



“Today, we further our commitment to helping children with a new pediatric AIDS treatment initiative – a groundbreaking and historic alliance. This alliance between public and private partners will promote better, more effective treatments for children living with HIV/AIDS.”

Mrs. Laura Bush
March 13, 2006

Building a New Public-Private Partnership for Pediatric AIDS Treatment

President George W. Bush's Emergency Plan for AIDS Relief is the largest commitment ever by any nation for an international health initiative dedicated to a single disease -- a five-year, \$15 billion, multifaceted approach to combating the disease in more than 120 countries around the world.

U.S. Department of State

U.S. Agency for International Development

U.S. Department of Defense

U.S. Department of Commerce

U.S. Department of Labor

U.S. Department of Health and Human Services

Peace Corps

An estimated 640,000 children worldwide are newly infected with HIV each year. In 2004, there were an estimated 2.1 million children under age 15 living with HIV infection, with 87% living in sub-Saharan Africa. A renewed commitment to effective antiretroviral treatment (ART) of HIV infection in children is essential; without treatment, the majority of infected children die before they are three years of age.

Barriers to Meeting Children's Needs

Key obstacles to providing children in resource-limited settings with access to treatment include the following:

- **Difficulties in diagnosing HIV infection in infants-** Traditional diagnostic tests for adults are not effective until a child is 18 months old, and technologies to improve pediatric diagnosis are not yet widely available.
- **Health care infrastructure and personnel limitations-** A limited number of health clinics and trained pediatric health professionals are available to serve children infected with HIV/AIDS. Often, guidelines and other tools to facilitate prescribing ART to children are unavailable to providers.
- **Limited information about pediatric dosing requirements at different ages-** Pediatric regimens can be difficult to administer and maintain because of their complexity and other challenges associated with dosing by weight.
- **Regulatory requirements-** While the U.S. Government has taken steps to “fast track” approval for antiretroviral drugs (ARVs), in-country registration processes and limited infrastructure in host nations can present barriers.
- **Fewer formulations for pediatric ARV-** Of the 21 innovator ARVs approved by the Department of Health and Human Services/Food and Drug Administration (HHS/FDA) for the treatment of HIV/AIDS in adults, 12 are approved for use in children, including only 7 for children under the age of two years. Four generic ARVs in pediatric formulations have been tentatively approved to date.

The U.S. Leads a New Partnership on Pediatric HIV/AIDS

The U.S. Government, through President Bush's Emergency Plan for AIDS Relief, is announcing an unprecedented public-private partnership to promote scientific and technical discussions on solutions for pediatric HIV treatment, formulations and access. These partnerships seek to capitalize on the current strengths and resources of:

- **Innovator pharmaceutical companies** in developing, producing and distributing new and improved pediatric ARV preparations;
- **Generic pharmaceutical companies** that manufacture pediatric ARVs or have pediatric drug development programs;
- **The U.S. Government** in expediting regulatory review of new pediatric ARV preparations and supporting programs to address structural barriers to delivering ART to children; and
- **Civil society/multilateral organizations** to provide their expertise to support the success of the partnership.

**Mailing address:
SA-29, 2nd Floor
2201 C Street, NW
Washington, DC 20522-2920
www.PEPFAR.gov**

U.S. President's Emergency Plan for AIDS Relief



“A few years ago, a little girl in Namibia was born to a mother and father who both had HIV; she had the disease, as well. The name her parents gave her translates as the phrase, “There is no good in the world.” Months ago, the girl was very sick and losing weight and close to death. But today, she and her entire family are receiving lifesaving medicine. Now she’s a beautiful, shy, thriving six-year-old, with a new life ahead of her, and there’s a little more good in the world.”

President George W. Bush
June 30, 2005

Building Hope for the Future

The U.S. Government and its partners will bring a wide range of expertise, seeking to maximize the utility of currently available pediatric formulations and to accelerate children’s access to treatment. This partnership will complement other efforts of the President’s Emergency Plan to support programs that expand treatment for adults and children, such as support for health care capacity-building and expedited regulatory review of drugs through HHS/FDA. The partnership will offer children and parents hope for a better day – the hope of families staying together, leading healthy lives, and living positively with HIV/AIDS.

The Partnership in Action

Initial steps contemplated by the U.S. Government and the partners include the following:

- The partners will work to **identify scientific obstacles** to treatment for children that the cooperative relationship could address.
- The partners will **take practical steps** and **share best practices** on the scientific issues surrounding dosing of ARVs for pediatric applications.
- The partners will **develop systems for clinical and technical support** to facilitate rapid regulatory review, approval, manufacturing and availability of pediatric ARV formulations.

The first meeting of the partnership was held on Wednesday, April 19, 2006. A second meeting of the partnership was convened on Tuesday, July 25, 2006.

U.S. Government Partners

Innovator Companies

Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Inc., GlaxoSmithKline, Merck & Co., Pfizer, Roche, and Tibotec

Generic Companies

Aspen Pharmacare, Aurobindo Pharma, Cipla Limited, Emcure Pharmaceuticals, and Ranbaxy Laboratories

Civil Society/Multilateral Organizations

Elizabeth Glaser Pediatric AIDS Foundation, UNAIDS, UNICEF, and the World Health Organization