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New Trade Deal Would Benefit Big Pharma At AIDS Programs' Expense

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WASHINGTON -- In 2003, with the AIDS pandemic developing into one of the most severe humanitarian crises in modern history, President George W. Bush pledged billions of dollars in relief funding for citizens of the world's poorest countries. Seven years in, the initiative, called the President's Emergency Plan for AIDS Relief (PEPFAR), is widely regarded as an outstanding success, responsible for saving millions of lives in 15 developing nations.

Vietnam has received more than $320 million from the program since 2004, giving thousands of people living with HIV access to critical, life-saving medicine for the first time. But a new trade deal the Obama administration is pushing to complete with Vietnam and seven other Pacific nations threatens to seriously hinder both U.S. and international efforts to combat AIDS -- including the government's own efforts in Vietnam.

According to leaked documents from the talks, U.S. negotiators are seeking to impose a set of restrictive intellectual property laws that would help American drug companies secure long-term monopolies overseas. The result? Higher prices for drugs. That's good for corporate profits, but disastrous for relief programs like PEPFAR that depend on cheaper generic medications to treat the global poor.

"This U.S. trade policy is going to undermine U.S. AIDS policy by driving up medicine costs and keeping new HIV/AIDS drugs monopolized for longer periods of time in Vietnam," says Peter Maybarduk, director of Public Citizen's Access to Medicines project. "We're setting up U.S. taxpayers to pay more for the same result or just accomplish less."

While the potential repercussions are most obvious in Vietnam, the trade talks have broader implications. Trade experts at Public Citizen, the Health Global Access Project and other nonprofits view the current negotiations, dubbed the Trans-Pacific Partnership, as part of the Obama administration's "beachhead strategy" to establish a new international trade standard on drug access -- just as the North American Free Trade Agreement did for scores of trade issues in 1993.

The Office of the U.S. Trade Representative, the federal agency with formal responsibility for the negotiations, is aware of the concerns. But a USTR spokesperson said the agency needs restrictive patent standards in order to "incentivize" drug companies to supply medicine. "Patents covering new methods of use or new forms incentivize development of adaptations of drugs that are often highly valued in developing countries, such as heat-stabilized medicines for places that lack reliable refrigeration capacity," she said.

The same view is frequently voiced by U.S. pharmaceutical giants, many of which have close ties to USTR and the Obama administration through key staffers who had careers at the Big Pharma heavyweights before moving to their government positions.

And plenty of economic data suggest that the American patent regime does not foster useful medical innovation. Pharmaceutical companies spend about twice as much money marketing their drugs as they do on researching and developing them, and a tremendous portion of drug research is conducted by universities and the federal government's National Institutes of Health. Much of the research pharmaceutical companies do conduct is simply not relevant to public health concerns, with money pouring into projects for hair loss, for instance, while funding for diseases that primarily afflict the poor, like tuberculosis, stays in perpetual short supply.

"The drug companies would say it generates research, but the evidence is very questionable, because much of the research is not directed at important diseases," says Nobel Prize-winning economist Joseph Stiglitz.

USTR's efforts have alarmed some congressional Democrats, eight of whom wrote a letter to USTR head Ron Kirk emphasizing that the Obama administration's trade proposals are significantly more restrictive than the access-to-medicine terms negotiated in trade deals with Peru, Panama and Colombia under President Bush in 2007.

"The 2007 bipartisan 'May 10th agreement' was an important step in moving U.S. trade policy back toward a more balanced approach to promoting innovation and health in trade agreements with developing countries," the Aug. 2 letter reads. "We are concerned about reports that the balance is once again shifting away from the progress achieved in those past efforts ... a move that would jeopardize treatment goals and millions of lives."

Nevertheless, in several rounds of negotiations, the Obama administration has continued to press for a hard-line patent regime, claiming that stricter rules build on existing requirements that encourage innovation.

The USTR spokesperson tells HuffPost that Vietnam, in particular, already has some patent requirements in place and that those standards have not hampered the U.S. AIDS relief effort.

