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U.S. at Odds With Europe Over Rules on World Drug Pricing

By DONALD G. McNEIL Jr.

Before the United Nations has even raised up to \$10 billion for its new fund to fight AIDS, the Bush administration and the European Union are engaged in a behind-the-scenes struggle over how that money will be spent, particularly on pharmaceutical drugs.

Communications between the United States trade representative and his European Union counterpart, obtained by The New York Times, show starkly opposing views on several key issues.

The Bush administration, like the giant pharmaceutical companies, opposes the creation of any system to regulate world drug prices, or the creation of a database where prices could simply be posted. The administration, while it has dropped moves against Brazil's production of cheap generic drugs, emphasizes that patent rights must be protected and wants the companies left alone to offer discounts when they see fit.

The Europeans appear to be siding with poor countries and campaigners for cheaper drugs.

No unified European position has yet been laid out, but different leaders and European Council resolutions favor a "tiered pricing system," endorse the right of poor countries to shop for cheap generic drugs from countries that ignore Western patents, and favor the creation of a worldwide database to show prices for all drugs from any supplier and to indicate whether the supplier is considered reliable.

While acknowledging that patents are important, the Europeans often note that they are blamed for driving up the cost of health care, and emphasize the exceptions to patent rights contained in world trade treaties.

"Basically, the European Union is saying that it doesn't want the fund to turn into a subsidy for Big Pharma, and the U.S. is saying the reverse," said Ellen 't Hoen, a drug price specialist at Doctors Without Borders, a medical charity that has led the fight for lower-priced drugs.

The United Nations' global fund to fight AIDS was proposed by Secretary General Kofi Annan at a special General Assembly in June. He asked donors to contribute \$7 billion to \$10 billion a year. So far, only about \$1 billion has been committed.

The rules governing the new fund are expected to be one topic discussed when President Bush meets the leaders of the world's seven wealthiest nations and Russia this week in Genoa, Italy.




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The Europeans — to the frustration of the Bush administration — have not defined what they mean by a tiered pricing system, although the assumption is that it would mean low prices for poor countries, high prices for rich ones and some sort of system for verifying that it was working.

Some leading members of the European Parliament appear to favor a system like that used for getting vaccines and contraceptives to the third world. For those, the pharmaceutical multinationals and their generic competitors in countries like India submit bids to international agencies like Unicef or the United Nations Population Fund, which handle distribution costs. The vaccines or contraceptives sell for a fraction — sometimes as little as one two-hundredths — of their prices in developed countries, and the makers still turn a small profit.

Price cuts by the multinational companies have been voluntary, in response to public indignation and counteroffers from generic producers.

The most obvious targets of the drive are anti-retroviral AIDS drugs, which 18 months ago cost as much as \$10,000 a year per patient, and now are offered by generic makers for as little as \$350 per year.

But AIDS also makes the body susceptible to secondary diseases like malaria, tuberculosis, pneumonia, meningitis, fungal infections and cancer. Pressure on pharmaceutical companies to offer poor countries discounts on virtually all therapeutic drugs is thus expected to mount.

The extent of the European-American debate is outlined in a letter sent in late June by Robert B. Zoellick, the United States trade representative, to Pascal Lamy, his counterpart on the European Commission.

In the letter, a copy of which was obtained by The Times, Mr. Zoellick expressed his distress that the commission was endorsing a tiered system. The Bush administration is "opposed to the creation of an international institution or convention to regulate drug prices," Mr. Zoellick wrote. "I also would question establishment of a verification process." Further, he stated that "we have practical and legal concerns with the concept of maintaining a database on drug prices."

The database, he wrote, would be "difficult to keep accurate" and "the sharing of drug pricing information can at times present problems under U.S. antitrust laws."

An official in Mr. Zoellick's office said the letter had two purposes. "One, we're challenging them to be specific about what they mean by a tiered pricing system," he said. "And, two, we're communicating that we're pretty skeptical."

Mr. Zoellick wrote that he was troubled by the reasons that Mr. Lamy's colleagues had offered for tiered pricing, including the argument that cheap drugs were still not available in Africa. Repeating an argument often made by spokesmen for the drug industry, he wrote that it was "more likely the result of the enormous infrastructure problems plaguing this region, rather than drug prices."

Millions of AIDS-infected Africans live in cities with hospitals or within walking distance of rural clinics, and have enough clean water to take pills. Many African countries now treat tuberculosis, which involves essentially the same regimen as AIDS requires — a daily handful of pills and occasional lab tests. Standard "first-line"

tuberculosis drugs, however, are priced much lower than anti-retrovirals; recently, drug companies began voluntarily lowering the prices of their "second-line" tuberculosis drugs, which are prescribed if other drugs are ineffective.

Mr. Zoellick's letter concluded by saying that the drug companies ought to be trusted. "We should expect companies to sell at the lowest possible prices," he wrote. "However, it appears to me that many companies are now doing so; there is no indication that their pricing commitments are short-term or of such limited quantity that we should doubt their sincerity."

Doctors Without Borders argued at a drug price conference in April that relying on the good will of pharmaceutical companies was not a sound approach for battling AIDS. The companies, the charity argued, deeply slashed their prices last year "only after immense international public pressure began to jeopardize the industry's image."

The official in Mr. Zoellick's office confirmed that the Bush administration still backed the policy started under the Clinton administration of not seeking trade sanctions on African countries that legitimately used patent-nullifying provisions under World Trade Organization treaties to get AIDS drugs. "And," he added, "about three weeks ago, we settled our W.T.O. dispute with Brazil. That's gone down fairly poorly with the pharmaceutical companies."

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