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# **HIV Vaccines for Developing Countries: Advancing Research and Access**

**Summary Report**

**HIV Vaccines for Developing Countries:  
Advancing Research and Access**

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Published by the Canadian HIV/AIDS Legal Network

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**Ce document est également disponible en français.**

**Este documento está también disponible en español.**

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# 1 Introduction

The mission of the Canadian HIV/AIDS Legal Network is to provide education, legal and ethical analysis, and policy development related to HIV/AIDS in Canada and internationally. This paper on HIV vaccine development arises from our strong belief that greater commitment and funding are needed to ensure an ethical vaccine research process, successful vaccine development for developing countries, and global access to HIV vaccines once they are developed.

This report is intended to complement and build on prior documents produced by the Canadian HIV/AIDS Legal Network related to human rights and HIV vaccine development.<sup>1,2</sup> The report is part of a larger project led by the Canadian HIV/AIDS Legal Network to facilitate dialogue among researchers, funders, affected communities, national governments and the international community on the legal, ethical, and human rights aspects of HIV vaccines, and to strengthen the policy foundations for global community mobilization and advocacy. The project has produced four outputs:

- a **background paper**, which describes the imperatives for funding HIV vaccine research for developing countries, the inadequacy of current approaches and the obstacles to more rapid research and development; and which identifies potential action steps to mobilize substantially greater support for such research;<sup>3</sup>
- an **international expert meeting**, held in April 2002 in Montréal, Canada which reviewed the current situation and the obstacles to greater funding and commitment to HIV vaccine research and development; identified opportunities for advocacy; and discussed a proposed action plan and advocacy tool;
- an **advocacy tool**, in English, French, and Spanish, which can be put to use quickly by community-based organizations and other advocates, and which sets out (in user-friendly fashion) the ethical, legal and human rights imperatives for allocating more resources levels for the development of HIV vaccines suitable for use in developing countries;<sup>4</sup>
- this **summary report**, available in English, French and Spanish.

This summary report includes the main points from the background paper and also incorporates the strategies and actions developed at the international expert meeting. Section 2 of this report outlines the human rights arguments for developing an HIV vaccine. Section 3 discusses four imperatives for advancing HIV vaccine research and access: (1) ensure commitment to HIV vaccine development; (2) expand public involvement in HIV vaccine development; (3) ensure HIV vaccine development; and (4) ensure HIV vaccine access. Section 4 presents a list of actions that should be considered to achieve the four imperatives. Finally, section 5 provides information on relevant resources, including a list of

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<sup>1</sup> Patterson D. *Resolving Legal, Ethical and Human Rights Challenges in HIV Vaccine Research*. Montreal: Canadian HIV/AIDS Legal Network, 2000. Available on the Network's website at [www.aidslaw.ca/Maincontent/issues/vaccines.htm](http://www.aidslaw.ca/Maincontent/issues/vaccines.htm).

<sup>2</sup> Thompson D. *HIV Vaccines in Canada: Legal and Ethical Issues – A Background*. Canadian HIV/AIDS Legal Network / Centre for Bioethics, Clinical Research Institute, 2002; Garmaise D. *HIV Vaccine in Canada: Legal and Ethical Issues – An Overview*. Canadian HIV/AIDS Legal Network, 2000. Both documents, info sheets and other materials are available on the Network's website at [www.aidslaw.ca/Maincontent/issues/vaccines.htm](http://www.aidslaw.ca/Maincontent/issues/vaccines.htm).

<sup>3</sup> Avrett S. *HIV Vaccines for Developing Countries: Advancing Research and Access – Background Paper*. Montréal: Canadian HIV/AIDS Legal Network, 2003. Available on the Network's website at [www.aidslaw.ca/barcelona2002/hivvaccinecomponent.htm](http://www.aidslaw.ca/barcelona2002/hivvaccinecomponent.htm).

<sup>4</sup> Avrett S. *HIV Vaccines for Developing Countries: Advancing Research and Access – Advocacy Tool*. Montréal: Canadian HIV/AIDS Legal Network, 2002. Available on the Network's website at [www.aidslaw.ca/barcelona2002/hivvaccinecomponent.htm](http://www.aidslaw.ca/barcelona2002/hivvaccinecomponent.htm).

organizations that hold international meetings on HIV vaccine research and access, a list of meetings scheduled for 2003, and a list of websites of organizations working in this field.

The groundwork for this paper's recommendations has been established at more than 20 international meetings and conferences during the period from 2000 to 2002. These gatherings have successively stated and restated commitments to accelerating the HIV vaccine effort. Now, more than ever, the foundation is set for action.

## 2 HIV Vaccine Development in a Human Rights Framework

HIV vaccine development is both a global health obligation and a human rights obligation. Both types of obligations are discussed below.

### 2.1 A Global Health Obligation

The global AIDS crisis is still beginning. HIV is the fastest spreading lethal infectious disease in the world today, and is, by itself, a major global health catastrophe.<sup>5</sup> In resource-limited countries, HIV and AIDS have unfortunately taken their place next to other major public health needs related to infectious disease, such as tuberculosis and malaria; next to basic environmental health challenges, such as clean air and water; next to challenges of basic nutrition, shelter, and education; next to unresolved political conflict; and next to egregious social and economic inequities. The current human and economic costs of HIV and AIDS will be vastly outweighed by the cost of the coming epidemic, especially if the world takes insufficient action. By any scale, the current overall effort against AIDS, including research on new treatments, vaccines, and microbicides, is not yet sufficient.

The scientific case for moving forward is clear. The feasibility of developing effective HIV vaccines is rooted in scientific data: several experimental HIV vaccines have been shown to protect monkeys against HIV infection and to generate immune responses in people. The evidence of potential feasibility of HIV vaccine development is equal to, or greater than, the immunologic and empiric evidence that existed for the feasibility of vaccines against Lyme disease, rotavirus and pertussis (whooping cough) before those vaccines entered into large-scale clinical trials. Furthermore, the scientific potential for an HIV vaccine may even be increasing more rapidly than the pace of global vaccine development funding, thereby widening the gap of relative underinvestment. In short, investment in HIV vaccine development efforts must accelerate not only because HIV vaccines are needed, but also because HIV vaccines are becoming increasingly possible.<sup>6</sup>

The powerful historical impact of other vaccines in halting disease supports the case for HIV vaccine development. In addition, given the relative cost and potential benefit of HIV vaccine development, the HIV vaccine effort should be seen as one of ethical benefit and justice. In their potential to address the disproportionate burden of HIV around the world, HIV vaccines represent a potential tool for a fairer and more just distribution of the response to the epidemic. As with low-cost HIV treatments, diagnostics, and potentially effective vaginal microbicides, it would be unethical not to invest in development of potential HIV vaccines and in efforts to make them accessible.

### 2.2 A Human Rights Obligation

The enjoyment of the highest attainable standard of health is recognized as a fundamental human right.<sup>7,8</sup> A human rights approach can anchor public health obligations, responsibilities and potential actions into an international legal framework. A large number of international treaties, charters, covenants and joint

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<sup>5</sup> UNAIDS. AIDS Epidemic Update. December 2001. Available on the website of UNAIDS at [www.unaids.org](http://www.unaids.org).

<sup>6</sup> A more detailed discussion of the science of HIV vaccine development can be found on the website of the International AIDS Vaccine Initiative (IAVI) at [www.iavi.org](http://www.iavi.org) or on the website of the U.S. National Institutes of Health at [www.niaid.nih.gov/vrc/](http://www.niaid.nih.gov/vrc/).

<sup>7</sup> Leary V. The right to health in international human rights law. *Health and Human Rights* (1994); (1)1; 24-56.

<sup>8</sup> Gruskin S and Tarantola D. *Health and Human Rights*. Cambridge: FXB Center for Health and Human Rights, Working Paper #10. 2000. Available on the Center's website at [www.hsph.harvard.edu/fxbcenter/working\\_papers.htm](http://www.hsph.harvard.edu/fxbcenter/working_papers.htm).

declarations reiterate the need to pursue and share technological advancements, including vaccines and treatments, against major diseases such as HIV. These treaties and joint declarations include:

- the 1945 Charter of the United Nations;<sup>9</sup>
- the 1948 Universal Declaration of Human Rights (UHDR);<sup>10</sup>
- the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR);<sup>11</sup>
- the 1975 Charter of Economic Rights and Duties of States;<sup>12</sup>
- the 1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind;<sup>13</sup>
- the 1978 WHO/UNICEF Alma-Ata Declaration;<sup>14</sup>
- the 1997 International Guidelines on HIV/AIDS and Human Rights;<sup>15</sup>
- the 1998 World Health Declaration;<sup>16</sup> and
- the 2001 UN General Assembly Declaration of Commitment on HIV/AIDS.<sup>17</sup>

The right to “share in scientific advancement and its benefits” is stated in the UDHR<sup>18</sup> and reiterated in other international treaties and declarations, such as the ICESCR<sup>19</sup> and the 1975 Charter of Economic Rights and Duties of States, which states that:

All States should facilitate the access of developing countries to the achievements of modern science and technology, the transfer of technology, and the creation of indigenous technology for the benefit of the developing countries in forms and in accordance with procedures which are suited to their economies and needs.<sup>20</sup>

These international public health, ethical and legal commitments compel governments, international agencies, and other institutions to act. Governments and advocates have a responsibility to translate international obligations into clear commitments and plans with timelines and outcomes that can be monitored and enforced.

