Drug aid a 'slippery slope'

Firms must protect patents, profits while helping Africa

By THERESA AGOVINO
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NEW YORK — C. L. Clemente speaks with the bluntness of a man who is beyond exasperated.

The Pfizer Inc. executive vice president has heard the endless criticism from AIDS activists who insist loudly and often that the pharmaceutical companies are more interested in protecting their patents and profits than ending the AIDS pandemic in sub-Saharan Africa. Clemente counters that Pfizer wants to help, but there are limits.

"We are not the Red Cross," Clemente said. "We are a for-profit company."

Slashing the prices of AIDS drugs for African countries has left executives worried they may be undermining the patents that are the linchpin of their industry.

In the last year pharmaceutical companies have slashed the prices of AIDS drugs for African countries, where 26 million of the world's 36 million HIV infected people live. In doing so, executives are left with several worries.

They worry they may be undermining the patents that are the linchpin of their highly profitable industry. And just as frightening is the prospect of activists for other diseases using the AIDS drug offers as a lever to pry out similar concessions. There are other risks — that the drugs will be diverted to a black market or that distribution problems in Africa will lead to a stronger strain of the virus.

"There is a very slippery slope involved here, and we have to be careful," said Rick Moser, divisional vice president for public affairs at Abbott Laboratories, which announced last month it will sell its two AIDS drugs and HIV diagnostic test in Africa at no profit.

A trickle of evidence confirms the negative scenarios.

Prominent AIDS activist James Love has suggested a generic version of Zerit, a patented Bristol-Myers Squibb Co. drug, should be available in the United States because it was developed with government funds. And Merck & Co. has agreed to slash prices on its two AIDS drugs in Brazil, in part to stop that country from importing a generic version.

"The drumbeat has started," said Clemente.

Last week, 39 pharmaceutical companies dropped a high-profile lawsuit against the South

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AIDS drugs for Africa

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African government. The suit sought to block a law that would allow the country to ignore valid patents and either import or produce generic drugs in certain circumstances to protect public health.

"The weight of public opinion was too great against the pharmaceutical companies, and even if they won, they wouldn't look good," said Christopher Milne, assistant director of the Center for the Study of Drug Development at Tufts University.

Milne said the drug companies ran a big risk in pursuing the case because a courtroom loss would have set a global precedent. "They would have opened the floodgates of countries wanting to import generics even wider," said Milne.

The South African government has pledged to consult the pharmaceutical companies in drafting the law and to honor international trade agreements. The World Trade Organization allows countries to import or make generic drugs in an emergency, but what constitutes such a crisis has never been clearly defined.

Brazil and many African nations aren't necessarily breaking any laws by importing generic drugs because often medicines aren't under patent protection in those countries.

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Still, analysts said it is problematic for generic versions of widely patented drugs to be circulating, even in small sales markets like Africa, because it weakens the drug companies' efforts to maintain a worldwide environment that respects intellectual property.

AIDS drug costs in HIV plagued Africa

Drug companies are under pressure from AIDS activists to discount the cost of the drugs in Africa, where 26 million of the world's 36 million HIV-infected people live. Here are the estimated costs for these antiretrovirals and protease inhibitors, which work in combination with similar drugs to suppress the spread of the AIDS virus.

Drug • daily dose Prices in U.S. dollars	Brazil	Uganda	Ivory Coast	U.S.
3TC (Lamuvidine) • 300 mg	1.66	3.28	2.95	8.70
ddC (Zalcitabine) • 2.25 mg	0.24	4.17	3.75	8.80
Didanosine • 400 mg	2.04	5.26	3.48	7.25
Efavirenz • 600 mg	6.96	NA*	6.41	13.13
Indinavir • 2,400 mg	10.32	12.79	9.07	14.93
Nelfinavir • 750 mg	4.14	4.45	4.39	6.47
Nevirapine • 400 mg	5.04	NA	NA	8.48
Saquinavir • 1,200 mg	6.24	7.37	5.52	6.50
Stavudine • 80 mg	0.56	6.19	4.1	9.07
ZDV/3TC • 600/300 mg	1.44	7.34	NA	18.78
Zidovudine • 600 mg	1.08	4.34	2.43	10.12

*Not available.

