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BEFORE THE SENATE COMMITTEE ON FOREIGN RELATIONS

JUNE 23, 2005

Mr. Chairman, thank you for this opportunity to appear before you and other members of this Committee to discuss the state of vaccine development globally and to describe the work of the International AIDS Vaccine Initiative, IAVI. We appreciate your interest in this critical matter and we look forward to working with you and other Senators in the future. Your role is crucial to ensuring adequate resources and incentives to accelerate vaccine development.

The United States has been a leader in the global response to this terrible epidemic, and it must continue to lead. We applaud President Bush and the Congress's work to significantly expand AIDS treatment and prevention in the countries hit hardest by this disease. This focus on the short term emergency is critical and appropriate, but without better tools, we will not be able to end this terrible epidemic. And that must be our goal; to have an effective end game strategy. As a result, we were also gratified by the outcome of last year's Group of Eight summit, chaired by the United States, which called for increased resources and coordination to accelerate the development of a preventive vaccine. Senator Lugar, we welcomed your leadership in introducing a resolution on AIDS vaccines in the wake of last year's G8. We hope that this year's G8 summit will agree to fulfill its earlier commitments and undertake creative and concrete new incentives to spur research and development. We also

applaud the important work on global AIDS undertaken by other members of this Committee.

On behalf of the International AIDS Vaccine Initiative, I want to express appreciation for the financial and political support provided by the United States to our organization, whose mission is to ensure the development and delivery of safe, effective, accessible vaccines to prevent HIV infection around the world, with a particular focus on developing countries hit the hardest by HIV/AIDS. IAVI's scientific and policy programs represent true collaboration and have also attracted funding from seven other governments, the European Union, the World Bank, corporations, and private foundations such as the Bill and Melinda Gates Foundation and the Rockefeller, Sloan, and Starr Foundations. Your funding has helped create a unique model of an efficient and global non-profit public-private partnership, committed to collaborating with the best scientists around the world, whether in London, Nairobi or New Delhi; in Ohio and Washington State; whether with a small biotech company, a large vaccine manufacturer, a leading academic researcher, or the outstanding scientists of our own government, including Dr. Fauci's team. Indeed, we are delighted that NIH has decided to conduct a test of one of their AIDS vaccine candidates at two of the sites IAVI developed in Africa – a tribute to the partnership we have fostered with developing country researchers and other key stakeholders in the field. This is exactly the type of collaboration that IAVI and other groups represented today recognize as critical, and the basis for our joint establishment of the Global Vaccine Enterprise. IAVI, as a founding member of that

Enterprise, has welcomed the opportunity to share our global experience, expertise and model of innovation.

As you know, Mr. Chairman, the devastation caused by HIV/AIDS is almost unprecedented in modern times. The facts are staggering: five million people worldwide are infected with HIV each year, including over 40,000 Americans. More than 20 million people have died of AIDS and it is likely that more than 100 million will have been infected or died of this disease before we have a vaccine. For the first time since the height of the epidemic in the US in the 1980s, more than 1 million Americans are infected and living with the virus that causes AIDS.

As you have already heard today, without a vaccine, the infection will always be with us and always on the move. As a physician, I believe that every life is sacred, and so providing treatment is vitally important. We must also focus on doing our best to prevent each and every new infection. However, current prevention strategies are only partially effective, and with lifetime treatment as today's only option for those infected, and with drug toxicity and viral resistance spreading, this does not bode well for a sustainable global solution. A preventive vaccine is the best long-term solution to blunting and ultimately ending the epidemic. Without one, the epidemic will continue to spread personal tragedy and economic hardship as well as political instability. Funding vaccine research is also an important investment in averting future treatment costs—an enormous future burden for public treasuries around the

world. Like all other viral infectious diseases, ultimately the most medically and economically effective prevention will be through a vaccine.

So why don't we have an AIDS vaccine after 20 years? Science remains the greatest challenge, but we have good reasons to believe that we can solve the scientific challenges that currently stand in our way. From our efforts to date, we have learned many useful things. Monkeys can be protected by certain types of vaccines; most people develop immune system responses that suppress the viral infection for years; and we are beginning to uncover individuals who make some promising antibody responses. We can build on these, but to do so, we need to match the best in academic scientific research to the best in industry. The magnitude of this epidemic, the worst infectious disease epidemic since the 14th century, compels us to work as quickly and as efficiently as possible. The IAVI paradigm is premised on this focused business model and has enabled us to do exactly that.