HIV vaccine development is interdependent with other global health efforts. Global health would benefit from the addition of a safe, effective, inexpensive and widely accessible tool for the prevention of HIV and AIDS. Conversely, public access to, and trust in, essential health information and services is a prerequisite for a successful HIV vaccine development and delivery program.

The obligation to prevent and control epidemic diseases (including HIV) by developing vaccines, and providing access to them, is also interdependent with other fundamental human rights related to research. These rights include the right to protection from research-related harm (including discrimination). Efforts

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<sup>9</sup> *Charter of the United Nations*, 26 June 1945 (entered into force 24 October 1945), TS 67 (1946).

<sup>10</sup> UN General Assembly Resolution 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948).

<sup>11</sup> *International Covenant on Economic, Social and Cultural Rights*, 993 UNTS 3.

<sup>12</sup> UN General Assembly. *Charter of Economic Rights and Duties of States* 1975. Chapter II, Article 13.

<sup>13</sup> UN General Assembly, Resolution 3384 of 10 November 1975, Articles 1, 3, 5, 6 and 7.

<sup>14</sup> World Health Assembly Resolution 32.30. *International Conference on Primary Health Care*. WHO with UNICEF (1979).

<sup>15</sup> UN High Commission for Human Rights. *International Guidelines on HIV/AIDS and Human Rights*. 1997, Guideline #1. Available on the UNAIDS website at [www.unaids.org](http://www.unaids.org).

<sup>16</sup> World Health Assembly Resolution 51.5. *World Health Declaration*. WHO (1998).

<sup>17</sup> UN General Assembly Special Session on HIV/AIDS. *Declaration of Commitment on HIV/AIDS*, June 2001, paragraphs 23, 70, and 89.

<sup>18</sup> UN General Assembly, *supra*, note 10 at Article 27(1).

<sup>19</sup> *International Covenant*, *supra*, note 11 at Article 15.

<sup>20</sup> UN General Assembly, *supra*, note 12, at Chapter II, Article 13.

to improve the capacity of individuals to understand health messages, and to act to protect their health, help to make HIV vaccines more accessible and, therefore, to increase their impact. Similarly, efforts to reduce poverty, to reduce harm from drug use, and to overcome the lack of access to medical care, could augment the impact of HIV vaccines in preventing HIV and AIDS. Reductions in social stigma associated with HIV infection, drug use, and sexual intercourse could reduce delays on the part of individuals in seeking HIV testing, HIV treatment, and counselling about HIV risk-reduction, and vaccination (where appropriate) thus also enhancing the impact of HIV vaccines.

Human rights advocacy related to HIV vaccine research has already yielded important successes related to individual rights and clinical research. Human rights advocacy should now expand its focus to embrace the broader goals of ensuring HIV vaccine development and access.

### 3 Four Imperatives for Advancing Research and Access

In order to advance research and access for an HIV vaccine, we must:

- ensure that there is a commitment to HIV vaccine development;
- expand public involvement in HIV vaccine development;
- ensure that HIV vaccine development occurs; and
- ensure access to an eventual HIV vaccine.

This section discusses each of these imperatives in turn.

#### 3.1 Ensure Commitment to HIV Vaccine Development

Rights-based arguments have often been slow to mobilize governments and other institutions, partly because relevant international treaties and declarations contain imprecise definitions of responsibilities, vague timeframes for implementation, and few mechanisms for monitoring and enforcement. In a speech in July 2000 at the International AIDS Conference in Durban, South Africa, Kenneth Roth of Human Rights Watch suggested that national government plans and timelines were key to ensuring leadership, public support for priorities, accountability and progress.<sup>21</sup> This echoed a call for specific commitments made in 1998 by the late Jonathan Mann:

What is needed is to develop AIDS vaccine candidates according to procedures and milestone-driven strategies which have produced highly successful vaccines which save millions of lives from diseases like polio, whooping cough, and measles... Science is an instrument of public health. The larger responsibility, central to the moral authority and legitimacy of our governments, is protection of public health.<sup>22</sup>

These commitments, procedures, and milestone-driven strategies are needed at all levels – local, national, and international – and from all players – governments, private sector, and civil society – to ensure a globally consistent and coordinated HIV vaccine effort over time. Governments, in particular, can devise and publicly adopt country-specific HIV vaccine plans and timetables, reinforced by mechanisms for monitoring and enforcement. The need to develop national plans for HIV vaccine development is supported by documents such as the International Guidelines on HIV/AIDS and Human Rights:

States should establish effective national frameworks for their response to HIV/AIDS which ensure a coordinated, participatory, transparent and accountable approach, integrating HIV/AIDS policy and program responsibilities across all branches of government.<sup>23</sup>

The development of national HIV vaccine plans – including national commitments to clinical trials, regulatory and ethical review capacity, and vaccine delivery infrastructure – can help to stimulate progress in vaccine development in a context of public dialogue and oversight. National HIV vaccine plans have already been developed in some (but not all) of the countries now supporting HIV vaccine development. Countries supporting HIV vaccine development include high-income countries, such as

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<sup>21</sup> Roth K. *Human Rights and the AIDS Crisis: The Debate Over Resources*. Human Rights Watch. July 2000. Available at [www.hrw.org/editorials/2000/aids-print.htm](http://www.hrw.org/editorials/2000/aids-print.htm).

<sup>22</sup> Mann J. *Paralysis in AIDS Vaccine Development Violates Ethical Principles and Human Rights*. IAPAC Newsletter, May 1998.

<sup>23</sup> *HIV/AIDS and Human Rights: International Guidelines*. UNAIDS and Office of the High Commissioner for Human Rights. 1997, Guideline #1. Available on the UNAIDS website at [www.unaids.org](http://www.unaids.org).

Australia, Canada, Japan, the United States, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Sweden, and the United Kingdom. They also include at least a dozen middle and low-income countries in the Caribbean (Cuba, Haiti and Trinidad), South America (Brazil and Peru), Africa (Kenya, South Africa and Uganda), and Asia (China, India and Thailand). Development of public plans for HIV vaccine development, as one component of the response to AIDS, is an important contribution to providing leadership in this area and to facilitating public dialogue about relative priorities and resource allocations.

Funding is also essential for HIV vaccine development. Analyses of overall global investment in HIV vaccine development by several leading HIV vaccine policy groups place the world's effort in 2000 for HIV vaccines at approximately \$470 million<sup>24</sup> per year.<sup>25, 26</sup> This number may have doubled by 2003. But even with recent increases, the amount represents a small investment relative to total world spending on health, education and research. In the late 1990's, the world's combined gross national product (GNP) was valued at approximately \$30 trillion. Each year, approximately \$1,750 billion of this was spent for health, another \$1,750 billion for education, and \$71 billion for health research and development.<sup>27, 28</sup>

The small amount spent on HIV vaccine research and development reflects an overall under-investment in development of drugs and vaccines for diseases affecting poor countries. In total, less than \$3 billion is spent worldwide each year on health research and development for HIV, malaria, tuberculosis and other tropical diseases. High-income countries spend less than \$500 million annually on health research targeted specifically to poor countries. Middle and low-income countries, with 85 percent of the world's population, spend only about \$2.2 billion a year on health research, which is about three percent of the world expenditures. In the late 1990s, international development assistance contributed only about \$0.35 billion annually for health research and development.<sup>29</sup>

Aside from grants from the Bill and Melinda Gates Foundation, and private investment in five vaccine companies, nearly all of the current HIV vaccine development funding – including funding at the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Bank, and the International AIDS Vaccine Initiative (IAVI) – ultimately comes from national government sources. Only five private-sector vaccine companies invest more than \$5 million of privately raised funds each year: Merck, VaxGen, Aventis-Pasteur, Wyeth and Chiron. In total, the private, for-profit sector currently invests only about \$50-\$70 million per year in vaccine development, an amount that is supplemented by contributions of approximately \$25 million from national governments.

