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HIV treatments, vaccines, and microbicides: toward coordinated advocacy

In November 2003, the Canadian HIV/AIDS Legal Network convened a meeting in Montréal of global experts working in the fields of treatments, vaccines, and microbicides. The meeting was historic in that it was the first occasion on which advocates from the three fields had the opportunity to meet and exchange views on policy priorities. In this article, John Godwin provides a summary of the background paper produced for that meeting and of the key outcomes of the meeting. The article describes the reasons why developing a joint advocacy agenda has emerged as a priority for advocacy organizations from the three fields, despite their differing histories and the fact that they have often been positioned as competitors rather than collaborators. The role of a human rights approach in informing joint advocacy and the relevance of the prevention–care–treatment continuum are considered. The article then examines possible areas for joint advocacy, including funding, clinical trials, public private partnerships, tax credits, liability issues, equity pricing, bulk procurement, regulatory issues, manufacture, delivery, and national plans. The article concludes by noting upcoming opportunities for joint advocacy efforts, and outlining the next steps to be taken by the Legal Network to support coordinated advocacy.

Introduction

Until recently, treatment, vaccine, and microbicide advocates have pursued their objectives in large part independently from each other. Whereas treatment activism has been focused on the immediate imperative of scaling up access to existing treatments, vaccine and microbicide

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advocates have emphasized the importance of taking the long-term view and have argued for investments in research that may not see a return in terms of product availability for a decade or more.

Yet if one scratches the surface, one finds that many of the strategic policy concerns in the three fields are the same. Although working to different time frames, advocates have a common interest in promoting innovative research into products designed for use in resource-poor settings, and in addressing access issues (such as expanding access to existing products, and putting in place measures to support rapid and equitable access to new products). Having recognized the common agenda emerging around these issues, the Legal Network is seeking to promote coordinated advocacy among the three fields.

The Network's initiative had its genesis in a satellite meeting of the XIV International AIDS Conference, Barcelona 2002, which focused on treatments and vaccines for developing countries.¹ That meeting voiced agreement that vaccine and treatment advocates should advance a joint agenda on overlapping policy concerns, and that a dialogue should be initiated with microbicide advocates to explore commonalities. To take this idea forward, in 2003 the Network developed a project called HIV Treatments, Vaccines and Microbicides: Developing an Agenda for Action, to explore the intersecting agendas of the fields and to foster coordination between advocates. The work of the project has included preparing a background paper and

convening an international expert consultation in Montréal in November 2003.²

We need new treatment and prevention options

A unifying factor for advocates is their commitment to broadening the range of options available to fight HIV. Globally, there are very few social environments in which currently deployed strategies are keeping HIV/AIDS in check. In the prevention sphere, difficulties are being encountered even in wealthy low-prevalence settings, as education and behaviour-change efforts confront a complex range of social and behavioural challenges. In the treatment field, side effects, drug resistance, and treatment failure are reminders that we need new and better ways to manage HIV disease. Cheaper and simpler treatment regimens, as well as monitoring tools and diagnostics, are urgently required to facilitate treatment scale-up in resource-poor settings. Research and development (R&D) efforts in the vaccine, treatments, and microbicide fields hold great promise of delivering powerful new tools for fighting the epidemic.

The prevention-care-treatment continuum

Underpinning an emergent common agenda is the recognition that prevention, care, and treatment form a continuum and represent essential and interrelated elements of a comprehensive response.

Treatment supports prevention. Where treatments are available, rates of onward transmission are likely to

be reduced as the lowering of viral load in individuals on treatment makes the transmission of HIV on average less likely per risk incident. Hence, where antiretroviral (ARV) therapies are readily available across a population, there may be a public health benefit in terms of reduction of HIV incidence. And there is evidence from ARV treatment pilots that a reduction in stigma and increase in HIV testing rates associated with expanded treatment access support behavioural prevention efforts because people are more willing to know their status and access prevention services.³

A reduction in stigma and increase in HIV testing rates associated with expanded treatment access support behavioural prevention efforts.

Extending this logic, vaccine and microbicide advocates point out that the relationship of new prevention technologies to treatments is also potentially mutually reinforcing. The conduct of large-scale vaccine and microbicide trials in low- and middle-income countries presents opportunities to build health-care infrastructure, train laboratory and clinical staff, and improve and expand treatment services for communities hosting trials.

