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Executive Order-Access to HIV/AIDS Drugs

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Friday May 26 12:08 PM ET

U.S. Could Extend AIDS Drug Help to Asia

GENEVA (Reuters) - The United States, which recently agreed to help make cheaper AIDS drugs available in sub-Saharan Africa, may relax patent laws for Asia and former states of the Soviet Union, a White House official said on Friday.

But Sandra Thurman, director of the White House Office for AIDS policy, said there was no timetable for extending the executive order signed by President Clinton two weeks ago.

The epicenter of the AIDS epidemic is in sub-Saharan Africa, but will move to Asia in 15 years and then to the former Soviet states, where intravenous drug use is the main way of transmitting the HIV virus, she added.

The presidential order allows sub-Saharan countries to obtain less costly AIDS medication through compulsory licensing and parallel importing, as long as the measures comply with the rules of the World Trade Organization (WTO).

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``That means that the United States will not stand in the way of any sub-Saharan African nation either doing compulsory licensing, which means producing their own drugs, or parallel importing, which is importing drugs at cheaper prices as long as it's done in a way that is consistent with regular WTO regulations," Thurman told a news briefing in Geneva.

``That was progress and I think it is indicative of the U.S. commitment to getting drugs to people who need them.

``Obviously, we're going to need to look toward Asia and the former Soviet Union as time goes on to see if we won't need to extend the same waivers for AIDS drugs to them," she said.

Pharmaceutical companies had opposed the move, arguing that countries' efforts to license local manufacturers to make generic copies of AIDS drugs violated their patent protections and compromised future research.

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- AIDS101.com - with news, basic information, origins, social impact of the disease, and biology.
- HIV/AIDS Treatment Information Service (ATIS) - information on federally approved treatments for HIV infection, treatment-related publications, and links to other treatment-related sites.
- JAMA HIV/AIDS Information Center - features information on prevention and treatment, reports and conference coverage, an education and support center, and a section on public policy.
- Johns Hopkins AIDS Service - with publications, resources, prevention and treatment information.

Washington File

10 May 2000

Text: Clinton Statement on New AIDS Drug Policy

(Action could bring life-saving drugs to sub-Saharan Africa) (710)

President Clinton signed an executive order May 10 that attempts to provide greater access to HIV/AIDS medications for sub-Saharan Africa where more than 5,500 people are dying from the disease each day.

Clinton explained the order in a letter to California Senator Diane Feinstein, who has actively represented the needs of AIDS sufferers. The order will give regional governments "the flexibility to bring life-saving drugs and medical technologies to affected populations." But it also protects the intellectual property rights of the U.S. manufacturers of those products, consistent with the rules of the World Trade Organization, he said.

The executive order follows a long controversy over increasing the flow of pharmaceuticals to Africa. Earlier attempts to achieve similar goals were defeated in Congressional negotiations over the Trade and Development Act of 2000. Clinton tells Feinstein that he would have preferred these issues to be addressed in that legislation, as she would have. But he says the executive order should have the same effect, enabling the United States "to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world."

Following is the text of the presidential letter:

(begin text)

THE WHITE HOUSE
Office of the Press Secretary

TEXT OF A LETTER FROM THE PRESIDENT TO SENATOR DIANE FEINSTEIN

May 10, 2000

Dear Senator Feinstein:

I am pleased to inform you that today I will sign an Executive Order that is intended to help make HIV/AIDS-related drugs and medical technologies more accessible and affordable in beneficiary sub-Saharan African countries. The Executive Order, which is based in large part on your work in connection with the proposed Trade and Development Act of 2000, formalizes U.S. government policy in this area. It also directs other steps to be taken to address the spread of HIV and AIDS in Africa, one of the worst health crises the world faces.

