

CAFTA and Access to Medicines

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Today, in a pre-CAFTA environment, very few people in Central America have access to medications for financial reasons – both because they themselves are poor and because their governments don't have enough money to provide medications for them. In all the CAFTA countries except Costa Rica, less than 5% of HIV patients currently receive antiretroviral treatment through their governments' public health systems. Under CAFTA, governments and individuals will be forced to buy higher priced medicines for longer periods of time – thus increasing the overall cost burden on public health systems for poor nations. This is particularly a concern for diseases like HIV/AIDS that require sustained treatment over the lifetime of a patient. Ironically, as the infected population grows, governments' ability to treat these patients is shrinking. CAFTA's effects will not be seen overnight because its intellectual property (IP) provisions apply to long-term procedures, especially those governing the introduction of new drugs to the market. Yet the inevitable result is that some of the lucky few currently on medications will be cut off, while an increasing percentage of the infected population will be left without access to life-sustaining drugs.

To better understand how CAFTA's IP regime works, we conducted a research trip to Guatemala in July 2004. In many ways Guatemala represents a window to the future, because the country has already enacted many of CAFTA's IP provisions by means of domestic law. It is the first of the CAFTA countries to do so. In other regards, the situation is fairly typical: at present, Doctors Without Borders provides 1100 Guatemalans with antiretroviral medications because neither they nor the government can afford to do so. The government provides medications to approximately 200. A handful of others receive donated medications from abroad, including children in orphanages and patients at one of the country's only AIDS clinics. But even still, only about a small fraction of the infected population is receiving treatment today. To make matters worse, according to the terms of its agreement with the Guatemalan government, Doctors Without Borders is scheduled to stop provided medications in Guatemala in 2006, leaving the government to assume the burden of these 1100 patients precisely at a time when it will be less able than ever to do so. This means many of the few patients who do receive antiretroviral drugs will be cut off.

Technical points: *how* CAFTA affects access to medications

1. CAFTA extends monopolies

The WTO's TRIPS agreement mandates a 20-year period of patent protection for pharmaceutical products as a way to encourage innovation and help producers recoup research and development costs. Yet CAFTA extends this period of market monopoly beyond existing international standards in at least three ways:

-CAFTA mandates the extension of patent protection even beyond the current 20 year limit, to compensate for procedural delays (either in granting patents, [Article 15.9.6a] or in securing marketing approval for pharmaceuticals, [Article 15.9.6b]). A longer period of patent protection means a longer period without competition, and therefore, higher prices.

-CAFTA introduces protection for pharmaceutical test data, a new category of intellectual property rights. CAFTA provides 5 years of market exclusivity by ensuring that generic producers cannot prove the safety and efficacy of their drugs by demonstrating their equivalency with brand-name products. Through this mechanism, CAFTA permits even products that are not eligible for patents, and even some whose patents have expired, to enjoy monopolies for 5 years.

- CAFTA requires a member country to grant this same 5 years of data protection even if the product in question has not been registered in its territory. This means that if a pharmaceutical company puts a new product on the market in the USA but not in Guatemala, for example, (which is common because Central American countries represent such small markets), Guatemala has to bar generic manufacture of that drug for 5 years. This could mean that a lifesaving drug would be unavailable, at any price, in the Guatemalan market during this time. Furthermore, if the company were to register the drug in Guatemala after these 5 years, under CAFTA it would enjoy 5 more years of domestic protection, effectively barring generic manufacture of that product in Guatemala for up to ten years.

The direct result of extended market monopolies is higher prices for consumers and governments. In this way, this free trade agreement contradicts the very principles of free trade.

2. CAFTA Undermines WTO Public Health Safeguards

The WTO's Doha Declaration (2001) establishes safeguards that allow countries in the developing world to enforce intellectual property rights without sacrificing the protection of public health in circumstances of extreme urgency. Yet specific provisions in CAFTA make it more difficult for countries to recur to these mechanisms.

Compulsory licensing is a process whereby governments can circumvent patent rules in exceptional circumstances to ensure access to necessary medication at a low cost or in large quantities by authorizing the generic production of a drug otherwise under patent. Yet because CAFTA introduces protection of test data in addition to patent protection, it effectively creates another hurdle that a government would have to surmount in order to deal with a public health emergency.

CAFTA does allow exceptions to the rule of test data protection "where necessary to protect the public" (Chapter 15.10.1d). Yet here the protection of public health is an exception, not the rule. The burden of proof falls to those who would argue the exception should be applied. Because of the interaction between Chapter 15 and other parts of the Agreement, specifically Chapter 10, invoking such an exception incurs great political and economic risk.

Chapter 10 allows private corporations to sue governments for practices that constitute "unfair barriers to trade." Comparable provisions in NAFTA have permitted corporations to sue governments – including the state of California – for imposing public health protections that result in diminished profits. For the small economies of Central America, the threat of multi-million dollar lawsuits constitutes an inherent deterrent to invoking public health safeguards. The agreement makes it less likely that countries will do anything that will limit the profits of corporations even if doing so could arguably fall within the rules laid out in Chapter 15.

Conclusion

While there exists a growing awareness of CAFTA's weak environmental and labor protections, few Americans are aware of the dire consequences its IP provisions will bring in terms of access to lifesaving medications. Not only do these provisions run counter to the very principle of "free trade" – imposing protections to shield specific corporations from market competition – they barter Central Americans' health for corporate wealth. This is unacceptable.

Edgar, an HIV positive man we met in Guatemala, asked us to carry a message to the US Congress: "You're negotiating with our health... See not only the economic aspect, but the human aspect [of your policies]."