AIDS Patients See Life, Death Issues in Trade Pact

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GUATEMALA CITY — Carmina Garcia rises before the sun each morning, taking pleasure in the first yellow rays of dawn. But it's the pink and white tablets that keep her going.

Found to be HIV-positive shortly before her husband died of AIDS-related complications last fall, an ailing Garcia was convinced of her own death sentence. But generic drugs have kept the virus in check and restored 60 lost pounds to her frame.

"I now have hope," said the 52-year-old grandmother and flower vendor, who gets her medicine free from a nonprofit clinic.

Public health experts fear that hope might fade for Garcia and thousands of the region's chronically ill if the Dominican Republic-Central American Free Trade Agreement, known as CAFTA, is approved this year.

Under the pact American pharmaceutical giants would gain a five-year edge on the development of new drugs by low-cost competitors. Generic versions of name-brand drugs are the main weapon for battling the AIDS pandemic in the developing world.

Healthcare activists say those intellectual property protections would drive up the cost of treating chronic conditions, particularly HIV/AIDS, sufferers of which routinely develop resistance to old medications. About 40 million people worldwide are infected with HIV, the virus that causes AIDS, and more than 275,000 of them live in the six Latin American CAFTA nations, according to United Nations statistics.

The prospect of less-affordable medicines has fueled opposition to CAFTA in Central America, particularly in Guatemala, where public opinion has turned overwhelmingly against the trade pact despite its passage by legislators here in March.

Similar concerns have been raised in other parts of the region, where three countries — Nicaragua, Costa Rica and the Dominican Republic — have yet to ratify the pact. In addition to Guatemala, it has been approved in Honduras and El Salvador.

Though CAFTA supporters hope to win U.S. approval of the pact before Memorial Day, they are still far short of the votes needed for passage. Critics in the U.S. — including many Democrats and labor unions — say the pact doesn't contain tough enough protections for labor and the environment.

With opposition mounting on both sides of the border, President Bush went to bat Wednesday for the controversial agreement, saying it was needed to "create jobs and to strengthen democracy in our hemisphere." Though Central America isn't a huge market, the Bush administration considers the pact key to building a free trade zone from Alaska to the tip of South America. U.S. supporters fear that a high-profile setback would weaken that effort and others around the globe.

The trade-off between protecting drug companies' intellectual property rights and providing low-cost drugs to poor nations is being grappled with by governments and health activists around the world.

U.S. trade officials readily acknowledge that they are trying to strengthen intellectual property laws worldwide to protect drug companies and other U.S. interests whose innovations are under constant attack by counterfeiters.

Similar provisions protecting big drug companies are part of U.S. trade pacts with Morocco, Jordan and Singapore — and are expected to be included in many future U.S. deals.

The Bush administration insists CAFTA will not endanger a Central American government's ability to import or manufacture generic drugs it needs to "protect public health" against epidemics such as HIV/AIDS or in cases of "extreme urgency or national emergency."

For many Guatemalans, this is far more than an arcane trade dispute. Competition from generics has helped drive down prices for some antiviral drugs by as much as 98% in Guatemala, where 78,000 people are infected with HIV. That has allowed relief agencies to stretch their budgets to treat more people like Garcia. Even so, it's estimated that as many as 80% of Guatemalans who need these medicines still lack them.

But like makers of toys, software and designer clothing, big drug firms say they need help in fending off copycats who swipe their innovations and then siphon off profits by selling illegally copied drugs in their most lucrative markets. Through reverse engineering, generic makers can quickly duplicate drugs that took U.S. firms years, even decades, to bring to market.

U.S. pharmaceutical companies, which spent more than $38 billion on research in 2004, are also worried about the safety of copycat drugs.

"The amount of innovation and risk that goes into the development of compounds is enormous," said Steve Schnittman, vice president of global clinical research for Bristol-Myers Squibb Co. "You need to reward that innovation and risk taking."

He said his company spent five years developing Reyataz, or atazanavir sulfate, a new HIV and AIDS drug that activists are eager to get in a low-cost generic version.

