congress [restricting immigrants' access to health service and education]. Many of these discriminatory acts, which affect children by depriving them of health services or education,

are based solely on a "crime" committed by their parents, whose sole crime is migrating to a new country, looking for better opportunities for themselves and their children.

Globalization and AIDS

How does AIDS fit into this complex of factors? On the one hand, AIDS is a perfect example of a disease due to globalization; on the other hand, HIV/AIDS is a disease that frequently follows commercial and migratory routes – yet it cannot be approached as a disease that one would stop with measures like mandatory testing or quarantine.

Among the member countries of NAFTA, access to care is not equal. People living with HIV/AIDS in Mexico frequently do not have access to the types of drugs or technological advances that those living in the United States or Canada have. While many people with HIV/AIDS in the United States and Canada are debating whether protease inhibitors should be made available to all, most persons living with HIV/AIDS in Mexico are still looking for simple primary care and essential drugs.

The social discrimination faced by migrants is compounded by the "affection deprivation" that they experience while living in a different culture, in a different language, geographically separated from their loved ones. This social stigmatization and lack of traditional support makes them much more vulnerable to HIV infection, as migrants frequently have casual sex without condoms, or turn to the use of intravenous drugs in an attempt to escape the harsh realities of their situation. In addition, cultural differences may not allow them access to HIV prevention information, as they may have difficulty understanding the language the message occurs in, or because the message is culturally inappropriate for them.

People Living with HIV/AIDS and Migration

People living with HIV/AIDS are vulnerable. This vulnerability is only increased when such people are also migrants. When illegal immigrants in the US find out that they are living with HIV/AIDS, they often do not seek out health care, fearing deportation. Moreover, they are frequently without the support of their families, or a social network that might provide alternative care and support. In this respect, HIV/AIDS augments and makes more evident the vulnerability of migrants.

Many migrants with advanced HIV/AIDS elect to return to Mexico and die near their loved ones. However, even after contributing to Social Security for years, legal migrants loose any benefits to which they are entitled if they leave the United States. This puts migrants who are living with HIV/AIDS in the difficult position of having to choose between the economic support to which they are entitled, and the support of their families.

To summarize, AIDS makes apparent and even amplifies the pre-existing vulnerabilities and hardships faced by those who migrate from Mexico to the United States or Canada. The discrimination faced by Mexicans in the United States constitutes, in itself, a specific vulnerability since it puts migrants at risk of HIV infection. Having contracted HIV/AIDS, their status as migrants, together with their condition, denies them access to the kinds of care and treatment available to others living in the same country.

Conclusions

Without a doubt, NAFTA, as well as other commercial treaties, should be re-evaluated, taking into consideration human rights issues, in order to avoid many of the inequities we are now seeing. The globalization of the world economy cannot be accomplished at the expense of the basic rights and dignity of its citizens. The social costs of such an error would quickly become enormous. To think that a free flow of products and capital could occur at the same time that the movement of people is treated in a more and more restrictive manner is not only naive, but, in the case of HIV/AIDS, could make the prevention and control of HIV infection nearly impossible. NAFTA lacks a social component that would take into consideration, in a progressive way, the equal protection of the citizens of all three member nations, in particular those who are sick, vulnerable, or excluded. We should not expect the US and Canada to provide care for all poor Mexicans, but we should look for ways to help Mexicans demand from their governments the same social supports already in existence in other nations.

As we look into the 21st century, we should ask ourselves what can be done. At the XI International Conference on AIDS, the Secretaries of Health of the United States and Mexico and the Minister of Health of Canada signed a declaration, a joint commitment to make AIDS an integral part of their countries' respective social agendas. We are starting to see some results of this declaration in Mexico: people living with HIV/AIDS have been invited to sit at the decision-making table, and to investigate ways to make the most advanced treatments available in Mexico. Over the next few years we should see more joint action from the three countries. We are presently in a position that would allow us to make the "NAFTA spirit" mean so much more than free trade among our nations. Let's not miss the opportunity.

- *Carlos del Río and Silvia Panebianco-Labbé*

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Canadian HIV/AIDS Policy & Law Newsletter

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CANADIAN NEWS

Canadian Human Rights Commission Releases Revised Policy on HIV/AIDS

The Canadian Human Rights Commission (CHRC) originally issued a policy statement on AIDS in 1988. In June 1996, the Commission released a revised version of the statement, based on current medical, scientific and legal information.

We reprint the full text of the 1996 policy and the background notes issued by the Commission.

Canadian Human Rights Commission Policy on HIV/AIDS

Everyone has the right to equality and to be treated with dignity and without discrimination, regardless of HIV/AIDS status.

To ensure the fulfilment of this principle the Commission has adopted the following policies:

1. Complaints

The *Canadian Human Rights Act* prohibits discrimination on the basis of disability. Individuals with HIV/AIDS may therefore seek protection under the *Canadian Human Rights Act*. People who are not HIV positive may also be subject to discrimination by virtue of their real or perceived membership in a risk group or their association with a person or people with HIV/AIDS. These individuals may also seek protection under the *Canadian Human Rights Act* on the basis of perceived disability.

The Commission will expedite the investigation of complaints alleging HIV/AIDS related discrimination.

2. BFOR/BFJ

The Commission will not accept being free from HIV/AIDS as a *bona fide occupational requirement* (BFOR) or a *bona fide justification* (BFJ) unless it can be proven that such a requirement is essential to the safe, efficient and reliable performance of the essential functions of a job or is a justified requirement for receiving programs or services.

As a result of new drugs and forms of intervention, people with HIV infection are now able to continue productive lives for many years. If individuals with the requisite workplace accommodation are able to continue to work they should be allowed to do so. Any decision made by an organization relying on health and safety considerations to exclude a person must be based on an individual assessment supported by authoritative and up-to-date medical and scientific information.

3. Pre and Post Employment Testing

HIV positive persons pose virtually no risk to those with whom they interact in the workplace. The Commission, therefore, does not support pre or post employment testing for HIV. Such testing could result in unjustified discrimination against people who are HIV positive.

4. Public Education

The Commission will assist in fostering improved public understanding of HIV/AIDS. The level of misunderstanding about HIV/AIDS remains high and contributes to the discriminatory treatment of people who are HIV positive or who are perceived to be so.

5. Workplace Policies

The Commission will encourage employers to develop an HIV/AIDS workplace policy to ensure employees are accurately informed about HIV/AIDS as it affects them in the workplace. This will avoid unnecessary fears about the disease and its transmission which could lead to discriminatory acts.

Background Notes to the Commission's Policy on HIV/AIDS

1. Introduction

The Commission originally issued a policy statement on AIDS in 1988. The present document, which revises the 1988 policy, outlines the CHRC's position on HIV/AIDS based on current medical, scientific and legal information.

The *Canadian Human Rights Act* prohibits discrimination on the basis of disability. Individuals with HIV/AIDS may therefore seek protection under the *Canadian Human Rights Act*. People who are not HIV positive may also be subject to discrimination by virtue of their real or perceived membership in a risk group or their association with a person or people with HIV/AIDS. These individuals may also seek protection under the *Canadian Human Rights Act* on the basis of perceived disability.

2. BFOR/BFJ

In its 1988 policy, the Commission referred to three situations which, at that time, it believed could result in a possible BFOR/BFJ. These three situations were:

- the health care setting;
- where employment requires travel to countries which ban entrance to people who are HIV positive; and,
- employment where the employee performs job duties which impinge on the safety of the public and performs those duties alone.

People with HIV/AIDS are now able, as a result of new drugs and forms of intervention, to continue productive lives for many years. If individuals with the requisite accommodation are able to perform the essential components of the job or receive programs or services in a safe, efficient and reliable manner they should be permitted to do so. Any decision made by an organization relying on health and safety considerations to exclude a person must be based on an individual assessment supported by authoritative and up-to-date medical and scientific information.

The Commission reviewed the BFJ/BFOR provisions of the 1988 policy in light of the many developments regarding HIV/AIDS in recent years. The 1996 policy has been adjusted accordingly.

2.1 Health Care

In May 1993, the Canadian Medical Association announced its policy on HIV in the workplace. The policy is instructive on the issue of the health care environment and HIV. Regarding health care workers the policy states:

> *There have been no instances in Canada of HIV infections in patients resulting from exposure to infected health care workers .... Health care workers with HIV infection should be afforded the opportunity to*

> *compete for jobs and continue to work at their usual occupation as long as they meet acceptable performance standards and are mentally and physically able to perform the essential components of work safely, efficiently and reliably.*

The Canadian Human Rights Commission concurs with this view.

2.2 Travel to Foreign Countries

The Commission has not received complaints from people with HIV/AIDS who have been denied employment due to travel restrictions. This may be as a result of policies in countries permitting entry for a short period to people with HIV/AIDS. For example, since 1993, non-immigrants who are HIV positive may file a waiver application to enter the United States for 30 days or less for reasons such as conducting business or attending conferences.

The CHRC does not have jurisdiction over foreign governments that require HIV testing for non-nationals to enter their country. However, Canadian federally regulated employers requiring employees to travel to countries which require HIV testing should take reasonable steps to avoid negative employment consequences for employees who are HIV positive. Failure of an employer to provide such accommodation could constitute the basis of a complaint of discrimination against the employer.

2.3 Public Safety

BFOR

At the time the 1988 policy was issued, it was believed that the symptoms of *AIDS dementia complex,* slowing of intellectual processing and poor attention, could occur at any stage of the disease. This raised concerns about positions where HIV positive employees perform job duties that impinge on the safety of the public and perform these duties alone.

More recent medical research indicates that AIDS dementia complex is a complication in the advanced states of HIV disease. Gradual, cognitive decline does not appear to occur during the early stages of HIV.

It is therefore unlikely that an employer would be able to establish a BFOR based on the concern of the sudden onset of dementia as the evidence suggests this condition is a complication of advanced HIV disease.

BFJ

The *Canadian Human Rights Act* provides that it is not a discriminatory practice for a service provider to deny goods, service or facilities to a person if the denial is based on a bona fide justification (BFJ). The Canadian Human Rights Commission policy on BFJ recognizes the service provider's right to ensure a person is able to comply with a requirement that is essential for the safe and effective delivery of the service.

Incidents have been reported of service providers refusing to provide services to a person who is HIV positive on the grounds that to do so would pose an unacceptable risk of infection to them or their employees and, therefore, would constitute a BFJ.

For example, it had been thought that rescue workers, such as police and firefighters dealing with trauma victims who were HIV positive might come in contact with the body fluids of HIV-positive people and, therefore, be at added risk of infection.

The CMA has, however, concluded that in such circumstances the risk of transmission is extremely low, and no cases of transmission have been recorded. As a general measure to minimize the risk of infection, the CMA states that workers should take reasonable precautions when handling human blood or other bodily fluids capable of transmitting HIV.

For the reasons explained above, the Commission would not generally accept a BFJ based on an alleged danger to the

service provider. It is well established that employee or customer preference is not a legitimate reason for a discriminatory action. Therefore, employee or customer concerns about dealing with a person who is HIV positive can not be the basis of a BFJ.

3. HIV Antibody Testing

Controversy has arisen over whether applicants and employees should be subject to HIV testing as a condition of employment.

The CHRC believes that in the employment setting medical testing should only occur where determination of the condition being tested for is necessary for the safe, efficient and reliable performance of the essential components of the job.

HIV positive persons pose virtually no risk to those with whom they interact in the workplace. The Commission, therefore, does not support pre or post employment testing for HIV because the results of such testing could result in unjustified discrimination against infected people. Regarding health care workers, the Canadian Medical Association Policy on HIV/AIDS states that:

> *The routine testing of health care workers for the HIV antibody is not justified. The CMA supports the application of universal precautions that enhance the protection of health care workers against potential infection from patients and vice versa.*

The Canadian Human Rights Commission supports this view.

4. Complaints Processing

Although people with HIV/AIDS may lead productive lives for many years, unfortunately there is still no cure for the disease. Due to the special nature of HIV/AIDS the Commission will expedite the investigation of complaints based on HIV/AIDS. This will help to ensure that complainants are able to receive the benefits of any redress that may be owed to them in a timely manner.

5. Education

The level of misunderstanding about HIV/AIDS remains high and contributes to the discriminatory treatment of those with HIV/AIDS and those who are perceived to be in high risk groups. Education is clearly the key to combating discrimination based on this misinformation and the Commission has and will continue to assist in fostering improved public understanding of HIV/AIDS.

6. Workplace HIV/AIDS Policies

Employers have a responsibility to ensure employees are accurately informed about HIV/AIDS as it affects them in the workplace. This will avoid unnecessary fears about the disease and its transmission which could result in discrimination. The employer's commitment to non-discrimination regarding employees with HIV/AIDS should be clearly expressed in a workplace HIV/AIDS policy. The policy should set out how the employer will deal with issues relating to HIV/AIDS in their particular workplace.

Employers without an HIV/AIDS policy will find themselves less prepared to deal with HIV/AIDS related issues such as confidentiality and non-discrimination. The relatively simple step of putting in place and communicating an HIV/AIDS policy sends a clear message to employees on the organization's commitment to equality.

7. For Further Information

For further information please refer to the CHRC pamphlet: *HIV/AIDS Discrimination: It's Against the Law*. For copies of the pamphlet or any other information please contact a Commission office.

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Canadian Declaration of Rights for People Living with HIV/AIDS

The following draft of a Canadian Declaration of Rights for People Living with HIV/AIDS was developed by the participants in the 1996 HIV Forum of the Canadian AIDS Society in Toronto on 4 June 1996.

HIV is a pandemic that constitutes an ever-increasing threat to humanity and affects all communities. People living with HIV/AIDS experience multiple losses which are compounded by both poverty and discrimination which constitute a violation of our human rights. Federal, provincial, territorial and municipal governments play a critical role in ensuring there is an effective societal response to preventing the spread of this fatal transmittable disease and supporting those already infected. The response of government to individuals and individual rights is a foundation of any response.

This Declaration of Rights is the expression of persons living with HIV/AIDS to realize the full and equal enjoyment of our rights and freedoms, without distinction and under all circumstances.

Therefore, we, as people living with HIV/AIDS in Canada, being participants in the 1996 HIV Forum of the Canadian AIDS Society, declare our individual and collective rights to:

i. Comprehensive protective legislation and anti-discrimination policies.

ii. Universal access and choice to a full continuum of care which allows us to live and die with dignity and grace.

iii. Unrestricted access to the therapies we choose.

iv. Explicit commitments to an ongoing and continual research agenda that will improve our lives and realize a cure.

v. Confidentiality pertaining to our HIV sero-status and safety in all environments should we choose to disclose.

vi. Full involvement in any decision-making process affecting our lives.

vii. Sufficient income and adequate housing which enable us to sustain our health.

viii. Full freedom of movement, travel, mobility and migration.

ix. Express our sexuality.

x. Absolute control of our reproductive choices.

xi. Remaining the parents of our children and continuing to be the children of our parents.

xii. Full access to information and services that reflect our needs and that are based on our language,

literacy and cultural background.

Ensuring the quality of life and health of persons with HIV/AIDS is a fundamental responsibility of government. Federal, provincial, territorial and municipal governments of Canada have a critical role to play. We call upon the federal government to renew its national commitment to HIV/AIDS and continue its leadership role in the planning, implementation and coordination of a national plan responding to HIV/AIDS in Canada. This plan must ensure our rights as stated here are respected and safeguarded.

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BLOOD AND BLOOD SAFETY

Another Update on the Krever Commission[1]

The Commission of Inquiry on the Blood System in Canada (the "Krever Commission") convened to hold its first hearing day on 22 November 1993. As of 21 December 1995, when Commission counsel called the last scheduled witnesses to testify at the National Hearings, more than 480 witnesses had been heard over a total of 235 hearing days.

The record before the Commissioner consisted of 48,843 pages of transcript and 1230 exhibits totalling approximately 100,000 pages. On 19 January 1996, a combination of governments, corporations and individuals joined the Canadian Red Cross Society in a legal challenge intended to constrain the Commissioner's ability to make adverse findings of fact in his final report on the events surrounding the contamination of the blood supply with HIV and hepatitis C. The joint applications for judicial review were heard by Mr Justice Richard of the Federal Court (Trial Division) from 22 May to 4 June 1996. On 27 June 1996, Mr Justice Richard issued a 67-page judgment in favour of the Commissioner. Twelve of the unsuccessful applicants have appealed the ruling to the Federal Court of Appeal. The hearing of the appeal will take place the week of 19 December 1996 in Toronto.

Applications for Judicial Review

The applications for judicial review were prompted by the fact that the Commissioner, through his counsel, had served each of the applicants with a notice setting out potential findings of fact that might find their way into his final report. These notices were delivered shortly following the testimony of the last scheduled witness before the Commissioner on 21 December 1996. The introductory paragraph to each of the notices specified that "... the Commissioner *may* make the following findings that *may* amount to misconduct within the meaning of the *Inquiries Act*," and invited the recipient to respond to the notice in person, through counsel or by way of final submissions delivered to the Commissioner.

Section 13 of the *Inquiries Act* (Canada) – the legislation that governs the conduct of all public inquiries established by the federal government – requires that "reasonable notice" be given before a report is made that contains a finding or findings of "misconduct" against any person. It further requires that the person be afforded "a full opportunity to be heard in person or by counsel." The *Inquiries Act* gives no clear direction, however, as to when during the course of the proceedings of a federal public inquiry this notice must be given. Nor does it set out in clear terms what, specifically, constitutes a "full opportunity to be heard."

The Applicants' Arguments

All of the applicants before Mr Justice Richard made the same two basic arguments in their challenge to the Commissioner's right to make adverse findings of fact against them in the final report.

The Role of Public Inquiries

The first argument focused upon the role of public inquiries generally, and asserted that it was beyond the jurisdiction of any commissioner – in this instance, Commissioner Krever – to make a finding or findings of fact tantamount to a

finding of civil or criminal liability. Mr Justice Richard rejected this argument on the grounds that section 13 of the *Inquiries Act* "... clearly contemplates that the investigation [undertaken by a public inquiry] may lead to an unfavourable report against a person showing bad conduct" (Reasons for Order, p 25). He went on to point out that "[t]he finding of facts, and in particular the facts that reveal what went wrong or why a disaster occurred can be an essential precondition to the making of useful, reliable recommendations to the government as to how to avoid a repetition of the events under review" (Reasons for Order, p 27).

With respect to the mandate of Commissioner Krever, in particular, Mr Justice Richard reviewed the federal Order-in-Council which established the Commissioner's terms of reference and concluded that

> [t]he terms of reference have been broadly drafted to include all activities of the blood system in Canada. The Inquiry is not an abstract inquiry into the process of a system. It is about why there was a disaster and what can be learned from that disaster. ...
>
> In my view, it is essential to the fulfilment of the mandate of this Inquiry that the Commissioner be able to uncover facts to explain to the public the contamination of the blood system and, on the basis of those facts, to make recommendations for the future safety of the blood system. (Reasons for Order, pp 29-30)

Adequate Procedural Protections

The second argument advanced by all applicants was that even if the Commissioner did have the jurisdiction to make the findings of misconduct set out in the notices they had received (which they challenged as set out above), he lost the ability to do so because he had failed to provide adequate procedural protections to the recipients of the notices during the course of the proceedings of the Commission. This argument was also rejected by Mr Justice Richard.

Mr Justice Richard placed heavy emphasis upon the fact that all but two of the institutional applicants had sought and received standing as a party before the Commission and participated fully in the proceedings of the Commission from its outset, including the drafting of the very rules of procedure they now sought to challenge, the development of the issues list in accordance with which witnesses were called and questioned, and the cross-examination of witnesses. In response to the applicants' argument that they would have conducted themselves very differently throughout the Commission process had they understood the scope of the potential findings of misconduct that might be made, Mr Justice Richard emphasized that "[a]ll of the institutions and corporations who received section 13 notices and which may be named by the Commissioner in adverse findings of fact were major stakeholders in the Canadian blood system in the relevant period. They clearly knew, or ought to have known, that the Inquiry would examine their conduct" (Reasons for Order, p 65). Each of the individual applicants had been associated with one or more of these institutional applicants during the time-frame in issue.

Conduct of Commission Counsel

A third argument, raised only by the Canadian Red Cross (and related applicants) and the Attorney General of Canada, asserted that the conduct of Commission counsel throughout the proceedings of the Inquiry was demonstrative of bias against them and that, as a result, the Commissioner ought to be prohibited by the Court from receiving their assistance in the preparation of his final report. Mr Justice Richard rejected this argument on the grounds that Commission counsel had not overstepped their appropriate role to date.

Wins?

Some press reports following the release of Mr Justice Richard's decision announced "wins" on the part of various federal and provincial government officials. In fact, Mr Justice Richard made no determination on the merits of the applications brought by these individuals. Rather, he simply incorporated by reference into his decision and Reasons for Order the position that certain of the individual applicants who received notices would not be named in any adverse findings of fact in the Commissioner's final report – a position articulated by the Commissioner through his counsel at the hearing of the applications for judicial review (Reasons for Order, p 66).

Hearings Resumed

The Commission hearings resumed on 15 October 1996 to allow those recipients of notices who wished to do so, to call evidence in response to the section 13 notices. As of 17 October 1996, Dr Michel Chrétien was the only witness to have been called. He testified on behalf of the Province of Ontario on 16 October 1996. The hearings will resume on 12 November 1996, when various current and former Medical Directors and officers of the Canadian Red Cross Society are expected to call witnesses over a period of approximately two months. This phase of the Commission's process will likely end in early 1997, allowing for the delivery of final submissions and preparation of the Commissioner's report for delivery to the Office of the Privy Council by 30 April 1997.

- *Lori Stoltz*

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ENDNOTE

[1]For further information, see PA LeFebour, D Elliott. Inquiry into the Blood System in Canada: The Krever Commission. *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 1(3): 5-6; D Harvey. David, Goliath and HIV-Infected Blood. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(2): 9-11; L Stoltz. Update on the Krever Commission. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 10.

Canadian HIV/AIDS Policy & Law Newsletter

Volume 3 Number 1 - October 1996

Taskforce on HIV/AIDS and Drug Use Created

On 18 April 1996, the Canadian HIV/AIDS Legal Network (Network) and the Canadian AIDS Society (CAS) opposed Bill C–8, the proposed (and since enacted)[1] illicit drugs legislation, in a presentation to the Standing Senate Committee on Legal and Constitutional Affairs.

For the occasion, the Network and CAS prepared a written submission outlining how Canadian drug laws and policies impact on the spread of HIV/AIDS and other bloodborne diseases such as hepatitis B and C.