Ten years ago, total global spending on AIDS vaccine research and development was less than $160 million. That may sound like a lot of money, but given the high cost of biomedical research and product development, especially against a foe as dreadful and complex as HIV, it was woefully inadequate. Basic scientific research was conducted, but very little emphasis was placed on actually developing a product, and what little product work was being done, was not designed to ensure its applicability for use in the countries that have the worst epidemics. The private

sector, where most vaccine product development expertise resides, generally stayed on the sidelines, because of the scientific challenges, political controversies, unclear market and resultant financial risks. To address this situation, IAVI was founded in 1996 to fill the gap between the public and private sectors and to establish an innovative new way of tackling global health crises.

Mr. Chairman, IAVI is now working in 23 countries and has raised almost $400 million in new funds. I am very proud of the progress my team in the U.S., Africa, India and Europe has made in so short a time. In the nine years since we were founded, IAVI and its international partners have brought six vaccine candidates from the laboratory to the clinic, for testing in human volunteers in nine countries -- countries that now have high quality infrastructure to conduct clinical trials and analyze results. Quality is critical, as the safety of all our participants is of paramount importance to us and to the global effort we are attempting to create. We are also now working in innovative ways to bring the industrial model to bear by harnessing recent scientific advancements to answer critical scientific questions, and to use that information to design and test new candidates. New models of applied research and collaboration—such as the neutralizing antibody consortium of government, academic and industrial researchers—are critical if we are to solve these enormously difficult scientific challenges.

It is critical that developing countries conduct AIDS vaccine trials because the incidence of new HIV infections is among the highest in these areas. We welcome

them as full partners in these efforts so that they ensure that trials go well, their manufacturing systems are available to help with product development, and that communities are prepared for the ultimate distribution and use of vaccines. Some of the emerging technological innovators such as India have enormous scientific talent to bring to the effort. Our activities in these countries will not only advance vaccine development, but provide very meaningful and sustainable development assistance that will provide long-lasting benefit these communities, including for current prevention and treatment efforts. We will also continue to engage with political, religious and community leaders in developing countries to ensure that once a vaccine is available, the vaccination effort succeeds at the grassroots level. We have been pleased by the enormous level of political will that many countries have now demonstrated in support of vaccine development.

We are also committed to engaging the private sector, because we need their unique expertise to accelerate the development of a vaccine. To that end, IAVI recently entered into our first product development agreement with a major global vaccine manufacturer to focus on vaccines designed to elicit immune responses against variants of HIV that circulate predominantly in Africa, although of course the ultimate goal of the collaboration is to develop vaccines that would be applicable worldwide. Like all of our partnerships, our agreement contains provisions to ensure that any AIDS vaccine that emerges will be made in adequate quantities and will be accessible to the poor living in developing countries.

I ask for your sustained and increased leadership and commitment. Research into designing and testing AIDS vaccines needs more funding. Today, total global spending including basic research, product development and clinical trials to develop a vaccine still is less than $700 million, hundreds of million short of what we believe is needed and a very small percentage of total spending on AIDS. IAVI and its partners in the Global Vaccine Enterprise estimate that approximately $1.2 billion needs to be spent annually in the coming years to speed the discovery and licensing of an AIDS vaccine. More incentives are needed to harness the expertise of the biopharmaceutical sector. An advance purchase commitment – a legally binding agreement to pay a decent price to companies that successfully make an AIDS vaccine for use in the developing world – would help overcome the substantial scientific and commercial risks they currently face. Other important incentives include liability protection and tax credits. We are delighted that new biodefense legislation under consideration by the Senate will also include the major diseases of poverty—AIDS, malaria and tuberculosis. We are optimistic that the United States Congress will continue to set an example for other all countries – rich and poor – in making vaccine development a priority and ensuring that it is included as part of the comprehensive HIV/AIDS agenda.

The Foreign Relations Committee could also encourage the PEPFAR, the Global Fund, and the World Bank to ensure that communities where critical prevention research is being conducted are prioritized for voluntary counseling and testing services and antiretroviral treatment. This collaboration and synergy would advance

prevention, treatment and research, would appropriately reward communities engaged in important global research, and make U.S.-funded efforts more successful and sustainable by building long term research capacity in these developing countries.

I thank you for this opportunity to highlight the need for a preventive AIDS vaccine and IAVI's efforts to develop a vaccine, and I look forward to answering any questions you may have.