A Trade Barrier to Defeating AIDS

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In Friday's Fixes column, I wrote about the Medicines Patent Pool, a new organization trying to make AIDS drugs better, cheaper and available sooner to people who need them in poor countries. It relies on voluntary donations of rights by patent holders, most of them pharmaceutical companies. Its success is crucial; new research shows that if we can dramatically increase the number of people on antiretroviral medicines, we can not only save millions of lives, but potentially cause the epidemic to die away.

Earlier this month, the patent pool received its first donation of rights from a pharmaceutical manufacturer, Gilead Sciences. It is an important step — but the terms Gilead negotiated are also confirmation of a dangerous new trend: middle income countries as a target market for drug makers. In the past, pharmaceutical companies have lowered prices in these countries to increase sales. The new strategy is to treat people in Egypt, Paraguay, Turkmenistan or China — middle-income countries, all — as if they or their governments could pay hundreds or even thousands of dollars a year each for AIDS drugs. This low-volume high-profit strategy might make business sense. But in terms of the war against AIDS, it means surrender.

In the world's most impoverished countries, AIDS drugs are cheap. It wasn't always that way. Until well into the Clinton administration, the United States government pressured even the poorest countries shamelessly if they tried to bring down the prices of medicine. Even newly democratic, AIDS-ravaged South Africa became the object of an all-out assault by the Clinton administration to get the country to repeal a law allowing it to break medical patents, a step that was perfectly legal under world trade rules. Washington was not interested in the health consequences. (A U.S. trade negotiator who worked on South Africa at the time told me that he had been unaware that AIDS was a major problem there.) Public outrage over South Africa ended Washington's pressure on poor countries. In 2000, President Clinton issued an executive order pledging that sub-Saharan African countries would not face trade sanctions for laws promoting access to AIDS medicines.

The order continues to be largely respected, and the group of countries who are generally able to get access to the cheapest drugs has grown to include the poorest countries from around the world — Afghanistan, Tajikistan, Bangladesh, Burma. Gilead's agreement with the Medicines Patent Pool covers these countries.

But countries just above this cutoff line are on their own. "There are countries that are considered to be "middle income" that will never be able to afford the high prices charged by innovative pharma companies," said reader A. Grant of New York (13). These nations are also losing the discounts that major manufacturers of AIDS drugs used to offer them. According to Médecins Sans Frontières, which tracks drug prices, prominent manufacturers of AIDS drugs have stopped offering discounts to middle-income countries, or now require that countries negotiate those discounts one by one.

Yet another assault on middle-income countries' ability to buy drugs comes in the form of trade deals. The ongoing negotiations for a free trade agreement between the European Union and India is particularly crucial, as India is drug maker to the world — 92 percent of people taking antiretroviral medicines in developing countries use generic medicines made in India; U.S. programs to provide AIDS medicines overseas rely on Indian generics as well. The European Union is pushing India to adopt laws that will undermine generic production.

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India is fighting back — in part because the generic drug industry is so strong. But this is a rare case of power being on the side of public health. The wealthy countries are largely doing the bidding of the pharmaceutical industry that seeks to keep prices high. Even In developing countries, health concerns are underrepresented in these negotiations. Trade agreements are not negotiated by health ministers, but by trade ministers, advised by powerful commercial interests. Their goal is access to foreign markets. They are often quite content to trade away health considerations.

The United States was supposed to have abandoned this approach. President-elect Barack Obama made a strong statement backing countries' rights to buy affordable generics and promised to "break the stranglehold that a few big drug and insurance companies have on these life-saving drugs." In addition, on May 10, 2007, Congress and President Bush agreed to standards for trade agreements that, among other things, protect the right to access to medicines.

But the Office of the United States Trade Representative does not see it that way. The office is now negotiating a new free trade agreement, the Trans-Pacific Partnership Agreement, with eight other countries.Inside U.S. Trade

reported that at a briefing this May, a U.S. trade official said that the office does not intend to respect the May 10 agreement. "2007 is 2007 and 2011 is 2011," the official reportedly said.

"Companies are finding new ways to be aggressive about protecting pharmaceutical monopolies that haven't been in past free trade agreements," said Peter Maybarduk, the global access to medicines program director at Public Citizen. Leaked drafts of the trade office's negotiating proposals for the Trans-Pacific agreement show that Washington has proposed eliminating formal ways that patents can be challenged before their registration and proposed measures to lower the standards for what can be patented — for example, allowing companies to extend their monopolies by making minor modifications in a product, whether or not they lead to improved results. According to Inside U.S. Trade, trade office officials have said they would likely follow what the pharmaceutical industry wants on the extremely controversial issue of data exclusivity — rules that discourage generic production by keeping data proprietary, requiring generic manufacturers to re-do clinical trials. (Reader Edward Low of Kuala Lampur (20) noted that one medicine became 845,600 percent more expensive in Guatemala after the country signed a free trade agreement with the United States. This is, bizarrely enough, true — data exclusivity was the culprit.)

A U.S. trade official told me that its proposals on data exclusivity are not yet set, but that Washington's goals in the agreement are "predictability and transparency" on drug prices.

Countries that take measures to lower drug prices also often find themselves on the trade office's Special 301 Watch List, a precursor to sanctions. Brazil, India and Thailand, among other countries, are on the lists for insufficient protection for intellectual property — even though their measures are fully within international trade law.

The list of people worried about the terms of U.S. trade agreements contains some unusual suspects. Last year, the then-governors of Vermont and Maine wrote to the Obama administration protesting what they saw as a particularly dangerous part of past free trade agreements: language that restricts government-run pharmaceutical pricing programs. Trade agreements with Australia and Korea contain these clauses. If Washington proposes the same thing in the Trans-Pacific agreement, it will be applying this policy to countries that are much poorer, including Vietnam, Malaysia, Chile and Peru. In addition, the introduction to the Watch List cites several countries for using a government's negotiating power to buy cheaper medicine.

Why would this bother these governors? Because this is exactly what states and the federal government do in America. They negotiate big discounts on the medicines they buy for Medicare Part B and Medicaid. Without those discounts, those programs could not survive. The Veterans Administration and the Pentagon, among other agencies, do the same thing. “Trade agreements, are, of course, reciprocal by nature,” wrote the governors, John Baldacci of Maine and James Douglas of Vermont. Washington argues that the fine print exempts U.S. programs — in the Korea agreement, this argument was explicit. It is difficult to decide what’s worse: the chutzpah of telling a poorer country that it can’t negotiate lower prices while the United States can, or allowing pharmaceutical company lobbying to result in the destruction of a substantial slice of American health care.

The pharmaceutical industry is seeking to take this a step further. The chief executive of Pfizer, Jeff Kindler, and the late John Barton, a Stanford University Law professor, proposed a global agreement on pharmaceutical prices that would, among other things, severely restrict the ability of wealthy and middle income countries anywhere to use such pharmaceutical pricing programs. Ambassador Ron Kirk, the U.S. Trade Representative, has said the idea deserves consideration.

Correction:

An earlier version of this article misstated the groups briefed by the Office of the United States Trade Representative in May. They were public health groups, not corporations with stakes in the deal. The article also erroneously reported about briefings held by the trade office. Public health groups do attend private briefings with the office, though some groups say that their letters to the office go unanswered.

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