As you know, the worldwide HIV/AIDS epidemic has taken a terrible toll

in terms of human suffering. Nowhere has the suffering been as great as in Africa, where over 5,500 people per day are dying from AIDS. Approximately 34 million people in sub-Saharan Africa have been infected and, of those infected, approximately 11.5 million have died. These deaths represent more than 80 percent of the total HIV/AIDS-related deaths worldwide.

To help those countries most affected by HIV/AIDS fight this terrible disease, the Executive Order directs the U.S. Government to refrain from seeking, through negotiation or otherwise, the revocation or revision of any law or policy imposed by a beneficiary sub-Saharan government that promotes access to HIV/AIDS pharmaceuticals and medical technologies. This order will give sub-Saharan governments the flexibility to bring life saving drugs and medical technologies to affected populations. At the same time, the order ensures that fundamental intellectual property rights of U.S. businesses and inventors are protected by requiring sub-Saharan governments to provide adequate and effective intellectual property protection consistent with World Trade Organization rules. In this way, the order strikes a proper balance between the need to enable sub-Saharan governments to increase access to HIV/AIDS pharmaceuticals and medical technologies and the need to ensure that intellectual property is protected.

I know that you preferred that this policy be included in the Conference Report on the Trade and Development Act of 2000, as did I. However, through this Executive Order, the policy this Administration has pursued with your support will be implemented by the U.S. Government. The Executive Order will encourage beneficiary sub-Saharan African countries to build a better infrastructure to fight diseases like HIV/AIDS as they build better lives for their people. At the same time, the Trade and Development Act of 2000 will strengthen African economies, enhance African democracy, and expand U.S.-African trade. Together, these steps will enable the United States to forge closer ties with our African allies, broaden export opportunities for our workers and businesses, and promote our values around the world.

Thank you for your leadership on this critically important issue.

Sincerely,

WILLIAM J. CLINTON

(end text)

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release May 10, 2000

EXECUTIVE ORDER

- - - - - - -

ACCESS TO HIV/AIDS PHARMACEUTICALS AND MEDICAL TECHNOLOGIES

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 141 and chapter 1 of title III of the Trade Act of 1974, as amended (19 U.S.C. 2171, 2411-2420), section 307 of the Public Health Service Act (42 U.S.C. 2421), and section 104 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2151b), and in accordance with executive branch policy on health-related intellectual property matters to promote access to essential medicines, it is hereby ordered as follows:

Section 1. Policy. (a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa.

Sec. 2. Rationale: (a) This order finds that:

(1) since the onset of the worldwide HIV/AIDS epidemic,

approximately 34 million people living in sub-Saharan Africa have been infected with the disease;

(2) of those infected, approximately 11.5 million have died;

(3) the deaths represent 83 percent of the total HIV/AIDS-related deaths worldwide; and

(4) access to effective therapeutics for HIV/AIDS is determined by issues of price, health system infrastructure for delivery, and sustainable financing.

(b) In light of these findings, this order recognizes that:

(1) it is in the interest of the United States to take all reasonable steps to prevent further spread of infectious disease, particularly HIV/AIDS;

(2) there is critical need for effective incentives to develop new pharmaceuticals, vaccines, and therapies to combat the HIV/AIDS crisis, including effective global intellectual property standards designed to foster pharmaceutical and medical innovation;

(3) the overriding priority for responding to the crisis of HIV/AIDS in sub-Saharan Africa should be to improve public education and to encourage practices that will prevent further transmission and infection, and to stimulate development of the infrastructure necessary to deliver adequate health care services;

(4) the United States should work with individual countries in sub-Saharan Africa to assist them in development of effective public education campaigns aimed at the prevention of HIV/AIDS transmission and infection, and to improve their health care infrastructure to promote improved access to quality health care for their citizens in general, and particularly with respect to the HIV/AIDS epidemic;

(5) an effective United States response to the crisis in sub-Saharan Africa must focus in the short term on preventive programs designed to reduce the frequency of new infections and remove the stigma of the disease, and should place a priority on basic health services that can be used to treat opportunistic infections, sexually transmitted infections, and complications associated with HIV/AIDS so as to prolong the duration and

Wednesday May 10 2:57 PM ET

U.S. Pledges AIDS Drug Help for Sub-Saharan Africa

By Lisa Richwine

WASHINGTON (Reuters) - The United States said on Wednesday it was retreating from a controversial policy, pushed by U.S. drug makers, in order to help make less expensive AIDS drugs available to millions of poor patients in sub-Saharan Africa.

