

Bush kills and harms millions for Pharma

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The Bush approach as it screws the world up and makes life horrible, spreads suffering and death.

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Early Tests for U.S. in Its Global Fight on AIDS

By DEBORAH SONTAG

This article was reported by Deborah Sontag, Sharon LaFraniere and Michael Wines, and was written by Ms. Sontag.

The Bush administration did not consult with Mozambique last year before designating the country as a beneficiary of its emergency AIDS plan. Mozambique was simply informed that it would be one of 12 African nations, and 15 countries overall, awarded substantial financial assistance.

The pledge of big money was certainly welcome, said Francisco Songane, the Mozambican health minister; AIDS has lowered life expectancy in Mozambique to 38. But the approach, perceived by many Mozambicans as arrogant and neocolonial, was not.

Mozambique, in southeastern Africa, had spent considerable time developing a national strategy to combat its high rate of H.I.V. infection. Other international donors had agreed to pool their contributions and let the Mozambicans control their own health programs. Thus, Mozambican officials recoiled when the Americans said earlier this year, "We want to move quickly, and we know that your government doesn't have the capacity," Mr. Songane said.

The Bush administration wanted the bulk of its funding to go toward more costly brand-name antiretroviral drugs for treatment programs run by nongovernmental organizations. But Mozambique had already decided to treat its people with 3-in-1 generic pills, which were cheaper and simpler to take. Also, Mozambique did not want an American program dependent on costly foreign consultants, N.G.O.'s and the largesse of

foreign political leaders, that would run parallel to its own.

There were confrontational meetings in Washington and in Maputo, the capital of Mozambique. And in the end, to the surprise of many, the Bush administration agreed to give Mozambique the kind of help it really wanted, by strengthening its laboratories, blood–transfusion centers and the Health Ministry itself – albeit indirectly, through a grant to Columbia University.

"What I witnessed in Mozambique was a disaster averted," said Dr. Steven Gloyd, an international health specialist at the University of Washington who works with Mozambique. "So, for countries like Mozambique, this may turn out to be a positive intervention, even though it could be a lot more."

Seventeen months after President Bush announced his five–year, \$15 billion emergency AIDS initiative, the program is belatedly getting under way, and surprising some critics of what is seen as its go–it–alone approach. In some cases, the plan is proving to be more adaptive and collaborative than had been expected, especially when countries are strong enough to stand their ground.

The plan is already directing considerable money into health clinics, laboratories, testing centers and hospices, AIDS treatment, prevention of H.I.V. and care of orphans.

For every Mozambique, however, where Washington has altered its plans to meet local objections, there is a Zambia, where local officials are in the dark. The Zambian health minister, Brian Chituwo, said his government did not have a formal meeting on the program with the American ambassador until May, 15 months after Zambia's role was announced. Further, he said, on everything but blood–transfusion services, which were negotiated, the Americans' plans for Zambia have "all come from Washington." The American plan, one senior United Nations official said, "has created turbulence wherever it has gone." But another, Michel Sidibe, praised the Americans for making a "major shift" in May by signing "a declaration of harmonization" in which they pledged to coordinate their anti–AIDS activities with other donors.

The president's program, a centerpiece of his compassionate conservatism, has been a prime topic of conversation at the International AIDS Conference in Bangkok – and a magnet for some protests. On Tuesday, President Jacques Chirac of France accused the United States of blackmailing developing countries into bartering their right to produce generic H.I.V. drugs for free–trade agreements. American officials dismissed the charge as groundless.

After decades when the pandemic in Africa spread unchecked, billions in anti–AIDS money is suddenly pledged to assist the continent, and questions about how to channel that outpouring have taken center

stage. The administration's AIDS effort is under sharp scrutiny because it so big, so unabashedly Washington-dominated and tinged by the administration's political ideology.

Many critics see big pharmaceutical companies behind the Bush administration's preference for costlier brand-name drugs, conservative Christians behind its heavy promotion of abstinence, and hard-line unilateralists behind its decision to bypass the Global Fund to Fight AIDS, Tuberculosis and Malaria in creating its own plan.

Randall L. Tobias, a former chief executive of the Eli Lilly & Company drug group and a Republican donor who became the administration's global AIDS coordinator last October, lamented the politicized environment and suggested that critics refocus their antagonism. "The enemy here ought to be apathy, denial and stigma," he said. "I don't know why people spend so much time fighting each other."