That claim directly conflicts with PEPFAR's official 2010 report (PDF) on its operations in Vietnam. Generic HIV drugs, which cost around $100 a year per patient, constitute 98 percent of the medicines that the U.S. buys for the Vietnam relief program, according to the report.

But the remaining 2 percent of drugs that are patented -- and thus far more expensive -- are a significant financial burden. Many of these patented medicines are "second-line" drugs, which patients need to combat HIV once the infection develops resistance to standard treatments. PEPFAR has expressed particular concern about Kaletra, a key second-line drug produced by Abbott Laboratories, one of a handful of multinational pharmaceutical companies with influence over the Trans-Pacific talks thanks to its position on a USTR advisory board.

"A key driver is the cost of Abbott products," reads the 2010 report on AIDS relief in Vietnam. "Expectations that the cost ... would fall by 50% in 2009 due to the introduction of generic versions were dashed when it was discovered that Abbott has patents pending in Vietnam and that Abbott intended to use the patents to prevent the procurement of generic alternatives."

"Work is continuing with intellectual property experts ... to determine if there are any legal grounds to enable the procurement of generic [Kaletra]," the report continues. That suggests patented medicine is a big financial hurdle for the program, contrary to USTR's claim. PEPFAR declined to comment for this article.

The framework proposed in a leaked draft of the Trans-Pacific pact builds off the U.S. patent regime, long maligned by public health advocates for fueling the highest drug prices of any nation. In Vietnam, such policies could end up extending already long-held monopolies on life-saving drugs, including Kaletra.

The World Trade Organization requires all countries to grant 20-year patents on medicine, but gives nations substantial leeway over which specific drugs actually receive patents. Less-developed countries with pressing epidemics often do not permit patent protections for drugs that receive monopoly rights in the U.S. Further, medicines that governments purchase for state-run health care programs are currently exempt under WTO patent rules.

According to leaked documents from the Trans-Pacific talks, the U.S. wants to require the eight other Pacific countries in the negotiations to grant patents on a wider swath of drugs and bestow a host of secondary patents that go beyond the simple chemical compound for the drug. These secondary patents can cover almost any characteristic of a particular medicine, from the color of a pill to a capsule's ability to resist heat.

Public health advocates refer to these types of patents as "evergreening patents" -- or even "junk patents" -- because they allow companies to extend their monopolies beyond the 20-year WTO window without actually creating a new medicine. The World Health Organization frowns on these secondary patents and has said they should be rejected.

But USTR is expressly seeking to require countries to issue patents on "any new form, use, or method of using a known product ... even if such invention does not result in the enhancement of the known efficacy of that product," according to the leaked draft of the trade agreement.

"It's an invitation to the pharmaceutical industry to extend drug monopolies and charge unaffordable prices for medicines," says Rohit Malpani, director of Oxfam's Access to Medicines campaign. "Not only do these restrictions deny affordable medicines to poor people in developing countries; they also encourage drug companies to focus on extending monopolies for existing medicines, instead of investing in research and development to develop the new medicines needed to improve treatment outcomes around the world."

The USTR spokesperson tells HuffPost that these secondary patents encourage companies to develop new uses for drugs and improve on existing drugs in ways that benefit developing nations. The agency also argues that even if a company obtained such secondary patents, the original compound would be available for generic competition.

But public health advocates say that, in practice, drug companies do extend their monopolies for years with these patents, by filing for protection on secondary aspects of existing drugs -- sometimes repackaged under a new brand -- that are essential for use in a certain regions.

The heat-stable version of Kaletra, for instance, is prized by doctors in Africa and hot Asian nations such as Vietnam, but under secondary patent regulations could remain cost-prohibitive for decades to come.

"USTR wants to create brand-new monopolies on older drugs, for formulations that are developed with the U.S. and European market in mind," says James Love, director of Knowledge Ecology International, a nonprofit focusing on how intellectual property rules affect the poor. "The fact that these formulations are more valuable in a country with poor cold storage isn't a reason to block generic competition in places where people live in shacks and depressing poverty."