It's a two-way street: treatment access provides a supportive social

context for rolling out new prevention products, while investing in health infrastructure and training to bring expanded access to treatments can enhance the capacity to trial and eventually deliver vaccines and microbicides. This has been the experience in Brazil, where the process of building laboratory, health-care, and community infrastructure to enable access to treatments is providing a basis on which vaccine and microbicide trials are able to proceed. Treatment access programs strengthen the health sector, as health-care workers gain skills, community confidence in services is generated, and there are reduced losses of health-care professionals to HIV illness. A strong health sector that is accessible to and supported by local communities is important for trialling and delivering new prevention products.

Further, the product categories themselves are interrelated. HIV vaccine research is likely to lead to the development of both therapeutic and preventive products. Some microbicide candidates incorporate ARVs as preventive agents. Trials of the use of ARVs by HIV-negative high-risk populations are commencing in 2004, in the hope that ARVs will prevent HIV transmission much like a vaccine. Distinctions between the product categories are increasingly blurred.

A human rights approach

The human rights approach provides a conceptual framework for linking advocacy in the three fields. It reminds us that prevention and treatment advocates pursue a common goal – the achievement of the highest attainable standard of health for both people living with HIV/AIDS and HIV-affected communities.

A rights framework implies a unified vision of treatment and preven-

tion goals that is inclusive of vaccines, microbicides, and treatments, and that recognizes the importance of continued support for existing prevention measures such as education and harm reduction. This concept was explored in detail by the 2002 Consultation on the UN's International Guidelines on HIV/AIDS and Human Rights. The Consultation led to the publication of Revised Guideline 6 on Access to Prevention, Treatment, Care and Support, which requires states to

take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.⁴

A rights approach also reminds us that the success or failure of R&D and scale-up efforts must be measured from a pro-poor, community-oriented perspective. Important aspects of a rights-based approach include:

- an emphasis on participation of communities in decisions affecting their rights;
- the universality of rights, in that they are intended to be enjoyed by everyone without discrimination;
- the responsibility of states to transfer the benefits of scientific progress and its applications to assist less wealthy nations in realizing the right to health;
- the concept of progressive realization of the right to health; and
- the centrality of the role of states in assuring public health and addressing epidemic diseases.

Legal obligations of states to respect, protect, promote, and fulfil human rights, including the right to health, derive from international law (principally the Universal Declaration of Human Rights⁵ and the International Covenant on Economic, Social and Cultural Rights⁶), regional human rights agreements,⁷ and some national laws.⁸ International commitments to the full realization of human rights related to HIV/AIDS are articulated in the UN's Declaration of Commitment on HIV/AIDS,⁹ in General Comments of the UN Committee on Economic, Social and Cultural Rights,¹⁰ and in resolutions of the UN Commission on Human Rights on the right to the highest attainable standard of health and access to medication.¹¹

While recognizing the unifying power of a rights-based approach, advocates at the 2003 Montréal consultation noted the challenges faced in advocating for a rights agenda in countries where a human rights culture remains underdeveloped, or in fora where priorities are determined by market interests, such as negotiations on free-trade agreements, rather than human rights.

Constructing an agenda

Research and clinical trials

Advocates have a common interest in arguing for enhanced programs of publicly funded basic research. Breakthroughs in areas such as virology and immunology stand to benefit treatment and prevention fields alike.

Building the capacity of countries to conduct large-scale clinical trials is a high priority for vaccine and microbicide researchers, given the large cohorts required to demonstrate the efficacy of preventive technologies in phase III trials. Building trial capacity will also facilitate trials of treatment

strategies, such as simplified treatment regimens, designed specifically for resource-poor settings.

Much work has been done in the last few years to define the ethical issues involved in conducting research in developing countries, notably the guidance on vaccine ethics provided

Advocates in all three fields have a common interest in arguing for enhanced programs of publicly funded basic research.

by the Joint United Nations Programme on HIV/AIDS (UNAIDS).¹² Mutual benefits would be gained from sharing practical approaches adopted in trials to issues such as informed consent, use of placebos, confidentiality, and standard of care for trial participants.