In an executive order, President Clinton promised U.S. officials would not stand in the way of countries that sought to obtain less costly, generic AIDS medication for their poorest citizens as long as the measures complied with international trade rules.

The announcement follows a more than year-long campaign by AIDS activists who complained that the Clinton administration, including Vice President Al Gore (news - web sites), was working on behalf of U.S. drug makers to bully developing countries from pursuing generic drugs.

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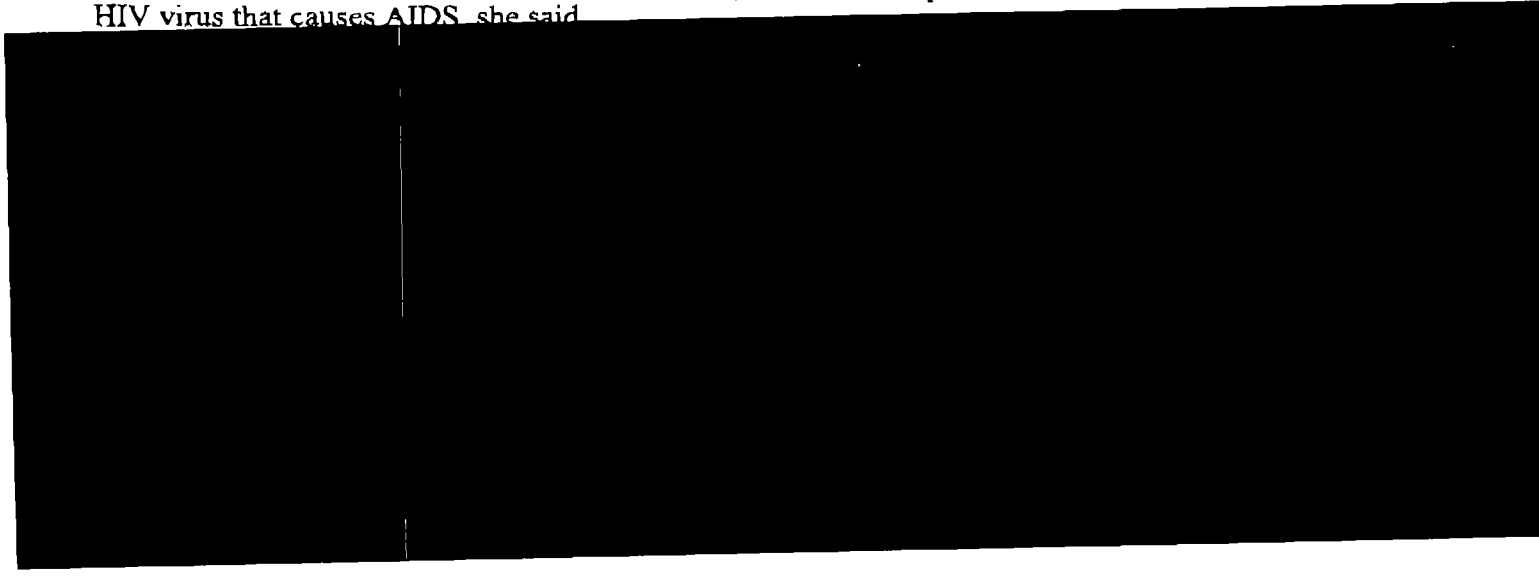
Pharmaceutical companies had argued that countries' efforts to license local manufacturers to make generic AIDS drugs violated the firms' patent protections and compromised future research. U.S. officials had threatened trade sanctions against countries that pursued such licenses.