The strict patent protections in the leaked draft of the Trans-Pacific negotiations come as no surprise to many public health advocates, who point to tight connections between the Obama administration, including USTR, and the pharmaceutical industry.

While doctors and nonprofits have been denied access to key documents and details of the negotiations, corporate executives and lobbyists -- including the top lobbyist at Abbott -- have been permitted to review key texts in the trade pact thanks to their positions on U.S. trade advisory boards.

The Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services , which provides USTR with input on medical issues, features representatives from three Big Pharma companies, as well as two chemical firms and seven medical technology companies. Another consultative group, the Industry Trade Advisory Committee on Intellectual Property Rights, includes representatives from drug giant Johnson & Johnson, as well as the drug industry lobbying groups PhrMA and BIO. A representative from the U.S.-China Business Council, an umbrella group that includes Abbott and heavyweights Merck and Pfizer, is also on the board.

"The issues under consideration could have dramatic impacts on public health systems across the developing world," says Malpani of Oxfam. "The lack of transparency has prevented public health and public interest groups from ensuring that the United States adopts a balanced approach towards intellectual property and access-to-medicines issues."

But public health groups don't point just to those advisory boards. Stanford McCoy, USTR's top trade negotiator for intellectual property, lobbied on intellectual property at the influential D.C. law firm Covington & Burling before moving to USTR in 2006. His top deputy, Kira Alvarez, was a lobbyist for the drug company Eli Lilly before joining the agency.

Then there's William Daley, President Barack Obama's chief of staff, who was on Abbott's board until he took his current role at the beginning of this year and who has, as The Huffington Post reported, a long history of supporting corporate patent rights on critical AIDS medicines.

Daley served on Abbott's board in 2007 when Thailand decided to import a generic version of Kaletra after its government declared AIDS a public health emergency. Though Thailand was acting within its rights under WTO treaties, Abbott withdrew applications for other life-saving medications in the country -- including the heat-stabilized version of Kaletra coveted by public health advocates -- in an effort to pressure Thailand into reversing its decision, a move that drew international criticism.

Abbott spokesman Dirk Van Eeden declined to comment on the Abbott board's activities surrounding the Thailand event, but says, "The patent system allowed the development of the medicines doctors and patients rely on today and makes it possible for scientists to develop the medicines people will need in the future."

An Obama administration spokesperson, who would only speak on the condition of anonymity, says Daley is not involved in official Trans-Pacific negotiations. But Daley has been lobbied on the trade pact by both the U.S. Chamber of Commerce and Senate Majority Leader Harry Reid (D-Nev.), suggesting he is playing at least an informal role in the negotiations.

The USTR spokesperson tells HuffPost that "the transparency and inclusiveness of these negotiations are unprecedented" and says the agency has reached out to several public health advocates for comment on the agreement.

The trouble is, USTR has asked for comment on documents that it bans public health professionals from actually viewing.

"It's pretty insulting for USTR to claim these negotiations are transparent," says Love, who notes that USTR has reached out to his group for comment. "As a practical matter, we can't offer much input unless we see the text or have someone at least explain what it says."

The USTR spokesperson declined to comment on the leaked proposal when asked by HuffPost. But the agency's secrecy is bewildering to public health advocates.

"The other countries can see the documents. The drug lobbyists can see the documents. Why can't we?" says Judit Rius Sanjuan, manager of Doctors Without Borders' Access to Essential Medicines campaign.

USTR also notes it released a "white paper" outlining its plans to ensure access to medicines for countries involved in the Trans-Pacific deal. But the white paper is scant on policy detail, instead laying out a series of goals. The publication of the white paper prompted immediate outrage from public health advocates, with Public Citizen's Maybarduke calling it "insulting" and "primarily window dressing." KEI's Love called it "a white wash." Doctors Without Borders' Sanjuan said, "USTR simply does not acknowledge that high priced brand-name drugs imposed by monopolies are a principal barrier to access to medicines."

"This is not an access plan, it's a clear subterfuge toward ensuring the Obama administration can continue to carry the water of Big Pharma," said Matthew Kavanaugh, director of U.S. advocacy for the Health Global Access Project (Health GAP), a nonprofit dedicated to expanding HIV treatment.