Funded by Health Canada, and coordinated by the Canadian Centre on Substance Abuse (CCSA) and the Canadian Public Health Association (CPHA), a Task Force on HIV/AIDS and Drug Use is now examining how to curb the further spread of HIV among injection drug users.

The Network/CAS Submission

The submission summarizes the results of Phase I of the Joint Project on Legal and Ethical Issues Raised by HIV/AIDS, when over 60 individuals and organizations consulted by the Project Coordinator expressed concern about the impact of Canadian drug laws and policies on the spread of HIV. A literature review undertaken as part of Phase I of the Project showed that many authors expressed a view that drug use should be treated as a health issue rather than a criminal activity, and that drug laws and policies need to be respectful of the human rights of persons using drugs.[2]

The submission emphasizes that Canada needs an honest, open, objective, nonpartisan reassessment of its drug policy: we need to examine the role, the appropriateness and the status of the criminal law at the centre of this policy and to investigate the alternatives that are available. Four fundamental principles under which a policy review should take place are identified:[3]

- public health;
- rational pharmacology;
- cost effectiveness; and
- respect for human rights.

Annexed to the submission is a paper entitled "Criminalization of Drug Use: Ineffective and Unethical?"[4] It argues that, particularly in view of the advent of HIV infection and the resulting increase in mortality for drug users, laws and policies should be revised because they have been increasingly recognized as ineffective in reducing or suppressing drug use and the harms resulting from drug use, and as impeding efforts to achieve these outcomes. The paper concludes:

> Social policy–makers must meet the challenge of developing policies that will reduce the harms from drug use while at the same time protecting the liberty of individuals. Current and possible future measures should be evaluated according to the following criteria: first, how effectively they reduce harms from drug

use; second, whether or not they are proportional to the harms defended against; and third, whether or not they can be justified ethically and economically. An approach to drug use is recommended that would match the degree of regulation to the harms from the use of each drug to the user and to society. Such an approach should be congruent with principles of human rights, ethics, and morals.

The Task Force

The Task Force, comprised of ten experts in the areas of HIV/AIDS, addictions treatment, law enforcement, criminal justice, drug users' organizations, and public health, and chaired by Dr Catherine Hankins, met for the first time in Ottawa on 8-9 October 1996. Key priority issues for action – including needle exchanges, methadone access and treatment, and enforcement policies – and strategic direction for each of the issues were identified.

Dr Hankins noted that

- in Montréal, HIV prevalence at the main needle exchange has reached 20 percent, up from 10 percent in 1990; and

- in British Columbia, where every day two injection drug users test positive, "there is mounting evidence of an explosive epidemic of HIV centred in Vancouver's Downtown Eastside."

According to Hankins, these developments point to an "urgent need for a national action plan built on partnership. HIV will continue to spread among injection drug users and to their sexual partners and infants unless concrete measures are undertaken in a timely way in HIV/AIDS prevention, addictions, public health, and health care service fields. Changes in legislation and police enforcement practices, as well as the active involvement of drug users in policy and programming deliberations are required if effective strategies are to be implemented."

The Task Force will produce a "National Action Plan on HIV/AIDS and Injection Drug Use" which will undergo a country-wide consultation with key stakeholders before being widely distributed in the spring of 1997.

Copies of the Network/CAS submission to the Senate, entitled "Bill C–8 — The Impact of Canada's Drug Laws on the Spread of HIV," can be obtained from the Network/Cas Project Office (Tel: (514) 987–3000 ext 6937#; fax: (514) 987–3422; e-mail: info@aidslaw.ca), and are available on the Internet at http://www.aidslaw.ca/

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ENDNOTES

[1] See infra, E Oscapella and D Riley. Senate Urges Review of Canada's Drug Laws, Policies, and Programs.

[2]For more information, see R Jürgens. Drug Laws and HIV/AIDS. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 1, 26–28.

[3] See also The Standing Senate Committee on Legal and Constitutional Affairs. Ottawa, 14 December 1995, 1020–1021 (Mr Benedikt Fisher speaking for the Canadian Foundation for Drug Policy).

[4] R Jürgens. Text of a paper presented at the colloquy "AIDS, Justice and Health Policy," Milan, Italy, 11 October 1991.

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Senate Urges Review of Canada's Drug Laws, Policies and Programs

Diane Riley and Eugene Oscapella first reported about Bill C-8 (then called Bill C-7), the Controlled Drugs and Substances Act, in a previous issue of the *Newsletter*.[1] At the time, they concluded that if the Bill was passed, the result would be "continued misdirection of resources, continued emphasis on criminalization of drug users, and the unnecessary infection with HIV, and death, of many Canadians." While the Bill that nobody likes has now been enacted, the Senate has urged that a comprehensive review of Canada's drug laws, policies, and programs be undertaken.

Passage of the Bill

On 19 June 1996, the Senate passed Bill C-8, the proposed *Controlled Drugs and Substances Act*. It then sent the Bill to the House of Commons so that the latter could approve the minor changes that the Senate had proposed to the Bill. The House approved the changes on 20 June and the Bill was given Royal Assent. That means that Bill C-8 has now been enacted. However, the Bill is not yet in force. It may be proclaimed in force sometime this autumn.

Reach of Canada's Drug Laws Expanded

Once the *Controlled Drugs and Substances Act* comes into force, it will replace Canada's main laws on "illicit" drugs – the *Narcotic Control Act* and parts of the *Food and Drugs Act*. The *Controlled Drugs and Substances Act* significantly expands the reach of Canada's drug laws and continues Canada's heavy reliance on a failed policy of criminal prohibition. Parliament – both the House of Commons and the Senate – has thus refused to moderate the harshness of the present law.

Wide Support for Harm Reduction and Decriminalization

In refusing to rethink the penalties for certain activities relating to drugs – possession, for example – Parliament has rejected the recommendations of the large majority of witnesses who appeared before Senate and House of Commons committees calling for decriminalization of the use of some or all currently illegal drugs. These groups included the Canadian Foundation for Drug Policy (CFDP), the Canadian Bar Association, the British Columbia Civil Liberties Association, the Law Union of Ontario, the Criminal Lawyers' Association, the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society. Numerous individual witnesses also supported decriminalization.

Several members of the Standing Senate Committee on Legal and Constitutional Affairs had earlier publicly stated their support for decriminalizing marijuana. Thus, the reluctance of the Senate Committee to carry through with this measure baffled many observers. An article in the Montréal *Gazette* (14 June 1996, at A9) quoted Committee Chair Senator Sharon Carstairs as saying that

> • the Senators on the Committee dropped the idea of recommending that there be no criminal charge for having a few "joints" of marijuana because they felt it would never pass the House of Commons (the Bill would have to be returned to the House for a vote on that issue); and that

• her committee members were concerned that decriminalizing marijuana possession would violate several international treaties that Canada has signed (several authorities would strongly disagree with the Senator on this point).

The article further states:

> But Carstairs said the panel members were indeed serious about decriminalization but foresaw that a recommendation would be futile at this point. "The majority of the Senators – and I was with them – felt all the evidence indicated decriminalization for simple possession is the way we should be going," she said in an interview.

The Senate's Recommendation

However, the Committee did attach an extremely important recommendation to its report on Bill C-8:

> The Standing Senate Committee on Legal and Constitutional Affairs strongly urges that a Joint Senate and House of Commons Committee be struck to review all of Canada's existing drug laws, and policies and programs.
>
> Without restricting its mandate, this Joint Committee should be authorized to:
>
> • reassess Government's approach to dealing with illicit drug use in Canada, its effectiveness in curtailing drug use, and its fairness of application;
>
> • develop a national harm-reduction policy to minimize the negative consequences associated with illicit drug use in Canada; and recommend how such a harm-reduction policy would be implemented, including viewing drug use and abuse as primarily a health and social policy issue;
>
> • study harm-reduction models adopted by other countries (treatment and alternative programs for illicit drug use); consider whether such programs should be implemented in whole or in part in Canada;
>
> • examine Canada's role and international obligations under the United Nations drug conventions to determine whether alternative measures to prosecution and punishment are possible under the conventions;
>
> • and if not, consider whether Canada should seek an amendment to the United Nations drug conventions which would allow alternative harm-reduction measures to permit signatory parties to comply;
>
> • revisit the LeDain Commission's findings and recommendations and determine what further action is needed; [note to reader: the LeDain Commission was Canada's last major study of the non-medical use of drugs; the Commission reported in 1973, but its proposals were never implemented]
>
> • explore the health effects of cannabis use; consider whether the decriminalization of cannabis would lead to increased use and abuse, both in the short- and long-term;
>
> • explore using the Government's regulatory power under the Contraventions Act as an additional tool to implement a harm-reduction policy.
>
> In addition, the Joint Committee should undertake intensive public consultations to determine the needs of different jurisdictions across Canada, including large urban centres where the societal problems associated with the illicit drug trade are more visible. The goal should be to devise a made-in-Canada drug strategy

where all levels of government work effectively together to reduce the harm associated with the use of illicit and legal drugs.

Health Committee Review of Drug Policy

Even before the Senate Committee recommended a joint Senate–House of Commons Committee on drug policy, the House of Commons Standing Committee on Health agreed to undertake a review of Canada's drug policies. This move may simply have been an attempt by the government to retain control over the process of reviewing Canada's drug laws. With an election fast approaching, a comprehensive review like that proposed by the Senate committee risks embarrassing the government. Liberal strategists may have considered it safer to propose a House of Commons committee inquiry with a much more restricted mandate.

The Committee began hearing witnesses in early October.

The main problem with the Health Committee's review of drug policy is the narrowness of its mandate. The Committee's terms of reference read as follows:

> 1. to receive evidence about the harmful impact of misuse and abuse of legal and illegal drugs on the social behaviour and physical health of Canadians;
>
> 2. to identify the relevance of variables such as age, sex, ethnicity, socio-economic status and geographical area on the demand for and effect of such substances;
>
> 3. to examine effective measures for reducing the demand for and use of such substances through education, prevention, treatment, and rehabilitation;
>
> 4. to make appropriate recommendations on future policy actions to reduce the demand for such substances.

The CFDP has stated its strong objections to the narrow mandate of the Health Committee. In a 12 September 1996 letter to the Committee, the Foundation stated:

> First, let me state our profound hope that the committee will broaden its terms of reference. The terms of reference as now stated completely avoid the critical issue: how Canada's drug laws and policies contribute to the harms associated with drugs. Unless the committee expands its mandate to deal with this issue, there is very little value in holding further hearings on drug policy.
>
> More appropriate terms of reference would be those proposed by the Standing Senate Committee on Legal and Constitutional Affairs in its report on Bill C-8.

The Health Committee has clearly decided to proceed with its review of drug policy without involving the Senate. There is apparently considerable interest among some Senators in proceeding with a Senate inquiry into drug policy, whether by way of a joint Commons–Senate committee or a special Senate committee. However, as of mid-October, no decision about whether to proceed with a Senate committee has been made public.

It remains to be hoped that, despite its narrow mandate, the House of Commons Health Committee may give drug policy reform groups the platform to argue for a re-thinking of Canada's drug laws and policies: we need an honest and open reassessment of Canada's drug policies and open, thorough and fair hearings on this subject.

- *Eugene Oscapella and Diane Riley*

You can write to the Chair of the Standing Committee on Health, the Hon Roger Simmons, to let him know of your interest in a fair, objective and thorough review of Canadian drug laws and policies; and that you want a broad inquiry into drug policy, not simply the narrow inquiry now proposed by the Committee (The Hon Roger Simmons, PC, MP, Chair, Standing Committee on Health, House of Commons, Ottawa, K1A 0A6; fax: (613) 992-5324).

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[1] 1995; 1(2): 1, 11-13; see also Bill C-7: An Update. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 5.

Canadian HIV/AIDS Policy & Law Newsletter

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PRISONERS AND HIV/AIDS

Final Report on HIV/AIDS in Prisons Released

***HIV/AIDS in Prisons: Final Report*[1] was released at a press conference in Ottawa on 17 September 1996. The release was part of the Joint Project on Legal and Ethical Issues Raised by HIV/AIDS, undertaken by the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society, and funded by Health Canada and the Correctional Service of Canada under the National AIDS Strategy, Phase II. Since then, more than 1000 copies of the document have been distributed in Canada and internationally. But the work on HIV/AIDS in prisons of the Joint Project has not come to a halt: the Network and CAS will continue to work on the issues to make sure that the 38 recommendations in the Report will be implemented.**

We reprint the press release prepared for the launch of the Report.

Governments Could Be Held Morally and Legally Responsible for HIV and Hepatitis Epidemic In Canadian Prisons

– New Report on HIV/AIDS in Prisons Demands Immediate Action –

OTTAWA – The federal and provincial prison systems have a moral and legal responsibility to act without further delay to prevent the spread of infectious diseases among inmates and to staff and the public, and to care for inmates living with HIV and other infections. "Currently they are failing to meet this responsibility, because they are clearly not doing all they could: measures that have been successfully undertaken outside prison with government funding and support – such as making sterile injection equipment and methadone maintenance available to injection drug users – are not being undertaken in Canadian prisons, although other prison systems have shown that they can be introduced successfully, and receive support from prisoners, staff, prison administrations, politicians, and the public," says Ralf Jürgens, Project Coordinator for the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society, and author of ***HIV/AIDS in Prisons: Final Report***, a 200-page report on HIV/AIDS in Canadian prisons to be released on 17 September 1996.

The Report recommends that prisoners be given access to condoms, bleach, sterile injection equipment, and methadone maintenance treatment. "These recommendations are not new," Jürgens emphasizes. "They have been made before by the Expert Committee on AIDS in Prisons and the World Health Organization." But implementing them has become even more urgent: the number of known cases of HIV in federal prisons in Canada has increased by 46% over the last two years.[2]

According to the Report, the Correctional Service of Canada (CSC) has failed to respond adequately to the recommendations made in 1994 by the Expert Committee on AIDS in Prisons, of which Jürgens was Project Coordinator. "In addition, CSC has fallen behind on its commitment to fulfil certain of the Committee's recommendations," Jürgens reports. "While many recommendations were accepted, only few have been implemented."

Although the Report acknowledges that, in federal prisons, some positive initiatives are being undertaken or planned –

such as bleach distribution, introduction of anonymous HIV testing, and education of prisoners by fellow-prisoners – it severely criticizes CSC for failing to implement a longer-term strategy to deal with the many issues raised by HIV/AIDS and drug use. "Instead of acting decisively to protect the health of prisoners and all Canadians, the system is reluctant to face the reality of HIV and drug use in prisons," Jürgens says.

Jürgens emphasizes that immediate action is required: rates of HIV infection among prisoners in Canadian prisons are already more than ten times higher than among the general population,[3] and studies show that at least every third prisoner is infected with the hepatitis C virus.[4]

With few exceptions, most notably British Columbia, the situation in provincial prisons is not better. According to the Report, they sometimes do not provide even the most basic preventive means that would allow prisoners to protect themselves from contracting HIV and hepatitis C.

Other prison systems – in Switzerland, Germany, Australia – have made sterile injection equipment or methadone treatment accessible to inmates. Evaluation of such programs by independent experts has demonstrated clear positive results: the health status of prisoners improved, a decrease in needle sharing was observed, there was no increase in drug consumption, and needles were not used as weapons. Prison staff, who initially were sceptical about the introduction of the programs, are now supportive of them. As stated by the warden of one Swiss prison, "Drugs are a reality in prisons. I can't close my eyes and ignore it. Staff support this project. Needle distribution has become part of our daily work, a non-issue."

Jürgens concludes, "It is high time that Canada adopts a more pragmatic approach to drug use, acknowledging that the idea of a drug-free prison is no more realistic than the idea of a drug-free society." He argues that because of HIV/AIDS and other diseases such as hepatitis C, prison systems – like society in general – cannot afford to continue focusing on the reduction of drug use as the primary objective of their drug policies. Although reduction of drug use remains an important goal, reduction of the spread of HIV and other infections is even more crucial. "Making bleach, sterile needles, and methadone programs available to inmates does not mean condoning drug use, but is a necessary and pragmatic public health measure." Russell Armstrong, Executive Director of the Canadian AIDS Society, adds, "Prisoners come from the community and return to it. They are sentenced to prison, not to be infected. If we neglect to protect their health, this will have negative consequences for the health of all Canadians, and governments could be held morally and legally responsible. We can save lives and money by acting without further delay." [...]

For more information and/or copies of the *Final Report*, contact the office of the Joint Project at (514) 987-3000 ext 6937#; fax: (514) 987-3422; e-mail: info@aidslaw.ca

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ENDNOTES

[1] R Jürgens. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996.

[2] Reported Cases of HIV/AIDS in Federal Penitentiaries. Ottawa: CSC, Health Care Services, April 1994 and March 1996.

[3] At least seven studies of HIV seroprevalence among incarcerated populations have been undertaken to date in Canada, showing HIV seroprevalence rates of between one and 7.7 percent. See, eg, C Hankins et al. HIV-1 Infection in a Medium Security Prison for Women – Quebec. *Canada Diseases Weekly Report* 1989; 15(33): 168-170; P Ford et al. Seroprevalence in a Male Medium Security Penitentiary – Ontario. *Canada Communicable Disease Report* 1994; 20(6): 45-47; D Rothon et al. Prevalence of HIV Infection in Provincial Prisons in British Columbia. *Canadian Medical Association Journal* 1994; 151(6): 781-787; L Calzavara. Preliminary Results from an Anonymous Unlinked HIV Seroprevalence Study of Inmates in Ontario. In: Correctional Service of Canada. *HIV/AIDS in Prisons: Background Materials*.

Ottawa: Minister of Supply and Services Canada, 1994, at 169-170.

[4] Studies undertaken in Canadian prisons revealed hepatitis C seroprevalence rates of between 28 and 40 percent: PM Ford, C White et al. Seroprevalence of Hepatitis C in a Canadian Federal Penitentiary for Women. *Canada Communicable Disease Report* 1995; 21(14): 132-134; M Pearson, PS Mistry et al. Voluntary Screening for Hepatitis C in a Canadian Federal Penitentiary for Men. *Canada Communicable Disease Report* 1995; 21(14): 134-136; RG Prefontaine, RK Chaudhary. Seroepidemiologic Study of Hepatitis B and C Viruses in Federal Correctional Institutions in British Columbia. *Canadian Disease Weekly Report* 1990; 16: 265-266; RG Prefontaine et al. Analysis of Risk Factors Associated with Hepatitis B and C Infections in Correctional Institutions in British Columbia. *Canadian Journal of Infectious Diseases* 1994; 5: 153-156.

Canadian HIV/AIDS Policy & Law Newsletter

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Methadone Treatment in Prisons: An Overview[1]

Treatment with methadone as a substitute for opiate use has been adopted in a number of prison systems worldwide - most recently, in the provincial prison system in British Columbia.[2] It is seen as an AIDS-prevention strategy that allows people dependent on drugs an additional option for getting away from needle use and sharing.

In this issue of the *Newsletter*, we provide a short overview of methadone treatment in prisons and report about the first case in Canada in which an accused was sentenced to a term of imprisonment with the specific goal of undergoing methadone treatment.[3] In our next issue, we will report about a similar case in The Netherlands and provide more details about the decision to make methadone treatment available in provincial prisons in British Columbia.

Background

There are ample data supporting the effectiveness of methadone maintenance treatment (MMT) in reducing high-risk injecting behaviour and in reducing the risk of contracting HIV.[4] There is also compelling evidence that MMT is the most effective treatment available for heroin-dependent IDUs in the community in terms of reducing mortality,[5] heroin consumption,[6] and criminality.[7] Further, in most countries where it has been introduced, MMT attracts and retains more heroin injectors than any other form of treatment.[8] Finally, there is evidence that people who are on MMT and who are forced to withdraw from methadone because they are incarcerated often "return to narcotic use, often within the prison system, and often via injection."[9]

Community methadone programs have rapidly expanded in a number of countries in recent years, including Canada (in particular, British Columbia),[10] and many national and international organizations have recommended the introduction or expansion of MMT in prisons.[11] It has been suggested that methadone is the best available option to prevent needle sharing in prisons,[12] and that increasing the number of places available for MMT in prisons should be considered as a matter of urgency for HIV-positive drug-dependent prisoners.[13]

In light of this, the Canadian Expert Committee on AIDS and Prisons (ECAP) recommended in 1994 that

> [i]n order to reduce the risk of infection from drug-injecting, ... the options for the care and treatment of drug users include access to methadone. Studies should be undertaken to establish the most effective ways of implementing methadone maintenance programs in penitentiaries. Once implemented, these programs should be evaluated, with participation of inmates and experts independent of CSC [the Correctional Service of Canada].[14]

At the time, this recommendation was rejected by CSC because, according to the Service, there was no "medical indication" to provide MMT for opioid-dependent inmates, and "there are relatively few maintenance programs outside CSC institutions to support methadone-dependent inmates following release."[15]

CSC is currently reconsidering its position and may well soon announce that MMT will become available to inmates in

at least some of its prisons, following the increasing number of prison systems worldwide offering MMT to inmates. As suggested by a study undertaken in New South Wales, the reduction of injecting and syringe sharing demonstrated in MMT in community settings also occurs in prisons[16] – an important reason to make MMT available to prisoners.

Aim of Methadone Maintenance

The main aim of methadone maintenance, as stated by Gore,

> is to help people get off injecting, not off drugs. Methadone dose reduction – with the ultimate goal of helping the client to get off drugs – is a longer term objective.[17]

Unfortunately, many prison staff and some prison systems, including some in Canada, have thus far not well understood the rationale behind MMT. As pointed out by Hall et al,[18] in the absence of education about its rationale, some prison staff regard the program as "pandering" to addicted prisoners by giving them free access to an opioid drug; they believe that its main rationale is the reduction of recidivism rather than the prevention of HIV transmission in prison. Similarly, CSC, in its 1994 response to ECAP's recommendations, neglected to consider the potentially life-saving effect of such programs, and took a very conservative approach that seems to have been shaped before the advent of HIV/AIDS. Today, it is accepted that making methadone maintenance available is necessary to save lives: it reduces injection drug use and the resulting risk of HIV infection. In other words, methadone maintenance may not be completely harmless, but its possible harms are insignificant when compared with the much bigger harms resulting from injection drug use – HIV/AIDS and hepatitis C in particular.

