

The false promise of untested AIDS drugs

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Monday, March 29, 2004

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URL: sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/03/29/EDGUM5S3411.DTL

Medical experts and officials from the United States, Africa and the United Nations are meeting in Botswana today to make decisions that could affect the future of the HIV/AIDS pandemic. At the summit, leaders will discuss the safety and effectiveness of so-called "all-in-one dose" or fixed- dose combination therapy for HIV/AIDS patients. While the prospect of such a simple treatment plan holds great appeal for patients in Africa and across the globe, it is absolutely essential that the decision to move ahead with these foreign-made, generic AIDS drugs is based on science.

Fearing the drugs could result in harmful setbacks in HIV treatment, the Bush administration last week prohibited using any of the \$15 billion in the president's global AIDS program on the drugs until they undergo further study. The millions of Africans suffering from AIDS merit the same gold standard of safety insisted on here in the United States, where the Food and Drug Administration serves as the final arbiter of whether a product comes to market.

The fixed-dose combination drugs, manufactured by two companies in India, are essentially "investigative new drugs." They are classified as generic drugs. They have not been tested or approved by the FDA. The World Health Organization was even cautious, saying its own prequalification of such drugs did not mean an endorsement of safety and efficacy.

The danger in rushing into untested HIV/AIDS therapies is not simply to the patients themselves, but also to the global community. The risks involved in these unproven products are unknown, but they have the potential for serious side effects and could promote the development of resistant strains of HIV. If new, untested drugs enter into the systems of HIV-positive patients, "the risk of suboptimal therapy can accelerate the emergence of drug-resistant HIV," says Dr. Terrence Blaschke of Stanford Medical School. For example, clinical trials conducted on a new three-drug combination were recently halted after researchers discovered that half of the subjects had drug-resistant strains of HIV.

Taking HIV drugs is not as simple as taking aspirin. Some of the proven HIV therapies must be carefully timed to avoid interactions with food, and others interact adversely with drugs used in treating diseases such as tuberculosis, which is common in developing countries. Patients taking fixed- dose combination drugs cannot even change doses.

With millions of lives at stake and \$15 billion in taxpayers' dollars on the line, U.S. officials in Botswana must insist on standards of safety and take caution in embracing a therapy that could inadvertently drive up HIV resistance and increase the scope of costs of fighting AIDS.

The fixed-dose combination issue takes on even greater significance in light of recent revelations over the mismanagement of U.S. funds by the World Health Organization and its fight against malaria. A study by a dozen malaria scientists and physicians found that more than 80 percent of malaria patients served by the WHO's program have been supplied with obsolete, ineffective malaria drugs.

Those advocating fixed-dose combination drugs often point to their WHO "prequalification" status as a basis for their safety. But the WHO, a membership body, has

no regulatory oversight like the FDA. Besides, the WHO does not even require that such drugs submitted for prequalification be tested for safety and efficacy.

Putting cost ahead of efficacy is no way to solve the HIV/AIDS pandemic. Victims of HIV/AIDS should not suffer the fate of those subjected to useless malaria treatments. The jury is still out on these fixed-dose combination drugs; if they pass FDA-level scrutiny, it would represent a welcome step forward in the fight against the pandemic. But as health officials prepare to make decisions on them, let's first recognize that such drugs wouldn't even be allowed to reach the U.S. market.

African AIDS patients must not be turned into unwitting guinea pigs. Nor should there be two standards of care: one for rich nations, the other for poor ones.

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