Still, the administration's refusal thus far to use its money to buy generics is complicating the roll-out of its own emergency plan. Like the Mozambicans, other African officials have resisted the distribution of brand name drugs as first-line therapy. As a result, in a half a dozen or more of the focus countries, the governments themselves or other donors are picking up most of the cost of life-saving drugs.

The goal set by President Bush in January 2003 was to treat two million people in five years. Under the plan, an estimated 6,000 to 10,000 people have started on antiretroviral drugs so far, according to a Congressional appropriations expert. The global AIDS office could not give a figure. In the slums of Lusaka, Zambia, American money was put to use quickly this spring renovating four clinics and training workers to distribute drugs. American doctors worked in concert with a local health official to salvage a stockpile of government AIDS drugs that were about to expire.

In late April, they started handing out drugs that ward off death for some very ill people, and within two months, they had 700 patients on antiretroviral therapy.

"There was a patient whose family had sadly sent her off to a hospice" to die, said Jeffrey Stringer, a doctor from the University of Alabama who is running the program. Recently, a health worker escorted the patient back home. "And there was a woman who couldn't crawl who has now gained weight and is walking around."

Dr. Stringer, who is working in collaboration with the Elizabeth Glaser Pediatric AIDS Foundation in Los Angeles, noted that he had not voted for President Bush. But he had to admit, he said, "They ponied up."

Other American experts are more skeptical.

"Sure, off the bat, you can put 5,000" on antiretroviral drugs, said Josh Ruxin, an assistant clinical professor of public health at Columbia and a consultant to Rwanda and Nigeria. "They're easy to ID, they're terribly sick, they need drugs now, they live in cities, they have cell phones. So that's the low-hanging fruit. But then what happens? You quickly reach a point where you can't treat more people unless you develop the national health systems, and that is not something I've heard the American government commit to in a big way."

For Bush, a 'Work of Mercy' Mr. Bush presented the President's Emergency Fund for AIDS Relief in his 2003 State of the Union address, which also began the countdown to the war in Iraq. He called it a "work of mercy," offering the soft power of American humanitarianism to counterbalance the imminent use of military force.

"As our nation moves troops and builds alliances to make our world safer, we must also remember our calling as a blessed country to make this world better," he said.

Mr. Bush declared a five-year goal of getting 2 million into treatment, preventing 7 million infections and providing care to 10 million infected people and AIDS orphans in what he called the most afflicted countries in Africa and the Caribbean.

The 14 focus countries named were: Botswana, Ethiopia, Guyana, Haiti, Ivory Coast, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia. Vietnam was added last month at Congress's insistence that there be another nation from a different region.

The sheer ambition of the proposal stunned advocates for huge increases in global AIDS funding into applause. Jeffrey Sachs, the Columbia University economist, called the president's commitment "historic" and a "breakthrough."

But at a time when American power was being imposed and questioned in the military arena, the AIDS plan struck some as another kind of unilateralism. They feared that Mr. Bush's program would undermine the multilateral Global Fund, which assists eight times as many countries, including India, China and Russia, whose infection rates are rising rapidly. And these experts thought it was retrogressive in its reliance on American universities, faith-based organizations and nongovernmental organizations, whose ability to pay higher salaries could drain workers from local public health systems that should be reinforced instead.

Dr. Paul Zeitz, executive director of the Global AIDS Alliance, said advocates were baffled. "We thought the international community had come to a consensus that there needed to be a new way of doing business where we all worked together and helped strengthen national capacities," he said.

When he took office, Mr. Bush had inherited a kind of global momentum toward an international AIDS fund, and a drumbeat for action was building at home, too. Senators Bill Frist and John Kerry formed a bipartisan team to fight for greater American involvement. The Rev. Franklin Graham, who delivered the invocation at Mr. Bush's inauguration, was catalyzing the evangelical community to get over its aversion to the disease and confront it as part of its mission.

The push for an international fund was led by, among others, Mr. Sachs and Secretary General Kofi Annan at the United Nations. But the Bush administration was a major force in shaping the Global Fund as an independent, multilateral, public-private partnership, and not a World Bank or United Nations program.

The Global Fund's approach was conceived as a reaction against years of inefficient and often ineffective foreign development programs. The idea was to funnel aid from multiple donors to the affected countries and let them run their own health programs, thereby eliminating waste, duplication and burdensome demands on patients.

Yet it took a couple of years for the Global Fund, which is based in Geneva, to persuade countries to develop plans that could be financed, and to get the money flowing from government coffers into health care. The Bush administration was impatient, and concerned that other countries were not contributing their share. The Global Fund did not seem the ideal repository for the billions it wanted to pour into the pandemic.