The largest national government HIV vaccine programs are those of Canada (Health Canada), France (Agence nationale de recherche contre le SIDA – ANRS), the Netherlands (Health Ministry), Sweden (Karolinska Institute), the United Kingdom (Medical Research Council – MRC), and the United States. The largest single source of funding for HIV vaccine research and development, by far, is the U.S. government, primarily through the National Institutes of Health (NIH) and the United States Agency for International Development (USAID). In total, the U.S. government invests approximately \$350 million

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<sup>24</sup> All funds in this report are in US\$.

<sup>25</sup> International AIDS Vaccine Initiative. *Accelerating the Development of an AIDS Vaccine for the World*. July 2001. Available on the website of IAVI at [www.iavi.org](http://www.iavi.org).

<sup>26</sup> Avrett S, Cappiello D, Collins C et al. *Six Years and Counting: Can a Shifting Landscape Accelerate an AIDS Vaccine?* Aids Vaccine Advocacy Coalition. Washington, DC: 2001. Available on the website of AVAC at [www.avac.org](http://www.avac.org).

<sup>27</sup> World Bank. *World Development Report 2000/2001*. Washington DC: 2001, tables 6-7.

<sup>28</sup> Neufeld V, MacLeod S, Tugwell P, Zakus D, Zarowsky C. The rich-poor gap in global health research: challenges for Canada. *Canadian Medical Association Journal*. 27 April 2001, 164 (8), pp. 1158-1159.

<sup>29</sup> OECD Development Assistance Committee. *Recent Trends in Official Development Assistance to Health* Geneva: OECD, November 2000.

annually,<sup>30</sup> accounting for more than three-quarters of all government spending and approximately two-thirds of the total worldwide investment.

Given the constraints of what philanthropy, private investors and for-profit companies can and will provide, most of the additional funding for HIV vaccine research will have to come from the national governments of high-income countries. National leaders can target increased national funding in several ways, including:

- increased national research agency funding to researchers and companies;
- increased international development funding to multilateral agencies such as the European Commission, the World Bank, and the WHO-UNAIDS HIV Vaccine Initiative;
- increased government funding for public-private partnerships (such as IAVI); and
- increased direct bilateral aid to low- and middle-income country governments to support HIV vaccine clinical trial infrastructure and vaccine delivery systems.

Increased funding for public-private partnerships can be used to replicate and expand existing partnerships and contribute to their efforts to engineer HIV vaccines for large-scale clinical evaluation; to build manufacturing capacity; and to leverage intellectual property arrangements for cooperation and access. Increased investment is also needed for clinical trial infrastructure in middle- and low-income countries. More than ten countries in the Caribbean, South America, Africa and Asia are conducting or planning HIV vaccine trials. They require new funding for health clinics, laboratories, storage facilities, trained medical personnel and technicians in order to provide quality primary health care and prenatal care. They require support for long-term volunteer cohorts. And they also need funding to help them build a national regulatory and ethical review capability that will ensure the highest quality of clinical trial design, one that will promote both scientific advancement and human rights.

### 3.2 Expand Public Involvement

Public input, involvement, and advocacy is critical to successful HIV vaccine development. In this context, the definition of “public” must include individuals who claim a wide range of affiliations, including public- and private-sector researchers, leaders of pharmaceutical and biotechnology companies, national government leaders, research trial participants, people living with HIV, local political leaders, religious leaders, business and labour union leaders, journalists, legal advocates, youth advocates, civil rights advocates, community educators, and local philanthropists and foundations.

Public mobilization is not simply about clinical trial implementation, but also about the broader process of vaccine development and access. The goals for public involvement in HIV vaccine development should be:

- increased **public understanding** about the basic concepts of HIV, public health, HIV prevention, vaccines, biomedical research and human rights;
- increased **public support** for HIV vaccine research, development and access, particularly through coalitions and partnerships that allow participation, information exchange, and ongoing communication, training and support; and
- increased **public participation** as measured by the inclusivity, diversity and dynamism of multisectoral involvement in HIV vaccine development collaborations and partnerships.<sup>31</sup>

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<sup>30</sup> A total of \$422 million is proposed for the U.S. NIH HIV vaccine programs in fiscal year 2003.

<sup>31</sup> These three goals were defined by a working group at the international expert consultation organized by the Canadian HIV/AIDS Legal Network in Montréal in April 2002.

A fundamental challenge to health in many parts of the world is the lack of individual understanding of, and community consensus on, basic standards and strategies for public health and human rights. Most of the world's population remains unaware or unconcerned about the imperatives of HIV prevention, vaccine delivery and access, and biomedical research for new health technologies. Simply advancing basic, clear and broad public understanding about these concepts could vastly accelerate the global effort for HIV vaccine research, development and access. Strategies for greater public understanding could include the following:

- developing user-appropriate materials on the basic concepts of HIV, public health, HIV prevention, vaccines, biomedical research and human rights;
- training, funding and partnering with experienced opinion leaders (such as political leaders, journalists, community advocates, research trial participants, researchers, government officials and company representatives) to support their efforts to communicate accurate information and to mobilize public support;
- supporting the capacity of potential and new opinion leaders to disseminate information and education; and
- integrating basic HIV vaccine information into all AIDS and public health messages.<sup>32</sup>

Vaccine education and advocacy materials already developed in Africa include:

- materials distributed by the WHO-UNAIDS HIV Vaccine Initiative as a result of community meetings held in Pretoria and Nairobi in 2000;<sup>33</sup>
- an African communications and media handbook contracted by UNAIDS;<sup>34</sup>
- a primer on vaccines published by ICASO and distributed through AfriCASO;<sup>35</sup>
- the IAVI Report distributed directly in Africa by IAVI,<sup>36</sup> and
- news articles produced through outreach and education among journalist networks in Nigeria<sup>37</sup> and Kenya.<sup>38</sup>

In the United States, national community educational materials include:

- regular publications by community groups such as the AIDS Vaccine Advocacy Coalition (AVAC);<sup>39</sup>
- recruitment materials published by VaxGen; and
- website information and bulletins published by the U.S. NIH and HIV Vaccine Trials Network (HVTN).<sup>40</sup>

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<sup>32</sup> This last item has been labeled by one ICASO vaccine advocate as an “A, B, C plus D” approach to HIV prevention, where “D” represents development of vaccines, microbicides, and other new technologies.

<sup>33</sup> Available on the UNAIDS website at [www.unaids.org/publications/documents/vaccines/vaccines/JC615-AAVP-E.pdf](http://www.unaids.org/publications/documents/vaccines/vaccines/JC615-AAVP-E.pdf).

<sup>34</sup> Adeyemi Y. African Media Handbook. Available on the UNAIDS website at [www.unaids.org/publications/documents/vaccines/vaccines/JC475-MediaHandb-E.pdf](http://www.unaids.org/publications/documents/vaccines/vaccines/JC475-MediaHandb-E.pdf).

<sup>35</sup> ICASO. *Developing Vaccines for HIV and AIDS: An Introduction for Community Groups* (2<sup>nd</sup> Edition). Available on the ICASO website at [www.icaso.org/vaccines/vaccineprimer.htm](http://www.icaso.org/vaccines/vaccineprimer.htm).

<sup>36</sup> Available on the IAVI Report at [www.iavi.org](http://www.iavi.org).

<sup>37</sup> Journalists Against AIDS. Available in the Nigeria-AIDS listserve archives at [www.nigeria-aids.org/eforum.cfm](http://www.nigeria-aids.org/eforum.cfm).

<sup>38</sup> For example, a journalist workshop was held in Kenya on HIV vaccines on 2-4 December 2001. The East African Standard ([www.eastandard.net](http://www.eastandard.net)) in particular has covered news related to HIV vaccine trials.

<sup>39</sup> Consult the AVAC web site at [www.avac.org](http://www.avac.org).

<sup>40</sup> HVTN. *The Community Advisory Board Bulletin* November 2001; vol 2, issue 10.

Most of these publications contain news about the planning and start of vaccine trials; details of basic trial protocols; updates on recruitment and retention; announcements of local and national meetings; and the perspectives of trial site community educators, trial participants and community members.

Even when information is provided, large-scale public support for HIV vaccine development will not automatically follow. Political leaders, people living with HIV, legal and civil rights advocates and religious leaders will not be instantly and spontaneously willing to step forward and embrace biomedical research. One reason for this relates to the vulnerability of many of the communities that most need HIV vaccines. Individual risk for HIV infection often corresponds to a lack of individual, social and economic power over one's health; and an absence or fragmentation of strong legal, political and social networks to support and discuss community health concerns. Other reasons include the political history of AIDS and of biomedical research in many countries and communities; the abstract and complex nature of HIV prevention, vaccine science and clinical research; and the fact that potential coalition partners – i.e., government officials, pharmaceutical company leaders, clinical trial site researchers and staff, research trial participants, political leaders, journalists and community advocates – often come from multiple social and economic strata and perspectives.