Some have objected to methadone treatment on moral grounds, arguing that it merely replaces one drug of dependence with another. They have said that "methadone does not really help people to get off drugs" and that "those in methadone maintenance programs only exchange one sort of dependence, that on narcotic drugs, against another, that on methadone." If there were reliably effective alternative methods of achieving enduring abstinence, this would be a meagre achievement. However, there are no such alternatives:

> [T]he majority of heroin-dependent patients relapse to heroin use after detoxification; and few are attracted into, and retained in drug-free treatment long enough to achieve abstinence. Any treatment [such as MMT] which retains half of those who enrol in treatment, substantially reduces their illicit opioid use and involvement in criminal activity, and improves their health and well-being is accomplishing more than 'merely' substituting one drug of dependence for another.[19]

Recommendation

As pointed out in *HIV/AIDS in Prisons: Final Report*, methadone maintenance is a medically indicated form of treatment that should be available to opioid-dependent persons regardless of whether they are outside or inside prison:

> Equivalence of medical care should mean that, at a minimum, prisoners who have been receiving methadone on the outside may continue to receive it inside if that is their wish and their practitioner's wish/decision. Further, where MMT is a treatment option available to opioid-dependent persons outside prisons, it should also be made available to them in prisons: because of the principle of equivalence of medical care, prisoners have a right to the same treatments available to persons outside prisons.[20]

The *Report* recommends that

> Prisoners who have been in methadone maintenance treatment on the outside should always be able to continue to receive such treatment in prison. Further, where such treatment is a treatment option available to opioid-dependent persons outside prisons, it should also be made available to them in prisons.
>
> In addition, opioid-dependent prisoners should have other treatment options, including methadone detoxification programs with reduction-based prescribing, which should be routinely offered to all opioid-dependent prisoners on admission.[21]

Prison systems will hopefully act soon to implement these recommendations.

- *Ralf Jürgens*

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ENDNOTES

[1] For the full version of this overview, see R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996, at 67-75.

[2] See the Sample Protocol for Methadone Maintenance Therapy. BC Corrections Branch, September 1996; and D Rothon. Guidelines for Methadone Maintenance Therapy in BC Correctional Centres. Revised version, 1 October 1996.

[3] See B Turcotte, infra. Judge Orders Methadone Maintenance Treatment in Prison.

[4] D Riley. Methadone and HIV/AIDS. *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 2(1): 1, 13-14. See also O Blix, L Gronbladh. AIDS and the IV Heroin Addicts: The Preventive Effects of Methadone Maintenance in Sweden. *Drug and Alcohol Dependence* 7: 249-256; DM Novick et al. Absence of Antibody to Human Immunodeficiency Virus in Long-Term, Socially Rehabilitated Methadone Maintenance Patients. *Archives of Internal Medicine* 1990; 150 (January).

[5] K Dolan, A Wodak. An International Review of Methadone Provision in Prisons. *Addiction Research* 1996; 4(1): 85-97, with reference to JRM Caplehorn. Retention in Methadone Maintenance and Heroin Addicts' Risk of Death. *Addiction* 1994; 89: 203-207.

[6] Ibid, with reference to E Gottheil et al. Diminished Illicit Drug Use as a Consequence of Long-Term Methadone Maintenance. *Journal of Addictive Diseases* 1993; 12(4): 45.

[7]Ibid, with reference to RG Newman et al. Arrest Histories before and after Admission to a Methadone Maintenance Program. *Contemporary Drug Problems* 1973(Fall): 417-430.

[8] Ibid, with reference to J Ward et al. *Key Issues in Methadone Maintenance Treatment*. Sydney: University of New South Wales Press, 1992.

[9] Correctional Service Canada. *HIV/AIDS in Prisons: Final Report of the Expert Committee on AIDS and Prisons*. Ottawa: Minister of Supply and Services Canada, 1994, at 73, with reference. See also D Shewan et al. Evaluation of the Saughton Drug Reduction Programme. Main Report. Edinburgh: Central Research Unit, 1994.

[10] See J Anderson. AIDS and Overdose Deaths in British Columbia. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 1, 25-26; D Riley. Harm Reduction Around the World. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 15-18 at 17.

[11] See, eg, the WHO *Guidelines on HIV Infection and AIDS in Prisons*. Geneva: World Health Organization, 1993; Advisory Committee on the Misuse of Drugs. *AIDS and Drug Misuse Update*. London: HMSO, 1993; Scottish Affairs Committee. *Drug Abuse in Scotland*: Report. London: HMSO, 1994.

[12] F McLeod. Methadone, Prisons and AIDS. In J Norberry et al (eds). *HIV/AIDS and Prisons*. Canberra: Australian Institute of Criminology, 1991, at 245, 248.

[13] H Heilpern, S Egger. AIDS in Australian Prisons – Issues and Policy Options. Canberra: Department of Community Services and Health, 1989, at 94.

[14] ECAP: *Final Report*, supra, note 9 at 79 (Recommendation 6.3(7).

[15] Backgrounder: CSC Response to the Expert Committee on AIDS and Prisons (ECAP). Ottawa: CSC, Health Care Services Branch, 24 March 1994.

[16] See K Dolan et al. Methadone Maintenance Reduces Injecting in Prison. *British Medical Journal* 1996 (forthcoming). For a comprehensive review of methadone provision in prisons internationally, see *HIV/AIDS in Prisons: Final Report*, supra, note 1.

[17] S Gore, cited in *HIV/AIDS in Prisons: Final Report*, supra, note 1 at 70.

[18] W Hall et al. Methadone Maintenance Treatment in Prisons: The New South Wales Experience. *Drug and Alcohol Review* 1993; 12: 193-203 at 197.

[19] Ibid.

[20] Supra, note 1 at 108.

[21] Ibid at 109 (Recommendation 5.4).

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Judge Orders Methadone Maintenance Treatment in Prison

In June 1996, the Québec Superior Court rendered an important decision regarding sentencing in *R* v *Povilaitis*.[1] For the first time in Canada, a judge ordered that an accused follow methadone maintenance treatment (MMT) for a three-year probation period.

The following article deals with this case and with the changes it may foreshadow in relation to methadone use in prisons.

Introduction

According to the Centre de recherche d'aide aux narcomanes (CRAN), approximately one-half of those dependent on heroin who seek help have committed criminal offences.[2] Some studies produce even higher statistics. It clearly emerges that heroin-dependent people have no choice but to commit offences in order to maintain their habit.[3]

The judicial system is attempting to manage the problem using measures that, in the opinion of many, unfortunately put too much emphasis on repression and imprisonment.[4] Such measures do nothing to address the sources of the problems associated with drug dependence. This is why preventive methods that maximize chances of rehabilitation are increasingly viewed as the only possible solution.

In this context, methadone, widely distributed in Europe and in the United States, seems to provide noteworthy results. Although the use of methadone in Canada is still limited,[5] the tone of the debate makes it possible to predict more common use of the substance as an effective means of fighting drug dependence in users of injectable drugs.

Use of Methadone

Methadone is a heroin substitute that eliminates withdrawal syndrome and significantly reduces the compulsion to consume opiates, doing so without euphoriant effects.[6]

Methadone maintenance treatment (MMT), together with health care and psychosocial monitoring, is intended for drug-dependent people who have developed a strong heroin dependency. This kind of program has been in use for around 30 years in various countries, and its effectiveness has been clinically and scientifically demonstrated.[7] "Each dollar invested in this type of program makes it possible to avoid spending five to ten dollars on health, imprisonment, welfare, etc."[8]

The use of MMT is not new in prisons either: various countries have tried the experiment with highly satisfactory results.[9]

For some time in Canada various bodies – including the Expert Committee on AIDS and Prisons (ECAP) and, more recently, the Canadian AIDS Society and the Canadian HIV/AIDS Legal Network – have been attempting to have the

Correctional Service of Canada (CSC) authorize the administration of methadone in penitentiaries.[10] In its response to the many recommendations contained in ECAP's Final Report, the CSC refused to provide a methadone maintenance program for inmates, stating that there is no "medical indication" to provide MMT for opioid-dependent inmates and "there are relatively few maintenance programs outside CSC institutions to support methadone-dependent inmates following release." [11] Many think that CSC neglected "to consider the potentially life-saving effect of such programs," and has taken "a very conservative approach that seems to have been shaped before the advent of HIV/AIDS."[12]

For this reason, the federal government has recently decided to relax regulations in order to facilitate access to methadone. This move, together with the pressure being applied by stakeholders interested in the issue, allow for some hope that the CSC will soon reconsider its position.

For their part, provincial correctional systems appear to be showing a certain openness to MMT in prisons:

- Tanguay, a prison for women in Québec, has already allowed inmates to continue methadone treatment begun before imprisonment; and

- in April 1996, after the issuing of a writ of habeas corpus, the Burnaby Correctional Centre for Women in British Columbia finally decided to provide methadone to a seropositive woman who was part of an MMT program before her imprisonment.[13]

These overtures are interesting but are not sufficiently widespread in Canada to meet the needs of imprisoned drug-dependent people, whence the importance of the decision in *Povilaitis*.

R* v *Povilaitis

Sentencing Hearings

Mr Povilaitis appears to be typical among convicted offenders. Having consumed heroin for nearly 20 years, he has a long police record. Most of his crimes have related to property offences committed in order to obtain heroin. On many occasions Mr Povilaitis was sentenced to terms ranging from three months to two years. However, none of them led to satisfactory social rehabilitation.

In March 1996, while he was voluntarily following detoxification treatment, Mr Povilaitis was arrested in connection with a series of breaking and entering offences. The prosecutor from the Attorney General's office argued for a sentence of four to five years in prison.

As mentioned above, the systematic imprisonment of drug-dependent people involved in criminal activities does not solve the problem at its source. This is why, in the Povilaitis case, we [the lawyers] opted for reduced detention combined with a methadone maintenance program.

The Sherbrooke detention centre, which manages prison sentences of two years less a day, was then the only institution in a position to offer MMT during the period of imprisonment. Our objective was therefore to convince the Court to hand down a shorter sentence so that it could be served in this provincial detention centre (all sentences of two years and more have to be served in prisons under federal jurisdiction).

To do so, we called five key witnesses other than the accused: a physician certified to administer methadone and declared to be an expert in neuropharmacology, the coordinator of a detoxification centre, a community police officer, the director of the detention centre of the Sherbrooke prison, and a psychologist specializing in drug dependence.

The physician stated in his testimony that heroin addition should be considered as a disease that has to be treated. According to him, a drug-dependent person who has developed a strong dependency on heroin has a 97 percent chance of relapsing where traditional detoxification methods are used.

In this regard, several studies have shown that "drug-dependent people who are already chronically dependent on opioids, if they cannot be placed in a methadone program, quickly drop the other methods of ambulatory treatment, inappropriate or inadequate for them, and find themselves on the street as heroin addicts with a very high risk of imprisonment and death."[14] Our client had in the past participated in five detoxification programs without significant success.

However, with a long-term methadone maintenance program the success rate may be over 50 percent, provided it includes therapeutic follow-up: an adequate dose of methadone does not in itself enable the severely addicted to deal with their problem.[15]

The Judgment

Tailoring the sentence to the individual case is a basic principle to which all judges must adhere. What is more, a balance must be maintained between protecting the public interest, deterrence, and social reintegration.

Lamer J stated in the *Lebovitch* case that where a heroin addict has already made adequate and satisfactory efforts to detoxify, the courts should encourage the continuation of such efforts, in particular by showing clemency in sentencing.[16] Accuseds would thereby receive a reduced prison sentence where they show a strong potential for rehabilitation.[17]

However, the court must be convinced that the accused is an appropriate candidate for MMT. Selection criteria may vary from program to program: generally, those eligible must be of legal age, have been addicted for several years, and have already made serious attempts to detoxify.

Motivation is without doubt the most important criterion. MMT with psychosocial monitoring requires sustained effort on the part of the subject. The mere fear of imprisonment is certainly a strong source of motivation but is not in itself sufficient. Drug-dependent people must feel a real will to overcome their dependency on opioids.[18]

For this purpose, psychologists often use the Minnesota Multiphasic Personality Inventory (MMPI) method to sound out their clients and assess their level of motivation. The MMPI test is well-recognized by the courts.[19] Mr Povilaitis's test results showed that he was strongly motivated.

In the event, taking into consideration Mr Povilaitis's rehabilitation potential, the Court showed clemency, handing down a prison sentence of two years less a day.

This sentence included a three-year probation period during which Mr Povilaitis will be obliged to complete the MMT program. In addition, he must undergo therapy, report regularly to a probation officer, and submit to weekly urine tests.

Furthermore, in order to ensure close control of the accused, the Court suspended the sentence in one of the files. Thus, in the event that Mr Povilaitis fails to meet any of the conditions imposed by the judge, not only would he be violating parole, but would also receive the prison sentence that was suspended.

Taken together, these measures clearly constitute an incentive to continue treatment.

Conclusion

The Povilaitis case has without doubt led to increased awareness of the issue in the prison community. Because the consumption of injectable drugs in prison and the risk of transmission of HIV and hepatitis C are realities that cannot be ignored, the means have to be found to combat the problem. MMT seems to present more advantages than disadvantages.

In Québec, a monitoring committee was created in order to analyze developments in Povilaitis's case. The committee will eventually have to submit recommendations to the department of health and public security. By dealing actively with this issue, the Québec correctional service is respecting one of the objectives it has set for itself: "To redefine the

type and level of services provided to offenders from the viewpoint of giving them a sense of responsibility."[20]

Furthermore, the courts should respond to the legislature's will to put a priority on the objectives of social reintegration and making offenders feel more responsible.[21] The recent implementation of the *Criminal Code* amendments relating to how sentences should be determined goes in this direction.

Accordingly, considering the clear link between the commission of offences and drug dependence, it is necessary for judges to be more familiar with the preventive and rehabilitative measures that make up MMT. This would make it possible to save valuable time during sentencing hearings, save considerable money, and facilitate access to this type of program for drug-dependent people with a criminal record.

- *Benoit Turcotte*

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ENDNOTES

[1] *R* v *Povilaitis*, Superior Court, Criminal Division, 1996, 450-01-004040-965, unreported.

[2] P Lauzon & S Brochu. *Doc. Janvier 1996: Projet-pilote d'intervention avec méthadone auprès de personnes judiciarisées*. Québec: CRAN, Recherche intervention substances psychoactives – Centre d'intervention en criminologie comparée, 1996, at 1.

[3] Ibid at 3, with reference to Inciardi & Pottieger (1986), Johnson & Kaplan (1988), and Sanchez & Johnson (1987).

[4] Correctional Services Québec. *Des orientations pour l'action*. Bibliothèque nationale du Québec, 1996, at 12.

[5] See, for example, D Riley. Methadone and HIV/AIDS. *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 2(1): 1, 13-14.

[6] J-J Déglon. Le traitement à long terme des héroïmanes par la méthadone. *Psychtropes* 1983; 1(2): 45.

[7] Lauzon & Brochu, supra, note 2 at 1.

[8] P Lauzon. L'état et la profession médicale doivent-ils fournir de la "drogue" aux toxicomanes? *Le Médecin du Québec* 1996; 31(1): 38.

[9] See R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996, at 67-72; and infra.

[10] Ibid at 67.

[11] Backgrounder: CSC Response to the Expert Committee on AIDS and Prisons (ECAP). Ottawa: CSC, Health Care Services Branch, 24 March 1994.

[12] R Jürgens, supra, note 9 at 72.

[13] C McLeod. Is there a Right to Methadone Maintenance Treatment in Prison? *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 22-23.

[14] J-J Déglon, supra, note 6 at 49, with reference to Cushman (1977), Gunne (1981), and Vaillant (1977).

[15] Ibid at 55.

[16] *R* v *Lebovitch* (1978), 8 CR (3d) S-41.

[17] *R* v *Jobin* (1989), JE-1158 (Québec CA); *R* v *Beauvais* (1978), 5 CR (3d) S-27 (Ont CA); *R* v *Rogal* (1984), 12 WCB 176 (BCCA); *R* v *O'Sullivan*, 2 June 1975 (BCCA); *R* v *Holt* (1983), 4 CCC (3d) 32 (Ont CA); *R* v *Marnoch* (1984), 11 CCC (3d) 286 (Ont CA).

[18] *R* v *Storr*, (1995) 33 Alta LR (3d) 163.

[19] H Pope, J Butcher, J Seelan. *The M.M.P.I. in Court: A Practical Guide for Expert Witnesses and Attorneys*. American Psychiatric Association, at 250.

[20] Supra, note 4 at 35.

[21] S Brochu & A Drapeau. *La pratique des tribunaux face aux renvois vers les centres de traitement de la toxicomanie*. RISC and CICC, April 1996, at 1.

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US – Improving HIV/AIDS Prevention in Prisons Is Good Public Health Policy

An editorial in the September 1996 issue of the *American Journal of Public Health* reminds us that people who are incarcerated are only temporarily separated from their respective communities. It continues by saying: "For many of us, they are our neighbors, our children, and our friends. Protecting the health of communities must include protecting the health of prison communities, and meeting this challenge is good public health policy."[1]

The editorial starts by pointing out that prisons in the United States are growing rapidly: in 1993, 4.9 million people were under some form of correctional custody (in prisons and jails, on parole, or on probation). Policies that mandate confinement for drug-related offences are responsible for the dramatic increases in imprisonment, and the concentration of injection drug users in prisons is associated with a high prevalence of HIV among inmates. As of December 1994, at least 4588 inmates had died of AIDS in US prisons.

According to the editorial,

> the second wave of the AIDS epidemic, which is building among injection drug users, their sexual partners, and their children, appears to disproportionately affect prison and jail populations. Typically in prison populations, high HIV seropositivity rates are found for injection drug users who inject drugs frequently and who have been in prison more than once. [references omitted]

The authors refer to an article by Mahon in the same issue of the *Journal*,[2] in which the author reports that a wide range of sexual behaviours occur between prisoners as well as between prisoners and staff; that many inmates regarded prison policies that prohibit sexual activity between inmates as "unrealistic and inhumane"; and that inmates felt that potential exposure to HIV infection and other sexually transmitted diseases "should not be a de facto form of punishment for engaging in prohibited sexual behavior."

After pointing out that few programs in prisons in the US make available the means for reducing risk by distributing condoms and dental dams, exchanging needles, or providing bleach for cleaning needles, the editorial emphasizes that

> [c]ontinued limitations placed on prevention services in correctional institutions may lead to higher public health expenditures. On the other hand, greater public health involvement in the development of guidelines for HIV testing, counseling, medical care, and technical assistance in the provision of HIV/AIDS, sexually transmitted diseases, and infectious disease prevention in correctional institutions is likely to reduce future local, state, and federal expenditures for HIV/AIDS treatment.

The authors conclude by saying:

> Effective HIV/AIDS prevention for prisoners requires a collaborative and comprehensive approach. This involves bringing together correctional systems, public health agencies, and community-based organizations to design an array of prevention and support services for inmates and ex-offenders. To ensure continued risk reduction, linkages must be established with communities. Those who are released from prison need assistance in gaining access to educational services, drug treatment, job training, and housing referral. Above all, communities have to work closely together to plan and formulate policies that are commensurate with their values and their specific needs.

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ENDNOTES

[1] J Gaiter, LS Doll. Editorial: Improving HIV/AIDS Prevention in Prisons Is Good Public Health Policy. *American Journal of Public Health* 1996; 86(9): 1201-1203.

[2] N Mahon. New York Inmates' HIV Risk Behaviors: The Implications for Prevention Policy and Programs. *American Journal of Public Health* 1996; 86(9): 1211-1215; for a summary, see New Studies on HIV/AIDS in Prisons. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(2): 18-19; R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996, at 36.

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US – Asylum Granted to Person Living with HIV

The US Immigration and Naturalization Service (INS) appears to be taking a supportive position with regard to HIV-positive applicants for US asylum from countries where life is particularly difficult for persons living with HIV/AIDS.

On 31 October 1995, an Immigration Judge (IJ) in New York issued a decision granting asylum on the basis that the applicant, a person living with HIV, is a member of a "particular social group" subject to persecution in his home country because of such membership. The applicant, a native and citizen of Ivory Coast and Togo (Africa) who discovered his HIV-positive status after suffering a seizure while in the United States, was able to demonstrate to the IJ's satisfaction that treatment for HIV infection is scarce or non-existent in Ivory Coast and Togo, that hospitals and families shun HIV-positive persons, and that they are generally isolated and ostracized as a group. The IJ granted asylum and withholding of deportation, finding that the AIDS epidemic in Africa is a "serious problem" and that the respondent "would in fact be persecuted because of his membership in a social group."[1]

Of perhaps even wider significance, since individual IJ decisions have no precedential value unless specifically designated as precedential by direction of the Attorney General, is a memorandum issued on 16 February 1996 by the General Counsel of the INS, directing that all cases involving HIV-positive claimants for relief from deportation should "be handled in a humanitarian manner, consistent with our obligations under international law and the Immigration and Naturalization Act (INA). Seropositive for HIV shall be considered in requests for discretionary forms of relief from deportation, and claims for asylum or withholding of deportation based upon membership in a particular social group shall be handled in accordance with the attached discussion on that subject, prepared at the request of the White House."

The attachment consists of a five-paragraph response by the INS to a recommendation from the President's Advisory Council on AIDS that the President should direct the INS to treat people with AIDS as "a social category protected under the asylum law." The response notes that the INS's flexibility is limited by the statute under which it operates, but then goes on to explain that in cases where it could be shown that people with AIDS are subject to severe official persecution by the government or "an entity the government cannot or will not control" the INS could exercise its discretion to waive the official exclusion of HIV-positive people from immigrating to the US "for humanitarian purposes, to assure family unity, or when it is in the public interest."

Thus, the General Counsel's memorandum does not go so far as to recognize a presumptive eligibility for asylum for HIV-positive aliens who find themselves in the US, but does suggest that the Service should be open and responsive to arguments in particular cases that within a particular country HIV-positive people may constitute a social group subject to official or quasi-official persecution severe enough to merit a waiver of deportation and grant of asylum.

In Canada, in 1994, the Immigration and Refugee Board granted refugee status to a Polish man persecuted because of his sexual orientation and HIV-positive status.[2]

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[1] *Matter of [Anonymous]*. A 71 498 940 (IJ New York, 31 October 1995), summarized in *Interpreter Releases*, 8 July 1996; 73: 901. Reported in *Lesbian/Gay Law Notes*, September 1996, at 124.

[2] [1994] DSSR No 92 (QL). See *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 1(3): 5.

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CHILDREN AND HIV/AIDS

The Children and AIDS International NGO Network

The Children and AIDS International NGO Network (CAINN) was established in July 1996 by a group of non-governmental organizations (NGOs) from around the world at a Satellite Symposium of the XI International Conference on AIDS. The Symposium was sponsored by the Interagency Coalition on AIDS and Development (ICAD).