After the 2003 State of the Union address, Richard Feacham, executive director of the Global Fund, said: "There was to some degree a mood in Washington of dichotomy" between the president's plan and the Global Fund. "People felt the need to make a choice and see a rivalry. We worked extremely hard to convey the message that the world needs both. You can't stop the pandemic in 15 countries. The Global Fund is in 130. We also focus on TB and malaria, the greatest killer of African children."

Right after the State of the Union address, Tommy G. Thompson, the secretary of health and human services, became the new chairman of the Global Fund, which made some European donors fear an American takeover. But Mr. Bush has instead moved to pull back. In his budget request for 2004, he sought to reduce America's contribution. And in his 2005 request, he is asking for a 60 percent cut in the contribution.

Congress, however, refused the Global Fund's allocation for 2004, instead nearly tripling the administration's request. It also increased the global financing to \$2.4 billion, of which \$1.9 billion goes for H.I.V./AIDS (and the rest for tuberculosis and malaria). Several members of Congress complained that \$2.4 billion was not a lot of money for a global health emergency, especially compared with more

than \$100 billion spent on military operations in Iraq.

The global AIDS coordinator's office, in fact, had only \$488 million in new money this year. It also used old money in new ways, though. By the end of the 2004 budget year, it will have committed – but not yet spent – \$865 million, one-fifth of which is committed to faith-based groups. Some \$253 million will go toward treatment programs, but the drug issue has made spending that money more difficult than expected.

Generic Drugs vs. Brand Names "We are using generics here because they are cheaper," Mr. Songane of Mozambique said. "And apart from being cheaper, they are prepared in a manner which is simple for our patients, and even simpler for our staff."

Like Mozambique, many countries prefer generics because they can be used to treat more people and because, given patent problems, only generics now come in fixed-dose combinations, which combine three drugs in one tablet, improving adherence to pill-taking schedules.

Foreign-made 3-in-1 pills have been approved by the World Health Organization and purchased in bulk by the Global Fund and many developing countries. But the Bush administration is insisting on brand-name antiretroviral drugs because the generics have not been reviewed by the Food and Drug Administration. The F.D.A., Mr. Tobias said, is the most stringent regulatory authority in the world and should make the determination whether drugs for an American overseas program are safe and effective, and of the highest quality.

Mr. Tobias noted that the World Health Organization recently withdrew two generic antiretroviral drugs made by Cipla of India from its list of approved treatments. (Its fixed dose tablets remain on the list.) This, he suggested, cast doubt on the W.H.O.'s screening procedures.

Cipla has said that the problem lay not with the product but with a contract research laboratory that it no longer uses. Tests are being repeated in different labs, and the company says it is confident that the drugs will be back on the approved list soon.

Further, earlier this month, researchers who studied Cipla's Triomune reported in the Lancet medical journal, that fixed-dose generic AIDS drugs work as well as brand-name drugs, according to the first clinical trial. Triomune costs as little as \$140 a year per patient, compared with about \$562 for the brand-name versions in the 3-in-1 pill.

In early spring, the Americans discovered that resistance to their rule on brand-name drugs was coming even from the American organizations who were getting multicountry, multiyear grants to set up treatment programs. The American organizations, which are expected to receive more than \$600 million over five years, are the Harvard School of Public Health; the Glaser foundation; the Joseph L. Mailman

School of Public Health at Columbia University; and a faith-based consortium led by Catholic Relief Services.

Some expressed their preferences for generics outright. Barry R. Bloom, the dean of public health at Harvard, said, "The Indian pills are terrific – you take just two a day." Allan Rosenfield, dean at Mailman, issued a statement urging the Bush administration to allow American money to purchase generics.

At an American-initiated conference in Botswana in late March, Jacqueline Patterson, who manages the program for a Protestant medical association that is part of the Catholic Relief Services' consortium, declared that most mission hospitals and clinics in Africa and the Caribbean were already using fixed-dose combinations and wanted to continue. She read comments from the field that voiced a collective anxiety about the imposition of brand-name drugs, resulting in fewer people in treatment and more skipping doses and sharing pills.

With countries like Mozambique, Namibia and Rwanda holding fast to their positions that generics would be their first-line drugs, American officials realized that their assistance in those places would be limited. They would be able to provide medicine for children, for whom only brand-name drugs are available, and for those adults, say, who had developed a resistance to the generics. But essentially, they would be providing technical support for the drug treatment program rather than the drugs themselves.