Public support for HIV vaccine development will depend on the creation of coalitions, partnerships, networks and alliances that facilitate stakeholder participation, information exchange, and ongoing communication, training and support. In turn, the success of these coalitions will depend on:

- the extent, diversity and dynamism of coalition membership;
- the degree to which coalitions are inclusive, participatory, and supportive in their activities and decision-making;
- the links that the coalitions develop with government officials, pharmaceutical company leaders, clinical trial site researchers and staff, and independent public opinion leaders (such as research trial participants, political leaders, journalists and community advocates); and
- plans and timelines for providing information, training and support that are clear and publicly available.

Coalitions can usefully inform, train and support their allies and partners to relay accurate information on:

- HIV vaccine development history, funding, products, research and trials, and access efforts;
- aspects of clinical trial design, including research recruitment and retention, informed consent protocols, risk-reduction protocols, and strategies to prevent social harms;
- models and strategies for integrating clinical trial plans and activities into ongoing community-based care settings, public health education efforts and HIV prevention efforts; and
- experimental vaccine products, proposed trial designs, and decision-making processes to license and deliver partially or fully effective vaccines.

Coalitions can also strengthen:

- community organizing strategies and skills;
- national policy and advocacy lobbying strategies and skills; and
- media and communications strategies and skills.

Successful coalitions, partnerships, alliances, and networks are already being developed. Examples include:

- ongoing work by the HVTN to support international working groups and community consultations related to clinical trials of HIV vaccines;

- ongoing work by the International Council of AIDS Service Organizations (ICASO) to create and support an international coalition of vaccine advocates to raise and address concerns about HIV vaccine development;
- ongoing work by AIDS Vaccine Advocacy Coalition (AVAC) to build a U.S.-based coalition in support of the global HIV vaccine effort;
- recent community workshops on HIV vaccines sponsored by the WHO-UNAIDS HIV Vaccine Initiative at regional AIDS meetings, including at the International Conference on AIDS in Asia and the Pacific (ICAAP) in Melbourne in October 2001, and at the International Conference on AIDS and STDs in Africa (ICASA) in Burkina Faso in December 2001; and
- meetings of the African AIDS Vaccine Programme in April and June 2002.

Broad public participation in the HIV vaccine development effort is also crucial. Public perceptions about HIV vaccine development will be enhanced wherever government officials, political leaders, researchers, research trial participants, journalists, community advocates and other leaders are publicly seated at the research table and clearly owning the process, while also maintaining their integrity as voices independent from any institutional interests and motivations.

Several models exist for public participation in vaccine development. One such model is the role played by the Australian Federation of AIDS Organizations (AFAO) in the Australian HIV Vaccine Consortium.<sup>41</sup>

Broadening participation in HIV vaccine development can be supported by strategies such as:

- strengthening the capacity of a broad range of people to participate in an informed way;
- developing structures and rules to ensure that new people can become involved in a meaningful way (such as membership guidelines and opportunities in vaccine development partnerships, clinical trial planning committees, and regulatory and ethical structures); and
- providing adequate incentives and support for sustained participation.

### **3.3 Ensure HIV Vaccine Development**

Private-sector, for-profit companies are indispensable to the effort to ensure development of HIV vaccines and other technologies in the world's poorest countries, particularly because they have the mission, structure and potential resources to bring new products to market as quickly and efficiently as possible. However, in HIV vaccine development, the private, for-profit sector is dissuaded by a combination of economic disincentives and opportunity costs, collectively (and dismally) called “market failure.” Few pharmaceutical companies are willing to risk hundreds of millions of dollars of investment in HIV vaccine research. In fact, given low profit margins, high volume production requirements and liability concerns related to vaccines, only a few large companies engage in any vaccine development and manufacturing. Hence, a laissez-faire approach to private-sector research and development will not result in the development of HIV vaccines suitable and accessible for use in the developing world in a reasonable timeframe.<sup>42</sup>

Total annual global investment by all companies in HIV vaccine development is probably less than \$150 million. Private-sector investment in HIV vaccine development is influenced by:

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<sup>41</sup> Presented by Robin Gorna of AFAO at the October 2001 ICAAP in Melbourne, Australia.

<sup>42</sup> Ainsworth M. et al. *Accelerating an AIDS vaccine for developing countries: Recommendations for the World Bank*. World Bank AIDS Vaccine Task Force, 2000. Available on the website of the International Academy of Chiropractic Neurology at [www.iacn.com](http://www.iacn.com).

- the anticipated costs of research and development;
- the anticipated costs of vaccine production;
- the anticipated demand for an HIV vaccine;
- expectations about pricing; and
- the opportunity costs of HIV vaccine development relative to other products.

Many strategies for increasing investment in HIV vaccine development have been advanced by industry, and by IAVI,<sup>43, 44</sup> the AIDS Policy Research Center of the University of California San Francisco (UCSF)<sup>45</sup> and AVAC. Most of these strategies focus on Europe and North America, where most of the major vaccine companies (Aventis-Pasteur, Chiron, GlaxoSmithKline, Merck and Wyeth) are based. Four of the major strategies that have been proposed are:

- direct government funding of private-sector vaccine development;
- research tax credits for private-sector vaccine development;
- public-private partnerships; and
- direct government sponsorship of research and development.

Each of these strategies is described below.

### **3.3.1 Direct Government Funding of Private-Sector Vaccine Development**

As of 2002, about a dozen pharmaceutical and biotechnology companies were involved in HIV vaccine development. Only about half of these companies use their own money to fund their HIV vaccine programs; this money comes from other product revenue or from private investors. Only one or two companies engage in HIV vaccine development work without any government funding. Both governments and IAVI promote private-sector investment through direct contracting. The NIH in the United States is now the world's most significant direct funder of private-sector HIV vaccine development.<sup>46</sup> IAVI acts as a mechanism to channel government funding for vaccine development, passing funding from the national governments of the United States, United Kingdom, Netherlands, Canada, Denmark, Ireland and Norway through to industry partners such as AlphaVax, Berna Biotech, Cobra Pharmaceuticals, IDT, Targeted Genetics and Therion.<sup>47</sup> Both the NIH and IAVI link their funding to pricing or intellectual property provisions in order to maximize the sharing of technological innovation and progress. They are able to do this while allowing each company enough ownership of products and technologies to provide the prospect of reasonable return on its own investment.

### **3.3.2 Research Tax Credits for Private-Sector Vaccine Development**

Research tax credits are an incentive aimed at enhancing the attractiveness of HIV vaccine research as an investment option. They are a familiar legislative option and policy tool. They also have a track record of success, with at least one study showing that a 10 percent decrease in the cost of research and

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<sup>43</sup> Widdus R. *AIDS vaccines for the world: preparing now to assure access*. New York, IAVI, July 2000. Available on the IAVI website at [www.iavi.org](http://www.iavi.org).

<sup>44</sup> Madrid Y. *A new access paradigm: public sector actions to assure swift, global access to AIDS vaccines*. New York: IAVI, June 2001. Available on the IAVI website at [www.iavi.org](http://www.iavi.org).

<sup>45</sup> Collins C and Morin S. *The policy of AIDS vaccines: exploring legislative options for advancing AIDS vaccine research and delivery*. San Francisco: UCSF, April 2001. Available on the UCSF Internet site at <http://hivinsite.ucsf.edu>.

<sup>46</sup> Reported on the NIAID vaccine website at [www.niaid.nih.gov/vrc/](http://www.niaid.nih.gov/vrc/) and summarized in the AVAC report *Six Years and Counting*, available on the AVAC website at [www.avac.org](http://www.avac.org). NIH contracts are awarded to more than 20 companies, including major vaccine companies such as Wyeth and Chiron.

<sup>47</sup> Reported on the IAVI web site at [www.iavi.org](http://www.iavi.org).

development causes more than a 10 percent increase in private-sector research and development in the long term.<sup>48, 49</sup>

Tax credits for HIV vaccine research and development should be modeled on, and incremental to, general tax credits for research and development, such as the Canadian Scientific Research and Experimental Development (SR&ED) tax incentive, the U.S. 1981 Research and Experimentation (R&E) Tax Credit, and tax credits within the U.S. 1983 *Orphan Drug Act*.<sup>50</sup> The ideal of supplementary tax credits specific to HIV and other diseases was endorsed in December 2001 by the Commission on Macroeconomics and Health.<sup>51</sup>

Research tax credit legislation has been proposed in the U.S. for 2003. It will call for a 30 percent tax credit on all research and development of vaccines for malaria, TB, HIV and other diseases that kill more than one million people annually, above and beyond the existing R&E Tax Credit.<sup>52</sup> This proposed legislation would enable smaller biotechnology firms to pass through a 20-25 percent tax credit to equity investors who provide new financing for this research and development.

