

G-8 ACTION TO ENDORSE AND ESTABLISH A GLOBAL HIV VACCINE ENTERPRISE

1. We reaffirm our commitment to combating the global HIV/AIDS pandemic. Both individually and collectively, we have increased our efforts aimed at HIV treatment, care, and prevention. We acknowledge the important role of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, UNAIDS, and WHO in fighting this pandemic. But the human and economic toll of the AIDS pandemic demands that these activities be complemented by accelerated efforts to develop an HIV vaccine. In 2001 and 2002, only seven vaccine candidates entered clinical trials, and only one entered advanced human testing, but proved to be ineffective. Vaccine development efforts have proceeded slowly, due largely to the enormous scientific challenges. The best way to meet these challenges is for scientists around the world to work together in a complementary manner.

2. We believe the time is right for the major scientific and other stakeholders -- both public and private sector, in developed and developing countries -- to come together in a more organized fashion. This concept has been proposed by an international group of scientists. Published as a "Policy Forum" in *Science* magazine. Klausner, RD, Fauci AS, et al: "The need for a global HIV vaccine enterprise." *Science* 300:2036, 2003. We endorse this concept and call for the **establishment of a Global HIV Vaccine Enterprise – a virtual consortium to accelerate HIV vaccine development by enhancing coordination, information sharing, and collaboration globally.**

3. The Enterprise should establish a **strategic plan** that would prioritize the scientific challenges to be addressed, coordinate research and product development efforts, and encourage greater use of information sharing networks and technologies. This plan should serve as a blueprint for helping to align better existing resources and to channel more efficiently to the needs at hand new resources as they become available. Specifically, the strategic plan should seek to:

3.1. Encourage the development of a number of coordinated global HIV Vaccine Development Centers: Each center should have the critical mass and scientific expertise to advance the development of a particular HIV vaccine approach. These centers could be self-contained, as is the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center at the U.S. National Institutes of Health, the European Research Institutes or could be virtual centers, such as those funded by the public-private partnerships of the International AIDS Vaccine Initiative (IAVI), the European Developing Countries Clinical Trials Program (EDCTP), the Gates Foundation, and others.

3.2. Stimulate the development of increased dedicated HIV vaccine manufacturing capacity: There is inadequate existing capacity to produce HIV vaccines for advanced clinical testing. Therefore, the resources and facilities involved in manufacturing potential HIV vaccines must be increased, particularly for testing of vaccine candidates that are currently in or will soon be in the developmental pipeline, like in the EDCTP.

3.3. Establish standardized preclinical and clinical laboratory assessment: Data gathered from clinical trials on a given vaccine candidate should be available and applicable to trials being conducted on other vaccine candidates. Therefore, standardized protocols and measures of effectiveness need to be adopted at the preclinical and clinical stages of vaccine development. In turn, laboratories need to be better linked to clinical trials, which will require wider use of novel confidentiality agreements and information-sharing technologies.

3.4. Expand an integrated international clinical trials system: Large, clinical programs capable of conducting phase I, II, and III trials of potential HIV vaccines have been established by the U.S. NIAID, France's Agence Nationale de Recherches sur le SIDA, Italy's National AIDS Program, IAVI, and the EU. This global clinical trials system should be expanded and coordinated. It should facilitate a multidisciplinary approach which draws in inputs from social and behavioral scientists, alongside biomedical teams.

3.5. Optimize interactions among regulatory authorities: Increased cooperation, communication and sharing of information among regulatory authorities in various countries and regions involved in licensing HIV vaccines are essential. This can be accomplished without reducing safety or manufacturing standards.

3.6. Encourage greater engagement by scientists from developing countries: Since most phase III trials will need to be conducted in the developing countries hardest hit by the disease, the international clinical trials system must involve local scientists, ethical review committees comprised of local and international representatives, and regulatory bodies.

4. We call on all stakeholders in the Global HIV Vaccine Enterprise to complete the development of this strategic plan by our next Summit.

5. The United States, in its role as president of the G-8, will convene later this year a meeting of all interested stakeholders in the Enterprise to encourage their collaborative efforts in HIV vaccine development. This meeting should clarify how the strategic plan is to be implemented. We support this conference becoming an annual event and we look forward to a report on the follow-up of the Initiative at the next G-8 Summit.

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