Advocates from all fields need to assess the impact of new research initiatives, with a view to recommending how they may be better coordinated and expanded. Major new programs include the European and Developing Countries Clinical Trials Partnership and the US National Institutes of Health's (NIH) Comprehensive International Program of Research on AIDS. Advocates have a common role in encouraging community involvement and transparency of trial programs. Advocates might focus on developing mechanisms for community participation in trial processes through community advisory or management input mechanisms, and identifying education and training requirements to support community participation. Measures to ensure that

trial participants' rights are protected, such as participants' bills of rights,¹³ may be another focus for advocacy.

A significant concern for those conducting trials is competition for site capacity. Dialogue among global players on a system for according priority access to trial sites is desirable. In the vaccines field, a Global HIV Vaccine Enterprise has been proposed that would bring the major global players in vaccine R&D together to prioritize the scientific challenges to be addressed, to prioritize product development efforts, and to engage in implementation planning.¹⁴ This proposal draws from the approach of the Human Genome Project, which involved many funders agreeing on a scientific road map, voluntarily dividing the work, and agreeing to production standards. There may be lessons to be learned from this for collaborative planning of HIV R&D more generally.

Participants at the Montréal consultation concluded that advocates should explore common community participation issues as a priority, and formed an informal working group to examine opportunities for collaboration. Prevention and treatment fields face common community-engagement, preparedness, recruitment, and retention challenges. To date, community-preparedness efforts tend to be ad hoc and product-specific. The three fields also face common epidemiological, social, and behavioural research needs, and similar challenges regarding long-term follow-up of research participants.

Funding

Advocates have a common interest in advocating for a better global funding deal for R&D, one that is responsive to the health needs of poor communities rather than being market driven.

Prevention-technology R&D is drastically underfunded, and research into treatments is dominated by private-sector interests. Donors need to be reminded that the Global Fund to Fight AIDS, TB and Malaria (the Global Fund) does not fund R&D and that product development initiatives therefore need direct donor support.

To supplement the work of the Global Fund, the Commission on Macroeconomics and Health recommended in 2001 that another fund be established to finance research on diseases of the poor.¹⁵ The Montréal consultation expressed the concern that because there continue to be difficulties in raising money for the existing Global Fund, it may be unwise to try to create another distinct research fund. The consultation concluded that it may be more useful to focus on fundraising for existing product development initiatives.

The Global Fund is supporting a range of treatment access initiatives. Enhanced treatment access and the strengthening of primary health-care delivery systems through Global Fund-supported projects will potentially result in significant benefits for vaccine and microbicide developers, in terms of both trial and delivery issues.

The Montréal consultation concluded that it would be useful for advocacy purposes to provide a cost estimate for global HIV R&D needs for all three fields, coupled with related scaling-up costs. This is based on the need to bring multiple products into phase III trials at the same time as scaling up treatment provision in trial communities. The consultation also called for greater support to the Global Fund, given its role in treatment scale-up and support for health systems development. As well, the consultation highlighted the importance of

debt relief for poor countries with underdeveloped health systems.

Purchasing and financing mechanisms

Structures need to be put in place to enable countries with similar needs and buying power to negotiate good prices when procuring health products. Establishing bulk-procurement mechanisms for ARVs is an important strategy to keep prices down. The World Health Organization (WHO) is currently investigating procurement mechanisms to help achieve its target of treating three million people by 2005 (3x5). Lessons from these approaches can be used to inform the bulk procurement of vaccines and microbicides as they become available.

Financing is required to ensure that poor countries are able to afford both to pay for large supplies of medicines, vaccines, and microbicides, and to invest in domestic delivery systems. One option is for the Global Fund to manage a scheme in conjunction with the World Bank and regional development banks. If the Global Fund proves successful in

Lessons from efforts to reduce the prices of antiretrovirals can be used to inform the bulk procurement of vaccines and microbicides as they become available.

guaranteeing better commodity security with existing products, it could play an important role in building the confidence of product

developers that future products will be purchased.