SOURCE: UNAIDS

AP

"The drug companies have to be vigilant at all times," said Mickey Smith, director of the Center for Pharmaceutical Marketing and Management at the University of Mississippi. "They don't want to create a template that would allow any group to disrespect patents."

In February, Cipla Ltd., an India-based maker of generic drugs, offered to sell a three-drug cocktail of AIDS drugs to nonprofit agencies for $350 a year per African patient, provided the patients receive the drugs for free. African governments can purchase the same drugs for $600 per patient.

Merck & Co., Abbott and Bristol-Myers Squibb all cut their prices after that offer, though all three companies insist the timing was unrelated.

Patents are the basis for high drug prices. The companies say the revenue allows them to recoup development costs and generate profits to fund new medicines. Pharmaceutical executives are quick to point out that this system created the AIDS drugs in the first place, and that if Abbott hadn't been charging $7,200 for a year's worth of Norvir in the United States, it couldn't sell it in Africa for roughly $1,000 a year.

Activist groups such as ACT UP and the Health Gap Coalition insist they have no desire to bankrupt pharmaceutical firms or kill the patent system. But in Africa they insist generic drug importation is necessary because it would pressure pharmaceutical companies to keep lowering prices.

Drug companies have powerful allies in their effort to keep generics at bay.

After meeting with pharmaceutical executives last week, U.N. Secretary General Kofi Annan said "intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people." And Harvard economist Jeffrey Sachs, active in the Africa AIDS fight, said it was important to respect patent rights when solving the crisis.

Analysts fear that, even with patent protection, reduced drug prices will eventually be too costly. Pharmaceutical companies have always had significant charitable programs, but the demands in fighting AIDS could be excessive.

Right now the costs are negligible, but then so is the number of people receiving the drugs. According to Sachs, only 100,000 people in Africa have access to AIDS medications.

Negative response from shareholders and others has also been scant.

Pfizer Inc. said it received a dozen letters criticizing its $50 million program in South Africa to give away Difulcan, a drug which treats brain infections in AIDS patients.

Other drug companies haven't reported a negative response and they say their commitment to AIDS is growing — for Abbott, the disease now accounts for the largest portion of its $100 million in charitable endeavors.

"All of a sudden these programs are on everyone's radar screen," said Jeffrey Chaffkin, an analyst with UBS Warburg. "It is not a problem now, but what about two years down the road? Where are you going to draw the line?"

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Pharmaceutical executives are skittish about detailing the finances behind their deep discounts out of fear of unnerving shareholders. Merck and Abbott say their drugs are sold at no profit, but executives don't want to say whether they will be losing money. Bristol-Myers Squibb has said it is selling its drugs at below cost, but it won't say by how much.

Drug companies have long been Wall Street darlings because of their consistent profitability and high profit margins.

In the last five years, the major pharmaceutical companies have outperformed the Standard & Poor's index. The industry's average net profit margin is 18 percent. Such hefty earnings, combined with high drug prices, have demonized the industry in the eyes of many.

Pharmaceutical executives fear their AIDS programs will trigger an avalanche of demands for deep discounts for other medicines from other interest groups.

That concern may be overstated because everyone from senior citizens to senators to state legislators have been seeking ways to make prescription drugs more affordable. The recent price cuts for AIDS drugs may provide more ammunition to those already itching for prescription drug price relief.

Smith believes the current AIDS crisis will only highlight Americans' ambivalence about health care. He maintains Americans enjoy the technological developments, but dislike the high prices and the concept of making money off disease.

"The drug companies are in an awful spot of having to balance the needs of their shareholders with the needs of the dying," Smith said. "Of course, people want to help Africa, but every time a drug is given away, sooner or later we pay for it."