### 3.3.3 Public-Private Partnerships

Public-private partnerships are an attractive way of encouraging otherwise neglected health research.<sup>53</sup> In the field of HIV vaccine development, several institutions, including IAVI, the NIH and the U.S. Military HIV Research Program, the South African AIDS Vaccine Initiative (SAAVI) and the French ANRS have created successful models for public-private partnerships. Two such models have been developed by (a) the NIH Institute of Allergies and Infectious Diseases (NIAID), which has major contracts with two companies, Chiron and Wyeth; and (b) the NIH Vaccine Research Center (VRC), which has contracts with two other companies, Vical and GenVec.

IAVI has created product-specific partnerships, linking private-sector vaccine developers with academic research facilities and clinical trial sites. The goal is to rapidly develop HIV vaccines for clinical evaluation in both high- and low-income countries. In each of these IAVI-sponsored partnerships, intellectual property and technology transfer agreements have been negotiated with all partners. These agreements state that if a vaccine is determined to be effective and licensable, and if the patent-owning partners decide not to license and produce that vaccine for use in particular countries or markets, the license for the vaccine can be made available to other manufacturers for those countries and markets. IAVI has now established five vaccine development partnerships:<sup>54</sup>

- a Kenya/Oxford partnership, linking the U.K. Medical Research Council and the University of Nairobi with vaccine manufacturing firms, Cobra Pharmaceuticals (U.K.) and IDT (Germany);
- a South Africa/AlphaVax partnership, linking South Africa's University of Cape Town, National Institute of Virology and Medical Research Council with the U.S.-based biotechnology company, AlphaVax;

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<sup>48</sup> Bloom N, Griffith R, van Reenan J. *Do R&D tax credits work? Evidence from an international panel of countries 1979 – 1994*. London: Institute for Fiscal Studies, 1998, IFS Working Paper Number W99/08.

<sup>49</sup> Warda J. Measuring the Value of R&D Tax Treatments in OECD Countries. *STI Review* 2002; 27: 184-206.

<sup>50</sup> Country-specific analyses of these general tax credits can be found for Canada in a 1996 evaluation on the website of the Department of Finance at [www.fin.gc.ca/resdev/fedsys\\_e.html](http://www.fin.gc.ca/resdev/fedsys_e.html); and for the U.S. R&E Tax Credit in a 1999 Congressional Research Service memorandum on the website of Congress at [www.house.gov/berry/prescriptiondrugs/resources/crs\\_pharm\\_tax\\_memo.pdf](http://www.house.gov/berry/prescriptiondrugs/resources/crs_pharm_tax_memo.pdf).

<sup>51</sup> Commission on Macroeconomics and Health. December 2001 Report. Action Recommendation 6.

<sup>52</sup> Communication with AIDS Vaccine Advocacy Coalition (AVAC).

<sup>53</sup> Reich MR. Public-Private Partnerships for Public Health. *Nature Medicine*, vol. 6, no. 6, June 2000.

<sup>54</sup> Email announcements by IAVI, archived on the IAVI website at [www.iavi.org](http://www.iavi.org).

- a South Africa/Targeted Genetics partnership, linking the U.S. Children's Research Institute and several clinical trial sites in South Africa and East Africa with the U.S.-based biotechnology company, Targeted Genetics Corporation;
- a Uganda/IHV partnership, linking the Ugandan Virus Research Center, the Institute of Human Virology at the University of Maryland and the University of Oxford with the Swiss biotechnology company, Berna Biotech; and
- an India/Therion partnership, linking India's Ministry of Health and Family Welfare, and the Indian Council for Medical Research with the US biotechnology company, Therion.

### 3.3.4 Direct Government Sponsorship of Research and Development

Public funding for basic research, initial vaccine design and development, and clinical trials infrastructure provides a useful balance to private-sector efforts, and can act as an incentive for the private sector by producing inventions and innovations that industry can use. Unlike industry, which is generally focused on time- and cost-limited outcomes related to profit, government research agencies can afford to be responsive to the public health interest and to less-focused goals related to the advancement of scientific knowledge.

Government research agencies have demonstrated a capacity to directly develop vaccines, such as when the publicly-funded NIH developed conjugate vaccines against *Hemophilus influenzae* type b (Hib) and *Staphylococcus aureus*.<sup>55</sup> National government investment also helps industry to facilitate vaccine development by enhancing global research capacity and clinical trials infrastructure. For example, hundreds of academic research centres around the world (such as the Uganda Virus Research Center, the University of Cape Town, and the University of Nairobi) have built their research capacity over time with resources from their own governments and with public funding from Europe and North America. Clinical trial sites, such as those sponsored by the Bangkok Municipal Authority and Mahidol University, are also supported and developed with resources from national governments and from U.S. and European government research agencies.

## 3.4 Ensure HIV Vaccine Access

Providing access to vaccines currently available for diseases other than HIV infection continues to be a global challenge. Although vaccination programs have been able to reach into war-torn and remote communities to eliminate diseases such as polio, international health agencies still struggle to support high rates of vaccination against most diseases throughout the world. Providing access to HIV prevention and treatment interventions will also continue to be a global challenge. Access to antiretroviral therapy for prevention of mother-to-child transmission, access to sterilized injection equipment, access to AIDS diagnostics and treatments, and access to health care and STD treatment, remain elusive.

The successes and experiences of AIDS treatment advocacy and HIV vaccine advocacy are linked. HIV treatment advocates continue to create new models for policy work on issues such as public involvement in biomedical research, access to experimental products, and national and international regulatory review and licensure of new products. AIDS treatment advocates are currently demonstrating success in using the law to improve access to essential medicines and health technologies. Current policy work (including legal analysis and advocacy) to make AIDS drugs and other treatments accessible to the world's poorest countries while allowing companies to recoup their costs and satisfy their shareholders, will pave the way for future pricing and distribution of vaccines and microbicides.

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<sup>55</sup> More information can be found on the U.S. NIH web site at [www.nichd.nih.gov/new/releases/cviawar2.cfm](http://www.nichd.nih.gov/new/releases/cviawar2.cfm) and at [www.nih.gov/news/pr/feb2002/nichd-13.htm](http://www.nih.gov/news/pr/feb2002/nichd-13.htm).

Possible strategies to help ensure HIV vaccine access include the following:

- addressing intellectual property and trade issues;
- influencing the global demand for HIV vaccines;
- tax credits for the sale of HIV vaccines;
- differential pricing;
- establishing liability compensation funds; and
- improving the infrastructure for vaccine delivery.

Each of these strategies is described below.

### **3.4.1 Intellectual Property and Trade Issues**

Patents and intellectual property laws, trade laws and regulatory structures – all of which allow inventors to own, sell, and profit from their inventions – are a powerful incentive for development of new technology, public dissemination of innovation, and technology transfer. International standards for intellectual property protection already exist in the joint agreements of the member states of the World Trade Organization (WTO).<sup>56</sup> These standards are intended to facilitate both the ownership of inventions for profit and public dissemination of those inventions, so that innovation is shared and applied. Legal frameworks for intellectual property have been generally successful in promoting eventual public access to innovation.<sup>57</sup>

Nevertheless, potential HIV vaccine producers face vaccine licensing processes and patent protections that vary from country to country; shifting rules and costs for the importation and sale of vaccines; and inconsistent national guidelines for vaccine delivery. Where more than one vaccine technology is involved in a collaborative research effort, companies also face potential disputes with other companies. Vaccine producers, including public and private manufacturers in poorer countries, would benefit from a more predictable playing field that provides incentives to meet public health needs. Global frameworks for licensing, intellectual property law and trade law related to HIV vaccines should be developed to ensure rapid HIV vaccine delivery.

Addressing international standards through the WTO is likely to be slow due to the intersection of interests from all types of pharmaceutical products and products in the agriculture, chemical and food industries. Two alternate models exist for addressing intellectual property in the context of HIV vaccines. One is a product-by-product approach, such as that used by IAVI, to establish intellectual property agreements that try to ensure eventual global access to future HIV vaccines, vaccine technologies and research data. The second is a country-by-country approach that harmonizes and supports improvements to trade law, regulatory review and intellectual property rights protection on a multilateral basis (such as within the European Union) or on a bilateral basis (such as between India and the United States).<sup>58</sup>

### **3.4.2 Global Demand for HIV Vaccines**

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<sup>56</sup> World Trade Organization. *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the “TRIPS Agreement”), Article 7.

<sup>57</sup> UN General Assembly. Resolution S-24/2, *Further Initiatives for Social Development*. July 2000: Part III, Articles 12, 101. Includes acknowledgment of the role of intellectual property on research and access.

<sup>58</sup> As one example of potential action, in March 2002, U.S. legislation was drafted to provide the Food and Drug Administration (FDA) with \$2 million to begin new technical assistance and partnerships with regulatory agencies in resource-limited countries to build regulatory capacity related to research on life-saving biomedical technologies. Reported on the website of AVAC at [www.avac.org](http://www.avac.org).