Another option is to establish a new international finance facility for global public health goods, linked to the Global Fund, to support treatment scale-up and to provide commitments to finance purchases of vaccines, microbicides, and other new health products. The proposal for a new finance facility to fund the achievement of the Millennium Development Goals (MDGs), which is being promoted by the UK at the G8, could play a role in this.

Pre-commitments to purchase bulk quantities of vaccines, microbicides, or new drugs could provide an incentive for private-sector R&D investment. Advocates at the Montréal consultation expressed concern, however, that while advance purchase commitments may lead to new R&D efforts, they would not necessarily result in countries actually wanting to use products. It was suggested that ensuring that the Global Fund is sustainable is preferable to focusing on purchase commitments.

Strategies for stimulating strategic R&D

Strategies for stimulating R&D include public private partnerships (PPPs), expanding public-sector roles, tax relief, and reducing liability risks. Injecting substantial new funds into public-sector R&D would provide immediate benefits for the three fields. Public bodies play very significant roles in basic research and product development, particularly in the case of products for which there is perceived to be little market incentive for private investment.

However, much of the global R&D expertise is located within the private sector. PPPs, such as those

pursued by the International AIDS Vaccine Initiative, provide effective models for harnessing this expertise. More effective PPP models could be developed through advocates examining best practices in PPPs in such areas as input by communities from the global South in partnership arrangements, and accountability and transparency mechanisms.

In the past, tax relief as a strategy to foster private-sector R&D has been promoted by vaccine advocates, and has potential benefits for the microbicide and treatment fields as well. However, it can be argued that it is more useful to invest funds directly in publicly funded research programs rather than subsidize private industry. Advocates in the US are backing away from tax credits as a strategy. Instead, pointing to the US government's recent investments in anthrax and smallpox research as a precedent, advocates are arguing for more direct incentives, such as government contracting with the private sector and public assistance with vaccine manufacturing.

Exposure to product liability lawsuits is a significant deterrent to vaccine development in litigious environments such as the US. Advocates have sought to address this by promoting no-fault compensation models that minimize exposure to risk of liability for HIV vaccine manufacturers. Vaccine and microbicide manufacturers could jointly build a public interest case, using the US bioterrorism precedent, for provisions to indemnify manufacturers from liability arising from use of HIV-prevention technologies because of the potential of these products to stem the epidemic. The Montréal consultation pointed out that in addressing liability issues, it is important to ensure that consumer

rights to compensation are not unduly eroded, particularly where consumers are relatively powerless, such as in poor communities.

Patents

Patent issues remain high on treatment access agendas, as indicated by ongoing debates about the World Trade Organization (WTO) TRIPS¹⁶ Council's position on the capacity of countries to import generic medicines.¹⁷ This issue is due to be considered again at the WTO's 2004 meeting.

Although clearly a priority issue for treatment advocates, obtaining a satisfactory resolution to the generic-medicines issue should also be viewed as a matter of concern for vaccine and microbicide advocates. Flexible patent rules that encourage generic competition, and that are responsive to the health and development needs of poor countries, are a common goal. The Montréal consultation pointed out that trade agreements with the US that require compliance with "TRIPS plus" provisions (provisions that go beyond what the WTO rules require) can result in the exclusion of generic competition in developing-country markets for extended periods and that advocates from the three fields therefore need to monitor trade agreements closely.

Advocates also have a common interest in investigating open collaborative intellectual property models, drawing, for example, from the experience of SARS research, the Human Genome Project, the Global Positioning System, and open source software. The World Intellectual Property Organization is considering convening a meeting in 2004 to consider such models, and the US NIH is increasingly supportive of open drug-development models.¹⁸

Equity pricing

Rapid implementation of differential pricing for essential medicines as a global norm has the potential to support treatment scale-up and to provide a framework for future HIV vaccines and microbicides to be made available at low cost.

The UNAIDS/WHO Accelerated Access Initiative makes ARVs available at reduced prices in poor countries by negotiating with manufacturers. The disadvantage of this approach is that it has resulted in ad hoc, country-by-country reductions and has not provided a systemic solution. Desirable features of a differential pricing approach are structures that ensure sustainability and set prices for poor markets as close as possible to direct costs of production. Voluntary approaches to differential pricing remain the preferred option of G8 governments. The G8 Evian summit health action plan refers to the G8's support for "pharmaceutical companies' voluntary long term commitments to provide essential medicines at substantially discounted prices."¹⁹

Differential pricing has to be placed in the context of a range of options to achieve affordability.