From now on, officials will take a softer stance, U.S. Trade Representative Charlene Barshefsky said, asking only that countries abide by the World Trade Organization's agreement on intellectual property. That agreement gives countries more leeway to pursue less expensive medicines, she said.

Barshefsky said the administration was announcing the ``very substantial'' policy change because the spread of AIDS, which the United States recently dubbed a threat to its national security, had reached crisis levels in sub-Saharan Africa. In some areas, more than 20 percent of adults are infected with the HIV virus that causes AIDS, she said.



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May 11, 2000, Thursday, Final Edition

SECTION: FINANCIAL; Pg. E02

LENGTH: 484 words

HEADLINE: Africa Gets **AIDS Drug** Exception; Clinton Order May Lower Prices

BYLINE: John Burgess , Washington Post Staff Writer

BODY:

President Clinton yesterday ordered that sub-Saharan Africa get special leeway in importing or manufacturing patented drugs to combat the devastating AIDS epidemic there.

Clinton acted following lobbying by African countries, which contend that patent protection is cutting them off from newly developed treatments even as the disease cuts deadly swaths across their societies. U.S. AIDS activist groups have also pressed for the action.

When U.S. patent laws are strictly enforced for **AIDS drugs,** the result is high prices, typically $ 10,000 a year or more to treat an AIDS patient in this country. Such sums are far out of reach for African countries, which want to buy or make knockoff versions of the drugs at far lower prices. Clinton's order could make it possible, under some circumstances, for them to obtain **AIDS drugs** at lower prices.

"The executive order finds the balance between protecting intellectual property rights and also promoting accessibility of the drugs" in Africa, said White House spokesman Joe Lockhart.

The order declared that the United States would not invoke a key clause in U.S. trade law against sub-Saharan African countries concerning protection of patents on **AIDS drugs.** It would instead hold them to the less stringent standard of a World Trade Organization agreement on intellectual property protection.

The Pharmaceutical Research and Manufacturers of America, the U.S. drug industry's main trade group, criticized Clinton's order. It sets "an undesirable and inappropriate precedent, by adopting a discriminatory approach to intellectual property laws, and focusing exclusively on pharmaceuticals," said President Alan F. Holmer in a statement.

Member companies are working with African countries to combat the disease, he said, and "continue to play an essential role in pioneering applied research and development, our best hope of winning the war against AIDS. Strong intellectual property protection is the only way to encourage this research." The industry contends that without it, it won't have the huge sums of money needed to develop the drugs.

Paul Davis of ACT-UP Philadelphia, an activist group, welcomed the decision. But he faulted it for only covering sub-Saharan Africa and **AIDS drugs.** "There are more killers than HIV/AIDS and lots of folks

have AIDS in other countries," he said.

Last year, the White House negotiated a deal with South Africa to exempt it on AIDS issues from the provision known as Section 301 of a 1974 trade law. Yesterday's order extends that policy to sub-Saharan Africa as a whole, where, according to the White House, 11.5 million people have died of AIDS, about 83 percent of the world total for the disease.

Under WTO rules that will apply to the countries, certain health circumstances allow countries to order that certain drugs be licensed for local use or imported from third countries.

LANGUAGE: ENGLISH

LOAD-DATE: May 11, 2000

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May 11, 2000, Thursday, Late Edition - Final

SECTION: Section A; Page 7; Column 1; Foreign Desk

LENGTH: 559 words

HEADLINE: Clinton Issues Order to Ease Availability of **AIDS Drugs** in Africa

BYLINE: By NEIL A. LEWIS

DATELINE: WASHINGTON, May 10

BODY:

President Clinton, in the face of strong opposition from the United States pharmaceutical industry, issued an executive order today to make **AIDS drugs** available far more cheaply throughout sub-Saharan Africa.

