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CAFTA Raises Prices, Limits Availability of Life Saving Drugs for U.S. Trade Partners

Pioneering Study of Guatemalan Drug Market Shows Costs of PhRMA-driven Policies

Washington, DC – In a report published online today in the peer-reviewed journal *Health Affairs*, researchers for the first time demonstrate how the U.S. - Central America Free Trade Agreement (CAFTA) keeps lower-priced generic versions of life-saving drugs off the shelves and out of the hands of some of the poorest people in our hemisphere. Guatemala is increasingly unable to produce or import affordable medicines because of intellectual property provisions in the trade deal that were demanded by the U.S. pharmaceutical industry and have been aggressively enforced by the U.S. Trade Representative (USTR). As a result, the cash-strapped Guatemalan public sector faces higher prices – up to 846 percent higher – for important drugs to fight diseases such as diabetes and HIV/AIDS. People with HIV/AIDS report cutbacks in access to needed drugs. The study’s authors call on President Obama’s new administration to reverse trade agreements that drive up the price of medicines in poor countries like Guatemala, as well as here at home.

“A doctor who knowingly denied lifesaving treatments to a poor patient to protect profits would face ethics charges,” said Ellen Shaffer, co-author of the study. “The same should be true for our national policies.” Shaffer and Joseph Brenner are co-directors of the Center for Policy Analysis on Trade and Health (CPATH), and co-authors on the report. In the report they document that competing demands by the U.S. pharmaceutical industry and U.S. officials to enact data protection, on one side, and patients-rights groups who opposed these rules on the other, caused Guatemala to reverse its laws on data protection five times between 1999 and 2005. Groups such as Mujeres Positiva, representing women with HIV/AIDS, are currently demanding that the domestic laws imposing data protection be repealed. Shaffer and Brenner interviewed public health officials and activists in Guatemala for their study, and note that while there has been no indication of a change in U.S. policy, a signal of support from the new Administration would be influential in changing Guatemala’s domestic laws.

In the article, “A Trade Agreement’s Impact on Access to Generic Drugs,” the authors focus on data exclusivity rules and patents that are among the intellectual property provisions of CAFTA and other free trade agreements. Particularly alarming is that the rules not only keep affordable new generics from entering the market; they also function retroactively to remove existing medicines from the shelves. While patents already allow brand name drug manufacturers like Novartis and Merck to suppress competition from generic drug makers in the U.S. and abroad, data exclusivity is an additional bonus for this multi-billion dollar industry. Securing data exclusivity is a simple process for these companies, but it places insurmountable bureaucratic burdens on generics manufacturers. Generic drug makers typically rely on the clinical trial data already generated by brand-name manufacturers to demonstrate the safety and efficacy of their products. But CAFTA prohibits generic drug manufacturers from using the brand-name clinical trial data for a fixed period of years, sometimes even after the brand-name drug is no longer under patent. Without these data, generic versions cannot be approved for market.

“We are talking about insulin, antibiotics and drugs for cancer and AIDS that are literally the difference between life and death,” says co-author Brenner. “The drug industry is already recovering its investments – and then some – from American consumers who pay the highest prices in the world. These data exclusivity rules serve no scientific or safety purpose and they crush competition abroad. It’s an economic double-dip for these companies.”

Brenner and Shaffer examined a total of 77 data-protected drugs. Detailed tables in the article illustrate the ways in which both patent and data exclusivity protections influence Guatemalan health officials to purchase brand name pharmaceuticals, often at hundreds of times the cost of their generic counterparts. They also provide examples of generic drugs that were blocked from being marketed in Guatemala in the first place.

Example: The insulin made by Sanofi Aventis U.S., brand named Lantus, cost \$50.31 per 100 ml in 2007 while a therapeutically equivalent generic insulin made by Drogueria Pisa de Guatemala cost \$5.95 per 100 ml. Because Lantus is protected by data exclusivity until 2016, Guatemalans will continue to pay 846 percent more for this product than they would pay for its locally manufactured equivalent.

Example: Omnicef is an antibiotic which treats infections including pneumonia, and is made by the Illinois-based company Abbot. Because the process for formulating this drug is patented in Guatemala, a generic version was prevented from being produced or sold.

Example: The leukemia treatment named Gleevec, made by Novartis, also enjoys patent protection, although its expiration date could not be determined. Until it expires, affordable generic alternatives cannot be developed or sold in Guatemala.

