



Highlights of [GAO-05-133](#), a report to congressional requesters

Why GAO Did This Study

In developing countries, only about 7 percent of people with HIV/AIDS receive treatment. In 2003, the Congress authorized the President's Emergency Plan for AIDS Relief, a 5-year, \$15 billion initiative under the Office of the U.S. Global AIDS Coordinator. The Emergency Plan focuses on 15 developing countries, with a goal of supporting treatment for 2 million people. Treatment regimens use multiple antiretroviral medications (ARV), which can be original or generic. Fixed-dose combinations (FDC) combine two or three ARVs into one pill.

Questions have been raised about whether the plan is providing ARVs preferred by the focus countries at reasonable prices. GAO compared the selection of ARVs provided under the plan with that provided under other major treatment initiatives, compared the prices of those selections, and determined what the Coordinator's Office is doing to expand the plan's selection of quality-assured lower-priced ARVs.

www.gao.gov/cgi-bin/getrpt?GAO-05-133.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

GLOBAL HIV/AIDS EPIDEMIC

Selection of Antiretroviral Medications Provided under U.S. Emergency Plan Is Limited

What GAO Found

The Emergency Plan provides a smaller selection of recommended first-line ARVs than other major HIV/AIDS treatment initiatives in developing countries. The plan's selection includes six original ARV products—the only ARVs that have met the plan's quality assurance requirement—and does not include some FDCs that are preferred by most of the focus countries because they can simplify treatment. In contrast, the other initiatives provide a selection that in addition to the six original ARVs includes generic ARVs and more of the preferred FDCs.

The original ARVs provided under the plan are generally higher in price than the generic ARVs provided under the other initiatives. The differences in the prices, quoted to GAO during June and July 2004 by 13 manufacturers, ranged from \$11 less to \$328 more per person per year for original ARVs than for the lowest-priced corresponding generic ARVs provided under the other initiatives. At these prices, three of the four first-line regimens recommended by the World Health Organization could be built for less—from \$40 to \$368 less depending on the regimen—with the generic ARVs provided under the other initiatives than with the original ARVs provided under the plan. Such differences in price per person per year could translate into hundreds of millions of dollars of additional expense when considered on the scale of the plan's goal of treating 2 million people by the end of 2008.

The Coordinator's Office has worked to expand the selection of quality-assured ARVs—including FDCs and lower-priced generics—that it provides to the focus countries under the plan. The selection of ARVs available under the plan is primarily limited by its quality assurance requirement. The Coordinator's Office is working with manufacturers to take the steps necessary for more ARVs to meet this requirement. However, if generic ARVs meet the plan's quality assurance requirement, a statutory prohibition on the purchase of any medication manufactured outside the United States if the manufacture of that medication in the United States would be covered by a valid U.S. patent could become a barrier to expansion because all ARVs are currently under U.S. patents. Unless the patent holders for ARVs that have met the plan's quality requirement give permission or the Coordinator's Office exercises its authority to purchase these products notwithstanding the patent requirement, the selection of ARVs provided under the Emergency Plan may not expand rapidly enough to address the AIDS emergency.

In commenting on a draft of this report, the Department of State, the Department of Health and Human Services, and the U.S. Agency for International Development expressed concern about how GAO addressed ARV quality. In the draft report GAO described the quality assurance requirements used by the Emergency Plan and the other initiatives and stated that quality is the primary factor determining the selection of products provided under each. However, evaluating the quality assurance processes used by each initiative was outside the scope of GAO's work.