The order declares that the United States government will not seek to interfere with countries in that region that may violate American patent law in order to provide **AIDS drugs** at lower prices. The language of the executive order is nearly identical to an amendment that was deleted at the behest of the drug industry from an African trade bill that Congress is considering this week.

The order issued by President Clinton essentially extended to most of Africa a special arrangement provided last year to South Africa.

"This order is intended to help stop the spread of this devastating disease by making H.I.V./AIDS-related drugs and medical technologies more accessible and affordable in sub-Saharan African countries," Charlene Barshefsky, the United States trade representative, said today. She said she believed it struck a balance between fighting the disease and maintaining integrity of patents.

In practice, officials said, that means that Washington will not object if African countries move to greatly reduce the price of **AIDS drugs,** either by licensing local companies to produce generic versions or importing the drugs from third countries where they are available at lower cost.

Both practices may be challenged under United States patent laws. But Senator Dianne Feinstein, the California Democrat who had co-sponsored the amendment that was deleted from the Africa trade bill, said the two practices were "fully consistent with World Trade Organization rules, which allow countries flexibility in addressing public health concerns." Senator Feinstein said that the deletion of the amendment she sponsored with Senator Russell D. Feingold, a Wisconsin Democrat, threatened to impede the fight against AIDS in Africa.

She said that some 34 million people in sub-Saharan Africa have been infected with the disease since its onset and nearly 12 million have died. "The fatalities in sub-Saharan Africa represent 83 percent of the world's total H.I.V./AIDS-related deaths," she said.

Alan F. Holmer, the president of the Pharmaceutical Research and Manufacturers of America, the principal

Wall Street Journal 5/11/00

75 CENTS

Into Africa

Makers of AIDS Drugs Agree to Slash Prices For Developing World

Five Firms' Pact With U.N. Will Still Leave Medicine Unaffordable for Millions

Black Markets and Generics

By MICHAEL WALDHOLZ
Staff Reporter of THE WALL STREET JOURNAL

In a landmark response to the AIDS crisis in Africa, five of the world's largest pharmaceutical companies are offering to slash the prices of HIV drugs for people living in poor nations.

The companies' unprecedented joint agreement, which is expected to be announced by the United Nations today, should make it possible for considerably more people in the devastated continent to gain access to the life-saving but extremely costly drugs that have revolutionized treatment in the U.S. and Europe.

Following delicate discussions with United Nations officials on ways to mount a broad attack on AIDS in developing lands, several companies are pledging to sell their drugs there for as little as pennies above manufacturing costs. Some are considering prices as much as 85% or 90% below the prices Americans pay, or about one-fifth of the already-discounted prices now charged in some African nations.

Assault on Drug Costs
The drug industry faces more political and legal attacks over drug prices and profits. Article on page B1.

"It's the first time the companies are collectively willing to discuss a truly significant decline in prices," says Peter Piot, director of the United Nations AIDS Program, who has been negotiating the agreement since early April. "It is something many of us have long hoped for."

Groundbreaking as the agreement is, it falls far short of a solution to the AIDS catastrophe in Africa, and it contains problems of its own. The pact may make it possible for tens of thousands of Africans, and someday maybe hundreds of thousands, to afford the drugs, yet the continent has an estimated 23 million people infected with HIV, the virus that causes AIDS. For most, even the new prices will remain too high.

Moreover, Africa has nowhere near enough of the trained medical people needed for the complex drug regimen, a failing the agreement says must be remedied. The AIDS therapy is a taxing program that must be followed to the letter; lapses risk not only a worsening of the disease in individual cases, but also the development of AIDS strains resistant to the drugs, with potentially deadly consequences for the whole world.

'Long Overdue'

"The companies' initiative is an excellent idea, long overdue," says Jose Zuniga, executive director of the International Association of Physicians in AIDS Care. But he adds: "If the offer isn't well thought-out and combined with funding to educate people about how to use the drugs or build health services to provide and monitor their use, the drugs' availability in Africa could be disastrous. These are potentially dangerous medicines."