ICAD is a Canadian-based coalition of 29 NGOs and AIDS-service organizations. At the symposium ("Influencing an AIDS Affected Children and Youth Policy and Programme Agenda"), representatives of 60 agencies from all regions of the world agreed to undertake immediate action to ensure that the needs and voices of children and youth affected by HIV and AIDS are no longer neglected. CAINN will work to mobilize NGOs, governments, multilateral organizations, funders, universities, religious organizations, businesses and other stakeholders to address the needs of AIDS-affected children. It will build a network of organizations and contacts at the global and regional levels, with the aim of

- ensuring better collaboration to advance children-and-AIDS issues;
- exploring and developing the best mechanism for future cooperation; and
- collaborating with UNAIDS and UNICEF on their joint Children in a World with AIDS initiative.

CAINN will

- work from the child's rights perspective as outlined in the UN Convention on the Rights of the Child;
- promote the involvement and participation of children and young people themselves in developing services and programs; and
- work closely with community-based groups involved directly with children, young people and their families; and encourage and support regional networks.

Immediate action will be undertaken to:

- collect information about programs and projects concerning children and young people;
- identify "best practices" and where there are gaps; and
- liaise with the regional and international AIDS conferences to be held in Africa, Asia and Latin America in 1997 and in Geneva in 1998, to ensure that children's issues will be raised.

CAINN held its first planning meeting in London, England from 13 to 16 November 1996. The meeting identified the priority children-and-AIDS issues the network plans to address and developed a work plan for participating NGOs.

- *Aine Costigan*

For more information about CAINN and/or a copy of the report of the Satellite Symposium, contact Bruce Waring at ICAD: tel: (613) 788-5107; fax: (613) 788-5052; e-mail: ICAD@web.net

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CRIMINAL JUSTICE

Sex Trade Worker Sentenced to Two Years for Biting

In May 1996, an HIV-positive transvestite sex trade worker was sentenced to two years less a day for biting a police officer.[1]

Facts

In October 1995, a scuffle occurred as an undercover officer arrested the accused for propositioning him on the street. The accused bit the officer on the hand, after which she told the officer that she "had AIDS." She was charged with aggravated assault, on the ground that the bite had "endangered the life of the complainant."

The defendant pleaded guilty to the charge. In his reasons for sentence, Cadsby J of the Ontario Court (Provincial Division) concluded that this was "an admission that she had objective foresight of the risk of infecting the complainant with HIV by her act in biting the complainant's hand."

Quoting from the judgment of the Newfoundland Court of Appeal in *R* v *Mercer*,[2] in which the court referred to the global impact of the HIV/AIDS epidemic and adverts to "the enormity of the consequences to individuals and society as a whole," the judge also concluded that "the incidence of HIV/AIDS is so great that it is a known worldwide health menace." The judge took into account the statements of the complainant police officer, specifically noting that he was young, married, and that he and his "distraught" wife had postponed their decision to start a family "in view of the danger he faces to his life." The officer reported that he was undergoing counselling and being tested for HIV antibodies every three months.

The Crown requested imprisonment for three to four years. The judge agreed that such a lengthy sentence was appropriate but refused to impose a sentence whose length would require incarceration in the federal correctional system "because of a lack of facilities in federal institutions in this province for the custody and care of inmates infected with HIV/AIDS." Indeed, he noted that "if the minimum appropriate custodial term in this case was a penitentiary sentence, the court would be required to impose a sentence that could result in a breach of Section 12 of the Charter of Rights. If these reasons stimulate some thought and discussion in the public and in government authorities as to the adequacy of arrangements in federal penitentiaries in this province, I will be listening."[3] The judge therefore sentenced the accused to two years less a day in a provincial facility.

Terms of her three-year probation include attending counselling and treatment for HIV/AIDS as directed by the probation officer and a prohibition on engaging in unprotected sex.

Comment

In prohibiting unprotected sex by the accused as a term of probation, Cadsby J in effect criminalizes the accused for even having sex with a consenting partner following disclosure of her HIV-positive status. At this point in Canadian

law, it has not been clearly established that unprotected sex even without disclosure of HIV status constitutes criminal conduct, and no case yet decided by a Canadian court has gone so far as to suggest that even disclosing one's HIV-positive status will not be sufficient to avoid possible criminal liability. This indirect expansion of the ambit of Canadian criminal law is of considerable concern.

The charge of "aggravated" assault was itself a misguided over-reaction by police and prosecutors: it is highly doubtful whether the bite in question presented any serious likelihood of "endangering the life" of the police officer. While HIV has been detected in saliva, the concentration is much lower than in other bodily fluids such as blood or semen, and the degree of exposure in a bite lasting a few seconds is insignificant. There have been no documented and confirmed cases of HIV transmission via biting since the beginning of the HIV epidemic, and scientific opinion overwhelmingly considers the risk of infection from a bite to be minuscule at most.

Furthermore, aggravated assault is not only the most serious degree of assault under the *Criminal Code*, but in practice it is also reserved for the most injurious and vicious instances of assault. Aggravated assault charges are infrequently laid even in cases of domestic violence and hate crimes such as gay-bashing, and sentences handed down in such cases are often a matter of months, not years, despite physical and emotional injuries far more severe than a bite that is exceedingly unlikely to have transmitted HIV. In fact, as of the date of sentencing, six months after the bite, the officer had still tested HIV-antibody negative; even with this information before it, the court nonetheless adverted to the enormity of the global AIDS epidemic in concluding that two years of imprisonment was an appropriate penalty for a bite to the hand.

Interestingly, Cadsby J specifically referred to another case in which an HIV-positive accused was charged with aggravated sexual assault. In *R v Winn*,[4] the accused, knowing he was HIV-positive, beat the victim about the head and face and ejaculated into her mouth, onto an open facial wound caused by the beating, and into her vagina. The victim suffered serious eye injury, a fractured cheek bone, and permanent nerve damage, but did not contract HIV. The accused had a lengthy criminal record, including violent crimes, and was sentenced to 12 years. Cadsby J described *Winn* as "one of the worst cases and one of the worst offenders." A simple bite to the hand, carrying considerably less risk of infection, appears minor by comparison; the sentence of two years' imprisonment and three years' probation is therefore that much more surprising.

The result would probably have been different if the bite had occurred during an "ordinary" altercation on a street or in a bar. Yet this case involved an HIV-positive transvestite sex worker as accused, and a married police officer. Given the unwarranted and determinative focus on the accused's HIV status in the reasons for sentencing, one cannot help but wonder what other biases may have affected the administration of justice here, given the image of gay and/or transgendered people as threats to the nuclear family, of sex workers as "AIDS carriers," and the stigmatization of people living with HIV/AIDS generally.

Not only did the judge accept without question the assumption that aggravated assault was the appropriate charge because of the supposed "danger" to the officer's life; the judge's reasoning further compounded the miscarriage of justice in this case. The judge was of the view that the accused's statement, made after the bite, that she was HIV-positive was evidence of her intent to endanger the police officer's life by exposing him to the possibility of HIV infection. Such reasoning has also been applied in several US cases where HIV-positive accuseds have been criminally charged for spitting, biting or spraying blood. Such incidents usually occur in situations of great stress or powerlessness – during suicide attempts[5] or, as was the case here, in physical encounters with police or prison officers.[6] Yet this conclusion is questionable. When the conduct in question carries little or no risk of viral transmission, such statements about HIV infection should not necessarily be taken as evidence of a criminal intent to kill or cause serious injury. Rather, in the cases seen to date, such statements arise from a sense of despair, frustration or powerlessness at the hands of police or correctional officers. In such cases, a threat that appeals to common fears and misunderstandings about HIV and modes of transmission – in a society where police have frequently worn latex gloves at demonstrations involving gay and/or AIDS activists – may be a means of self-defence against physical aggression, rather than an indication of murderous intent. An accused who truly intended to murder another would be unlikely to choose the highly indirect and ineffective method of biting or spitting. Indeed, in his reasons, the judge acknowledged that the bite was not "premeditated but was as a result of her arrest and the struggle that followed." Despite this, the Court was evidently of the view that the accused was dangerous and "the public interest is that this danger be minimized."

Appeal

An appeal of the sentence is expected to be heard this fall.

- *Richard Elliott*

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ENDNOTES

[1]*R* v *Thissen*, unreported, 16 May 1996, Ont Ct (Prov Div).

[2] 84 CCC (3d) 41.

[3] In an earlier case, *R v Downey* (1989) 42 CRR 286, the Ontario District Court had held that a prisoner with HIV/AIDS was not receiving adequate treatment for his disease, in violation of s 12 of the Charter.

[4] 24 OR (3d) 750 (Prov Div); for more details, see HIV-Positive Rapist Sentenced to 12 Years. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(2): 8.

[5] *State v Haines*, 545 NE 2d 834 (Ind App 2nd Dist 1989).

[6] *Brock v State*, 555 So 2d 285 (Ala Cr App 1989); *Weeks v State of Texas*, 834 SW 2d 559 (Tex CA 1992), aff'd by Texas Ct of Criminal Appeals, 14 Oct 1992; *People v Richards*, cited in: W Curran, L Gostin & M Clark. Acquired Immunodeficiency Syndrome: Legal and Regulatory Policy Analysis i-ii, 204-207 (1986, republished by US Dept of Commerce, 1988).

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US – Court Reverses HIV-Positive Rapist's Attempted Murder Conviction

Reversing lower court decisions, Maryland's highest court ruled that a rapist's knowledge that he had HIV was not, by itself, sufficient evidence to sustain an attempted murder conviction.[1]

While incarcerated in 1991, appellant Smallwood was diagnosed HIV-positive and said that he would practise safe sex in order to avoid transmitting the virus. In 1993, Smallwood and an accomplice robbed a woman at gunpoint. Smallwood then sexually assaulted the woman, causing "slight penetration," without a condom. Convicted in a bench trial, Smallwood received concurrent sentences for attempted murder, assault with intent to murder, and reckless endangerment. Smallwood argued that the evidence could not support a conviction of attempted murder or assault with intent to murder.

The intermediate appeals court upheld the convictions, but the Court of Appeal, Maryland's highest court, reversed. Distinguishing the cases on which the intermediate appeals court had relied, the Court of Appeals observed that each of those cases involved defendants with a clearly manifested intent to kill.[2] In contrast, the risk of HIV transmission in this case, although real, did not by itself rise to the level required to prove a specific intent to kill, ie, that transmission of HIV was *probable*. Absent that intent, the judgments for attempted murder and assault with intent to murder had to be reversed. The defendant continues to serve a sentence for the lesser charge.

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ENDNOTES

[1] *Smallwood v State of Maryland*, 1996 WL 428978 (Md, 1 August 1996). Reported in *Lesbian/Gay Law Notes* September 1996, at 129.

[2] See, eg, *State v Haines*, 545 N.E. 2d 834 (Ind Ct App 1989), where a bloody assault was accompanied by statements that the defendant wanted to "give the victim AIDS."

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EUTHANASIA

Toward an End-of-Life" Treatment"?

One thing everyone in our society agrees upon is the fact that we all have to die, but how we die often gives rise to controversies in the "developed" world, torn between respect for the principle of the individual's right to choose his or her manner of dying and the desire (which some would consider paternalistic) to ensure that the dying are accompanied by others to the end of their life.

This article is not meant to act as an apology for one option or the other, but rather to demonstrate the bias inherent in certain overly sensationalistic arguments.

Pain: A Determining Factor in Requests for Euthanasia?

In an article on euthanasia that appeared in a previous issue of the *Newsletter*, Ogden appears to argue that pain is not one of the determining factors in requests for euthanasia or assisted suicide made by people in the terminal phase of their illness.[1] Ogden bases this observation on his study[2] of two groups, one of people living with HIV, the other of people directly or indirectly associated with euthanasia cases. In my view, this methodological procedure, it would be over-hasty to draw the conclusion from this methodogical procedure that a request for euthanasia will, in the end, be the sole result of a clear and predetermined process of end-of-life planning. Responses regarding future events generally change over time and are therefore of limited significance in terms of how they may be interpreted, all the more so when the respondents express their reactions at a given time to a future event (their death) or to a past event (the death of another).

Pain Control

Since the beginning of the 1990s, a number of US studies have documented as high a prevalence of pain in the various stages of disease suffered by those with AIDS as by those with cancer. Although some authors assert with excessive optimism that 95 percent of pain is controllable, the point is whether the pain is being effectively controlled. Ogden documented 34 cases of euthanasia or assisted suicide in which "pain was *apparently* well-managed" [emphasis added], but we must be realistic and admit that control of pain in these cases did not measure up to current pharmacological standards. As Foley states,[3] there are many cases in which uncontrolled pain, badly managed symptoms, or persistent depression push the sick person (regardless of the pathology involved) to consider assisted suicide or euthanasia as being the only available options.

The World Health Organization has already twice criticized the obstacles to implementing effective pain-management programs.[4] Myths and prejudices concerning the use of opiates are still deep-seated among many health professionals. As Bradley points out,[5] for some care providers the prescription of morphine means impending or accelerated death. Others see in the prescription of such drugs a danger of dependency or risk of respiratory depression.

Beyond the problem of an overly circumspect use of narcotics, the WHO and several commentators have raised the problem of legal restrictions on the prescription and obtaining of powerful antalgic substances. We also have to consider the particularly narrow interpretation of the 1961 Single Convention on Narcotic Drugs by industry regulatory

bodies, as well as the obvious lack of education of health professionals[6] with regard to pain mechanisms and treatment procedures. Some even cite hospital regulations that, designed to counter the misuse of medications, limit the number and type of medications necessary for controlling pain and symptoms. The literature on the subject[7] goes so far as to say that all these elements contribute to "criminalizing" effective pain-fighting therapies.

In other words, although pain is still an important field of investigation for scientific researchers, the current situation still lags behind the sum of knowledge that has been acquired in this area. An approach that deals purely in terms of pharmacological management would be too reductionist here; the spiritual, social and moral dimensions of suffering have to be taken into account. However, modern medicine has not yet integrated into its ethos pain and suffering as basic elements of dying, and end-of-life care and treatment is considerably affected as a result.

Should Euthanasia Be Legalized?

It is clear that legalizing euthanasia would not encourage the pursuit of such an integration process. Most people who favour legalizing euthanasia defend their position by arguing that each person should have the freedom to choose between palliative care and solutions such as assisted suicide and euthanasia. This argument reveals two sweet illusions with which those who favour legalization delude themselves: the illusion, as Roy points out,[8] that "euthanasia would remain truly voluntary and that patients would not be in any way influenced in requesting death were it legally and socially accepted"; and the illusion that our humanitarian and compassionate society would continue to invest in the development and implementation of programs for end-of-life care and treatment. We have only to look at the current situation to be convinced of the contrary.

Neo-liberal policy is responsible for a sharp reduction in health services, and every day the budgetary knife trims off a little more in the way of funding from palliative care units that maintain a high percentage of medical staff without meeting the profitability criteria developed by most institutions in the management of their operations.[9] In this context Ogden rightly points out the risks of palliative over-zealousness: palliative medicine is not free of the temptation to prolong the period and the act of dying.[10] A constructed ethical approach would make it possible to avoid this pitfall but, even more important, palliative care should not be idealized to a point at which its purpose becomes completely falsified. Faced with the ultimate violence of death, there is no good or better solution – there is only a way of going about dealing with it. The rhetoric of those who favour legalizing euthanasia is in fact a real headlong rush to establish a new set of norms around the concept of a "good death" by basing such norms on the overworked notion of dignity.

The deformations of a sick body are often such "that they can wreak havoc on the idea we may form of the border between the human and the non-human."[11] But for all that, need the atrocity associated with this image attest to "a lack of dignity of the sick"?[12] Under the guise of a compassionate discourse, the pro-euthanasia movement situates its approach to dying in a universe centred on that image. Apart from the illusion of freedom that the notion of controlled death conveys, it paradoxically isolates dying and death, thereby reinforcing the sick person's feelings of loneliness in the face of his or her fate, and ending in "a cultural distancing of death from all the humanity of life lived together."[13] Legalizing euthanasia means implicitly that our society is committed to avoiding a helping relationship and that the law should be used as a steamroller to level the individuality and particularity of each sick person. Maintaining the legislative status quo against euthanasia will oblige us to construct our relationship to dying and to death. To this end, we must free ourselves from the limits inherent in the pharmacological approach to pain and accord more importance to dealing with the affective, social and psychological dimensions of each individual's suffering. Our society should not seek to impose a way of dying on individuals; it should attempt to help and protect its sick and dying with the same humanity with which it continues its battle to prevent suicides among the severely depressed and teenagers lacking in the will to go on living.

Conclusion

The impressive program of the 11th International Congress on Care of the Terminally Ill (Montréal, 7-11 September 1996) illustrates the immense efforts that must still be made to better prepare ourselves to help people in the final stages of life. Consequently, I believe that the most urgent need is to engage our energies in this direction rather than in the overly legalistic and reductionist path leading to the legalization of euthanasia.

There is a danger of falling into a kind of compassionate sensationalism in a world in which AIDS, old age, dementia, and disabilities are still catalysts for merciless social exclusion. We might incidentally ask ourselves, as Marin does, why the debate about euthanasia and assisted suicide is polarized almost exclusively around such situations. "Other diseases, altogether as deadly, sometimes involving much suffering, do not give rise to this type of claim, quite the contrary."[14] Our society is moved by the fate of children and adolescents with cystic fibrosis or muscular dystrophy, yet no one is proposing euthanasia to them, or offering a helping hand to put an end to their distress.

- *Bertrand Mongodin*

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ENDNOTES

[1] R Ogden. Euthanasia: A Reply. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 21.

[2] R Ogden. *Euthanasia, Assisted Suicide & AIDS*. New Westminster: Peroglyphics, 1994.

[3] K Foley. The Relationship of Pain and Symptom Management to Patient Requests for Physician-Assisted Suicide. *Journal of Pain and Symptom Management* 1991; 6(5): 289-297.

[4] WHO. *Cancer Pain Relief and Palliative Care. Report of a WHO Expert Committee*. Geneva: The Organization, 1987 and 1990 (Technical Report 804).

[5] K Bradley et al. Le contrôle de la douleur chez les enfants mourants: un défi pour le personnel soignant. In: D Roy & CH Rapin (eds). *Les Annales des soins palliatifs*. Montréal: Centre de bioéthique, Institut de recherches cliniques de Montréal, Amaryllis Collection 1993; 2: 113-121.

[6] T Marmet. Une formation en soins palliatifs influence-t-elle l'attitude des médecins dans la prescription des opiacés en fin de vie? In: D Roy & CH Rapin (eds). *Les Annales des soins palliatifs*. Montréal: Centre de bioéthique, Institut de recherches cliniques de Montréal, Amaryllis Collection 1993; 2: 43-51.

[7] C Stratton Hill, WS Fields (eds). Drug Treatment of Cancer Pain in a Drug-Oriented Society. *Advances in Pain Research and Therapy*, vol 11. New York: Raven Press, 1989, at 5-18.

[8]D Roy. Soins palliatifs et éthique clinique. In: D Roy & CH Rapin (eds). *Les Annales des soins palliatifs*. Montréal: Centre de bioéthique, Institut de recherches cliniques de Montréal,

Amaryllis Collection 1992; 1: 173-186.

[9] B Mongodin. Care and Treatment of Terminal-Phase AIDS. *Canadian HIV/AIDS Policy and Law Newsletter* 1996; 2(3): 22-23.

[10] P Lesage-Jarjoura. Acharnement palliatif: risque possible. In: D Roy & CH Rapin (eds). *Les Annales des soins palliatifs*. Montréal: Centre de bioéthique, Institut de recherches cliniques de Montréal, Amaryllis Collection 1992; 1: 157-161.

[11] D Oppenheim. L'horreur en médecine. *Revue de médecine psychosomatique* 1991(28 December): 37-56.

[12] I Marin. La dignité humaine: un consensus? *Esprit* 1991(February): 97-101.

[13] P Baudry. La mort provoque la culture. In: M Auge (ed). *La mort et moi et nous*. Paris: Éditions Textuel, Le Penser-Vive Collection, 1995,

at 53-67.

[14] Supra, note 11.

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US – Federal Court Finds California Assisted-Suicide Law Unconstitutional

A person living with AIDS, joining Dr Jack Kevorkian as a co-plaintiff, has won a declaration that California Penal Code section 401, which makes it a felony for any person to deliberately aid, advise, or encourage another to commit a suicide, violates the Due Process Clause of the US Constitution.[1]

The plaintiff, a 35-year-old person living with AIDS, was first diagnosed as probably HIV-positive in July 1984, before the availability of HIV-antibody testing, was diagnosed with AIDS in 1993, and is now in a terminal state, desiring assistance to commit suicide. Dr Kevorkian is, of course, the well-known "suicide doctor," whose licence to practise medicine in California was suspended in 1994 as a result of his publicized activities along these lines. Marshall J decided that Kevorkian, because he is not presently licensed in California, does not have standing to bring this challenge, and so ruled only on the claim of the person living with AIDS.

Marshall referred to the 9th Circuit's recent decision in *Compassion in Dying v State of Washington*,[2] in which the court held that the State of Washington's law against assisting suicide was unconstitutional under the Due Process Clause as applied to physician-assisted suicide. Following the reasoning of the 9th Circuit, Marshall found that the California statute violates due process by imposing "undue burden" on terminally ill patients because the statute "does not merely place some restrictions on the right to assisted suicide, but categorically prohibits all such conduct."

Marshall refrained from ruling on the plaintiff's Equal Protection Clause claim, observing that the 9th Circuit had avoided addressing this issue by premising its decision solely on the Due Process Clause. Lacking a California Supreme Court decision on this point, Marshall noted that some California Court of Appeal rulings indicated the unlikelihood that the statute would be found to violate the state constitution.

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ENDNOTES

[1] *Kevorkian v Arnett*, 1996 WL 539534 (11 September 1996, US District Judge Consuelo B Marshall, C.D. Cal). Reported in *Lesbian/Gay Law Notes* October 1996, at 142.

[2] 79 F.3d 790, stay granted sub nom. *Washington v Glucksberg*, 116 S.Ct. 2494, rehearing en banc by full court denied, 85 F.3d 1440, petition for cert filed, No 94-35534 (1996). For a discussion of the case, see T Lemmens. US Appeal Courts Rule in Favour of Assisted Suicide. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 1, 42-43.

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PUBLIC HEALTH

AIDS and Public Health Measures: A Global Survey of the Activities of Legislatures 1983 - 1993[1]

In her book, Zeegers Paget examines the reaction of legislatures to the AIDS epidemic. Her intention was to go beyond a mere comparative survey of the activities of legislatures and to try to develop insights into how and why legislatures have responded to the AIDS epidemic in the way they have.

Zeegers Paget examines the activities from three different angles:

- by comparing the societal and legislative responses to the epidemic;
- by looking at whether and, if so, how the medical profession has influenced legislative responses to HIV/AIDS; and
- by studying the contents of legislative responses in detail.

