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International AIDS
Vaccine Initiative

December 15, 1999

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Ms. Sandy Thurman
Office of National AIDS Policy (ONAP)
736 Jackson Place, NW
Washington, DC 20503

Dear Ms. Thurman, *Sandy:*

On behalf of the board and staff of the International AIDS Vaccine Initiative, I hope this letter finds you well as we approach the year 2000.

The dawn of a new Millennium seems an appropriate moment to take stock of the past and to look ahead. In that vein, I am pleased to report that we saw considerable new momentum last year in the quest for a globally accessible AIDS vaccine. Without underestimating the significant challenges that remain, we at the International AIDS Vaccine Initiative enter the 21st Century more convinced than ever that the world can achieve this goal with all deliberate speed.

Earlier this month, UNAIDS and WHO reminded us of what is at stake. There were 5.6 million infections and 2.6 million deaths this year, bringing to 16.3 million the cumulative death toll. More than 95% of new cases remain in developing countries, where there is almost no access to treatment. In Africa, HIV infections in women now outnumber those in men. In industrialized countries, the decline in deaths due to antiretroviral therapy is tapering off. Beyond the death toll and human suffering, AIDS continues to roll back hard won development gains in many regions of the world. A broadly accessible vaccine is truly the world's best and only hope for ending this pandemic.

Given the sobering epidemiology, what accounts for our optimism? A quick review of the history will help to explain. In 1994, when the first explorations that led to the creation of IAVI occurred, AIDS vaccine research was at a low ebb. Vaccines were a low priority at government research agencies, and pharmaceutical and biotech companies were leaving the field. IAVI was founded in 1996 to accelerate scientific progress, enlist political support through advocacy and education, and encourage industrial participation in AIDS vaccine development. I'm pleased to report encouraging progress on all three fronts.

In science, researchers have gained critical new insights into the structure and workings of HIV, as well as how the human immune system can keep the virus in check. This is allowing them to design new and better vaccine candidates. The tools of biotechnology have also led to new approaches. We're seeing more and more evidence that non-human primates, when inoculated with certain vaccine candidates, can mount protective responses against HIV-like viruses.

Page Two

In the quest for support, AIDS vaccine development is clearly gaining political – as well as financial – backing from heads of government, parliamentarians and members of affected communities. Heads of government or health ministers of the United Kingdom, China, India, South Africa, the United States, the Netherlands, Uganda, Kenya and France, among others, have given high priority to vaccine development. Significantly, none of this support has come at the expense of vital AIDS prevention, basic research or care.

Lastly – and of great importance because most vaccine development expertise resides within private industry – more pharmaceutical and biotech companies are venturing into or accelerating AIDS vaccine research. Among international agencies, particularly The World Bank, there is increasing recognition of the failures of the market with respect to vaccines specifically designed for developing countries, and the need for innovative public-private partnerships to overcome them.

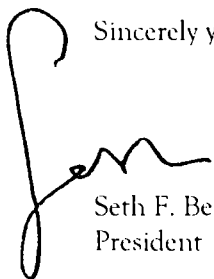
As for IAVI, 1999 was a year of growth and maturation. Our scientific program gained breadth and depth with the addition of key personnel with expertise in immunology, vaccinology, virology, process development, manufacturing, and regulatory affairs. With two IAVI-sponsored vaccine candidates moving through the product development pipeline and two more about to be launched, our vision is being realized. We've also internationalized and strengthened our public affairs and country program staff.

This growth would not have been possible without the clear recognition among funders of the need for a focused AIDS vaccine development organization. The Bill and Melinda Gates Foundation's commitment of US\$25 million, the United Kingdom's pledge of £14 million and the Dutch government's initial gift of 5 million guilders, along with continuing support from the Rockefeller, Sloan and Starr Foundations, were combined with generous contributions from a growing roster of visionary donors from around the world.

Perhaps the most rewarding development this year has been the deepening of relationships with our partners and the establishment of such IAVI-like organizations as the South African AIDS Vaccine Initiative and the Australian HIV Vaccine Initiative. No single nation or organization can end this pandemic. We are therefore gratified that IAVI successfully joined forces with a growing roster of national, international and community-based organizations. Recent declarations of support for an AIDS vaccine from the Commonwealth Heads of Government, the South African Development Community and the European Union, as well as greater commitments to AIDS vaccine development from such national research agencies as the U.S. NIH and CDC, France's ANRS, are enormously encouraging.

Working together, we will bring this epidemic to an end. All of us look forward to staying in touch in the New Year. As always, we welcome your ideas and suggestions.

Sincerely yours,



Seth F. Berkley, M.D.
President

Thank you for all your interest &
support. It is great to be
working with you.
Happy Holidays!