Pooled demand for vaccines from the Global Alliance for Vaccines and Immunizations (GAVI), which obtains vaccines for 74 low- and middle-income countries, constitutes one of the largest single sources of international vaccine demand.<sup>59</sup> The success of GAVI's efforts will have a major bearing on the extent to which major vaccine companies invest in HIV vaccines for the world. While companies are unlikely to make any profit from large-scale GAVI purchases of HIV vaccines, the promise of even a minimal cost-return on the production of millions of vaccine doses will enable companies to plan to provide such large amounts, and thus produce vaccines in sufficient quantities to supply most of the world. High-income countries should be providing or promoting direct funding for GAVI to ensure the success of its efforts.

National government purchase of HIV vaccines will also constitute an important part of company vaccine revenues, and thus contribute to the capacity of industry to supply the world. As the recent history of other vaccines has shown, national demand for HIV vaccines is not guaranteed.<sup>60, 61, 62</sup> Government demand for HIV vaccines will be influenced by a number of factors, notably:

- public health recommendations by committees advising the health ministries – such as the Brazilian National Advisory Committee on Immunizations; the National Advisory Committee on Immunization (NACI) in Canada; the Technical Committee of Vaccination (CTV) in France; the Medical Council of India; the Medicines Control Council of South Africa; the Joint Committee on Vaccines and Immunisation in the U.K.; and the Advisory Committee on Immunization Practices (ACIP) in the U.S.;
- the opinions of public health professionals about the scientific data on efficacy of the HIV vaccine;
- the perceived impact of vaccination strategies on HIV infection and disease;
- safety and moral concerns related to infant and adolescent vaccination against AIDS;
- the views of officials on the importance of addressing AIDS in their countries;
- general public opinion and politics related to AIDS;
- issues of nationalism as they relate to the vaccine design, to manufacture, to research data, and to the approval process for new drugs; and
- political expediency in relation to all of the above.

The importance of these factors points to the need:

- to educate the committees that advise health ministries;
- to inform and educate health professionals about data and potential implementation of HIV vaccine schedules; and
- to develop evidence-based guidelines for use of HIV vaccines.

The private, retail market, where national licenses can be obtained and where individuals and health care providers are able and willing to pay, might be the source of highest potential marginal profit for HIV vaccine manufacturers. The willingness and ability of individuals, providers and health care systems to pay for HIV vaccines is not certain. It will be influenced by the same politics concerning vaccine safety

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<sup>59</sup> See GAVI December 2001 newsletter on the GAVI website at [www.vaccinealliance.org/newsletter/dec2001/report.html](http://www.vaccinealliance.org/newsletter/dec2001/report.html).

<sup>60</sup> WHO position paper on Haemophilus influenzae type B conjugate vaccines, available on the WHO website at [www.who.int/vaccines](http://www.who.int/vaccines) ; and WHO updated fact sheet, available at [www.who.int/vaccines-documents/DoxGen/H4-Inno.htm](http://www.who.int/vaccines-documents/DoxGen/H4-Inno.htm).

<sup>61</sup> Miller M. and McCann L. Policy analysis of the use of hepatitis B, Haemophilus influenzae type B, streptococcus pneumoniae conjugate and Rotavirus vaccines in national immunization schedules. *Health Economics*, January 2000.

<sup>62</sup> Reported on the GAVI website ([www.vaccinealliance.org](http://www.vaccinealliance.org)).

and infant and adolescent vaccination that have continued to plague vaccination campaigns throughout Western Europe and North America.<sup>63</sup> Individual retail demand for HIV vaccines might also be different from demand for other vaccines because of the specific populations at greatest risk for HIV and the political history of HIV in many countries. Unlike diseases such as Lyme disease, hepatitis B, or hepatitis A, HIV infection remains stigmatised and connected to issues of morality. Perceptions of, and demand for, HIV vaccines that have been developed by governments and private companies will be affected by the attitudes of vulnerable communities towards public health authorities and public institutions. Public health recommendations for the use of HIV vaccines will have to be augmented by extensive work with media and AIDS advocates to avoid controversy and contradictory messages about new HIV vaccines.

### **3.4.3 Tax Credits for the Sale of HIV Vaccines**

Sales tax credits could accelerate the invention and production of vaccines for distribution in low-income countries. These credits are an incentive that could be used primarily for companies that have substantial overall revenues and that intend to manufacture and sell HIV vaccines on a large scale (i.e., currently the five major vaccine companies, Aventis-Pasteur, Chiron, GlaxoSmithKline, Merck and Wyeth). Sales tax credits have been included in 2002 US tax legislation proposals.<sup>64</sup> The proposed tax credits would apply to future sales of vaccines for malaria, tuberculosis, and HIV/AIDS or any infectious disease killing more than one million people annually. The proposed tax credits would be 100 percent, providing an incentive of a dollar of tax credit for every dollar's worth of qualifying vaccine sold to a qualifying organization. This could represent as much as \$1 billion of additional funding for future vaccine purchases.

### **3.4.4 Differential Pricing**

Differential pricing – also referred to as “tiered pricing,” “equity pricing,” or “preferential pricing” – refers to the practice of offering very low vaccine prices for poor countries to ensure access for their populations, while keeping vaccine prices high enough elsewhere to enable manufacturers to obtain a return on their investment. Differential pricing for vaccines already exists. Prices for pediatric vaccines for low-income countries can be as low as one to five percent of the prices for the same vaccines in high-income countries. GAVI and the United Nations Children’s Fund (UNICEF) succeed in getting these low prices from vaccine manufacturers through large volume (tens of millions of doses), bundled purchases of combination vaccines and through multi-year purchase guarantees.<sup>65</sup> Assuming that the same systems are used for negotiating and purchasing HIV vaccines, it is likely that the global pricing structure for HIV vaccines would be similar. The challenge of differential pricing for HIV vaccines will be to create advocacy and tolerance in high-income countries for higher vaccine prices, and for policies that support rigid market segmentation to prevent resale of low-priced vaccines from one country to another. One possible strategy for meeting this challenge is to create mechanisms to make price differences less apparent, such as sale-donation combinations.<sup>66</sup>

### **3.4.5 Liability Compensation Funds**

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<sup>63</sup> Reported on the website of the Immunization Action Coalition at [www.immunize.org/genr.d/vaxsafe.htm](http://www.immunize.org/genr.d/vaxsafe.htm).

<sup>64</sup> *The Vaccines for the New Millennium Act*. 107<sup>th</sup> Congress. First Session. s 895. Available on the website of The Orator.com at [www.theorator.com/bills107/s895.html](http://www.theorator.com/bills107/s895.html).

<sup>65</sup> Children’s Vaccine Initiative. *CVI Forum: Special Vaccine Industry Issue*. 1996; Number 11.

<sup>66</sup> Vaccine sale-donation combinations are already used to support low-cost vaccine access by poor countries; one example is an Wyeth donation of 10 million doses of Hib conjugate vaccine to GAVI, announced in 2000 on the Internet of the State Department at <http://usinfo.state.gov/regional/af/usafir/t0030202.htm>.

Liability for vaccine-related injury is a disincentive for HIV vaccine development in the major markets of the North America and Western Europe. Legal battles are generally initiated under product liability and consumer protection laws. Recent examples of vaccine liability as a disincentive include:

- a 1992 decision by the U.K. Department of Health to stop using a SmithKline Beecham measles-mumps-rubella (MMR) vaccine after an escalation of lawsuits;
- a January 2002 U.K. class action lawsuit initiated over possible side effects from similar MMR vaccines produced by Aventis Pasteur, GlaxoSmithKline and Merck; and
- a February 2002 decision by GlaxoSmithKline to end production of Lyme disease vaccine amid sagging demand and hundreds of lawsuits from people alleging vaccine side effects.

In the last case, the Lyme disease vaccine, given in three doses and provided to hundreds of thousands of people, had undergone additional safety review by the U.S. Centers for Disease Control, which reported in January 2002 that a review of 905 reports of side effects showed no unusual or unexpected problems.<sup>67</sup>

Vaccine-related liability has been addressed in these countries largely through legislated compensation funds, such as those established through the 1979 U.K. *Vaccine Damage Payments Act* and the 1986 U.S. *National Childhood Vaccine Injury Act*. These funds are paid for through an excise tax on vaccines. They provide a no-fault alternative to the tort system to compensate claims of adverse vaccine reactions, thus shielding vaccine companies from liability and litigation as an incentive to ensure supply. In 2002, in both the U.K. Parliament and the U.S. Congress, there were debates about the need to revisit the funds' compensation amounts, threshold requirements for proof of harm, and other eligibility criteria.<sup>68</sup> Nevertheless, work should proceed now to add HIV vaccines to the list of vaccines that are covered by these funds.