The Montréal consultation noted that differential pricing has to be placed in the context of a range of options to achieve affordability. Licensing of generics and legislated price controls are proving more effective than voluntary differential pricing

in supporting treatment scale-up in contexts such as South Africa. Initiatives to negotiate discounted bulk supplies of generics, such as those achieved by the Clinton Foundation, and the strategies being pursued through the WHO's 3x5 initiative, may mean that differential pricing of brand-name products is less important as a treatment access strategy. The consultation concluded that it was important for advocates to work together to support price transparency – for example, through a mandatory system for the monitoring and reporting of global prices of therapeutics, diagnostics, and preventive technologies for HIV.

Regulatory issues

Streamlining regulatory requirements is important to reducing delays in approving trials and to licensing new products. Most developing countries have only a limited regulatory infrastructure. The lack of regulatory capacity in the South means that approval of products for marketing is often heavily influenced by the decisions of the US Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medical Products.

A pathway to licensure for products designed for use only in the developing world needs to be defined. Vaccine and microbicide advocates have pointed out that a partially effective HIV vaccine or microbicide, which might not be approved by regulators in the US or Europe because the efficacy level is considered too low, could nonetheless be highly appropriate for use in countries with rapidly emerging epidemics. This indicates the need to provide a new framework to extend the mandate of Northern regulators so that they can make decisions based

on the needs of developing countries, rather than just Northern markets.

UNAIDS, the WHO, and the FDA need to be supported in expanding their roles in the provision of financial assistance and technical advice to countries to ensure informed national regulatory decision-making. Efforts to strengthen national regulatory infrastructure should be prioritized in countries where clinical trials are being conducted, and in countries that are well placed to play a regional leadership role (for example, Thailand and South Africa). Harmonization of regulatory measures may reduce the need for trials to be repeated in multiple countries. Countries with similar epidemiological and population characteristics could benefit by pooling their regulatory expertise and linking approval processes.

WHO prequalification of therapeutics and vaccines is providing developing countries without strong regulatory capacity with a reliable process for assessing products. The Montréal consultation concluded that WHO initiatives, such as its prequalification process, should be pursued with greater urgency and expanded both because they can support treatment scale-up and because they may prove useful for future HIV vaccines and microbicides.

Manufacturing

The lack of manufacturing capacity is a major factor in the lengthy delays in getting pharmaceutical products to market in the South. This issue may become even more significant as the focus of product development shifts to small biotechnology companies and non-profit organizations that do not have the capacity to invest in manufacturing. Substantial private- and public-sector invest-

ments in manufacturing will be required to meet global demand for an HIV vaccine or microbicide. The public sector needs to demonstrate a willingness to assist the private sector in managing the risks involved in creating sufficient capacity to meet projected demand. Scaling up manufacturing capacity will necessitate a better understanding of potential demand for products which, in turn, needs to be based on a better understanding of the potential impact of different products in different epidemiological contexts.

The Montréal consultation concluded that advocates have a common interest in advocating for a program of financial assistance to support investment in manufacturing facilities in the global South. An initial focus may be to build the capacity of countries with some level of existing pharmaceutical manufacturing infrastructure.

Delivery

The usual pattern has been for rich countries to enjoy access to new health technologies years in advance of developing countries. This is not an acceptable model for HIV treatments, vaccines, or microbicides. Improving delivery systems for existing treatments, vaccines, and contraceptives is key to preparing for the delivery of new products. Treatment activists have helped to provide the environment in which access to new therapies is seen as a consumer right. The continued vibrancy of this movement may be critical to generating local support for the rapid rollout of vaccine and microbicide products as they become available.

Delivery issues for vaccines and treatments will likely overlap, given the involvement of medical staff in

prescribing, dispensing, and administering products. There are many intersecting health-promotion issues, given the need to develop coherent messages that educate communities about the health benefits of each product. Communities will need to understand the implications of partially effective vaccine and microbicide products, and the need to sustain condom use and other prevention strategies. Research will be required to assess consumer attitudes to products, the likely demand

The Montréal consultation emphasized the crucial role of community mobilization in supporting delivery.

for product uptake, and consumer responses to partially effective prevention products.