Left in the dark by the official channels of trade pact negotiations, public health groups must rely on documents illegally sent to them to stay informed. Much of the concern among Oxfam, Doctors Without Borders, Public Citizen and KEI stems from a leaked version of the trade pact's intellectual property chapter, posted online at KEI. The nonprofit groups would not disclose who leaked the draft, citing the need to protect their source, and USTR would not comment on the validity of the document.

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If the draft's proposals pan out, the final deal would tighten patent laws, stymieing AIDS efforts in Vietnam and other Pacific nations. Over the past 10 years, as patents have expired on early HIV medications, market competition from generic drugs has driven prices down by roughly 99 percent, according to data compiled by Doctors Without Borders. Those lower prices have allowed more than 6 million people worldwide to access life-saving medication that would have been otherwise unaffordable.

Still, the high prices of new, patent-protected second-line HIV drugs remain a problem. Over time, most people infected with HIV will develop resistance to standard treatments and need the second-line drugs, according to the WHO, meaning demand for these drugs will only increase over time.

Further, older medications often come with severe side effects -- the federal government's report on Vietnam AIDS relief cites "severe anemia" as a common one. These older drugs are also less effective in developing nations, according to experts, because they need refrigeration, which is often not readily available, or have highly complex treatment schedules that either require regular laboratory access or prove hard to follow for people living on a few dollars a day without a consistent routine. Newer drugs, such as the heat-stabilized version of Kaletra prized by PEPFAR for its Vietnam efforts, could address many of these issues -- if they were affordable.

"We need the newer medicines, which are massively more expensive and more likely to be patented," says Health GAP's Kavanaugh. "As these new classes of medicines come onto the market, they could revolutionize HIV care. But if we change patent laws in places like Vietnam, they will never be affordable there."

Public health advocates say patent restrictions have also caused AIDS treatment gaps in the U.S. As prices fell dramatically for AIDS medicine globally over the last 10 years, prices for new HIV/AIDS drugs in the United States have jumped by 60 percent, according to data from the AIDS Healthcare Foundation -- in large part because of the restrictive patent system in the U.S.

Newer medications are more effective and come with fewer side effects, making them far preferable to older generic drugs. But the high prices on these critical new medications have sparked a funding shortage in the federal government's domestic AIDS relief program, forcing more than 9,000 low-income Americans onto waiting lists for HIV drugs. "The waiting lists are a national disgrace," says James Driscoll, a consultant to the AIDS Healthcare Foundation, a nonprofit dedicated to eradicating HIV.

Driscoll and other public health advocates emphasize that this waiting list exists in the world's richest country -- a sign that applying the same patent standards in developing countries could prove disastrous.

The Obama administration's efforts to restrict the ability of developing countries to access medication goes beyond HIV treatment: The standards currently being pushed by USTR in the trade deal would apply to all drugs, including vaccines and treatments for heart disease, cancer and other life-threatening illnesses.

But the effect the Trans-Pacific deal could have on AIDS treatment is particularly poignant, with the government spending millions on PEPFAR programs in Vietnam. Of the roughly 300,000 people estimated to be living with HIV in Vietnam, only 31,000 are receiving life-saving medication through PEPFAR. Just 30 percent of adults with "advanced HIV" in Vietnam are receiving drugs through all existing relief efforts, according to the most recent U.N. estimate.

Over the last 10 years, millions of people have received live-saving AIDS drugs because patents have expired. But if USTR succeeds in establishing new, more restrictive patent standards, that trend could stop, hindering efforts to close the still formidable global HIV treatment gap.

"This is about the White House protecting these companies, like Pfizer, Merck, Abbott and Bristol-Myers Squibb," says KEI's Love. "It's going to mean that either the U.S. pays more foreign aid, or we just let people die."

This story was updated to include information on USTR's access-to-medicines white paper.

Clarification: This story previously attributed data on the 60 percent increase in U.S. AIDS medication prices over the past decade to Doctors Without Borders. The data was compiled by the AIDS Healthcare Foundation.