Rules on drug copying are tightening all over the globe. By year-end, the World Trade Organization will require most of its 148 members to begin honoring pharmaceutical patents for 20 years. But healthcare advocates are particularly alarmed at what they see as a U.S. effort to use smaller trade pacts such as CAFTA to throw up even higher barriers to generic drug makers.

For example, WTO rules permit member countries to override patents and authorize generic production of name-brand medicines that are needed to protect the public health. The mere threat of this so-called compulsory licensing has helped keep drug prices down. However, if CAFTA is approved, experts say, the ability of Central American nations to use that leverage would be severely restricted.

In addition, under CAFTA, generic-drug manufacturers seeking government approval to produce a drug would be required — for the first five years after a drug is registered — to conduct their own clinical trials rather than piggyback on originators' work. That would add considerable time and expense, critics say, making it much less attractive for generic makers to pursue the Central American market, which represents less than 1% of drug sales worldwide.

"It's especially disgraceful to impose these kinds of obligations on very poor countries for the purpose of some broader business plan when the consequences in these countries are life and death," said Robert Weissman, director of Essential Action, a Washington corporate accountability watchdog.

On a recent morning in a gritty section of Guatemala City, elderly women waited alongside middle-aged laborers and young mothers cradling babies at an AIDS clinic operated by the relief group Doctors Without Borders.

Discrimination against infected people is rampant in Guatemala. Those who reveal their illness risk losing their jobs and being shunned by family and friends. Those at rallies to demand more AIDS funding here typically wear paper bags over their heads so that they won't be recognized on television.

Sandra, a 32-year-old former prostitute who did not want her last name published, didn't know she was infected with the deadly disease until her preschool-age son died of AIDS complications two years ago. She contemplated suicide, but credits the clinic's counseling and antiviral medication for bringing her back from the edge.

"I'd be dead without those pills," she said.

Doctors Without Borders pioneered the use of generic AIDS drugs in Guatemala, where it treats 1,700 patients. The agency's most widely used medication is a generic version of the antiviral cocktail AZT/3TC, which it purchases from a supplier in India for $216 per patient per year. Guatemala's social security system last year paid $4,818 per patient for the original made by GlaxoSmithKline, according to Doctors Without Borders figures.

Clinic administrators say that price differential is a big reason the agency now runs the country's largest treatment program. Still, a small but growing number of its clients need expensive new medications such as lopinavir, marketed by Abbott Laboratories under the name Kaletra.

The $480-a-bottle antiviral is so coveted on the black market here that staffers at the Guatemala City clinic keep it in a locked refrigerator inside a secure storage room. A generic version does not exist, and probably won't anytime soon in Central America if CAFTA is approved, AIDS activists said.

Pharmaceutical firms are responding to the heat. Under the United Nations-sponsored Accelerated Access Initiative, five leading companies — GlaxoSmithKline, Bristol-Myers Squibb, F.Hoffman-La Roche, Boehringer Ingelheim and Merck & Co. — are offering cut-rate AIDS medicines to poor countries. But at $1,100 to $1,600 per year per person, those prices are still well above what some generic manufacturers are charging for similar medications in Central America, activists say.

Most governments would prefer to let the free market set prices by letting generic manufacturers in and forcing pharmaceutical companies to compete.

But countries such as Guatemala are finding that's not so easy. In 2003, the nation revised its intellectual property laws to conform to CAFTA. Pressured by an angry public, legislators repealed the law late last year and replaced it with a new one meant to promote more generic competition in pharmaceuticals.

After the U.S. accused Guatemala of reneging on its CAFTA commitments, the legislators flip-flopped again. In early March the Guatemalan Congress restored the data-exclusivity provision and quickly voted to approve CAFTA. The nation erupted with protests in which scores were injured and at least one demonstrator was killed.

"I'm doing a lot of things now that I never thought I would," said Garcia, the HIV-positive grandmother, after she participated in an anti-CAFTA protest without the customary paper bag mask. "I'm fighting for my life, their lives."