The following is a summary of the book provided by its author.

Introduction

The question of what lessons can be learned from the legislative response to HIV/AIDS is important: new, deadly diseases may in the future again appear on the world scene. The research undertaken provides an insight into the historical context of legislative responses to AIDS and should, to a certain degree, help us to predict and understand the potential legislative responses to future epidemics.

The results of the research have both theoretical and practical implications:

- On a theoretical level, the book provides a descriptive and analytical categorization of possible legislative reactions, and takes initial steps toward explaining them.
- On a practical level, it invites public health policymakers to learn from one another, by giving an overview of various options chosen by different legislatures.

Limitations

For a number of reasons, only tentative conclusions could be drawn from the available data.

- Legal responses to HIV/AIDS have been changing very rapidly; conclusions are limited to the 10-year period under study.
- The analysis was based only on jurisdictions that made their data available (either directly or through the World Health Organization (WHO)), which may have influenced the conclusions.

- The methods used to analyze the data were mostly indirect; as a result, the data can do no more than strengthen or weaken the plausibility of the formulated hypotheses.

- The large amount of data collected – more than 200 jurisdictions were included in the study – meant that no in-depth comparison between jurisdictions was possible.

The Societal Influence on the Activities of Legislatures

Can the legislative response to the AIDS epidemic be explained, at least in part, in terms of societal influence on the activities of legislatures? A hypothesis was formulated that if the legislative reaction is due to, and therefore follows, the societal reaction to the AIDS epidemic, a global pattern in the reaction of legislatures should be seen and the legislative reaction of jurisdictions that have not yet reacted can be predicted to a certain degree.

Based on an analysis of societal reactions to epidemics in general, three stages are defined:

- denial that the epidemic is occurring within a given society;

- recognition that the epidemic is present; and

- mobilization against the further spread of the epidemic.

Data from 210 jurisdictions were analyzed. In 94 percent of jurisdictions, this (presumed) pattern of societal reaction is, as was expected, reflected in the legislative reaction. Legislatures seem, on the whole, to have followed the development of the societal reaction to the AIDS epidemic:

- First, public authorities are inclined to a non-reaction or to measures intended to keep AIDS out of the jurisdiction (which corresponds to the denial stage of the societal reaction).

- Thereafter follows a phase of societal recognition and of development of legal instruments aimed at ensuring the collection of epidemiological information on the epidemic.

- Finally, in the mobilization stage of the societal reaction, legal instruments are developed regarding prevention/treatment programs to prevent the further spread of HIV.

Legislatures that have not yet reacted will very likely show the same developmental sequence. Future research, including that on the implementation of legislation and social policy and quasi-legal instruments, and a more detailed investigation of the societal reaction, are needed to support this hypothesis.

The Influence of the Medical Profession on the Activities of Legislatures

The AIDS epidemic has confronted legislatures with a new problem requiring expert, technical knowledge. Faced with this problem, legislatures have looked to the medical profession for help and support regarding technical and medical aspects. On the other band, the medical profession has looked to the legislatures for help and support: AIDS is not only a deadly disease, but has public health, human rights, social, economic and psychological consequences. It soon became clear that legislatures and the medical profession had to work together.

The objective of this part of the study was to examine whether the medical profession has influenced legislatures in their reaction to the AIDS epidemic, and whether AIDS has changed the relationship between medical profession and legislature. Four subjects were examined in detail:

- the protection of health-care workers;

- disclosure of a patient's HIV status to health-care workers;

- the duty to care for seropositive patients and people with AIDS; and

- the problems surrounding seropositive health-care workers.

Information on the activities of the medical profession was obtained through contact with medical associations that are members of the World Medical Association. The analysis was limited by two factors:

- Only few materials were received and it was decided to limit the study to ten jurisdictions (Finland, France, Germany, Hong Kong, The Netherlands, South Africa, Sweden, Switzerland, the United Kingdom and the United States).

- The data examined included only the guidelines of the medical associations, not information about actual practice.

Protection of Health-Care Workers

Medical associations are more likely than legislatures to adopt measures on this subject. While legislatures turned more toward general precautionary measures, the medical associations sometimes allow for testing of patients, albeit under strict conditions.

Disclosure of HIV Status

Regarding the question of whether health-care workers can be informed of the seropositive status of a patient, not enough data was found to compare the legislatures' response with that of the medical associations. Medical associations may be more likely to adopt measures on this subject and to tend more toward the possibility of informing under strict conditions.

Duty to Care

Medical associations and legislatures agree that there is a duty to care for patients with HIV/AIDS. Medical associations have adopted statements on the ethical duty to care, while legislatures have created standards governing access to care and reimbursement of care.

HIV-Positive Health-Care Workers

The legislatures have refrained from specific action, and only a limited number of medical associations have adopted statements on this issue.

Influences

Has the medical profession influenced legislatures in their reaction to AIDS? This question could not be answered with any assurance due to the limited data available. The data did show that

- the medical profession and the legislatures approached the social problems posed by AIDS in a similar way;

- the AIDS epidemic did not change the basic relationship between medical associations and legislatures: medical associations generally adopted measures earlier than legislatures, and these were more detailed than the legislative instruments; and

- legislatures appear to be reluctant to adopt legal instruments on medical matters, especially when the subject to be regulated is ethically, technically or otherwise controversial. In effect, legislatures leave a wide discretion to the medical profession, stepping in only when needed to protect interests the profession seems to be according too little weight.

The Contents of the Legislative Response to AIDS

How have legislatures responded to the AIDS epidemic? Three models were formulated as a basis for a systematic analysis:

- the voluntary model based on individual responsibility to prevent the further spread of AIDS;
- the administrative control model, where public health authorities have the primary responsibility to protect public health; and
- the compromise model, which combines individual responsibility with the duty of public authorities to protect public health.

The three models were introduced as a tool to delineate differences and similarities in the legislative responses of the 199 jurisdictions included in this part of the study. However, there are some limitations:

- the division into models involved an oversimplification of reality; and
- the allocation of the different forms of public health measures to the three models is to some degree subjective.
- the voluntary model is probably underrepresented in the sample of legislative responses, since it does not require a specific legal basis.

It was expected that the compromise model would be used the most: legislatures want to balance the protection of public health with respect for the individual's human rights.

Four important public health measures were studied:

- testing for the presence of HIV antibodies;
- reporting of AIDS, HIV or related symptoms;
- contact tracing and partner notification; and
- isolation.

With regard to testing, the voluntary model was favoured by the largest group of jurisdictions, followed by the administrative control model; with regard to reporting, the administrative control model clearly predominated; and with regard to contact tracing and isolation, the compromise model. Many legislatures try to control the AIDS epidemic by placing restrictions upon HIV-positive persons and persons at risk. In this, they seem to be relying on methods used in the past for the prevention of the spread of other diseases.

In general, the primary concern of legislatures is the reporting of AIDS, which in most cases is made mandatory and nominal (administrative control model). The second concern is the protection of the human tissue supply, which is usually dealt with by adopting routine testing of donors or donated tissues (voluntary model). If legislation on isolation and contact tracing is adopted – which is the case in only a few jurisdictions – behaviour-based isolation and patient referral are preferred over other methods (compromise model).

Concluding Reflections

Legislatures are seeking to balance the protection of public health and the protection of the individual. On the one hand, effective measures must be adopted to prevent the epidemic from spreading and, on the other hand, authorities must ensure that the human rights of every individual are protected. Even though restrictions on human rights can be acceptable in certain situations, for instance when the health of the public is endangered or the life of an identifiable person is put at risk, public authorities must always take human rights into account.

In the case of AIDS, this search for a balance is a prominent theme. AIDS is a disease spread through highly personal behaviour (sexual relations, injecting drug use). The individual aspect of AIDS and the protection of individual rights have thus commanded specific attention. At the same time, if the epidemic is to be controlled, this very individual behaviour may need to be effectively regulated, which may require oppressive, intrusive and expensive measures. Looking at the contents of the legislative response, this search for a balance can be clearly seen. The more restrictive a measure (eg, isolation), the fewer legislatures adopt it, and the more legislatures try to use the compromise model instead of the administrative control model (eg, behaviour-based isolation instead of disease-based isolation). For each legislature, the balance will be struck differently.

In the medical fields examined, legislatures have adopted the role of "hesitant balance-seeker" in their relation with the medical profession. Even though legislatures are reluctant to adopt legal instruments in this delicate, technical, and ethically controversial area, leaving the adoption of recommendations to the medical profession, they do have a control function in balancing the protection of health-care workers and individual rights of patients (eg, if the medical profession proposes to test all patients).

- *Dineke Zeegers Paget*

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ENDNOTE

[1] TDM Zeegers Paget. Proefschrift, Rijksuniversiteit Groningen (The Netherlands), 1996.

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INTERNET NEWS

Bypassing the Media's Common Paradigm of Sensationalism *vs* Silence

This issue of "Internet News," now a regular feature of the *Newsletter*, provides an overview of prison sites and of other interesting additions to the ever-growing amount of information on HIV/AIDS-related issues available on the Internet.

HIV/AIDS in Prisons: Media Coverage

The mass media's coverage of the issue of AIDS in prisons often focuses on spectacular statistics about the rise in HIV prevalence among inmates. This is usually followed by responses of prison officials emphasizing their ever-convenient fear of being seen as condoning drug use. Taken together, simple, short, snappy sound bites make for a "good" 30-second news item, giving the public the impression that the media is taking a balanced, informed position. The issues are carefully cultivated as "controversial ones," but factual information is sparse. For example, despite the fact that the release of *HIV/AIDS in Prisons: Final Report*[1] became a "media event" with over 20 articles in newspapers across Canada and national TV and radio coverage, the Canadian public has with rare exceptions been poorly informed by the media about the real dimensions of the problem and the contents of the Report, which was often portrayed as a statistical study. A more informative summary of the document and the Report itself are now on the web, at <http://www.odyssee.net/~jujube>, for browsing and/or downloading. Generally, a growing array of information on prison issues is surfacing on the Internet.

The Prison Law Page

<http://www.wco.com/~aerick/prison.htm>, also known as *The Other Side of the Wall*, and its daughter pages, ***Links in the Chain***, <http://www.wco.com/~aerick/links.htm> and ***Links in the Work of Justice***, <http://www.wco.com/~aerick/crim.htm>, all designed and maintained by Arnold Erickson, from a Californian NGO, are good starts for a search on North American HIV/AIDS and prison issues.

Reading or downloading the many documents on these three pages could last many hours, and, if you wanted, keep you busy until the next issue of the *Newsletter* is published. Information abounds on prison issues – often focused on the US, but with some international materials – including education, health, criminal law and justice, human and civil rights, reference material on law and legislation, prisoner support, and letters from inmates with AIDS. These are not just sites with organizational summaries, but with lots of contents on-line.

Keywords and keyphrases (for reasons of space): Health and Well-Being; Prison Law and Legal Decisions & Papers; Criminal Law Reform and Justice Policy; Habeas and Prison Litigation Update; the American Civil Liberties Union's (ACLU) Information Service on AIDS and TB in Prison; Correctional HIV Consortium (a US nonprofit HIV/TB service organization); Native American Prison Issues; HIV Positive Inmates' needs; HIV in Illinois Prisons: report by the CDC with subsequent correspondence to corrections department; *The Lancet*'s bibliography re health care in prison; a doctor's Open Letter to Prison Doctors on working with women inmates with AIDS, etc. Linked journals and magazines include: *Active Transformation* Online; *Captive Audiences*: A review of prison journals; *Journal of Prisoners on Prisons*; *The Key*: resources for gay and lesbian prisoners; *Prison Legal News*; *Prison Life Magazine* and *Prison News Service*, etc. Strongly recommended.

Prisoner-Related Resources

<www.acsu.buffalo.edu/~heurich/prisoners.html> is an equally important site, although my description is brief. This is a well- structured guide to many other prison and prisoner-related resources on the Internet, including indexes, links to journals and other specialized web sites. A strong point here is the information given about newsgroups and listservs.

JusticeNet Prison Issues Desk

<http://www.igc.org/justice> features several sections, including one on urgent actions, a good index, and a useful text search function. Maintained by the Prison Activist Resource Center, this site calls itself "the source for progressive and radical information and resources on prisons and the criminal prosecution system ... for educators and activists." The Center also operates a moderated e-mail discussion list ("prisonact-list") on prison issues — political prisoners, death penalty, medical neglect, brutality, statistics, etc. AIDS is becoming a more and more important topic among its 12 to 20 postings per week. To subscribe, send this message <subscribe prisonact-list> to <majordomo@igc.org>.

Initiative Zelle

<http://members.aol.com/initzelle/index.html> contains information about a project undertaken in German prisons (most pages are in German, with a few summaries in English). Importantly, this site discovered through *The Other Side of the Wall* has opened the door to another world of prisons – Europe.

The Penal Lexicon

<http://www.penlex.org.uk> is the best way to access information on European penal affairs and prison law and policy – information that is difficult to track down by the common (US) search engines. The focus is primarily on prisons in England, Wales and Northern Ireland, but is extending to other European countries. *The Penal Lexicon* aims "to keep up with the flow of reports, which until now have had a limited circulation. The objective is to throw light on the twilight world of prisons and the treatment of prisoners." Among many other things, you will find in its table of contents: What's New?, The Best of the Press, Prison Service Policies, Health Care, Research Publications, Periodicals, UK Case Law, European Court of Human Rights, European Convention of Human Rights, Drugs and Treatment, Book Reviews, and an impressive list of links to other sites.

The Penal Lexicon also provides information about the *European Network of Services for Drug Users in Prison*,[2] which, among other things, was instrumental in helping to arrange training for prison workers in Greece and – using the knowledge it has collected of methadone maintenance in Spanish prisons – has advised the management of Parkhurst Prison (UK) on its practice of methadone maintenance. One of their pages, entitled *Europe, Drugs, Prisons and Treatment*, <www.penlex.org.uk/eurodrug.html>, contains summaries on drug laws, prison systems, drug treatment services and drug services in prisons in Belgium, Denmark, France, Greece, Italy, Portugal, the Republic of Ireland, Luxembourg, The Netherlands, Spain and the United Kingdom. For a good dose of inspiration and a warning about systemic complacency in the fight against HIV in prisons, start with an article at <http://www.penlex.org.uk/healthhv.html>, and use one of the backwards links to other contents, including a report on prison issues at the XI International Conference on AIDS.

Back to Canada. Because our drug legislation is so relevant to the issues raised by HIV/AIDS in prisons, it is useful to stay informed about developments in the area of drug laws and policy, through the Canadian Foundation for Drug Policy's website, <http://fox.nstn.ca/~eoscapel/cfdp/cfdp.html>; for more information on the House of Commons Standing Committee on Health review of drug policy, see also <http://www.ccsa.ca/polrerf.htm>.

Other Interesting Sites

With the notable exception of Ontario's site, governmental sites are not updated very frequently (besides photos and biographical notes of elected members of parliaments), but the web of NGOs and agencies in numerous fields is expanding rapidly and becoming richer in content. Here are a few suggestions that can lead you further.

Web Spinners' Index to Canadian Equality-Seeking Groups on the Web

<http://fox.nstn.ca/~nstn1439/groups.html>

***Canadian AIDS Treatment Information Network* (CATIE)**

<http://www.catie.ca>

Human Rights Internet (HRI)

<http://www.hri.ca>

Info-SIDA Québec / Ressources Internet

<http://www.Vir.com/%7Eamazones/infosida/internet.html>

BC Centre for Excellence in HIV/AIDS

<http://cfeweb.hivnet.ubc.ca/Guidelines/home.html>

Clinical Trials Research Group

<http://www.mcgill.ca/CTRG>

Last October's ***2nd International Health and Human Rights Conference***, organized by the François-Xavier Bagnoud Center for Health and Human Rights, has an unofficial site at <http://www.fxb.org/confer/intro.html>.

Be aware that you can now do a **keyword search** in all of the XI International AIDS Conference's abstracts, from the HIV/AIDS section of the (US) National Institute for Health's site at <http://sis.nlm.nih.gov/aidswww.htm>.

GayLawNet, an already thorough and well-structured site, has been recently enhanced with a stack of HIV/AIDS law fact sheets: <http://www.geocities.com/WestHollywood/3181/hiv.html>.

The website of the ***Intrntn'l Gay & Lesbian Human Rights Commission***, <http://www.iglhrc.org>, also deserves a bookmark.

- *Jean Dussault*

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ENDNOTES

[1] R Jürgens. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996.

[2] For more information, see the *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(2): 19.

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UPCOMING EVENTS

8th International Conference on the Reduction of Drug Related Harm

The 8th International Conference on the Reduction of Drug Related Harm will take place in Paris, France, from 23 to 27 March 1997.

The Conference will consist of plenary sessions featuring invited speakers, major sessions, symposia and workshops. Themes will include:

- HIV and AIDS;
- human rights;
- international law;
- penal issues;
- prison policy;
- prostitution;
- women and drugs; and
- workplace policies.

For more information, contact the 8th International Conference on the Reduction of Drug Related Harm, The Conference Secretariat, HIT Conferences, Cavern Walks, 8 Mathew Street, Liverpool L2 6RE, UK. Tel: (44-151) 227-4423; fax: (44-151) 227-4023; e-mail: hrc@hit.demon.co.uk

3rd International Conference on Home and Community Care for Persons Living with HIV/AIDS

The 3rd International Conference on Home and Community Care will take place in Amsterdam, The Netherlands, from 21 to 24 May 1997.

The theme of the Conference is "Meeting the needs of the infected and affected." As stated by Lode Wigersma, chair of the Conference,

> [t]he provision of primary and community care services for people living with HIV and AIDS is an increasingly important issue in resource-constrained countries as well as in industrialized countries. The number of infected and affected persons is rapidly grpwing, basic support structures such as the core and

extended family are being strained by AIDS, and hospital care lacks sufficient community-oriented expertise. Home and community care services, especially in large parts of the developing world, are overburdened. The sustainability of these services depends primarily on local and national cooperation, and the acknowledgment of the value of home and community care by the authorities. In addition, international cooperation provides the opportunity to benefit from many other experiences and builds networks through which international support can and must be acquired.

The Conference will provide a platform for people affected by HIV/AIDS and workers in professional and voluntary AIDS care outside the hospital. Their problems and solutions will be communicated and debated.

For more information, contact the Conference Office, Bureau PAOG Amsterdam, Mariska Timmers/Clemens Walta, Tafelbergweg 25, 1105 BC Amsterdam, The Netherlands. Tel: (31-20) 566-4801; fax: (31-20) 696-3228; e-mail: F.Wolters@inter.nl.net

3rd International Conference on Biopsychosocial Aspects of HIV Infection

The 3rd International Conference on Biopsychosocial Aspects will take place in Melbourne, Australia, from 22 to 25 June 1997.

The Conference will include six tracks:

- prevention and health promotion;
- clinical issues and care;
- culture and community;
- health systems and policy;
- AIDS and development; and
- human rights, ethics and law.

Themes will include:

- social and ethical dimensions of drug and vaccine trials;
- euthanasia;
- stigma, discrimination, denial; and
- public policy and action (including the importance of national AIDS strategies).

For more information, contact the Conference Secretariat, The Meeting Planners, 108 Church Street, Hawthorn, Victoria, 3122 Australia. Tel: (61-3) 9819-3700; fax: (61-3) 9819-5978; e-mail: meeting@iaccess.com.au

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Home Testing for HIV: Potential Benefits and Pitfalls

No home test for HIV has as yet been approved for sale in Canada. What are the potential benefits and harms of such tests, and what questions need to be addressed in Canada before they can be made available?

"HIV Home Testing"

The term "HIV home testing" often creates confusion, as it is used to refer to two different forms of testing:

- home collection or home-access testing; and
- home self-testing or home validated testing.

It is important to distinguish the two different forms when considering their respective impacts. In the following text, the broad term home testing will only be used where the text refers simultaneously to both forms of testing.

Home Collection (or Home-Access) Testing

Under this system, a person collects her/his sample at home using a home collection kit. The specimen with identification number is then mailed to a testing facility and approximately seven days later the person can call for the result. Depending on the test result, counselling is given either by voice mail (negative result) or person-to-person (positive result).

Home collection kits thus do not provide "on-the-spot" test results in a matter of minutes, as is the case with home pregnancy tests and home self-tests (or home validated tests).

Home Self-Tests (or Home Validated Tests)

These saliva-based tests can be carried out entirely at home without involvement of an outside party. If the HIV indicator is negative, a person testing her/himself is encouraged to repeat the test in three to six months. If the HIV indicator is positive (indicated by, eg, a colour change), the person is encouraged in the instructions to visit a physician or an HIV testing clinic for further testing. For obvious reasons, counselling is not an integral part of this system. Although the instructions may urge the user to contact health-care facilities in case of a positive result, it is left to his/her initiative to do so.

These are screening tests, not diagnostic tests. They have also been referred to as "HIV indicators" because, rather than providing an HIV diagnosis, they indicate the need for further testing.[1]

Background

Evolution in the Field of HIV Testing

The evolution or revolution in the field of HIV testing is the result of technological developments that allow body

fluids other than serum or plasma to be used for the detection of HIV antibodies. As pointed out by Schopper and Vercauteren, traditionally HIV tests have been based on the detection of HIV antibodies in serum/plasma derived from whole blood collected by venipuncture, and hence required trained health-care workers for collection and laboratory facilities for testing. The use of body fluids other than blood – such as saliva or urine – for detecting antibodies to HIV is an attractive alternative for several reasons:

- saliva specimens can be collected or self-collected virtually anywhere – in the home, on the street, in bars;

- non-invasive sampling methods are safer for the subject and for the health-care worker: there is no danger of contamination through unsterilized syringes or needle-stick injuries;

- there are similar advantages in the use of urine specimens, and the infectivity of both body fluids seems to be very low.[2]

Another sampling method involves collecting spots of blood on filter paper. Blood is usually obtained by finger prick using a spring-loaded lance. Quantities sufficient to saturate at least two spots on absorbent filter paper should be obtained, air-dried, and stored in a sealable plastic bag.

Until recently, the performance of HIV tests – even those using body fluids other than serum or plasma – were confined to a laboratory setting. Today, HIV tests can be performed at home, and home collection and home self-tests have become a practical reality.