### 3.4.6 Vaccine Delivery Infrastructure

As companies become able and willing to manufacture and supply HIV vaccines for the world, a key factor in facilitating global access will be the capacity of national delivery systems to reach people at risk for HIV and AIDS.<sup>69</sup> To pave the way for the delivery of HIV vaccines, all countries should develop national health programs that can reach adolescents and young adults with public health vaccines (such as hepatitis A and B vaccines), STD screening and education, and credible HIV prevention, treatment, and care strategies. Ways to do this could include:

- establishing programs to administer vaccines, STD education and screening, and credible HIV prevention, treatment, and care through existing institutions – not only through public and private health care systems, but also through schools, the military, workplace, churches and missions, and NGOs. These programs should include education and training of personnel, and quality assurance monitoring. The goal should be to create vaccination programs with a surrounding context of health education and health care;
- creating vaccination and public health education and screening requirements linked to school enrollment, military service, employment, food assistance or maternity and childcare assistance; and

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<sup>67</sup> Reuters news release, 26 February 2002, at [http://biz.yahoo.com/rf/020226/n26120004\\_1.html](http://biz.yahoo.com/rf/020226/n26120004_1.html).

<sup>68</sup> For the UK, see the government website at [www.cabinet-office.gov.uk/regulation/act/proposals.htm](http://www.cabinet-office.gov.uk/regulation/act/proposals.htm). In the U.S., the debate is centered in the House Energy and Commerce Committee among Reps. Burton, Weldon, and Waxman.

<sup>69</sup> Brugha, *Lancet* 2 February, 2002. In this February 2002 article in *Lancet*, researchers from the London School of Hygiene and Tropical Medicine suggest the success of GAVI's vaccine distribution in 52 countries correlated strongly to the strength of pre-existing capacity and health infrastructure in those countries.

- supporting vaccination and other public health campaigns with communications efforts and data collection to build popular and political commitment (such as national vaccination days or national campaigns with set targets for the numbers and percentages of people vaccinated).

Specific delivery systems cannot be developed for HIV vaccines until the major parameters of those vaccines are known – parameters such as their protective effect against infection and disease, their level of efficacy, the number of required doses, the duration of protection, the route of administration, refrigeration requirements and cost. However, GAVI and its multilateral partners (the WHO, UNICEF, the United Nations Population Fund, and the World Bank) have worked with national public health systems to create new national health programs reaching adolescents and young adults with sound HIV prevention, treatment and care strategies. These systems can be implemented now in countries around the world, and a specific HIV vaccine strategy can be added in later.

## 4 A Framework for Action

This section outlines specific actions that should be considered to achieve the four imperatives described in Section 3.

### 4.1 Ensure Commitment to HIV Vaccine Development

Successful HIV vaccine development and access will require a coordinated and concerted global effort over the next ten years and beyond. Achieving and sustaining this effort will involve defining responsibilities, resources and implementation timeframes; and creating mechanisms for accountability and coordination. Commitments and milestone-driven strategies are needed at all levels and from all sectors.

Commitments by national governments, through national plans and specific funding targets, are particularly important to the global HIV vaccine effort. National plans are especially needed in all of the countries now engaged in HIV vaccine development. These plans should cover strategies and timelines for: preclinical and clinical research; vaccine development and manufacture; regulatory review and approval of new clinical research and new vaccines; field safety and effectiveness research; and public health use and accessibility of vaccines. Specific, increased funding targets are needed, particularly for national governments of high-income countries.

To obtain increased commitment and funding, vaccines advocates should consider the following potential actions:

1. Define and compare models for national HIV vaccine plans. This would involve research and consultations on, and analysis of:
  - experiences in initiating national planning;
  - processes and resources for developing and finalizing national plans;
  - models for participation and transparency in national plan development;
  - specific components and the language of national plans;
  - the degree of enforceability of, and accountability to, tasks, timelines and lines of responsibility; and
  - anecdotal and quantitative evidence of the positive impact of plans.
2. Define and compare models for national funding of HIV vaccine development. This would involve research and consultations on, and analysis of:
  - current and ideal levels of HIV vaccine-related funding at large national research agencies such as the U.S. NIH, the Japanese National Institutes of Health, the French ANRS, and the U.K. MRC;
  - current and ideal levels of funding from national governments to HIV vaccine-related programs at multilateral agencies such as the European Commission, the World Bank, the WHO and UNAIDS;
  - current and ideal levels of funding from national governments to public-private partnerships (such as IAVI); and
  - current and ideal levels of direct bilateral funding from national governments in high-income countries to governments in low and middle-income countries to support HIV vaccine clinical trial infrastructure; technology transfer for HIV vaccine research,

development, and manufacture; regulatory and ethical review capacity; and public health infrastructure for vaccine delivery.

3. Work at a national level to propose and expand national plans and funding commitments. This would involve meeting with policy-makers and decision-makers to propose models, options and targets; and building national coalitions to support expanded national plans and funding commitments.

## 4.2 Expand Public Involvement

The HIV vaccine effort now involves more than 25 national governments and dozens of communities, private-sector companies, research institutions, and other local, national and international agencies. Once developed, HIV vaccines may be licensed and used in every part of the world. The effort for HIV vaccine development and access is therefore global, long-term and complex. Energy and expertise from many sectors are needed to ensure that HIV vaccines development and access is supported, coordinated, and locally relevant. A wide range of input and perspectives is also needed to ensure that the development and use of HIV vaccines is done in a context of achieving broad public health and human rights goals.

To obtain expanded public involvement in HIV vaccine development, vaccine advocates should consider the following potential actions:

1. Define and compare models for public understanding, support and participation. This would involve research and consultations on, and analysis of:
  - best-practice programs, strategies and tools to increase public understanding about HIV vaccine development. This would include models for educational methods, materials and networks to support dialogue and learning about basic concepts of HIV, public health, HIV prevention, vaccines, biomedical research and human rights. This would also include some compilation of helpful materials already in use;
  - best-practice strategies to build public support for HIV vaccine research, development, and access. This would also include the description of current successes by all sectors, including government, industry and civil society. Such successes include:
    - models of transparent and accessible networks that allow individuals who could support the HIV vaccine to have ongoing access to information and dialogue; and
    - models of coalitions across geographic, professional and institutional affiliations, and across gradients of social and economic power.
  - current models to ensure public participation in HIV vaccine research and development, such as bylaws and guidelines governing membership and participation in clinical trial planning committees, vaccine development partnerships, and ethical and regulatory review committees.
2. Build public understanding by working at a local, national, and international level:
  - to develop and disseminate user-appropriate materials about basic concepts of HIV, public health, HIV prevention, vaccines, biomedical research and human rights;
  - to train, fund and partner with experienced opinion leaders – such as political leaders, journalists, community advocates, research trial participants, researchers, government officials and company representatives – to ensure that they accurately understand current HIV vaccine issues, and to support their efforts to communicate accurate information and mobilize positive public attention;

- to support the capacity of potential and new opinion leaders to disseminate information and education about HIV vaccine development and broader issues of public health; and
  - to integrate basic HIV vaccine information into general AIDS and public health messages.
3. Build public support by advocating with governments, industry, community organizations and other institutions to create and expand networks at a local, national and international level that can:
- provide information about HIV vaccine development history, funding, products, research, development and access efforts;
  - provide information about aspects of clinical trial design, including research recruitment and retention, informed consent protocols, risk-reduction protocols and strategies to prevent social harms;
  - support integration of clinical trial planning, recruitment and education into ongoing community-based care settings, public health education efforts and HIV prevention efforts;
  - support information and dialogue about experimental vaccine products, proposed trial designs, and decision-making processes for efficacy testing, licensure and delivery of vaccines;
  - support community organizing strategies;
  - support national lobbying and advocacy strategies; and
  - support media and communications strategies.
4. Build public participation by working at a local, national, and international level:
- to improve bylaws and guidelines governing membership and participation in clinical trial planning committees, vaccine development partnerships, and ethical and regulatory review committees in order to allow new people to become involved in a meaningful way; and
  - create adequate incentives and support for initial and sustained participation.

### **4.3 Ensure HIV Vaccine Development**

A laissez-faire approach to private-sector research and development is not sufficient for timely development of HIV vaccines suitable and accessible for use in the developing world. Private-sector, for-profit companies could invest unique expertise and resources for HIV vaccine development, but are dissuaded by economic disincentives and opportunity costs. Governments need to take steps:

- to encourage direct government funding of private-sector HIV vaccine development;
- to enact research tax credits for private-sector HIV vaccine development;
- to support public-private partnerships focused on HIV vaccine development; and
- to increase government funding of research, development and delivery infrastructures.

