

In New Trade Pacts, U.S. Seeks To Limit Reach of Generic Drugs

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As public-health groups urge wider use of generic drugs to lower the cost of treating AIDS and other diseases in developing countries, U.S. trade negotiators -- prodded by the drug industry -- are taking the opposite stance in new trade pacts, seeking to strengthen protections for costlier brand-name drugs.

In a series of complex, wide-ranging trade talks with other nations -- which are intended to govern everything from crops and clothes to music and video discs -- the U.S. aims to defend U.S. companies from competition from foreign copycats. But public-interest health groups say that when it comes to critical drugs, U.S. efforts are keeping prices too high for the poor.

"Medicines are treated like a commodity, the same as Barbie Dolls or computer software," says Rachel Cohen of Doctors Without Borders, a nonprofit emergency-relief organization. Essential medicines, she says, should not be treated simply as products needing protection or else "poor people pay the price."

In response, the drug industry has argued that current practices in many countries simply make it too easy for generic drug makers to quickly introduce cheap copies of branded products, thus profiting from costly investments in research made by developers of branded versions. The industry also notes that many makers of branded drugs do provide low or no-cost drugs for AIDS and other life-threatening diseases to developing countries.

But activists and makers of generic drugs counter that the U.S. protections block developing countries' ability to access generic drugs and put price leverage in the hands of brand-name makers at a time when HIV and AIDS are exploding in the developing world. Of the nearly 40 million people with HIV or AIDS globally, less than 10% currently have access to drugs that can transform the infection from a death sentence to a chronic condition -- and most of them are in Western countries. In the developing world, the drugs are not as widely available and often are too expensive for many.

The issue of generic drugs -- and access to them -- will be high on the agenda at the XV International AIDS Conference starting next Sunday in Bangkok. (See [related article](#)².)

The U.S. strategy doesn't seek to indefinitely deny the availability of generic drugs. But it does seek to delay their introduction.

In many countries, including the U.S., makers of generic drugs often can win approval simply by proving that their products are equivalent to the original drugs. But the key provision sought by the U.S. in new agreements restricts trading partners from approving for five years a generic-

drug application if it relies on test data compiled by the original drug's manufacturer. In essence, that grants branded drug-makers temporary exclusivity, already available inside the U.S.

The goal is to shore up new global protections for U.S. drug makers in other countries. As part of the General Agreement on Tariffs and Trade negotiated a decade ago, a major trade agreement known as TRIPS was negotiated covering global intellectual property such as trademarks and copyrights. One part of the agreement on Trade-Related Aspects of Intellectual Property Rights required signatories to grant 20-year market exclusivity to patented drugs, a provision that is currently being phased in around the world.

But the exclusivity protection was granted only to new drugs that seek protection after a country has implemented a new patent system. It doesn't apply to drugs currently in circulation. And some developing countries were given until 2016 to implement such a patent system. That means drugs that are newly available, or currently in development, may not win patent protection in many countries in the near-future, and thus could be vulnerable to generic drug makers.

The U.S.'s data-protection clause provides protection for branded drugs while those patent systems are being set up. It also protects products that aren't new or lack a patent because companies haven't applied for one, a common scenario in developing countries.

Moreover, another rule negotiated in trade talks requires foreign regulators to consider the patent status of a drug seeking market approval. Typically, regulators ignore patent issues, leaving claims to patent offices and courts.

So far, the U.S. has reached agreements including the new protections with Jordan, Chile and Singapore. The protections appear in agreements awaiting congressional approval with Australia, Morocco and the six Central American countries -- Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic -- that are part of the proposed Central American Free Trade Agreement. Late last month, the U.S. also launched trade talks with Thailand seeking the same protections.

But intentionally or not, such agreements are, in some cases, "either pushing prices up or preventing their fall," says Richard Feachem, the Geneva-based executive director of the Global Fund to Fight AIDS, Tuberculosis and Malaria, an international public-private partnership that links governments and donors.