For the companies, the initiative holds big risks. Cutting prices so deeply will expose closely guarded secrets about manufacturing costs and profit margins. This is likely to feed a clamor in the U.S. for curbs on drug prices. At the same time, companies fear that if they don't sharply cut prices for poor nations, those nations will turn en masse to generic AIDS drugs that are being produced in several countries in violation of corporate patents. Finally, the initiative holds the risk of spurring a black market in AIDS drugs.

The participants in the breakthrough drug-cost agreement are Bristol-Myers Squibb Co., Glaxo Wellcome PLC, Merck & Co., Boehringer Ingelheim GmbH and Roche Holding AG. Mindful of antitrust law, they haven't discussed specific prices among themselves but only in individual negotiations with U.N. officials.

Broad Effort Sought

Exact prices aren't likely to be settled upon for several more weeks. But Glaxo, for instance, has made clear it is willing to offer its Combivir for $2 a day. This is a mixture of AZT and 3TC, two drugs that form the backbone of AIDS therapy. Two dollars is about one-third of Combivir's current daily cost in Uganda and one-fifth of its price in the U.S. People close to the negotiators say the company might be willing to go even lower in price. Long-term AIDS therapy often requires the addition of at least one other drug, such as a protease inhibitor, which could drive the price up to between $5 and $7 a day.

A "joint statement of intent" being released by the U.N. today makes clear that pricing is only one piece of the puzzle. It calls as well for new efforts in prevention, health-care infrastructure, international funding and political commitment by afflicted nations. A major obstacle to combating AIDS in sub-Saharan Africa is that many nations have been slow to acknowledge the extent of the epidemic, which has left millions of children orphaned, slashed life expectancies, swamped health-care services and crippled already-enfeebled economies.

As things stand, only the fortunate few in many developing countries have had access to modern AIDS therapy. Richard Constant Okou, 36 years old and infected

Please Turn to Page A12, Column 1

Five Firms to Cut AIDS Dr

Continued From First Page

since 1988, has been able to keep working at a bank in Uganda, and thereby keep paying for his children's education, because he takes daily doses of three anti-HIV medicines. "I can't afford the drugs," he says, noting his monthly salary of about $500.

Mr. Okou, who wears loose-fitting sandals because one of the drugs produces a painful nerve condition in his feet, says he regularly receives a "care package" of the drugs from a doctor in Europe he once met. Several weeks ago, he had just enough drugs on hand to last a few more days. "I just got an e-mail saying a friend will be bringing me more drugs soon," he says. "It's not very reliable."

Richard Constant Okou

Mindful of the tremendous need, the U.N.'s Dr. Piot and others have implored the drug industry for more than three years to cut prices. Responses before today have been spotty and individual. Pfizer Inc. recently agreed to give away Diflucan, its costly drug for AIDS-related fungal infections, in South Africa. Bristol-Myers Squibb last year said it would donate $100 million over five years to bolster health-care services in Africa. Other drug makers have made somewhat similar commitments, but the companies haven't previously worked together on the acute affordability problem.

What sparked today's five-company response was an impassioned plea by U.N. Secretary General Kofi Annan at a special session on AIDS in December. At the meeting, Glaxo Chairman Sir Richard Sykes said his company was committed to a policy of offering "preferential" prices to poorer nations. Afterward, Bristol-Myers Vice Chairman Kenneth Weg suggested that he and Sir Richard encourage a trade group to convene a series of private talks with executives from their companies plus Merck, Roche and Boehringer Ingelheim. Following a meeting in London in early March, the five agreed on a new system of preferential pricing, and on April 3, Mr. Weg presented the idea to Dr. Piot.

Even with the new prices, the combination of three or more drugs needed to quell the virus will cost perhaps $150 or $200 a month. That's far below the $800 or so a month the combo now costs in Africa (or $1,000 a month in the U.S.). But per-capita income in Africa is less than $50 a month, and few African countries or employers pay for any health care. Even much cheaper drugs for ills such as malaria, tuberculosis and sexually transmitted diseases other than AIDS aren't widely available outside Africa's urban areas.