Example: In some cases, data protection bestowed on a brand name is retroactive, resulting in removal from the shelves of a generic that had already been in use. This was the case with the brand name drug Plavix, made by New Jersey based Sanofi-Aventis. Plavix is prescribed to prevent heart attacks and is currently protected under patent and data exclusivity in Guatemala until 2019. Two Guatemalan companies that had been producing its generic version have had their registrations revoked.

The entire article can be viewed at the Health Affairs website: <http://content.healthaffairs.org>.

CPATH's research demonstrates empirically that CAFTA and similar trade agreements come at a high cost to all U.S. trade partners. As Brenner points out, trade agreements can override domestic laws that permit reimportation of lower-price drugs, preferred drug lists and other measures that lower prices. The pharmaceutical industry is involved in legal contests internationally against a range of provisions that lower prices, including patent laws and countries' rights to license, produce and export generic drugs.

According to CPATH's Congressional testimony earlier this summer, there are currently 27 representatives from the pharmaceutical industry on the various U.S. trade advisory committees, compared to 20 in 2005, and four sit on the top Advisory Committee for Trade Policy and Negotiations (ACTPN). Brenner and Shaffer also note that the U.S. has several times listed Guatemala among the countries on its watch list for intellectual property violations in the USTR's Special 301 Report, published annually in May. They say trade rules and pressure from the U.S. turn governments like Guatemala's into police for the pharmaceutical industry, and undermine their mandates to protect public health. Says Brenner, "the idea of free trade is to create open, competitive markets that ultimately bring down everyone's costs and protect national sovereignty. This is clearly not the case for Guatemalans – or Americans – when it comes to pharmaceutical products."

CPATH is making the following three requests of the Obama administration:

- 1) First, do no harm. The President should immediately suspend enforcement of intellectual property provisions in CAFTA (data exclusivity, patents and linkage) which keep lower-priced, life saving generic medicines out of sick people's hands. The Administration should proactively cooperate with Central American governments that move to suspend these provisions. In 2007, Congress recognized the life threatening impact of these very provisions and successfully removed them from President Bush's Peru Trade Promotion Agreement.
- 2) Second, prioritize public health in U.S. trade policy. The President should instruct the Trade Representative to include health experts and advocates in all levels of trade policy development, effective immediately. In addition, the Administration should move to create a Tier 2 Public Health Advisory Committee on Trade (PHACT) as called for by two bills currently before Congress: HR 2293 and S.1644. The President should give this legislation his full support.
- 3) Third, craft trade policy consistent with U.S. foreign policy. President Obama has repeatedly articulated his intention to implement a foreign policy more collaborative than his predecessor's, and this

should also apply to international trade. The World Health Organization (WHO) has proposed a comprehensive framework for trade that balances the need for pharmaceutical innovation with the needs of developing countries to access affordable medicines. The President and his Trade Representative should take their lead from that organization.

The Center for Policy Analysis on Trade and Health (CPATH) is a project of the Center for Policy Analysis, a nonprofit organization dedicated to improving population health in the United States and internationally. CPATH is a widely recognized leader and a reliable resource in the debates on global trade and health. CPATH has encouraged public health leaders to articulate their stake in protecting public accountability.

CPATH conducts multi-disciplinary research, analysis and advocacy about the impact of international trade and increased privatization, deregulation, and decentralization of vital human services on health. Focusing on the relationship between trade and health, CPATH has assessed the impact of trade agreements and proposals, including NAFTA, GATS, FTAA, and World Trade Organization disciplines, on the health care system in the United States, including "safety net" services such as community clinics and public hospitals, and on domestic regulations in the United States that protect population health which might be subject to challenge as unnecessary barriers to trade.

Health Affairs, published by Project HOPE, is the leading journal of health policy. The peer-reviewed journal appears bimonthly in print, with additional online-only papers published weekly as Health Affairs Web Exclusives at www.healthaffairs.org. The full text of each Health Affairs Web Exclusive is available free of charge to all Web site visitors for a two-week period following posting, after which it switches to pay-per-view for nonsubscribers. Web Exclusives are supported in part by a grant from the Commonwealth Foundation.

The print edition of *Health Affairs* containing the Shaffer and Brenner article will be published in January, 2010.