In May, the Bush administration announced that it would set up a new expedited review for generic antiretrovirals, including the 3-in-1 pills. If approved, the drugs would be eligible for use in the AIDS plan, it said.

An executive at an American foundation engaged in global AIDS work said it remained to be seen whether "the F.D.A. process is real, a stalling tactic, or ultimately a tool for the R-and-D companies." But, he said, his foundation was encouraging foreign drug companies to submit dossiers to the agency.

So far, no foreign drug companies have applied for the expedited review. William F. Haddad, an American representative for Cipla, said the Indian company was left with unanswered questions about the accelerated approval process. "When they come back to us with answers, Cipla will make up its mind about whether to apply," he said. "But the bottom line is that this is a political act, not a scientific one. Why is the World Health Organization's stamp of approval O.K. for the World Bank and the Global Fund and not for the U.S.?"

Abstinence vs. Condoms

With its focus on treatment, Mr. Bush's plan is profoundly changing a two-decades-long emphasis on H.I.V. prevention as the American strategy abroad. The prevention efforts are continuing but, on

Congress's mandate, they are being given a new emphasis on abstinence, with \$86 million devoted this year to promoting abstinence.

World Relief International, the humanitarian arm of the National Association of Evangelicals, is to receive \$9.6 million over five years to promote abstinence. Deborah Dortzbach, international director for its H.I.V./AIDS programs, said World Relief would use a network of churches, schools and "Choose Life" clubs in Haiti, Kenya, Rwanda and Mozambique.

"We teach abstinence as an opportunity," she said, "as a way to delay the gift of sexuality and its pleasures until they can experience it with responsibility."

A guide for World Relief instructors includes a detailed chapter on condom use and how to negotiate the use of a condom with a reluctant partner. Ms. Dortzbach acknowledged, however, that many pastors were reluctant to discuss condoms at all with youths and needed some persuasion to mention them during marriage counseling.

Any discussion of condoms, Ms. Dortzbach said, emphasized that condoms were not perfectly safe and that "the only guarantee for protection is abstinence," which is the Bush administration's message.

That message is predicated on the success of the A B C model in Uganda, which stands for Abstain, Be Faithful, Condomize. Critics say, however, that the Americans are paying too little attention to "C."

The American government is probably buying more condoms now than at any time in its history, Mr. Tobias said, but Congress did not want a broad distribution of condoms to be the primary prevention tool, as it has been historically. In Africa, too, some experts question the efficacy of condoms, given that infection rates continue to climb as many men refuse to use them.

The Bush administration's strategy does suggest condoms for "high risk" individuals like prostitutes, soldiers, drug users and "serodiscordant" couples. But critics say everybody in a sub-Saharan country with a sky-high infection rate is high risk.

"In their approach, they ignore the basic reality that a large share of unmarried adolescents are already sexually active and so at high risk," said Jodi L. Jacobson, executive director of the Center for Health and Gender Equity in Maryland. "They also ignore the fact that marriage doesn't protect married teens and women from H.I.V., and that sexual violence and coercion are facts of life."

The Longer Term In Maputo, health officials said that they were struck by the Americans' obsession with numeric goals.

"To see an increase in numbers of people on antiretrovirals, that was their only concern," said Mr. Songane, the health minister. "But this is a complex disease. We can not judge the success of our fight just by the numbers of people on treatment."

The Mozambicans wanted to move gradually and to strengthen their health sector at the same time. They did not want to neglect other health issues, like malaria, childhood diseases and maternal health. They did not want to use nongovernmental organizations where the Americans would pay the salaries, buy the drugs and purchase the vehicles that would travel to the villages to distribute the drugs.

"In one year, two years' time, who is going to follow those people?" he asked. "When the N.G.O. is gone, who is going to take over?"

Dr. Paul Farmer, an American renowned for his treatment programs in rural Haiti, said international projects intending to help poor countries should pay heed, as Mozambique does, to the need to integrate AIDS treatment with overall health care.

"When you're in a clinic in rural Haiti and someone comes in with a broken arm or in obstructed labor, you can't say, 'Sorry, we only do AIDS prevention and care,' " said Dr. Farmer, a Harvard professor. "The massive loss of life due to H.I.V. disease is only one symptom of a very sick world in which hundreds of millions are going without any modern medical care at all. Addressing AIDS properly offers a chance to set some of this right."

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