

Bush's AIDS Relief Plan Will Delay Drugs, Reward Big Pharma

By Jim Lobe | May 26, 2004

Africa and AIDS activists say the Bush Administration's pledge to expedite its approval process for low-cost, generic anti-retroviral drugs by the U.S. Food and Drug Administration will really slow delivery of drugs to those suffering while undermining the authority of the United Nations and World Health Organization.

"The net effect is to continue to delay the delivery of life-saving drugs to the most needy," said Salih Booker, executive director of Africa Action, a Washington-based grassroots network and frequent critic of the administration's anti-AIDS plan.

"It looks to us like an elaborate ruse to protect the interests of the patent-holding U.S. drug companies while, at the same time, undermining the World Health Organization's own approval process."

Bush's \$15 billion anti-AIDS initiative for Africa and the Caribbean is redundant at best and deceptive at worst, critics say.

"Instead of reinforcing the WHO's pre-qualification process, they are slowing things down by creating a redundant and parallel U.S.-led review process," said Paul Zeitz, director of the Global AIDS Alliance.

The administration, which has been under strong pressure from anti-AIDS groups and U.S. lawmakers to approve inexpensive fixed-dose combination drugs, or FDCs, produced by generic manufacturers in India, Brazil and other developing countries for use by the President's Emergency Plan for AIDS Relief, announced Sunday it would soon put in place a FDA "fast-track" approval scheme that could approve "high-quality" drugs in as little as two to six weeks.

"It's an oxymoron to call this a fast-track initiative when the WHO has already approved these drugs for use," Zeitz added.

Generic manufacturers of FDCs, which combine drugs from multiple sources into single pills that are taken twice daily, now charge as little as \$140 per

person, per year. That's about one-fifth the cost of the same combination of drugs—which must be taken in the form of six pills a day—manufactured by brand-name companies.

The WHO, which has its own review process to determine the safety and effectiveness of medicines, has already approved a number of FDCs produced by generic manufacturers for use by the World Bank, the United Nations Children's Fund, and the Global Fund to Fight AIDS, tuberculosis and malaria.

But the Bush Administration has taken the position that such drugs must also be reviewed for safety and effectiveness by the FDA in order to qualify for use by agencies receiving U.S. anti-AIDS funds, despite the fact that many of the steps taken by WHO in its review process are identical to the FDA's.

That position has frustrated activists, who argue that the WHO's review process is sufficiently rigorous to pass muster, and that setting up a parallel process not only undermines the U.N.'s credibility, but also would create additional delays to getting life-saving drugs to hundreds of the roughly 8,000 people—including 6,000 Africans—who die of AIDS each day.

Nonetheless, the administration depicted Sunday's announcement in Geneva by Health and Human Services Secretary Tommy Thompson as a major breakthrough that would not only expedite approval but also encourage competition between generic manufacturers and brand-name companies for the FSC market.



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Skeptical Despite Good News

Zeitz agreed that Washington's recognition of FSC drugs is "good news," but he and other activists said they remain skeptical about the agenda behind it.

Noting that three big U.S. pharmaceutical companies—Bristol-Myers Squibb, Gilead Sciences and Merck—announced Sunday that they are jointly pursuing development of their own one-dose-a-day anti-AIDS drug, Zeitz suggested the administration appears to be setting a "pathway for these companies to get fast-track approval for their products, so the U.S. government will purchase only U.S.-produced drugs.

"Right now, these are five times more expensive, and we can't assume that what the FDA will approve is going to be cheaper than what is already available from the generic manufacturers. At this point, however, it looks very unlikely," Zeitz said.

Meanwhile, generic manufacturers will have to submit to an FDA process that does not yet exist and that will cost them both time and money, others charge.

"By creating a parallel process, they're making it much more expensive and time-consuming," said Jen Cohn, a spokesperson for HealthGAP, another anti-AIDS activist group. "By forcing the generic manufacturers to go through yet more hoops, they're ensuring that Big Pharma (as the major drug companies are often called) will get market share before generics can get on the scene."

Indeed, two other western companies, Britain's GlaxoSmithKline and Germany's Boehringer Ingelheim Corp, said they are also considering a co-packaging deal for FSCs.

But U.S. officials insisted Monday that the administration does not intend to stack the deck against generic manufacturers. U.S. Global AIDS Coordinator Randall Tobias said the aim of the plan is "to put effective treatment into the hands of those who need it in the hardest-hit developing nations and to provide these life-saving services as widely as possible."

"With FDA review, we will have a gold-standard assurance that a combination product will be safe and effective," added Tobias, the former chief executive of another big U.S. drug company, Eli Lilly.

But Zeitz said he's not convinced generics will get a fair review. He said the rhetoric about the FDA's providing a "gold standard" is particularly worrisome.

"Setting up the FDA as a global, supranational health authority is a very dangerous precedent," he said. "WHO was asked by its member states to establish an international standard called the pre-qualification process so that it could play the role of honest broker for both the global North and the global South. Now the U.S. is undermining the credibility of that international program."

Zeitz added he felt the FDA should confine itself to regulating drugs for use in the United States.

Africa Action's Booker echoed that view. "Once again, it's U.S. unilateralism at odds with the greater interests of the global community, in this case costing lives in Africa and the Caribbean.

"Frankly, it's unconscionable that a year and a half after the president's commitment to lead the global struggle against AIDS the U.S. still refuses to allow its funds to be used to purchase the lowest-cost version of life-saving drugs, which would enable the treatment of many more people," Booker said.

"Given the administration's ill intent, we must call on Congress to pass legislation that orders PEPCAR funds to use the most cost-effective drugs available in the interests of saving both taxpayers' money and more lives."

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