A Proposal for the U.S. Government to Help Fast Track the Development of Promising AIDS Vaccine Candidates for Use in Africa

Background: In March, President Clinton will host a White House conference to encourage pharmaceutical industry participation in the development of AIDS, malaria and TB vaccines. At approximately the same time, the International AIDS Vaccine Initiative (IAVI) is scheduled to launch the development of two promising new AIDS vaccine candidates in conjunction with private industry and scientists from South Africa and Uganda.

Proposal: That the White House conference serve as the venue to launch these two new vaccine candidates for Africa, and that President Clinton announce that the Administration will provide \$5 million to \$10 million a year in financial support to IAVI. The White House Conference would thus be the site for the birth of two new, tangible, goal-oriented public-private partnerships whose products would enter into human trials in Africa by 2001 [NOTE: There is a precedent for this. In 1998, U.K. Secretary of State Clare Short launched IAVI's first two vaccine candidates for Africa in London. They are due to enter Phase I testing in Kenya and South Africa this year.]

Why should the U.S. government partner with the International AIDS Vaccine Initiative?

- **Speed:** Unencumbered by bureaucracy, IAVI speeds promising AIDS vaccine candidates through the product-development pipeline.
- **True public-private partnerships:** The publicly funded IAVI contracts with pharmaceutical and biotech companies to develop vaccine candidates.
- **Access for Poor Countries:** IAVI secures guarantees from its industry partners to ensure that resulting vaccines are made readily available in developing countries at a reasonable price.
- **A global crisis demands a global response:** IAVI is working with scientists, governments and policy makers around the world to ensure the rapid development and deployment of AIDS vaccines, the best hope for ending the epidemic.

Two New Promising Approaches: IAVI's scientific program seeks to maximize the number of promising vaccine approaches in human clinical trials. IAVI's blue-ribbon Scientific Advisory Committee has scoured the globe and determined that the approaches we propose to announce at the White House should be moved forward with all deliberate speed. IAVI will continue to seek other promising approaches for fast tracking.

Inexpensive to manufacture and easy to administer: One of IAVI's new vaccines may confer immunity with a single injection, rather than a series of injections. The other could be administered orally. This makes them ideal for use in developing countries.

IAVI Needs Support from the U.S.: IAVI is a collaborating center of the United Nations Joint Program on AIDS. Launched in 1996 by the Rockefeller Foundation (total support: \$12 million), IAVI draws funding from the World Bank (\$4 million), the Gates Foundation (\$26.5 million), and the governments of the United Kingdom (£14 million) and the Netherlands (5 million guilders). USAID has made an initial contribution of \$188,000. U.S. support would secure the President's legacy and leverage funds from other sources for the focused \$500 million vaccine development effort that this crisis demands.



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statement

on

Clinton announcement.

— Victor

P.S. — Look forward
to talking Monday.



**International AIDS
Vaccine Initiative**

Press Release

FOR IMMEDIATE RELEASE
Thursday, January 27, 2000

Contacts: Victor Zonana, 212-655-0201
Dr. Seth Berkley, 917-216-2022

INTERNATIONAL AIDS VACCINE INITIATIVE APPLAUDS CLINTON INITIATIVE TO DEVELOP AND DISTRIBUTE VACCINES IN DEVELOPING COUNTRIES

DAVOS, Switzerland – Seth Berkley, M.D., president of the International AIDS Vaccine Initiative, issued the following statement at the World Economic Forum in response to U.S. President Bill Clinton's Millennium Vaccine Initiative:

"President Clinton's initiative is a giant step forward in the global effort to develop and deploy affordable vaccines for the world's leading killers. We salute the President for his leadership and call upon other countries to join the effort.

"President Clinton has put forward a balanced and forward-looking plan that should energize vaccine development at every level, from the university lab bench to the pharmaceutical industry board room. President Clinton's initiative also recognizes the critical need to enhance medical infrastructure in developing countries and to provide existing vaccines to the world's poorest countries.

"We are especially gratified that President Clinton has recognized the vital role of the pharmaceutical industry in vaccine development. The \$1 billion tax credit for malaria, TB and AIDS vaccines should be a powerful incentive for private industry investment in vaccine development. We look forward to working with the Administration and the Congress as they work through the details of this proposal.

"Now that the President has expressed his willingness to put money on the table, we challenge the pharmaceutical industry to take up the cause, or to work with us to improve the proposal. With 15,000 new HIV infections every day, there is no time for political posturing or game playing.

"We also strongly support the U.S. proposal for the World Bank to increase health spending by \$400 million to \$900 million annually. Under the leadership of James Wolfensohn, the World Bank has recognized that an AIDS vaccine for developing countries is an international public good that won't happen without innovative public-private partnerships."

The International AIDS Vaccine Initiative is an international nonprofit scientific organization founded in 1996 whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.

IAVI's work focuses on three areas: accelerating scientific progress, mobilizing political support through advocacy and education, and encouraging industrial involvement in AIDS vaccine development. For more information, visit www.iavi.org.