FDA Approval of the First Home Test Kit

When the first home test for HIV was developed in the United States, many AIDS activists and the American Medical Association opposed its introduction, and in 1987 the Food and Drug Administration (FDA) refused even to consider it for approval. The controversy was resurrected in 1993, when Johnson & Johnson purchased the rights to the home testing technology from its inventor. Subsequently, Johnson & Johnson launched a vigorous campaign to win FDA approval.[3] On 14 May 1996, its home collection kit, the so-called Confide HIV Testing Service (Direct Access Diagnostics), received approval.[4]

The Confide Testing Service

This kit is comprised of three integrated components:

- an over-the-counter home blood-collection kit;

- HIV-1 antibody testing at a certified laboratory; and

- a test result centre that provides test results, counselling and referral anonymously.

Those wishing to undergo testing purchase the Confide kit at their local pharmacy or, by calling a toll-free number, have the kit delivered to their home. The kit contains a pre-test counselling booklet, a step-by-step instruction guide, the collection material, and a protective envelope. Using the lancet provided, users prick their fingers and apply three drops of blood to a special collection card. The card is pre-coded with a unique Personal Identification Number assigned to each kit. The card is then mailed to a testing facility using the postage-paid, pre-addressed envelope. At the laboratory, both enzyme-linked immunosorbent assays and confirmatory tests are performed. After about seven days, the user can call another toll-free number to obtain the test result, punching in a unique code number. Those who test negative listen to a recording informing them of the meaning of the result and offering them the option of speaking to a counsellor. Positive results are reported by a counsellor, who provides referrals to follow-up clinical services and social-service agencies.[5] All components of the testing service are subject to several regulations and are closely monitored by the FDA. Both the testing and counselling facilities need annual accreditation and HIV testing procedures have to comply with FDA regulations.

Competition

A competitor, Home Access Health Corporation, received FDA approval on 22 July 1996 for its so-called Home Access test.[6] As of October 1996, both companies were already accepting mail orders from across the United States, were increasing national retail availability, and had started national advertising.[7] Only New York and California have laws that block the sale of these tests in their states, but New York is considering the introduction of a new regulation to pave the way for their sale.[8]

Other US companies have applied for FDA approval of their home collection kits.[9] Several versions of home self-test kits, although they have not yet been approved by the FDA, are also already being promoted in the United States,[10] and at least one company, SmithKline Beecham, has announced that it will seek approval to market to consumers its saliva-based test, which is currently approved for use by doctors only.

Saliva-Based Tests

Thus far, the United States is the only country where such a test has been approved for initial diagnosis of HIV infection; in other countries, such tests have been used only for surveillance purposes. As pointed out by Schopper and Vercauteren, "[m]ost European countries have reservations about saliva tests for diagnostic purposes as their performance is still inferior to that of the conventional specimens and their sensitivity for seroconversion specimens is as yet unknown."[11]

International Developments

Several governments, including those of Australia, Austria, France, Germany, Japan, The Netherlands, Switzerland, and the United Kingdom, have stated that the public use of diagnostic tests for determination of the HIV serostatus of an individual should not be done without pre- and post-test counselling.[12] In the United Kingdom and Austria, legislation currently prohibits the sale or supply of HIV test kits or any component of such kits to members of the public. However, times are changing and other countries may follow the US in the near or distant future and approve over-the-counter home specimen collection kits.

Canadian Developments

The 1993 Workshop

On 16 July 1993, Health Canada organized a workshop on home HIV self-test kits. Its purpose was to gather perspectives on home testing from representatives working at the federal, provincial, and community levels, before receiving any application by a manufacturer for a home testing device. Two issues were seen as the driving force behind the need for discussions:

- the advance in HIV-antibody detection technologies; and
- the push by insurance companies to use such tests.

It was reported that Canadian insurance companies have used saliva-based tests to "screen applicants for HIV" and that applicants whose test indicated possible HIV infection have been advised by the insurance companies that they should have a confirmatory blood test done. As pointed out by participants at the meeting, this represents more than just "screening" applicants and contravenes provincial health legislation: it is not permitted in Canada to use saliva tests as a diagnostic tool.

Home Self-Test Marketed to Canadians

On 13 May 1996, a US-based company named 1-888-444-TEST Inc held a press conference in Toronto to publicize, and market to Canadians, their mail-order, saliva-based, home self-test kit for HIV. The test kits, priced at $90 for a set of two, were offered for "personal use." The company was violating federal regulations by offering the kits before they

had even been submitted for evaluation of their reliability. The Health Protection Branch (HPB) of Health Canada asked the company to cease all activities and submit an application for pre-market evaluation in order to obtain a Notice of Compliance.

According to media reports, an official of the company announced that the company would submit the test to Health Canada for testing.[13]

The Approval Process

In Canada, the sale of *in vitro* diagnostic devices for the detection of HIV infection is governed by the *Food and Drugs Act* and the *Medical Devices Regulations*. All medical devices offered for sale in Canada must meet the requirements of sections 3 and 19 to 21 of the *Food and Drugs Act* and parts I to IV of the *Medical Devices Regulations*. In addition, *in vitro* diagnostic devices for the detection of HIV infection are subject to Part V of the *Regulations*.

Part V of the *Medical Devices Regulations* stipulates that all manufacturers must obtain authorization before offering for sale in Canada *in vitro* diagnostic devices for the detection of HIV infection. Authorization for sale, in the form of a Notice of Compliance, may be obtained by submitting, to the Director

- evidence of quality assurance;
- evidence of safety and effectiveness; and
- drafts of all labels and package inserts to be used in connection with the device.

In accordance with the *Regulations*, the Medical Devices Bureau will accept, review and evaluate submissions for over the counter HIV home test kits for their scientific merit. Appropriate preclinical studies and clinical trials will have to validate all technical aspects of the kits, such as sensitivity, specificity, reproducibility, stability, etc, in comparison with an approved, professional use system for the collection and testing of blood or any other appropriately validated specimen. Other issues of safety and effectiveness directly related to the use of the test such as comprehension of the instructions by consumers, safe handling, etc also will have to be validated by data obtained from a properly designed clinical trial conducted in the target population.

In cases where the safety and effectiveness of the kit has been substantiated, in accordance with sections 35 and 36 of the *Medical Devices Regulations*, HPB will issue a Notice of Compliance.

With regard to the sale or advertisement of mail-order HIV home test kits (mailed from within or from outside Canada) that have not received a Notice of Compliance (as in the case of the 1-888-444-TEST Inc), HPB considers this a violation of sections 34 and 35 of the *Medical Devices Regulations*. In such cases HPB has "and will continue to take appropriate compliance action to stop this practice."[14] In contrast, when private Canadian citizens purchase HIV home test kits outside Canada and bring them back for their personal use, this is not considered a violation of the *Food and Drugs Act* or of the *Medical Devices Regulations*, provided there is no attempt to distribute the kits.

As of November 1996, no home test for HIV had been approved for sale in Canada. In an interview on 30 August 1996, Dr Choquet of the Medical Devices Bureau of HPB said that, for confidentiality reasons, Health Canada could not reveal if any company has applied for review of its home test for approval. According to Choquet, the approval process for HIV test kits typically takes about one year.[15]

As expressed by Schopper and Vercauteren, the "current reluctance of several governments of industrialised countries to approve HIV home collection and home self-test kits for open marketing may be due to fear that the potentially negative consequences of this new technology could be more important than its positive effects."[16] The following sections therefore explore the main arguments used by proponents and opponents of home testing.

Claimed Benefits of Home Testing

Expansion of Testing

Advocates of home testing for HIV have stated that there is an urgent need for a new mode of testing. They point out that, despite the establishment of sites for anonymous HIV testing, many people are reluctant to come forward and be tested:

> • nearly one-half of all HIV-positive Americans did not get tested until they were within a year of being diagnosed with AIDS-related illness; and
>
> • approximately one-third were within two months of an AIDS diagnosis when they first tested positive. [17]

According to proponents of home testing, the anonymous character and convenience of this type of testing will encourage more people to come forward for testing:

> Now, for the first time, testing for HIV can be done anonymously from the convenience of one's own home. No appointment is necessary, and there is no need to take time off work. You can test whenever it's convenient for you.[18]

However, while some very limited data exist on people's attitudes toward home collection kits, no similar data exist to substantiate the often-made claim that "people want" home self-test kits. In one US study conducted in 1992,[19]

> • 29 percent of all respondents, and 42 percent of respondents deemed "at risk" of HIV infection, said they would be very or somewhat likely to use home *collection* tests, and
>
> • 22 percent of all respondents, and 31 percent of those deemed "at risk" of HIV infection, said they would choose home collection testing over all other testing options.

Persons were more likely to say that they would use a home collection test if they were male, younger and non-white, and had less than a university education, a lower income, risk factors for AIDS, or a self-perceived risk of AIDS.

The results need to be read with caution: people surveyed were neither told about the cost of the test, nor were they asked about the reasons for preferring home collection testing.

In 1996, *The Advocate*, a US magazine targeting a gay readership, conducted an informal poll among its readers. Fifty-two percent of (an unknown number of) respondents said that they would be more likely to get tested if they could use a home *collection* kit, while 42 percent responded that availability of the kits would make no difference, and six percent said that they were not sure.[20]

Increased Access to Anonymous Testing

At present, anonymous testing is not easily accessible to all Canadians. Indeed, as noted in *HIV Testing and Confidentiality: A Discussion Paper*,[21] it is only available at certain designated clinics, in certain provinces. For some people, especially those living in remote areas and/or in provinces where anonymous testing is currently not offered, getting to these centres is simply not feasible. A home test might offer them the only opportunity to be tested anonymously.

Less Invasive than Conventional Tests

The new kits are less invasive than traditional testing methods: they require only a few drops of blood from a pinprick, or a swab of saliva. Some have suggested that this will increase people's willingness to be tested. For example,

> • a European multi-centre study of prostitutes showed that many who refused to allow their blood to be drawn for HIV testing would consent to the taking of a saliva sample;[22]

> • a Canadian study found that offering the option of testing with saliva collection kits, as an alternative to drawing blood, increased the willingness of intravenous drug users to submit samples from 69 to 83 percent.[23]

The new test kits might also be the only testing option for those who, for religious reasons, object to the drawing of blood.

However, with regard to home self-tests, it needs to be noted that they are often only screening tests: if a person tests positive, she/he will have to seek confirmatory testing, which would be done through drawing of blood and would not be anonymous, unless undertaken in an anonymous HIV testing clinic.

Positive Impact on Public Health

Proponents of home testing have argued that the main benefits of increased access to and use of HIV tests would be earlier treatment, decreased costs, and decreased sexual transmission of HIV. As Donna E Shalala, Secretary of the US Department of Health Services, put it,

> [t]oo many [people] do not know their HIV status. Knowledge is power, and power leads to prevention. The availability of a home test should empower more people to learn their HIV status and protect themselves and their loved ones.[24]

Earlier Treatment

> Early access to treatment based on early knowledge of HIV status will be of benefit to the individual if and where such services are available.[25]

However, in the vast majority of countries few treatment options for asymptomatic persons are accessible, and even in Canada access to new treatments remains a significant problem. There can be no doubt that early knowledge of HIV positivity can be beneficial, but only where access to treatments is provided.

Decreased Costs

It has been suggested that the availability of home testing might reduce demand for, and costs associated with, testing at publicly funded testing sites:

> The main arguments are that HIV-negative persons would only need one test, done at home, with little or no counselling, thus reducing human resource and overhead costs. In addition, people would pay themselves at least for the first test, thus reducing public sector cost mainly in instances where governments provide HIV tests free of charge.[26]

As stated by Frerichs,

> [o]nly about two percent of individuals who come to government testing and counselling centers are HIV-positive. Money that is spent on the many HIV negative individuals cannot be spent on treatment for HIV positives. Money that is spent on HIV negative individuals cannot be spent on extended care for persons harbouring the virus. So by supporting a system in which only two percent coming in are HIV-infected, we are spending an enormous amount of money on HIV-negative individuals that could be reallocated in more effective ways to slow down the epidemic.[27]

In another text, he concludes that

> [i]t is too expensive and inefficient for most countries to offer clinic-based diagnostic testing to people who have not been previously screened with HIV indicators. ... The savings from not testing and counselling endless numbers of HIV negative persons would be spent on better serving those who are

> infected, including long-term follow-up, education and support.[28]

However, this view neglects to take into consideration the benefits of voluntary counselling and testing to those who are negative: counselling may be especially important for those who are negative but have engaged in risk behaviours.

Decreased Sexual Transmission

It has been suggested that the availability of HIV home testing would lead to a decrease in sexual transmission of HIV. This is based on the assumption that

- more people will be tested sooner and, once they find out that they are HIV-positive, will not engage in unsafe behaviours; that
- couples "could screen each other for the presence of HIV antibodies and then act on the findings"; or that
- partners could "quietly" screen each other.[29]

Concerns About Home Testing

> Overall the risks and potentially negative consequences of the home test should be expected to be much greater in situations where the powerless are not well protected by law and regulations, where the status of women is not equal to that of men, where quality control of medical devices and procedures is difficult, where regulations are not enforced, where literacy rates are low, and where health services are either scanty or difficult to access.[30]

Although support for home testing appears to have grown considerably over the past few years, a number of concerns and questions remain to be addressed:

- the extent to which testing will have a beneficial impact on public health;
- the tests' accuracy;
- the lack of adequate counselling;
- the potential for abuse;
- the effect on existing testing services; and
- the extent to which individuals living in remote areas who learn their serostatus through home testing will have access to medical treatment from a knowledgeable practitioner.

Questionable Impact on Public Health

> [The effectiveness of] testing as a preventive or behaviour modification strategy remains unclear. This is particularly true of any kind of HIV antibody testing being performed without pre and post-test counselling.[31]

Would availability of home testing really have a beneficial impact on public health? As stated by Schopper and Vercauteren,

> [a]lthough nobody would deny the potential benefits of HIV testing for the individual, its public health impact remains a contentious issue. Overall the evidence for the impact of HIV testing in bringing about behaviour change is mixed. It has been shown that voluntary counselling and testing (VCT) can enhance safer sexual behaviour in discordant couples if both partners are tested and counselled. However, on a

> public health scale little change in behaviour has been documented in heterosexuals if they are tested alone. ... In addition, some studies have documented an increase in risky behaviours after testing in HIV-negative persons. The major problem is that there are only few reliable data from epidemiologically sound studies, and that there may be many confounding variables, such as the quality of the counselling provided with the testing, the initial risk perception of the individual, the attitude of family members or the social environment. Thus after ten years of experience with HIV testing ... we are not able to draw definite conclusions about the role of HIV testing in controlling the further spread of HIV. The main argument for making HIV tests widely available and accessible remains that every person should have access to information about her own health status in order to make informed personal choices about HIV prevention and care. [references omitted][32]

Additionally, as is the case with any form of anonymous testing, home testing would make the reporting of names of persons testing positive impossible. Some believe that increasing access to anonymous testing would only further hamper efforts to control the HIV epidemic through contact tracing and other traditional public health measures.

Accuracy

The accuracy of the new testing methods remains controversial. As pointed out by Schopper and Vercauteren, a

> number of issues relate to the accuracy of the tests, including their sensitivity and predictive value; quality of the test at the time of use depending not only on the manufacturer, but also on transport and storage at the sales point and at home; quality of the sample collected; understanding of the window period; and, more generally, the level of education needed to correctly understand the testing procedure. For home self-tests there are additional issues such as errors of manipulation if done by lay persons; interpretation of results and action to be taken for confirmatory testing.[33]

Some of the new tests seem to be accurate and reliable: for example, the FDA based its approval of the Confide test on studies showing that

> • 99.95 percent of HIV-negative and 100 percent of HIV-positive samples were correctly identified;[34] and that
>
> • people from various backgrounds were able to follow the kit's instructions well enough to obtain a sample suitable for testing.[35]

In contrast, according to Schopper and Vercauteren, "the accuracy of the new generation of capillary blood, urine and saliva tests which could potentially be used as home self-tests has not yet been evaluated extensively, nor has their reliability been confirmed if performed by lay persons."

Of particular concern is that data on accuracy of tests are usually obtained under optimal conditions by trained technicians and may not always reflect a real-life situation:

> The accuracy of simple rapid tests that require subjective interpretation is closely linked with training. Non-trained operators such as lay persons can easily misinterpret test results. Kit inserts from strongly promoted home self-tests ... claim high reliability, while virtually no external data are available. It is clear that these statements should be validated by independent studies.[36]

Further, there are some difficulties in confirming positive results.[37] This has led Schopper and Vercauteren to conclude:

> Today, the slightly lower sensitivity and the difficulty to confirm a positive result remain the major drawbacks of the non-serum/plasma specimens. The level of sensitivity currently observed with non-serum/plasma specimens would be of concern when used for diagnostic purposes, but is acceptable for surveillance programmes.

Lack of Counselling

> In order to guarantee the individual benefits from an HIV test, to reduce the fear and occurrence of the negative effects of testing, and to increase the possible public health benefits, counselling has been promoted as an essential element of voluntary testing. Ideally, the counselling process should start before HIV testing occurs to discuss the need for testing, provide accurate information about HIV, clarify technical aspects of HIV testing, discuss past risk behaviours and risk reduction strategies and help explore the implications of the test result, particularly if positive. Counselling after the test should provide emotional support, and help the person to find the most appropriate medical and social care.[38]

Pre- and post-test counselling are widely considered essential components of HIV testing, and there are serious concerns about the possible negative consequences of the absence of pre-test and, in the case of home self-testing, also post-test counselling. Pre-test counselling is important because it

provides an opportunity to enquire about a testee's support network. Counsellors usually take this opportunity to suggest testees seek the moral support of family or friends throughout this stressful time, and especially when returning for the test results.

Post-test counselling may be even more important.

- Those who test negative need to be counselled about ways to remain HIV-negative.

- They also need to be informed about the "window period" between actual infection and the time when an HIV test will be able to detect it. If not, they may be falsely reassured by a negative test result.

- People who test positive typically comprehend little of what is told to them immediately after receiving results, therefore follow-up sessions are essential to help them cope with this news.[39]

Importantly, it has been argued that post-test counselling over the phone cannot be as effective as person-to-person counselling: in post-test counselling sessions, a counsellor has to be alert to testees' emotional reactions to their test results. This is especially important when clients test positive, as this can cause a great deal of emotional distress and result in panic and suicidal thoughts. In the moment of shock, clients may simply hang up the phone, thus foreclosing any opportunity of helping them to deal with their reactions. Finally, counsellors rely heavily on visual clues such as body language to direct their counselling.[40] Such nuances would be lost over the telephone.

In contrast, proponents of HIV home testing argue that

- pre-test counselling is not essential; and that

- counselling after home testing "could be provided more efficiently through telephone contact, which would be cheaper and guarantee anonymity. Persons who test positive would be referred to and/or take themselves the initiative to contact appropriate health services."[41]

Further, responding to the argument that person-to-person counselling is essential because of the risk of suicide upon learning of a positive test result, some say that suicidal thoughts are more closely linked to the onset of symptoms, rather than to the positive test result itself.[42]

Finally, it has been claimed that telephone counselling might actually be superior in quality to the face-to-face counselling many people currently receive. One commentator has said that

> corporate sponsors of home testing products can train counsellors specifically to engage in full-time HIV counselling. The potential superiority of telephone counsellors would be derived from their specific training as HIV counselors and from the experience they would receive from performing that function on a full-time basis. Both training and experience can provide professionals with a level of expertise difficult to

> replicate among physicians engaged in more diversified activities.[43]

Proponents of home testing insist that telephone counselling be evaluated against actual practice, not idealized standards.[44] While admitting that face-to-face counselling provided in specialized testing clinics may indeed be more effective than telephone counselling, they recall that most Canadians are tested by their doctors, many of whom may not have much experience with, or time for, counselling: telephone counselling may be an improvement on the support that most people who are tested are receiving in practice. Others point to the success of suicide hotlines as evidence that telephone counselling can be effective in crisis situations.[45]

However, Schopper and Vercauteren caution against such arguments, pointing out that there would have to be some type of quality control of the telephone counselling process, and that

> it is not clear who would provide this service and pay for it. If this is the responsibility of the test manufacturer, as has been suggested, the incentive to train, supervise and maintain qualified counsellors is limited, if this is not linked to a periodic accreditation system.[46]

Potential for Abuse

> One of the main concerns voiced by opponents to home testing is the potential abuse by institutions – employers, insurance companies, police, border controls – and by sexual partners, in particular men against women.[47]

Those who support home testing argue that the possibilities for abuse may not be very different from those that already exist, and that a potentially beneficial technology should not be banned because it may be abused.[48] A better approach, they argue, would be to minimize the potential misuse of home tests by enacting or strengthening laws that punish those who test people against their will or without their knowledge.

However, concerns remain: the ease with which home tests can be forced on someone else and the easy, rapid access to results, either in the home or by phone, makes them attractive and convenient for those who might want to test others without their consent. According to Schopper and Vercauteren, there are at least two reasons why home testing would be more amenable to abuse than laboratory-based testing:

> • it is easier to do under coercion; and
>
> • there is less guarantee of confidentiality, as the result is directly available in the home or through a telephone call.