The Patent Issue

Many in Africa will surely see the drug obstacles in Africa is that less than 5% of its HIV-infected people know their status. "How can you treat people who aren't aware they are infected?" he says. Lowering prices "is a good step forward, but it doesn't solve the problem, not by any means."

Other concerns about an influx of somewhat-more-affordable AIDS drugs in developing countries are that this could tempt corruption among government employees or produce civil protest among those unable to get the medicines. And if the low-priced drugs fell into the wrong hands, the result could be black-market AIDS medicines showing up in developed nations where prices are much higher.

Pilot Program

The companies' price pledge is likely to startle many Africans battling AIDS. Just two weeks ago, Peter Mugenyi, who runs an AIDS clinic in Kampala, Uganda, went to Geneva to press Dr. Piot to organize an international effort to lower prices and improve services. "Can you even begin to imagine," Dr. Mugenyi says, "how a doctor feels when he knows there is treatment for a merciless disease but no way to get it to your patients simply because of its cost?"

Dr. Mugenyi has been involved in a pilot program set up by UNAIDS—which is linked to both the U.N. and WHO—to promote drug affordability. It is an effort by a small team of UNAIDS staffers who have struggled since 1997 to wrest significant price cuts from drug makers and prove that lower prices could blunt the African AIDS epidemic. Many believe this effort, led by a physician named Joseph Saba, helped lay the groundwork for the price promises now being made.

The idea actually came from a former Glaxo executive, Peter Young, who in 1996 was looking for a way to get Glaxo's AZT and 3TC into developing nations. He approached the U.N. in 1996 with a proposal: If it would make sure the drugs were used properly, Glaxo would offer them at reduced prices. Mr. Young sold the idea to his bosses at Glaxo by arguing that unless it cut prices, Africans would eventually buy large quantities of AIDS drugs from illegal generic producers, and then those patent violators, fattened by profits, might extend their sales to developed nations. That would threaten products generating about $1 billion a year in revenue for Glaxo.

A U.N. group under Dr. Saba created test programs in Uganda and the Ivory Coast. Setting up a nonprofit company and wangling some funding from drug makers, Dr. Saba began bargaining for discounts on HIV drugs in return for making sure they didn't fall into black-market hands. The nonprofit company agreed to sell the drugs only to patients treated by doctors or clinics that could prove they knew how to use them.

Glitches Arise

Right off, the plan ran into problems. Doctors were flooded with requests for the drugs after UNAIDS announced the project

aole outside Africa's urban areas.

The Patent Issue

Many in Africa will surely see the drug companies' proposal as laudable but late and insufficient. Skeptics, especially some African governments long antagonistic to multinational corporations, are sure to view it as a cynical public-relations effort to mute the thunder of criticism in the U.S. and in poor nations over high drug prices. The action comes two months before the World AIDS Conference in Durban, South Africa, where activists have been planning noisy demonstrations to demand drug-company concessions.

One of their demands is that companies allow wider use of generic copies of their AIDS drugs. Over the past year, several African governments have threatened to buy these inexpensive generic versions, which are being produced in Brazil, Thailand and India without regard to company patents. In one dramatic example, a day's supply of AZT that sells for $10 in the U.S. is sold by generics makers in Brazil for $1.08.

One indication of the rising generic threat: The Clinton administration yesterday reiterated a trade policy that would allow African nations facing health emergencies to authorize companies to make generic AIDS drugs, regardless of U.S. patents.

Enforcing patents, even in desperately poor nations, is an important component in the five companies' agreement. Several say they agreed to take part only after the director-general of the World Health Organization, Gro Harlem Brundtland, gave a January speech in which she, too, appealed to the drug companies. In an effort to "inspire" an industry response, she says, she pointedly stated that to "stimulate innovation," WHO believes drug makers' "intellectual property rights" should be protected.