The Montréal consultation emphasized the crucial role of community mobilization in supporting delivery, and noted the potential for integrated community education programs to address: (a) the mutually supportive relationship of treatments, vaccines, and microbicides; and (b) issues specific to partially effective products.

National plans

National planning is a key strategy for ensuring political support for vaccines, microbicides, and treatments. Countries need to start contingency planning now to enable vaccine and microbicide delivery systems to be operational as soon as possible after new products are licensed.

The Montréal consultation reviewed plans already developed in

Uganda, Thailand, and Brazil, and concluded that important elements of national plans include:

- a human rights framework;
- commitment to the participation of community representatives in the planning process;
- recognition of the links between prevention and treatment; and
- consideration of the impact of trade agreements on domestic public health priorities.

The Montréal consultation concluded that it is important for national plans to reflect a comprehensive response that considers the interrelationship of vaccines, microbicides, and treatments, and agreed that advocates should develop a checklist of desirable elements for inclusion in national plans relating to R&D and access to new treatment and prevention technologies.

Opportunities to advocate the agenda

A number of opportunities for advocacy were identified, and the Montréal consultation agreed to work toward a common action plan to guide advocacy efforts in the period 2004-2006. The consultation stressed that global policy interventions would fail unless they are supported by policy work at the national and local levels. Convening three-way meetings of advocates at the national level was proposed as one way of ensuring that advocacy priorities could be set locally as well as through action at global and regional levels.

WHO patents review

The World Health Assembly agreed in May 2003 that the WHO would establish a "time-limited body" to review

patent issues and incentive mechanisms for the creation of new products against diseases that affect developing countries, and that the body would report by January 2005. Advocates could benefit by agreeing on proposals to be put to the WHO review, either independently or through joint proposals.

G8 summits

The 2003 G8 resulted in a disappointing health action plan. Advocates should coordinate their efforts to ensure that the 2004 and 2005 summits result in more concrete outcomes. Joint proposals targeting the host US and UK governments for these summits should be prepared well in advance and with broad cross-sectoral support, including from UN agencies.

The UN Millennium Project

The UN MDGs are highly significant in informing the priorities of global donors. The UN's recommended strategies for achieving the MDGs will influence the major global bilateral and multilateral agencies. As well, the MDGs are the central point of reference for discussions about financing development. UN action on the MDGs can be influenced through input to the UN's Millennium Project, which is due to report to the UN Secretary-General in mid-2005, and through the UN Conference on Trade and Development XI, to be held in São Paulo in June 2004.

UN Special Rapporteur on the Right to Health

The UN Special Rapporteur on the Right to Health, Paul Hunt, is conducting a three-year investigation from 2002 to 2005. It may be beneficial for advocates to present a joint

plan of action to the Rapporteur on priority measures that the UN system might undertake in order to promote access to new health technologies. The Montréal consultation agreed that Paul Hunt would be alerted to the existence of the action plan being developed by advocates.

UN Declaration of Commitment on HIV/AIDS compliance reporting

Performance indicators were developed by UNAIDS in 2002 for use in monitoring progress toward achieving targets established by the Declaration of Commitment. Countries are required to report progress periodically to UNAIDS using the indicators. It would be useful to develop more precise indicator sets to monitor R&D and access measures relating to vaccines, treatments, and microbicides.

International convention on R&D

Public health goods might benefit from agreements similar to those used to put human genome research into the public domain. Treatment advocates have begun to promote the need for an international convention, treaty, or trade agreement on health R&D that would commit countries to contribute to health R&D, provide an equitable basis for sharing the cost burden of R&D, and establish mechanisms for exchanging research results and transferring technology.

The Montréal consultation noted the importance of this proposal, although there was a difference of views regarding the utility of a convention solution. The Global Forum for Health Research, to be held in Mexico in November 2004, may be an appropriate forum for exploring global agreements.