In addition, home self-tests that provide an immediate result

> could be used directly at border controls, by future employers and by sexual partners with little or no consent of the person tested. Given the level of persistent discrimination and stigmatization in many countries, this potential for abuse is worrisome.[49]

Impact on Current Testing Procedures

Another cause for concern are the effects that availability of home tests may have on existing testing options. It has been argued that increasing reliance on home testing would relieve the burden on present testing facilities and allow resources to be redirected to other sectors such as prevention and research. However, authorities could be tempted to allow publicly funded testing options to wither away in an attempt to economize. Further, a study of HIV testing in an Australian state where a user fee was introduced for HIV tests suggests that when the burden of paying for testing shifts to the individual, the numbers of people seeking testing decreases, even if testing is still offered free of charge at certain sites.[50]

Lessons from Home Pregnancy Tests

As pointed out by Schopper and Vercauteren, the only other home self-test to detect a health condition – as opposed to monitoring an already diagnosed health condition such as high blood pressure or diabetes – that has been widely used is the home pregnancy test. Of course, the consequences of a positive HIV test are quite different from those of a positive pregnancy test:

> Learning that one is pregnant can be viewed in a variety of ways. Such news could be taken as positive or negative depending on a wealth of factors like economic status, social status, housing status, employment status, health status etc. Furthermore, were a woman to view being pregnant as a negative situation she could affect this reality in a number of ways through adoption, abortion or an attempt to change her circumstances in various ways.[51]

Nevertheless, some of the lessons learned from pregnancy tests could be useful when considering HIV home tests. In particular, studies have shown that

- test results will be on average less accurate when a test is done by a lay person; that
- the user needs to be well educated to understand operating procedures and optimal timing of the test; and that
- the user needs to have immediate access to health services for confirmation of test results and/or care.[52]

Possible Responses to Home Testing

Regulation and Its Limits

Those who argue that the potential harms from making home collection and/or home self-testing available far outweigh the potential benefits, may argue that their introduction into the Canadian marketplace should be blocked. However, although the law is broad enough to forbid most attempts at advertising these products to Canadians, little can be done to hinder individuals from purchasing them outside Canada and bringing them back for personal use:

> [I]t appears that the United States will soon adopt a policy in favour of home HIV testing. This may render moot the question in Canada, as it is likely impossible to completely block the use of such a test in Canada. The advertising and sale of the test in Canada could be prohibited, but likely Canadians could easily access the test either in the United States, or by mail from the United States.[53]

Establishing Preconditions for Approval: Bayer's Approach

Another possible approach would be to adopt a policy that would allow the sale of those home testing kits that meet a set of criteria designed to minimize their potentially harmful effects. Manufacturers would have to demonstrate that their kits offer accuracy and standards of counselling comparable to those expected from conventional HIV tests. Perhaps if home testing kits were first offered on a limited trial basis we could better assess their risks and benefits. Bayer suggests that, as a condition of government approval of home test kits, post-marketing studies be carried out, including:

- a comparison of home testing with current practices, not idealized standards;
- demographic information on test users, information about the quality of telephone counselling, and data on consumer satisfaction;
- a comparison with face-to-face encounters; and
- the effects on the existing system of public testing and counselling.[54]

Schopper and Vercauteren's Approach

According to Schopper and Vercauteren, a very cautious approach to the evaluation of home test kits for HIV should be taken. While acknowledging that the new testing technologies may have enormous merits and may in many ways change our approach to the HIV epidemic,

> we need to acknowledge that many technical, psychological and social questions remain unanswered. Given the nature of HIV infection – lifelong, incurable and fatal – and the stigma attached to it, it would seem irresponsible to provide these new tests to lay persons for self-testing before answering at least some of the most essential questions.[55]

These questions relate to both forms of home testing, but may in some cases have to be addressed separately:

- What is the intrinsic accuracy of the currently available HIV home collection and home self-tests?
- What is their reliability if used by lay persons, including timing after their risk behaviour?
- What is the probability that persons identifying themselves as HIV-positive through home testing will not seek confirmatory testing, and what would be the consequences of such behaviour?
- How cost-effective is home collection or home self-testing as compared with clinic-based testing?
- What is the demand for and acceptability of these tests in different sociocultural environments?
- What are the expressed needs and fears of potential users?
- What is the importance of providing counselling before and after the test? Does it depend on the result being positive or negative?
- How can post-test counselling be provided in low-resource settings?
- What action will individuals take after receiving an HIV test result at home?
- What is the potential for abuse in different settings and how can it be prevented?

Schopper and Vercauteren suggest that relatively small-scale qualitative and quantitative research studies may enable us to provide some answers, and that the experience with the home collection test kits that have been approved in the US should be monitored closely. In addition, she suggests that some minimum requirements that must be fulfilled for any tests be defined, including:

- any test marketed as a self-test must have an internal control mechanism that validates the test result;
- no test should be marketed in another country before having been approved by the regulatory body of the country of production, as there is a danger that low-quality tests be brought onto the market in developing countries with weak or no regulatory bodies; and
- clear guidelines must be provided with the test on how to confirm a positive result.

Finally, Schopper and Vercauteren suggest that the new testing technologies could be used in existing voluntary testing and counselling centres to provide clients right away with an indicative test result:

> In case of a positive primary result a blood sample can immediately be drawn to perform further testing for confirmation, making the whole system more client friendly and probably more cost effective. In addition, this approach may reduce the high drop-out rates currently witnessed in some settings after initial counselling and the collection of the blood sample.

Conclusion

Availability of HIV home testing may have great potential benefits, but clearly also has great potential harms. Contrary to what has been stated by former US Surgeon General C Everett Koop,[56] home test kits are certainly not the "single most important weapon we can employ in the fight against AIDS." Indeed, this statement is more a reflection of the failure of AIDS policy in the US – a country where needle exchange programs still have not been authorized, although they have been proven to significantly reduce levels of infection among injection drug users – than a sign of the effectiveness of home test kits. It is also a reflection of the widespread but unproven belief that testing equals prevention, an approach that is all the more dangerous when it leads to a de-funding of those prevention efforts that have proven successful, such as counselling, education, provision of wide access to preventive means such as condoms and sterile needles, and, generally, community-based efforts to prevent the further spread of HIV.

At present, we do not know enough about home collection and, in particular, home self-tests. At the same time, individuals can already import such kits into Canada for their own use. How should Canada approach the many issues raised? The main concerns will be the absence of face-to-face counselling, the risk of abuse, and the impact on existing testing facilities, rather than accuracy and reliability of the tests: it does seem safe to assume that at least some tests – in particular, home collection tests – will not be able to be opposed on the basis that they are inaccurate or unreliable. People providing counselling, those who have tested positive, and those caring for and working with them will have to be consulted to be able to better assess the potential impact of making home testing available in Canada. They will be best equipped to answer some of the questions raised by Schopper and Vercauteren, and can assist in the design and carrying out of the studies that will provide the answers to those questions. Of particular need for study is the potential effect of permitting HIV testing with only telephone counselling (home collection) or no counselling at all (home validated).

Home test kits are devices with potential benefits for individuals, unproven benefits for society, and huge commercial interests behind them. Their introduction carries many risks that need to be better assessed before they are made widely available in Canada.

Generally, home collection kits may be more likely to gain approval for use than home validated kits. They offer better accuracy and show a greater potential for incorporating counselling as a component of the test than do home self-tests. The latter may still have a potential use within the framework of existing testing and counselling settings.

- *Michael Palles and Ralf Jürgens*

As a male who has been living with HIV for fourteen years, I cannot imagine testing myself. I can't. ... Counselling is what has kept me alive, the positive attitude, and the help and support. But to throw it out and say here, test yourself, I think we're really asking for trouble.

> - person living with HIV, reported in A Picard. Home HIV Test Sparks Hot Debate. *The Globe and Mail*, 10 July 1996, at A5.

[T]he introduction of HIV home tests on the market is nothing less than a revolution in the history of health and medicine. This would be the first time ever that an individual has the ability to diagnose, by himself, a chronic, incurable, and most probably fatal condition.

- *Doris Schopper*

[A]lthough technical knowledge on this new testing technology is relatively advanced, virtually no information exists on the potential impact widespread availability of home tests would have on individuals, on population groups that are at higher risk of or more vulnerable to HIV infection, and on society at large. At present it is thus impossible for policy makers and planners to make an informed choice about the use of these tests. If we want to abide by the Hippocratic principle of "primum non nocere" [first do no harm], it is essential that sound research on the questions raised be undertaken immediately in a variety of settings, ... and that decisions on the use of home collection and home self-tests by lay persons be based on the results.

- *Doris Schopper*

Let us base our policy decisions not on the availability of the technology, but on the sound scientific data and consultation with consumers, including persons living with HIV and AIDS. Above all, the science, and not the technology, should drive us.

- *Michael Merson*

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ENDNOTES

[1] Comment by R Frerichs at the Home HIV Screening Debate, XI International Conference on AIDS, Vancouver, 8 July 1996.

[2] D Schopper, G Vercauteren. Testing for HIV at Home. What Are the Issues? *AIDS* 1996 (forthcoming), with further references.

[3] N Freundlich. The Trials of a Home HIV Test. *Business Week*, 18 March 1996, at 56.

[4] Health Notes. Home Testing for HIV Infection. *United Press International*, 15 May 1996.

[5] Direct Access Diagnostics. The Confide HIV Home Testing and Counselling Service. Publicity distributed at the HIV & Telemedicine Symposium, Vancouver, 9 July 1996.

[6] New Home HIV Test Goes on Sale Nationwide. *Bangor Daily News*, 25 July 1996.

[7] M Wilke. J&J's Confide Faces Legal Battle, New Rival. *Advertising Age* 1996; 67(32): 3; C Hutchcraft. AIDS Tests Join At-Home Diagnostics. *Chicago Tribune*, 7 October 1996, at 4-1.

[8] Home Tests for HIV Available by Fall. *The Times Union* (Albany, NY), 26 July 1996, at B2.

[9] R Bayer. Testing for HIV Infection at Home. *New England Journal of Medicine* 1995; 332: 1296. See also the revised version of this article, infra.

[10] Schopper & Vercauteren, supra, note 2.

[11] Ibid.

[12] Ibid, with references.

[13] W Immen. Mail-Order HIV Saliva Test Raises Concerns. *The Globe and Mail*, 13 May 1996.

[14] Correspondence received from C Choquet, Health Protection Branch, Health Canada, on 14 November 1996.

[15] Communication with C Choquet, Health Protection Branch, Health Canada, 30 August 1996.

[16] Schopper & Vercauteren, supra, note 2.

[17] Testimony before FDA Blood Products Advisory Committee. Washington DC: Centers for Disease Control and Prevention, 1994, cited in Bayer et al, infra.

[18] Direct Access Diagnostics, supra, note 5.

[19] K Phillips et al. Potential Use of Home HIV Testing. *New England Journal of Medicine* 1995; 332: 1308.

[20] Advocate Poll Results. *The Advocate*, 23 July 1996, at 8.

[21] M Palles, R Jürgens. Montréal: Canadian HIV/AIDS Legal Network and Canadian AIDS Society, 1996.

[22] European Working Group on HIV Infection in Female Prostitutes. HIV Infection in European Female Sex Workers: Epidemiological Link with the Use of Petroleum-Based Lubricants. *AIDS* 1993; 7: 401.

[23] CJ Major et al. Comparison of Saliva and Blood for Human Immunodeficiency Virus Prevalence Testing. In: British Columbia Centre for Excellence in HIV/AIDS. *HIV/AIDS Research in British Columbia. A Ten Year Retrospective*. Vancouver: The Centre, 1996, 200 at 203.

[24] HIV Home Test Could Aid Prevention, Awareness. *The Nation's Health*, July 1996, at 6.

[25] Schopper & Vercauteren, supra, note 2.

[26] Ibid, with reference to SR Salbu. HIV Home Testing and the FDA: The Case for Regulatory Restraint. *Hastings Law Journal* 1995; 46(2): 403-457. See also Bayer et al, infra.

[27] Supra, note 1.

[28] R Frerichs. HIV Testing – A Reply. From owner-sea-aids@bizet.inet.co.th, 2 October 1996.

[29] Schopper & Vercauteren, supra, note 2, with reference to R Frerichs. Personal Screening for HIV in Developing Countries. *The Lancet* 1994; 343: 960-962.

[30] Schopper & Vercauteren, supra, note 2.

[31] Graydon, supra, note 13.

[32] Schopper & Vercauteren, supra, note 2 with many references.

[33]Ibid.

[34] HIV Home Test Could Aid Prevention, Awareness, supra, note 25.

[35] Home HIV Test Is Found to Be Reliable and Effective. *AIDS Weekly Plus*, 2 October 1995, at 29.

[36] Schopper & Vercauteren, supra, note 2, with reference.

[37] Ibid, with many references.

[38] Ibid.

[39] Ibid.

[40] Communication with Margaret Shore, Hassle-Free Clinic, Toronto, on 26 August 1996.

[41] Schopper & Vercauteren, supra, note XX with reference.

[42] BM Branson, HD Gayle. Home Testing for HIV – It's Coming. Are You Ready? *International AIDS Society Newsletter*, March 1996, at 4.

[43] Salbu, supra, note 26, at 424.

[44] See Bayer et al, infra.

[45] Ibid.

[46] Schopper & Vercauteren, supra, note 2.

[47] Ibid.

[48] Salbu, supra, note 27 at 427.

[49] Schopper & Vercauteren, supra, note 2.

[50] EM Stevenson, SC Thompson, N Crofts. HIV Testing and Policy Change, an Analysis Based on Statewide HIV Testing Data. Abstract Mo.C.212, XI International Conference on AIDS, Vancouver, 7-12 July 1996.

[51] Graydon, supra, note 13.

[52] Schopper & Vercauteren, supra, note 2.

[53] W Flanagan. Comment on the Discussion Paper on HIV Testing and Confidentiality. Toronto, 10 October 1996.

[54] See infra.

[55] Schopper & Vercauteren, supra, note 2.

[56] Cited in Bayer et al, infra.

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Testing for HIV Infection at Home

The Food and Drug Administration (FDA) in the United States has licensed diagnostic kits that make possible testing and counselling for HIV infection in the privacy of a person's own home. The kits have engendered a sharp controversy. Former Surgeon General C. Everett Koop has described such test kits as the "single most important weapon we can employ in the fight against AIDS."[1] Opponents warn that the prospect of catastrophic effects far outweighs the intended advantages.[2]

The over-the-counter kit will radically change the role of health professionals at critical junctures in the testing process. The kits thus far approved by the FDA are home collection, not home testing, kits. A customer pricks his/her finger with a lance provided in the kit, places a drop of blood on filter paper, and sends it to a laboratory where both enzyme-linked immunosorbent assays and confirmatory tests are performed. After a specified period, results are available over the telephone to the customer, who punches in a unique code number. Those who test negative listen to a recording informing them of the meaning of the result and offering them the option of speaking to a counsellor. Positive results are reported by a counsellor, who provides referrals to follow-up clinical services and social-service agencies. Infected persons have the option of follow-up telephone counselling for a specified number of sessions. The entire process remains anonymous.

Background

More than 60 parties testified at hearings before the FDA's Blood Products Advisory Committee in June 1994.[3] After reviewing the testimony, the FDA "concluded that [the] OTC [over-the-counter] home specimen kit ... may be approvable."[4] The first home collection test, Johnson & Johnson's Confide HIV Testing Service, received approval for marketing in May 1996. A competitor, Home Access Health Corporation, received FDA approval on 22 July 1996, and another similar test by ChemTrak is awaiting approval.[5] On 23 December 1994, the FDA approved the OraSure HIV test, the first saliva-based collection kit for HIV-antibody screening, for use by physicians. Epitope (Beaverton, Oregon), the firm that developed the test, has indicated that it will seek approval for home use by nonphysicians.[6]

The test kits raise a number of questions:

- Would they be used by people at risk for HIV infection who thus far have not been tested?
- Would those tested suffer because they would not receive face-to-face counselling?
- How would such testing affect public health practices?

After careful consideration, and taking into account the limits of the available data, we have concluded that the potential benefits of home-access testing outweigh the potential risks.

When first proposed seven years ago, home-access HIV testing met with virtually unanimous opposition.[7] The American Medical Association, the Centers for Disease Control and Prevention (CDC), and the gay community all denounced the idea as threatening the foundations of America's formal HIV-testing policy, predicated on the importance of pre- and post-test counselling. With so forceful a public reaction, it is not surprising that in 1989 the

FDA prevented marketing of the test, expressing skepticism about "whether a person can reliably and safely perform the test and interpret the results without benefit of medical advice and professional counseling."[8]

The reconsideration of home testing has been made possible by a profound shift in the political climate and by refinements in the ability to offer counselling by telephone. No longer is there a solid wall of opposition from people engaged in public health, medicine, research, gay activism, and service to patients with AIDS. Support - some cautious, some enthusiastic - has come from those who in the past viewed home-access testing as anathema. Most important, the CDC has withdrawn its opposition.[9] Some newspapers and magazines, such as the *Los Angeles Times*,[10] have voiced editorial support.

The conflict over the home-access HIV test raises some public-policy issues unique to AIDS and other issues that touch on matters with even broader implications - the role home-diagnostic techniques should have in the evolving practice of medicine in America and the extent to which federal regulatory bodies should protect people from technically accurate devices that may produce psychologically burdensome results.

Expanding Access to Testing

Central to the argument for home-access testing is concern that many at risk for HIV infection have not been tested. The CDC has reported that about a third of the people infected with HIV were not tested until they were within two months of receiving a diagnosis of AIDS - about half not until they were within a year of diagnosis.[9] Many women do not discover they are infected until they give birth to an infected child.[11] Given that the rate of HIV transmission can be reduced substantially by treating infected women with zidovudine during pregnancy, this is especially troubling. Although persons at higher risk have been tested and counselled to a greater degree than the remainder of the population (42 percent, as compared with 20 percent in the general population, according to the 1989 National Health Interview Survey), most people at risk have not been tested.[12]

Phillips et al report that 29 percent of the respondents to the 1992 National Health Interview Survey stated that they would be "very" or "somewhat" likely to use home HIV tests if they were available.[13] For respondents defined as being at risk for infection, the comparable figure was 42 percent. Twenty-two percent of all respondents and 31 percent of those at risk indicated that they would choose home-access testing over other alternatives.

The "worried well" - people whose personal risk of HIV infection is quite remote but who nevertheless seek reassurance from testing - represent a potentially enormous market. Many of the worried well use government-funded HIV testing sites but could afford the projected retail costs - $30 to $40 - thereby freeing up public resources.

Caution is necessary, however. The prospect of the middle class turning to home HIV testing has aroused concern about the future of publicly supported HIV testing and clinical services. Would broad use of home-access testing ultimately reduce the options for those who depend on public clinics? At a time when there is pressure to cut government spending, this issue requires careful attention.

Telephone Counselling

Can telephone counselling succeed in encouraging those who test negative for HIV to maintain or adopt sexual and drug-using behaviour that protects against infection? Can such counselling meet the immediate emotional needs of those who test positive, help ensure that they are evaluated clinically, and encourage behaviour that prevents HIV transmission? For some, telephone counselling is too impersonal, given the psychological issues involved. For others, the very remoteness of a telephone conversation is attractive. The anonymity of telephone counselling may make it easier for callers to reveal painful feelings or embarrassing information. Reliance on the telephone as a counselling tool is hardly unprecedented. For decades, trained volunteers have staffed suicide and crisis-intervention hotlines. Hotlines increase rates of quitting among smokers.[14] Indeed, many opponents of home-access testing operate AIDS hotlines.

For those who test negative for HIV infection, the typical reaction is overwhelming relief. It is possible, of course, that a person receiving such a result over the telephone would hang up without listening to the recorded counselling message. Opponents of home-access testing maintain that a "teachable moment" would thus be squandered. Yet, how

different is the situation that prevails at publicly funded HIV-antibody testing sites, where as many as a third of those tested fail to return for test results and post-test counselling?[15] We believe that no approach to counselling can avoid such problems.

Clinicians and researchers alike report the stunned reaction, the sense of pained disbelief, that often accompanies a report of HIV infection - not surprising, given the grim prognosis. Severe adverse reactions, even suicides, it is argued, may result from telephone notification. Despite oft-repeated fears that telephone counselling would increase the risk of suicide, there is no evidence that this is the case. People with HIV infection are at a higher risk of suicide than either the general public or those with other chronic or terminal illnesses. This risk, however, appears to be related to the appearance of symptoms rather than to notification of HIV infection.[16]

In considering its risks and benefits, one should compare telephone counselling with prevailing practice, not with an idealized notion of testing and counselling. In the 1992 National Health Interview Survey, 17 percent of those surveyed reported receiving their HIV test results by telephone, and 16 percent by mail.[17] Of respondents who had been tested for HIV, 55 percent reported that they received no counselling at the time and 69 percent reported that they received no post-test counselling.[18] Although open to question about the accuracy of respondents' memories, these findings point to a wide gap between official aspirations and clinical practice. A recent study by the CDC of 43 publicly funded testing sites raises further questions. "In most clinics seropositive individuals received one post-test counseling session of approximately 20 minutes duration.... Post-test counseling sessions for seronegative individuals lasted approximately 10 minutes and often consisted of admonitions to reduce risk and discussions of the need to be retested in the future."[19] Given these realities, carefully monitored telephone counselling might improve on the current experience of many people tested for HIV.

False Positive Tests

The results of HIV testing, like those of other diagnostic tests, must be interpreted in the light of the likelihood of a positive test result in the person being tested. False positive results would be more likely in people at low risk for infection, such as the worried well. In populations with a low prevalence of HIV infection, the number of positive results might be small, but the rate of false positive results might be high.[20] Fortunately, false positive results occur in HIV testing at a very low rate,[21],[22] but high-quality laboratory analysis of specimens is essential. Telephone counsellors must be alert to these issues and to the importance of further testing and clinical evaluation. The conditions of licensure of the tests should address these issues.

Adolescents

The purchase of home HIV test kits by adolescents arouses special concern. The right of competent adults to make choices, even foolish choices, does not apply to minors. The ethical principle of respect for persons requires that those who are especially vulnerable be protected against harm. Although this perspective has influenced the opposition to home-access test kits, some clinicians who treat adolescents have a different view. Dr Kenneth Schonberg, of Montefiore Medical Center in New York City, urged the FDA not to erect barriers to the purchase of the test by adolescents. "The adolescents at highest risk are ... more alienated from society, and most intimidated by our systems of care. [Home-access testing] has the potential for greatest value to our at-risk adolescents."[23]

Restricting purchase by minors might also impede access to the tests by adults. For instance, requiring that HIV test kits be kept behind the counter at drugstores or demanding proof of age might foster the same kind of embarrassment that the sale of home kits is meant to overcome.

In our view, the data currently available do not support restricting access for minors. Restrictions might be considered at a later date, when more data are available. It is noteworthy that teenagers may currently purchase home pregnancy kits over the counter; in most states they may also be tested and treated for venereal diseases under statutes specifically exempting them from parental-consent requirements.

Public Health Issues

Some lawyers and public health officials are concerned that completely anonymous testing might not be compatible with policies and state statutes that mandate the reporting of those with HIV infection by name to confidential registries, partner notification, and face-to-face pre-test and post-test counselling.[24] Nevertheless, the health departments in three states with large AIDS case loads - New York, California, and New Jersey - have all endorsed the home test, despite potential conflicts with legislation requiring face-to-face pre-test and post-test counselling and, in New Jersey, reporting by name. Reporting the names of people with HIV infection, as required in about 25 states, would not be possible in the case of those who used home test kits.

Ironically, some opposition to home-access testing is predicated on the assumption that it would effectively identify large numbers of infected people in need of care. Given limited resources, it has been asserted that it would be unethical to encourage such identification. This argument is troubling. The lack of good medical and social services for people with HIV infection is an argument for increasing those services, not denying people access to personal medical information.[25] Indeed, in an atmosphere of fiscal constraint, the supply of such services may not be increased without a demonstration of both need and demand.

There is speculation about the potential for abuse of home-access testing.[26] Parents might force teenage children to be tested; employers, insurers, or health-care providers might coerce people into being tested. Are the possibilities of abuse so fundamentally different from those that already exist? After all, hospitals,[27] doctors,[28] and employers can already obtain blood samples and test without consent. The possibilities of abuse are not an argument against home test kits. Rather, they make clear the need to enforce existing statutory protections against testing without consent and discrimination, including the federal Americans with Disabilities Act,[29] and, if necessary, to consider additional protective legislation.