"We saw her statement as a call to action," says Per Wold-Olsen, president of Merck's Europe, Middle East and Asia operations. The joint agreement contains the same sort of promise to protect intellectual property. Mr. Wold-Olsen has declined so far to tell the U.N. or WHO exactly how much Merck will cut prices. "We have signaled that we will be flexible," he says. "We will be very flexible."

Profit Margins

The companies are reluctant to say they will price drugs at cost because doing so would reveal a coveted industry secret: that profit for these and other drugs, once research costs have been covered, can equal 90% of the prices charged. The drug makers already fear that pressure for price controls would rise with certain legislative proposals to have Medicare pay for outpatient prescription drugs. Offering much lower prices in other countries could also increase U.S. price-control pressures, they worry.

Within Africa, deep price cuts could set off a wave of other changes in health care. "With the prices so high, there was little incentive for the governments to build the health infrastructure to provide care," says James Wolfensohn, president of the World Bank, which is part of the new agreement. "The companies' offer may now stimulate that effort and inspire wealthy nations to help fund it." The World Bank has tentatively agreed to provide added grants and loans to help educate health providers and buy the medicines.

Mr. Wolfensohn says one of the biggest

Right off, the plan ran into problems. Doctors were flooded with requests for the drugs after UNAIDS announced the project at a news conference in Kampala in 1997. "Doing so was a very big mistake," says Dr. Mugenyi. "People came here saying they wanted the new medicines they'd read about in the papers and heard about on the radio. But we didn't have the medicines yet, and of course people didn't even understand how expensive they'd still be or that the drugs were going to have to be taken daily for the rest of their life."

It wasn't until mid-1998 that the nonprofit company got its first shipment of discounted AIDS drugs from Bristol-Myers, Glaxo, Roche and several other companies. And then, the price discounts were wiped out when Uganda devalued its currency by almost half. As a result, a three-drug combination needed to keep AIDS at bay still costs $800 to $1,000 a month in Uganda. In a country where 1.5 million people are infected, fewer than a thousand are buying the drugs from the nonprofit.

However, research by Axios, a Dublin-based drug-marketing consultant that helped Dr. Saba, suggests that thousands more could afford the combination therapy if its price fell to $100 or so a month. It's a critical point, because Dr. Saba's pilot program has come under intense criticism from international public-health providers, who argue that focusing so much effort on the enormously costly medicines is an impractical, wealthy-nation response to a poor-nation problem.

Far more Africans would benefit, this argument goes, if the continent's limited resources were used to buy low-priced drugs for sexually transmitted diseases or malaria, to improve water sanitation and nutrition and to educate people in how to *avoid* HIV infection. This, the critics say, could be accomplished with an influx of money supporting local healers, religious groups or the thousands of grass-roots nongovernment organizations that provide much of the social and health-care service on the continent.

"I understand that argument," says Dr. Saba, a Lebanese-born, French-trained physician who once worked for WHO in Rwanda. "But why should those who could use the drugs suffer because the drugs aren't the solution for most everyone else?"

Subsidies Sought

The companies and the U.N. hope that with drugs' prices brought somewhat closer to affordability, subsidies to help pay for them may be forthcoming from employers, African governments and donor organizations such as the World Bank or U.S. and European governments. The argument that Axios, the marketing consultant, makes to drug companies is that by lowering prices dramatically, they can spur a market for their products where one doesn't now exist.

"We've been advising the drug companies they need to do two things," says the head of Axios, Brian Elliott. "Drop the price and provide some funding to underwrite the cost of expanding health services, such as HIV testing or counseling programs, that will assure the drugs are used correctly."

Before the creation of the UNAIDS program, the few hundred people receiving HIV therapy in Uganda were those well-off enough to buy the drug abroad or people such as Mr. Okou using a wide number of creative techniques. What the UNAIDS