International and regional HIV/AIDS conferences, 2004-2006

International AIDS conferences (Bangkok 2004, Toronto 2006) and regional conferences provide an opportunity to publicize and build support for a consensus agenda on R&D and related access issues. The media attention the global conferences attract is an opportunity for joint media work on a single issue of agreed priority, such as highlighting successes in combining treatment scale-up strategies with prevention trials.

Next steps

The Montréal consultation agreed to support the development of a Statement of Commitment from advocacy organizations, which will set out a commitment to advocate for a comprehensive HIV response, principles to guide joint advocacy (such as a human rights approach and the prevention–care–treatment continuum), and top-line priorities for joint action. A plan of action that sets out opportunities for joint advocacy for the 2004-2006 period will also be developed. The Canadian HIV/AIDS Legal Network is playing a coordinating

role for these initiatives. A satellite meeting to follow up on the issues raised at the consultation will be held at the XV International AIDS Conference in Bangkok in July 2004.²⁰

– John Godwin

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¹ The satellite was organized by the Legal Network, the AIDS Law Project (South Africa), and the Lawyers Collective (India), and co-hosted by UNAIDS.

² The background paper was funded by the International AIDS Vaccine Initiative (IAVI); the global consultation meeting was funded by UNAIDS, the WHO–UNAIDS HIV Vaccine Initiative, IAVI, the International Partnership on Microbicides, Health Canada, and the Canadian International Development Agency.

³ T Kasper et al. Demystifying ARV therapy in resource-poor settings. *Essential Drugs Monitor* No 32, 2003.

⁴ Office of the High Commission for Human Rights/UNAIDS. *HIV/AIDS and Human Rights International Guidelines: Revised Guideline 6: Access to prevention, treatment, care and support*. Geneva: UNAIDS 2002, at 14.

⁵ Articles 25(1) and 27(1).

⁶ Article 12. The right to health can also be derived from a range of other international treaties and covenants, eg, Convention on the Rights of the Child, Article 24; Convention on the Elimination of All Forms of Discrimination Against Women, Articles 11 and 12.

⁷ African Charter on Human and Peoples' Rights, Article 16; American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, Article 10; European Social Charter, Article 11.

⁸ Over 60 nations include health rights in their constitutions: P Hunt. *Report of the Special Rapporteur on the Right*

to Health. Report to the 59th Session of the Commission on Human Rights, February 2003, at 7.

⁹ Article 55.

¹⁰ See *General Comment 14: The Right to the Highest Attainable Standard of Health*. Doc E/C, 12/2000/4.

¹¹ 2001/33, 2002/32, 2003/29.

¹² *Ethical Considerations in HIV Preventive Vaccine Research: UNAIDS Guidance Document*. Geneva: UNAIDS, 2000; *The Ethics of Research Related to Healthcare in Developing Countries*. London: Nuffield Council on Bioethics, 2002 (available at www.nuffieldbioethics.org/publications); *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Bethesda, MD: National Bioethics Advisory Commission, 2001 (available at www.georgetown.edu/research/nrcbl/nbac/pubs.html); *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: Council for International Organizations of Medical Sciences (CIOMS), 2002.

¹³ Eg, South African Preventive HIV/AIDS Vaccine Trial Participant Bill of Rights (www.saavi.org.za/bill_of_rights.htm).

¹⁴ R Klausner. The need for a Global HIV Vaccine Enterprise. *Science* 2003; 300(5628): 2036-2039.

¹⁵ *Report of the Commission on Macroeconomics and Health: Investing in Health for Economic Development*. Geneva: WHO, 2001, at 192.

¹⁶ TRIPS refers to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights.

¹⁷ See R Elliott. TRIPS from Doha to Cancún ... to Ottawa: global developments in access to treatment and Canada's Bill C-56. *Canadian HIV/AIDS Policy & Law Review* 2003; 8(3): 1, 7-18.

¹⁸ See discussion of models at www.cptech.org/ip/health3/rndtif/.

¹⁹ Online via www.g8.fr/evian/english/home.html by clicking on "Health – A G8 Action Plan."

²⁰ These documents, as well as a report that introduces the issues and incorporates feedback from the meeting, will be published in English, French, and Spanish in 2004. All documentation is available on the Legal Network's website at www.aidslaw.ca/Maincontent/issues/vaccines.htm.