Future Research

FDA regulations permit post-marketing evaluations of products licensed through expedited review.[30] Such a process ensures that a product can be brought to market before all outstanding questions are resolved. The scope of post-marketing information that will be required from companies as a condition of licensure of home-access HIV test kits has been a point of contention. If too little is required, problems associated with the test may not be discovered. If too many studies are required, this could represent a de facto denial of licensure, given the costs involved. But beyond manufacturers' post-marketing studies, the federal government and private funders should examine the broader social effect of home-access testing. Useful information would include:

- a comparison of home-access testing with current practices, not idealized standards;
- demographic information on test users, information about the quality of telephone counselling, and data on consumer satisfaction;
- a comparison with face-to-face encounters; and
- the effects on the existing system of public testing and counselling.

For the FDA, the central ethical and policy question has been whether home-access HIV tests should be licensed, despite the possible risk to some people of serious psychological sequelae. Protection of the public is the essential element of regulations and statutes on prescription drugs and medical practice. In this instance, the evidence of potential serious risk is less than compelling, and the potential individual and public health benefits are great. Barring the licensure of home-access testing would have been an act of unwarranted paternalistic and unwise public policy. Now that the FDA has approved two home-access testing kits, it will be crucial to monitor how this long debated technology functions in the real world.

- *Ronald Bayer, Jeff Stryker, Mark D Smith*

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Foundation and by a center grant (P50-MH43520) from the National Institute of Mental Health.

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ENDNOTES

[1] CE Koop. Testimony, FDA Blood Products Advisory Committee, Washington, DC, 22 June 1994.

[2] HR Harris. Medical groups, AIDS activists reject at-home testing. *Washington Post*, 9 April 1994, at G1.

[3] WE Leary. Government panel hears call for expanded AIDS testing. *New York Times*, 23 June 1994, at A18.

[4] Food and Drug Administration. Home specimen collection kit systems intended for human immunodeficiency virus (HIV-I and/or HIV-2) antibody testing: revisions to previous guidance. *Federal Register* 1995; 60(36): 10087-10088.

[5] Health Notes. Home Testing for HIV Infection. *United Press International*, 15 May 1996; New Home HIV Test Goes on Sale Nationwide. *Bangor Daily News* 25 July 1996; M Wilke. J&J's Confide Faces Legal Battle, New Rival. *Advertising Age* 1996; 67(32): 3.

[6] First saliva-based test will be on the market in a few weeks. *AIDS Policy Law* 1995; 10(l): 1, 10-2.

[7] WE Leary. Home tests for AIDS: concept is attractive, but experts are wary. *New York Times*, 16 March 1989, at 15.

[8] Banned at home: an FDA ruling on AIDS test. *Time*, 18 April 1989, at 26.

[9] Testimony before FDA Blood Products Advisory Committee. Washington, DC: Centers for Disease Control and Prevention, 1994.

[10] Delay that could prove deadly: FDA should quit stalling on HIV self-test. *Los Angeles Times*, 30 January 1995, at B4.

[11] CB Wofsy. Intravenous drug abuse and women's medical issues. In: BK Silverman, A Waddell, eds. Report of the Surgeon General's Workshop on Children with HIV Infection and their Families. Washington, DC: Department of Health and Human Services, 1987, at 32-34.

[12] JE Anderson, AM Hardy, K Cahill, S Aral. HIV antibody testing and posttest counseling in the United States: data from the 1989 National Health Interview Survey. *American Journal of Public Health* 1992; 82: 1533-1535.

[13] KA Phillips, SI Flatt, KR Morrison, TJ Coates. Potential use of home HIV testing. *New England Journal of Medicine* 1995; 332: 1308-1310.

[14] DJ Ossip-Klein, GA Giovino, N Megahed, et al. Effects of a smokers' hot-line: results of a 10-county self-help trial. *J Consult Clin Psychol* 1991; 59: 325-332.

[15] RO Valdiserri, M Moore, AR Gerber et al. A study of clients returning for counseling after HIV testing: implications for improving rates of return. *Public Health Rep* 1993; 108: 12-18.

[16] F Starace. Suicidal behaviour in people infected with human immunodeficiency virus: a literature review. *Int J Soc Psychiatry* 1993; 39: 64-70.

[17] National Center for Health Statistics. CA Schoenbom, SL Marsh, AM Hardy. AIDS knowledge and attitudes for 1992: data from the National Health Interview Survey. Advance data from vital and health statistics. No 243. Hyattsville, Md: Public Health Service, 1994. (DHHS publication no (PHS) 94-1250.)

[18] K Ocamb. Home HIV testing is near. *POZ*. June-July 1994, at 48-52.

[19] LS Doll, MB Kennedy. HIV counseling and testing: what is it and how well does it work? In: G Schochetman, JR George, eds. AIDS testing: a comprehensive guide to technical, medical, social, legal, and management issues. 2nd ed. New York: Springer-Verlag, 1994, at 302-319.

[20] KB Meyer, SG Pauker. Screening for HIV: can we afford the false positive rate? *New England Journal of Medicine* 1987; 317: 238-241.

[21] DS Burke, JF Brundage, RR Redfield et al. Measurement of the false positive rate in a screening program for human immunodeficiency virus infections. *New England Journal of Medicine* 1988; 319: 961-964.

[22] M Gwinn, MA Redus, TC Grenade et al. HIV-1 serologic test results for one million newborn dried-blood specimens: assay performance and implications for screening. *Journal of Acquired Immune Deficiency Syndromes* 1992; 5: 505-512.

[23] SK Schonberg. Letter to DA Kessler, Commissioner, Food and Drug Administration, 29 June 1994.

[24] A Schrader. Do-it-yourself HIV tests could be available soon: under Colo. law, their sale would be illegal. *Denver Post*, 8 February 1995, at B4.

[25] Working Group on HIV Testing of Pregnant Women and Newborns. HIV infection, pregnant women, and newborns: a policy proposal for information and testing. *Journal of the American Medical Association* 1990; 264: 2416-2420.

[26] H Rosin. Bad Blood. *The New Republic*, 27 June 1994, at 12-14.

[27] K Henry, M Maki, K Crossley. Analysis of the use of HIV antibody testing in a Minnesota hospital. *Journal of the American Medical Association* 1988; 259: 229-232.

[28] M McKee. $418K award for woman given AIDS test without her consent. [San Francisco] *Recorder*, 9 June 1992, at 4.

[29] Home testing principles. Washington, DC: AIDS Action Council, 1994.

[30] SR Salbu. HIV home testing: the case for regulatory restraint and the FDA. *Hastings Law Journal* 1995; 46: 403-457.

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US – Doctor Settles HIV-Testing Case for $10,000

A doctor who performed an unauthorized HIV test after sticking himself with a needle during surgery has agreed to settle a lawsuit by the patient with a $10,000 payment plus attorneys' fees to the public interest law firm that represented the patient.[1]

In settlement papers filed in the case, the doctor admitted that after sticking himself while performing cosmetic surgery on his patient, he took a blood sample for HIV testing while the patient was under anesthesia and had the test performed without securing the patient's authorization. The patient later discovered the test had been performed when he was looking over his medical records on a follow-up visit to the doctor's office.

The doctor contended that he was unaware that Massachusetts law required express patient consent for an HIV test.

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ENDNOTE

[1] *Gavann* v *Wooldridge*, CA No 95-2521C (Mass Sup Ct, Suffolk County, 1 July 1996). Reported in *Gay/Lesbian Law Notes*, Summer 1996, at 110-111.

Canadian HIV/AIDS Policy & Law Newsletter

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US - List of 4000 Persons with AIDS Leaked

A list of 4000 persons with AIDS was leaked from the Pinellas County, Florida, Health Unit.[1]

Public health officials are custodians of considerable confidential information about the identity of persons living with AIDS and, where HIV test results are reportable, persons living with HIV who do not meet the clinical definition for AIDS.

The news about the leak surfaced in anonymous letters to the editor of newspapers in Tampa and St Petersburg, reporting that an employee of the Health Unit had been bragging about his possession of the missing computer disk. The disk later turned up in possession of the *St Petersburg Times*, which placed it in a sealed envelope and gave it to the newspaper's attorney for her safekeeping. The Health Unit employee, who had taken the disk to a gay bar and offered to look up names for his friends and also used the list "to check out his dates," was subsequently dismissed.[2]

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ENDNOTES

[1] Reported in *Lesbian/Gay Law Notes* October 1996, at 144, with reference to *St Petersburg Times*, 20 September 1996.

[2] Reported in *USA Today*, 10 October 1996, at A3.

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Compassionate Access to Experimental Drugs: Balancing Interests and Harms[1]

Discussing the issue of compassionate access to experimental drugs involves careful consideration of several interests and values.

- First, we want to ensure that "catastrophically ill" people receive the best treatment that is currently available. This could sometimes include giving them access to promising non-approved therapy.

- Second, vulnerable people, such as those who are catastrophically ill, deserve at least as much protection against potential harm as others. The notion of consent should not be an excuse to allow exposure to unpredictable physical and financial harm. Saying that people with HIV/AIDS have nothing to lose is obviously incorrect. Even those who are in the final stages of the disease can be seriously harmed by taking non-approved drugs. Harm can include earlier death but also seriously increased suffering.

- Third, a drug-approval system exists not only to protect individuals against harm; it also serves to ensure the efficacy and safety (a positive risk/benefit ratio) of a drug. This is of major importance, both for future patients who might need a drug and for the entire population, who pay for the use and sometimes also for the development of drugs. Spending money on worthless or even harmful drugs is depriving patients of other care. Our resources are definitely limited.

I was asked to comment on the impact of the proposed policy on the liability of Health Protection Branch (HPB), pharmaceutical companies, and physicians who prescribe a non-approved drug. Although more research is needed on this subject, it seems to me that legal liability is not the central issue. Solving legal liability is clearly not sufficient to create an ethically sound system.

What is the aim of liability or tort law? Tort law aims at compensating people for damage resulting from a breach of a duty of care. It also does more than that. By creating a system of financial liability, people are also urged to act carefully toward others. The duty to inform patients of potential harms further obliges physicians and pharmaceutical companies to respect people's self-determination.

Under the proposed policy, the duty of physicians to inform patients should resemble the researchers' duty toward research subjects. Warning them that the drugs are not approved, explicitly mentioning that HPB cannot guarantee the efficacy and safety of the experimental drug, mentioning all the potential risks, and so on, might be sufficient to prevent serious liability claims.

But the system of liability law has not been considered sufficient to protect the interests of patients and the population at large. A system of drug approval has been created because we believe that economic pressures to commercialize drugs quickly, the desperation of people who are terminally ill, the sometimes naive belief of researchers and manufacturers in a new drug, and so on, might jeopardize the health of individuals. While the deterrent aspect of liability claims might prevent some harm, appropriate protection requires a more proactive approach, especially when health is at stake. This is particularly true

for vulnerable populations, who could easily be convinced to use a drug, whatever the side effects and the potential harm. It is sometimes argued that depriving terminally ill patients who want to participate in a medical experiment is

paternalistic and unacceptable, because it deprives them of their only hope. Indeed, the whole drug approval system is paternalistic, but that does not make it unacceptable. It aims at protecting the population against powerful economic forces against which individual people are ill-armed. People have a right to the best available treatment, but they also have to be protected against harm. Moreover, drug approval also ensures that scientifically valid studies are conducted on the efficacy and safety of a drug. The conduct of these scientifically valid trials are of major importance for people with HIV/AIDS. We have to be careful that a policy, while offering only an appearance of immediate benefit, does not harm the entire HIV/AIDS population in the long run.

I would only want to point out some issues that should receive further consideration.

- First, the issue of payment for non-approved drugs should be discussed. Pharmaceutical companies should not use the Special Access Program to introduce drugs without going through the traditional approval procedure, to recover, for example, a part of the production costs. Payment by the patient for non-approved drugs might have to be prohibited. It is also essential to address this issue if we are to avoid, in the context of HIV/AIDS, a two-tiered system of health care. We have always rejected this in Canada for obvious reasons of justice. Such a system would affect people who are already stigmatized in society, such as injecting drug users with HIV/AIDS, who would unlikely be capable of paying for novel treatments. Drugs are either promising and should be freely offered to everyone, or they are not. Pharmaceutical companies that conduct clinical trials should contribute to a system of compassionate release of medication, at least to those who participated in the trial.

- Second, the procedure for emergency release should use existing structures of research review. The protection of terminally ill patients and the interests of society require more safeguards. For medical research, HPB counts on local Research Ethics Boards to control the ethical and scientific validity of research. These research ethics boards consist of representatives of the community, physicians, nurses, lawyers, ethicists and so on. A similar system of approval for Emergency Drug Release could be developed. The HIV/AIDS community should be involved for emergency approval of drugs that show promise in treating the disease or slowing down disease progress. Individual patients should not be left to their own, sometimes desperate, decision-making, but should be represented and assisted by people who understand their interests. Current means of communication make it possible for physicians in isolated regions to obtain help from committees in urban centres.

These are only some of the issues that should be addressed to find a reasonable balance between the interests of the catastrophically ill and society at large. It should be clear that these interests are not necessarily conflicting. A basic control on the release of drugs is in the interest of both people with HIV/AIDS and the community at large.

- *Trudo Lemmens*

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ENDNOTE

[1] Text of a presentation to the House of Commons Subcommittee on HIV/AIDS. Ottawa, 13 December 1995.

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Compassionate Access to Experimental Drugs and Catastrophic Rights[1]

This submission is based on widely accepted principles of research ethics, as expressed in Canada's Medical Research Council Guidelines on Human Research as well as in other national and international statements.

Empirical Background

Some points should be made to set the factual stage for the conclusions that follow, which centre on ethical considerations.

Patient Access

The issue of patient access to experimental drugs is commonly understood as centering on new and promising drugs under development for diseases such as HIV/AIDS. The issue is, however, much broader. We also need to consider the implications of reforms for drugs with no evidence in their favour whatsoever – eg, for drugs that have been scientifically and clinically discredited, for "me-too" drugs offering no significant advantage over drugs currently available or in advanced stages of testing. We must also focus on new dosages or treatment schedules or combinations of available drugs, keeping in mind the many influences upon a drug's safety and effectiveness, and the fact that persons ill with AIDS may at any given point be taking literally dozens of pills a day.

Other Disease Models

Because discussion of expanded access to experimental drugs is broader than a question of HIV/AIDS, we should look at other diseases for the lessons of history. Cancer is a particularly good model, both because of its often catastrophic implications and because of our knowledge of it and long experience in studying it. The vast majority of promising new anti-cancer agents introduced in Phase I testing never prove useful enough to even proceed to Phase III testing, let alone to final regulatory approval. And the vast majority of cancer patients in Phase I testing never experience clinical benefit from their experimental treatment; in one very large survey done by Estey, Hoth, and Leyland-Jones, .014 percent experienced total remission, and only about 2 percent had even partial remission. The idea that there are powerful and secret remedies for illness withheld by bureaucratic restriction is unfortunately a myth.

Consent to Research

Another unfortunate fact: Patients who are desperately ill sometimes consent to research with the idea that they have nothing to lose. This is a mistake. No disease is so dreadful and imminent that it cannot be made worse by the inapt application of an experimental treatment. This lesson, taught years ago in the AIDS context with the suramin experience, has been powerfully reinforced since, most notably with the tragedy of five subject deaths in association with the Phase II testing of fialuridine, that had been a promising treatment for hepatitis B (a common co-infection of AIDS).

Ethical Background

Compassionate access to experimental drugs is an issue that falls between the chairs of medical treatment and research. While the nature of the intervention is research, the intention of the patient requesting an experimental drug, and the

physician seeking to satisfy this request, are therapeutic in nature: at the minimum, to provide hope; at a maximum, to be of real benefit.

Ethical Obligations

Three principles serve as a useful summary of ethical obligations. They apply to both the therapeutic and research context:

- Respect for persons, and especially for autonomy, grounds the need to respect patient and experimental subject choice as expressed in informed consent.

- The principle of beneficence requires that patients and subjects seeking medical attention be helped, or at least not be harmed.

- Justice requires that medical interactions, whether in therapy or research, respect norms of fairness and equity.

However, these principles – respect, beneficence, and justice – apply differently in research and treatment.

A treating doctor in obtaining consent informs a patient of the reason for treatment, its effects and side effects, and its alternatives. This information is certainly not available in the same way in the research context, where informed consent may be little more than an investigator sharing uncertainty with a patient. Research does not carry the same warrant of benefit as does treatment, and issues of justice in research often focus on the relative positions of persons on and off trial.

There is in addition an important difference in the potential for conflict of interest. A doctor treating a patient is understood to have as his or her main object the best interests of the patient. A clinical investigator enrolling a subject faces of necessity a mixture – if not conflict – of interests, in concern for the scientific integrity of the trial as well as the physical integrity of the subject. When a research study is designed by a pharmaceutical company, the investigator's ability to attend to a patient's sole and individual interest may be still further compromised.

For these reasons, the procedures taken to ensure that ethical principles are respected cannot be the same in research as in treatment. In treatment, autonomy within the doctor–patient relationship is primary, and only after-the-fact control is exercised: by medical committees that review misadventure, through potential lawsuits, etc. In research, prospective review is needed, both by a research sponsor and by an independent Research Ethics Board (REB) that brings to bear independent medical, scientific, and ethical expertise, as well as lay representation, to ensure that the rights and interests of subjects are protected.

Catastrophic Right

When a catastrophic right is defined as "the right of a catastrophically ill adult to elect, in consultation with a physician, any therapy whatsoever that does not cause direct harm to others," the ethical procedure appropriate to treatment, rather than research, is chosen. The same would be true of the emergency release program described in the Drugs Directorate Discussion Paper on Renewal Project D-10. The treatment model relies upon a doctor supplying a patient with a well-grounded treatment recommendation, based on the sole interest of the patient, who then may choose to accept it after being adequately informed. The safeguards of expertise and informed patient choice are unavailable in the context of nonvalidated treatments. If the manufacturer of the drug in question can impose conditions upon access, such as special follow-up tests and examinations, then an incipient conflict of interest is present as well.

Research Ethics and Positive Right to Treatment

A universally accepted principle of research ethics is that a patient's right to treatment should not be compromised by enrolling in a trial. For this reason, as one pertinent example, it is unethical to employ a placebo as a control arm when studying a new treatment for a disease for which a standard treatment approach has been developed.

As a positive right, however, a patient's right to treatment or health care does not imply that a patient has a right to be supplied with any and all treatments that s/he desires, provided only that a physician is prepared to accede to the patient's request. A positive right means a right to be provided with some good, as opposed to a negative right which means a right to be free of interference. The positive right to be provided with treatment has been restricted to those treatments that have been accepted by the medical community, commonly following scientific investigation. This point must be particularly emphasized within the Canadian context, for our provision of government-funded health care has serious public financial implications.

Whether a new form of right – "catastrophic rights" – should be recognized is not, of course, settled by what has just been said. But such rights are not recognized at present; logic does not compel them, nor do they follow from our current ethical commitments to provide health care.

Justice

Justice requires that any reform of policy be conceived and accomplished in an equitable manner. Justice has been violated in the past when some patient populations and diseases have received inordinately low or inordinately great infusions of research funding. Issues of justice are particularly important when considering diseases that disadvantage certain segments of the population that have been historically the objects of prejudice, or are currently underserved. These points of course apply to HIV/AIDS. Globally, persons affected by HIV, such as male homosexuals, have been such targets. Reforms need to consider as well the heterogeneity of the patient population. Persons with AIDS contracted by intravenous drug use are doubly disadvantaged, and do not have the same access to up-to-date information and medical attention that others with AIDS possess, including those most active in speaking out for AIDS patients. To be equitable, reforms must not be designed for the sole satisfaction of that segment of the patient population that is highly motivated and educated.

Considerations for Policy

The following points suggest implications for policy development.

Confronting Conflict of Interest

Little in the background material supplied indicates adequate attention to the problem of conflict of interest. This problem looms largest vis-à-vis the role to be assigned to pharmaceutical companies. Perhaps of greatest concern is the failure to precisely describe when companies may charge – and how much – for nonvalidated treatments. At present in Canada, it is common for REBs to review studies in which companies attempt to externalize the costs of studying the new drug – for example, by denying payment to the control arm of a study or, in some cases, by evading payment on behalf of an experimental use or dose of a drug that has already been registered. Any attempt to further erode the drug company responsibility to fund its own research, by way of allowing charges to patients or third parties for nonvalidated drugs, should be resisted. Such payment should at most be permitted on behalf of the marginal cost of producing the drug consumed in fact.

Drug Companies and Research Ethics

It is fair to say that drug research in Canada involves a partnership between drug companies and research subjects; without the willingness of persons to submit themselves to a research protocol, companies would be out of business. Many REBs have taken the position that to satisfy this partnership, companies must agree to supply those research subjects who had been assigned to placebo with the test drug if the trial's results are positive.

Drug research involves a further partnership as well, with the Canadian public and government. Drug companies take advantage of a favourable tax and financial climate, and a sophisticated health-care infrastructure, supported by the taxpayer. Reciprocity and equity suggest that companies be made to understand that open-label supply of experimental drugs in conformity with policy and ethics is part of the cost of doing business in Canada. This has particular relevance to another aspect of the problem of access to experimental drugs that has not been addressed. Outside of those studies on HIV disease itself, it has become common, and even routine, to find that HIV-positive persons are excluded from clinical studies. It is time to consider whether and when HIV-positive persons should be allowed on a parallel study of

these new treatments, which, because of the protean nature of HIV disease, are often relevant to many persons with AIDS.

Conclusion

The NCBHR [National Council on Bioethics in Human Research] Clinical Trials Panel is concerned with such questions as: "When should persons on placebo be switched to an active agent? Is it ethical to extend access to asymptomatic persons whose life might thereby be shortened?" These and other questions are currently being considered by Canadian REBs and by networks of Canadian researchers, yet these groups are given no formal consideration in the background documents and have not been assigned any role to play. This is a mistake that should be rectified. I have explained the reasons why it is dangerous to leave the question of access to nonvalidated treatment within the bounds of doctor–patient interaction. We have in place across the country, in the form of Research Ethics Boards, bodies with the appropriate expertise and sensitivity to provide objective, reasonable, prospective evaluation of such interactions. Imagination is needed to explore how these Canadian resources may be mobilized toward the end of safe and easy access to experimental treatments.

- *Benjamin Freedman*

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ENDNOTE

[1]Text of a presentation to the House of Commons Subcommittee on HIV/AIDS. Ottawa, 13 December 1995.