"There's a wide consensus by the United States and others that essential drugs must be made available at low cost," Dr. Feachem says. But in Jordan, he says, which recently signed a trade agreement with the U.S., AIDS drugs purchased with Global Fund monies cost an average of \$7,000 a year per patient, compared with the average \$250 to \$400 paid in other countries supported by Global Fund grants.

In turn, U.S. trade officials and drug-industry groups cite Jordan as a robust example of free-trade benefits. "What we've seen is a blossoming of their pharmaceutical industry," says a spokesman for the U.S. Trade Representative's office in Washington. "Their exports went up

30%. There have been 30 new drug-product introductions. We've seen an increase in the trade relationship."

The U.S. trade office and the drug industry have presented a united front in promoting the data-exclusivity provision. Each year, for instance, the industry's main trade group, the Pharmaceutical Research and Manufacturers of America, or PhRMA, makes recommendations to the U.S. trade representative on which countries should be included on an annual "watch list" that the office issues to rate intellectual-property protections. Some can face the threat of trade sanctions. In comments on its list this year, the trade representative noted that it had "focused" on protection of test data.

Mark Grayson, deputy vice president of PhRMA, says the trade group has an "open" and "collaborative relationship" with the U.S. Trade Representative's office. PhRMA doesn't have anyone attending the current round of trade talks between the trade representative and Thailand, now going on in Honolulu, but Mr. Grayson says that when the talks shift to Washington "we might have people available" if the trade representative wants to clarify a point.

"USTR might bounce things off us and say this is what's going on, and get reactions from us and every other industry," he says.

For example, PhRMA recently singled out Thailand for the failure of its new Trade Secrets Act to enact what it called "sufficient data protection." When the trade office issued its most recent watch list on May 3, it cited Thailand for failing to enact effective data protection, echoing PhRMA's complaints.

Thailand is caught between opposing needs. It must respect U.S. patent law or risk jeopardizing the U.S. market for its products from jasmine rice to Thai silk. But as a country hard-hit by AIDS, Thailand makes affordable generic drugs for patients who cannot pay U.S. drug prices, charging them \$30 a month per patient. It treats 35,000 Thais with state-manufactured AIDS generics, and aims to expand the program to reach 50,000 this year. But newer brand-name treatments likely would be off-limits to generic copies under the U.S. trade pact.

In Bangkok, Achara Eksaengsri, a pharmacist with the Thailand's Government Pharmaceutical Organization, says that as the AIDS virus mutates, patients will need to bolster their regimens with more of the newer patented drugs like efavirenz (Bristol-Myers Squibb's Sustiva) and lopinavir (in Abbott Laboratories' combo pill Kaletra). That would be difficult at best under the trade rules being sought by the U.S.

It is the early days for the new rules, and their impact on the fast-evolving AIDS treatment scene is a matter of debate. "There's a lot of scare-mongering that goes on," says Susan Finston, associate vice president for intellectual property of the PhRMA.

But Federico Alberto Cuello Camilo, an economics professor in the Dominican Republic who advises that country's chamber of deputies, predicts the proposed trade rules "basically will kill the pharmaceutical industry in this region." Dominican-made generic drugs account for 49% of the country's drug market, and cost consumers half as much as branded U.S. counterparts, he

says. But that is because the Dominican government approves drug copies that rely on the original manufacturer's drug data. The CAFTA data provision, if implemented, would block such products for at least five years.

"Is it fair to condemn our poor people to treating today's illnesses with yesterday's medicines?" he asks.

In Guatemala, few drugs on the market have a patent. Pfizer Inc.'s Viagra is one, according to drug-industry trade group Fedefarma. But last year Guatemala passed a new five-year data-exclusivity law that the U.S. and the drug industry had been seeking. The law currently protects at least 12 products from generic competition, including the AIDS drugs Reyataz and Fuzeon, as well as drugs for cancer and sepsis.

Previously, after Guatemala removed 15 years of data protection, the U.S. trade office had placed Guatemala on a "priority" watch list, raising the specter of potential trade sanctions. When Guatemala passed the five-year protection, it was moved back to the more benign "watch list."

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