To ensure HIV vaccine development, vaccines advocates should consider the following potential actions:

1. Define and compare models and current efforts for accelerating research and development of HIV vaccines and other new public health technologies. This would involve research, consultations and analysis to identify:

- the current plans, funding sources, contract mechanisms, amounts, destinations and deliverables of direct government funding for private-sector vaccine development. Assessment could be focused on the best-practice experiences of major national research agencies such as the U.S. NIH, Health Canada, the French ANR, the Japanese NIH and the U.K. MRC, and on the perspectives and experience of the private-sector companies involved in partnering with these agencies;
  - the proposed language and current status and prospects of research tax credits for private-sector HIV vaccine development;
  - the current models for public-private partnerships in HIV vaccine development, and the successes and challenges experienced by those partnerships; and
  - the current plans, funding sources, contract mechanisms, amounts, destinations and deliverables of direct government funding for research, development and access. For example, an assessment could focus on the successes and challenges reported by major national research agencies and researchers concerning funding of basic science research, targeted pre-clinical research and product development, clinical trials and clinical trial infrastructure, and vaccine manufacturing capacity.
2. Work at a national level to propose and expand best-practice models. This would involve meeting with policy-makers and decision-makers to propose new initiatives and targets. It would also involve building networks to support the creation and expansion of:
- direct government funding of private-sector HIV vaccine development;
  - research tax credits for private-sector HIV vaccine development;
  - public-private partnerships focused on HIV vaccine development; and
  - government funding of research, development and delivery infrastructures.

#### **4.4 Ensure HIV Vaccine Access**

Fundamental to the goal of HIV vaccine development is the future accessibility and use of HIV vaccines. Access and use will be determined by global demand and by the capacity to supply the product. Improvements today in access to vaccines, medicines, and other health interventions can lay the foundation for future access to HIV vaccines. Governments need to take steps now:

- to address intellectual property rights, international trade law and regulatory systems in order to increase access to new health technologies, while maintaining adequate health and human rights protections and incentives for private-sector invention and product development;
- to increase global demand for vaccines;
- to expand sales tax credits, liability compensation systems and support for differential pricing for future HIV vaccines; and
- to improve infrastructures for vaccine delivery.

To ensure access to HIV vaccines when they become available, vaccines advocates should consider the following potential actions:

1. Document and compare models and current efforts to ensure that developing countries fully share in the scientific achievement and benefits of new HIV vaccines and other health technologies. This would involve research and consultations on, and analysis of:
  - the international environment for HIV vaccine-related inventions and ownership, including a review of current HIV vaccine-related patents;

- the environment and contractual arrangements for vaccine licensure, trade and technology transfer, including arrangements in vaccine development efforts to ensure sub-licensing and local manufacture to provide access to potential HIV vaccines;
  - standards and models for international and national vaccine procurement, distribution, delivery and access, including progress of current global vaccine programs such as GAVI;
  - the current literature and estimates of potential demand for HIV vaccines;
  - the proposed language and current status and prospects of vaccine-related sales tax credit legislation, liability compensation legislation and legislative initiatives to demonstrate support for global differential pricing; and
  - challenges and successful models in the delivery of new vaccines throughout the world.
2. Work at a national and international level to propose and expand best-practice models. This will involve:
- meeting with policy-makers and decision-makers to propose new initiatives and targets; and
  - building networks to support the creation and expansion of:
    - proposals within intellectual property rights law, international trade law and regulatory systems to increase access to new health technologies, while maintaining adequate health and human rights protections and incentives for private-sector invention and product development;
    - national and international initiatives related to global demand for vaccines;
    - expansion of sales tax credits, liability compensation systems and support for differential pricing for future HIV vaccines; and
    - improved infrastructures for vaccine delivery.

## 4.5 Conclusion

It is clear that governments and other stakeholders must move forward on several fronts if an effective and accessible HIV vaccine is to become a reality. The strategies and actions advanced in this paper should be reviewed and prioritized. Whatever strategies and actions are adopted, vaccine advocates will need to work at a national level to monitor and hold governments and other stakeholders accountable. This will involve regularly documenting progress toward milestones and funding targets, and proposing remedies and action through meetings, reports and other advocacy.

## 5 Resources

This section contains (a) information on organizations that sponsor national meetings on HIV vaccine research and access; (b) a list of international meetings slated for 2003; and (c) a list of websites of organizations working on these issues (along with a brief description of each website).

### 5.1 Organizations

Local and regional meetings and workshops are organized on a continual basis by the following organizations. Consult the website listed for updated information.

**African AIDS Vaccine Programme (AAVP)**

[www.who.int/hiv-vaccines](http://www.who.int/hiv-vaccines)

**Commission on Macroeconomics and Health**

[www.cmhealth.org](http://www.cmhealth.org)

**Harvard AIDS Institute**

[www.aids.harvard.edu](http://www.aids.harvard.edu)

**HIV Vaccine Trials Network (HVTN)**

[www.hvtn.org](http://www.hvtn.org)

**Institute of Human Virology (IHV)**

[www.ihv.org](http://www.ihv.org)

**International AIDS Vaccine Initiative (IAVI)**

[www.iavi.org/events\\_z\\_conferences.html](http://www.iavi.org/events_z_conferences.html)

**International Council of AIDS Service Organizations (ICASO)**

[www.icaso.org](http://www.icaso.org)

**National Minority AIDS Council (NMAC)**

[www.nmac.org](http://www.nmac.org)

**Pan American Health Organization (PAHO)**

[www.paho.org](http://www.paho.org)

**U.S. National Institutes of Health**

[www.niaid.nih.gov/daids/vaccine/meetings.htm](http://www.niaid.nih.gov/daids/vaccine/meetings.htm)

**WHO-UNAIDS HIV Vaccine Initiative (HVI)**

[www.who.int/hiv-vaccines](http://www.who.int/hiv-vaccines)

### 5.2 Selected International Meetings in 2003

January            World Economic Forum – Davos, Switzerland

February	Conference on Retroviruses and Opportunistic Infections – Boston, U.S.
March	UN Commission on Human Rights – Geneva, Switzerland
April	International Conference on Antiviral Research – Savannah, U.S.
May	AIDSWatch Lobbying Days – Washington, DC, U.S. European Congress of Clinical Microbiology – Glasgow, Scotland
June	G8 Summit – Evian-les-Bains, France
July	IAS Conference on HIV and Pathogenesis – Paris, France World Vaccine Congress – Montréal, Canada
August	International Conference for People Living with HIV/AIDS
September	AIDS Vaccine 2003 International Conference on AIDS and STDS in Africa (ICASA) – Nairobi, Kenya
October	International Conference on AIDS in Asia and the Pacific (ICAAP) – Kobe, Japan 56 <sup>th</sup> World Health Assembly
November	WHO-UNAIDS Vaccine Advisory Committee – Geneva, Switzerland
December	Pan American STI/AIDS Congress – Punte del Este, Uruguay

### 5.3 Websites

#### **AIDS Vaccine Advocacy Coalition**

Contains useful resources, including the HIV Vaccine Handbook and an annual advocacy report.  
[www.avac.org](http://www.avac.org)

#### **Canadian HIV/AIDS Legal Network**

Contains several publications related to HIV vaccine policy.  
[www.aidslaw.ca](http://www.aidslaw.ca)

#### **Global Alliance for Vaccines and Immunizations**

Contains updated information and articles about access and use of vaccines around the world.  
[www.vaccinealliance.org](http://www.vaccinealliance.org)

#### **HIV InSite**

Contains useful references on HIV vaccines, including a 2001 monograph on access.  
<http://hivinsite.ucsf.edu>

#### **Immunization Action Coalition**

A U.S.-based advocacy site with materials supporting vaccination programs.  
[www.immunize.org](http://www.immunize.org)

#### **International AIDS Economics Network**

Information on the economic aspects of vaccine development.  
[www.iaen.org](http://www.iaen.org)

#### **International AIDS Vaccine Initiative**

A major resource on HIV vaccine development.  
[www.iavi.org](http://www.iavi.org)

#### **International Council of AIDS Service Organizations**

Contains a community primer on HIV vaccines.  
[www.icaso.org](http://www.icaso.org)

#### **National AIDS Manual**

A central source of HIV/AIDS information on the internet.

[www.nam.org.uk](http://www.nam.org.uk)

**United States National Institutes of Health**

Contains a wealth of background information about the science of HIV vaccine development.

[www.niaid.nih.gov/vaccine](http://www.niaid.nih.gov/vaccine)

**UNAIDS**

Contains documents including the guidance document on Ethical Considerations in HIV Preventive Vaccine Research, and the 2000 Nairobi Declaration.

[www.unaids.org](http://www.unaids.org)

**World Health Organization**

Contains useful information about vaccine development and deployment.

[www.who.int/vaccines](http://www.who.int/vaccines)

**World Medical Association**

Contains the revised version of the Declaration of Helsinki.

[www.wma.net](http://www.wma.net)