AARP warns trade deal could lock in high drug prices

10/24/13

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The powerful senior lobby AARP is pressing negotiators to reject plans to include language in major trade deal that would bind the United States to a 12-year market exclusivity period for makers of brand-name biologic medicines.

AARP warned the top U.S. trade official against allowing the language in the Trans-Pacific Partnership (TPP), a 12-nation trade deal now under consideration.

The provision would effectively lock in high prices for the popular drugs and could undermine public programs including Medicare and Medicaid, according to the nonpartisan group, which represents Americans 50 and over and their families.

"AARP strongly believes the final trade agreement should not bind the U.S. to a 12-year market exclusivity period for brand-name biologic drugs," the group wrote this week in a letter to U.S. Trade Representative Michael Froman.

Biologics — drugs developed through biological processes — are used to treat a variety of ailments, including multiple sclerosis, rheumatoid arthritis and different forms of cancer. The medication, however, is often far more expensive than conventional "small-molecule" drugs.

The price can be prohibitively high for patients — even those with comprehensive insurance policies. “With annual costs that can reach as high as $400,000, the high price of biologic drugs not only has adverse effects on consumers, but also on other health care payers, including public programs like Medicare and Medicaid," according to the letter, signed by Nancy A. LeaMond, executive vice president of AARP’s State and National Group.

The high prices, critics charge, stem from drugmakers’ exclusive rights to test data, which makes it difficult for generic versions or "biosimilars" to enter the market.

The Biologics Price Competition and Innovation Act, signed into law by Obama more than three years ago as part of the healthcare reform law, allows for 12 years of exclusivity for the drugs.

Proponents of the 12-year window, including the Pharmaceutical Research and Manufacturers of America (PhRMA), say the period is needed for their member companies to see returns on their investments in research and development of the drugs.

But Obama’s budget proposals, including his fiscal 2014 plan, have repeatedly called for the window to shrink to seven years. The administration estimates the policy change could save billions of dollars for federal health programs.

AARP backs that plan, projecting a $3.8 billion savings and the introduction of biosimilars with prices that are 40 percent lower than the brand-name versions.

“However, should the U.S. agree to the TPP with a provision requiring a 12-year market exclusivity period for brand-name biologics, U.S. policymakers would be prevented from taking action to reduce the costs associated with biologic drugs for U.S. consumers,” LeaMond told Froman.

Leaders of the TPP countries have said they expect to complete the talks before the end of the year.
October 22, 2013

Ambassador Michael Froman
United States Trade Representative
600 17th Street NW
Washington, DC 20508

Submitted electronically via correspondence@ustr.eop.gov

Dear Ambassador Froman:

As the nation's largest nonprofit, nonpartisan organization representing the interests of Americans age 50 and older and their families, we are writing to comment on the ongoing negotiations surrounding the Trans-Pacific Partnership (TPP) and the issue of market exclusivity for biologic drugs. It is our understanding that market exclusivity is one of the outstanding issues negotiators are working to resolve with the goal of completing the trade agreement before the end of the year. AARP strongly believes the final trade agreement should not bind the U.S. to a 12-year market exclusivity period for brand-name biologic drugs.

Biologics are fast becoming the future of pharmaceuticals. These drugs are used to treat many diseases – such as multiple sclerosis, rheumatoid arthritis, cancer and others – that often affect older populations. However, the cost of these drugs can put these treatments out of reach for those who need them most, even for those with comprehensive health insurance. The daily costs associated with biologics are approximately 22 times higher than the daily costs associated with small-molecule drugs. With annual costs that can reach as high as $400,000, the high price of biologic drugs not only has adverse effects on consumers, but also on other health care payers, including public programs like Medicare and Medicaid.

The Patient Protection and Affordable Care Act (ACA) recognized there was a need for less expensive follow-on biologics, or biosimilars, both to help ensure access to biologic drugs and to reduce the economic burden they impose. However, the ACA created a 12-year market exclusivity period for brand-name biologics even though the Federal Trade Commission concluded that no additional exclusivity beyond the term of the patent was necessary to maintain innovation and competition in the industry. Numerous generic drug manufacturers have said the 12 years of market exclusivity provided by the ACA makes developing biosimilars prohibitively risky from a business perspective.

The Administration itself has proposed reducing the exclusivity period for brand-name biologics in its most recent FY 2014 budget and previous budgets. AARP strongly supports this proposal and believes increasing the availability of biosimilars will be a critical element of any comprehensive effort to contain health care costs. In fact, AARP has endorsed
reducing the market exclusivity period for brand-name biologics from twelve years to seven that would result in a $3.8 billion savings (OMB, 2012) and biosimilars with prices that are 40 percent lower than their brand-name counterparts (CBO, 2011). However, should the U.S. agree to the TPP with a provision requiring a 12-year market exclusivity period for brand-name biologics, U.S. policymakers would be prevented from taking action to reduce the costs associated with biologic drugs for U.S. consumers. AARP also believes the U.S. should seek to deter so-called “evergreening” practices under the TPP, and manufacturers should have to demonstrate a clear, significant clinical advantage over the reference product in order to receive an additional period of exclusivity.

Thank you for considering our comments. If you have any questions, please do not hesitate to contact me or KJ Hertz on our Government Affairs staff at (202) 434-3732 or khertz@aarp.org.

Sincerely,

Nancy A. LeaMond
Executive Vice President
State and National Group

cc: Barbara Weisel, Assistant U.S. Trade Representative for Southeast Asia and the Pacific, Office of the U.S. Trade Representative.
Froman pushing Congress to finalize trade deals

By: Doug Palmer
October 29, 2013 05:08 AM EDT

President Barack Obama was often criticized in his first term for moving too slowly on trade, but now his chief negotiator is pressing Congress to pick up the pace as the White House pushes to conclude a landmark trade deal in the Asia-Pacific by the end of the year.

"We think it would be good to get [trade promotion authority] as soon as possible with as broad bipartisan support as possible," U.S. Trade Representative Michael Froman told POLITICO in an exclusive recent interview.

That legislation, also known as "fast track," would allow Obama to submit trade agreements to Congress for straight up-and-down votes without any amendments, giving other countries confidence that any deal they reach with the White House won't be picked apart by U.S. lawmakers unhappy with one provision or another.

( PHOTOS: POLITICO Pro Trade event)

But there is little momentum in Congress toward passing the legislation, a situation many Republicans blame on Obama, saying that he has yet to make a serious push for the bill.

Weeks of drama over Republican attempts to defund Obamacare and the resulting government shutdown also have kept trade off the congressional agenda, while Obama has identified the budget, farm bill and immigration legislation as his priorities for the rest of the year.

Congress last passed TPA legislation in 2002, clearing the way for the Republican administration of former President George W. Bush to negotiate trade deals with more than a dozen countries.

Obama waited until negotiations on the proposed Trans-Pacific Partnership agreement had been going for more than three years before formally asking Congress for the legislation.

Senate Republicans tried to pass the bill two years ago, but they were blocked by Senate Democrats who said the time was not yet right to take up the measure.

Now, Froman and his team at USTR are pushing to finish the TPP talks by the end of the year, putting pressure on Congress to move a TPA bill to set the stage for the final phase of talks.

( Go pro with POLITICO Pro Trade)
However, months of technical-level talks between Democratic and Republican staff on the committees of jurisdiction in Congress still have not produced a bill, even though both Senate Finance Committee Chairman Max Baucus (D-Mont.) and House Ways and Means Committee Chairman Dave Camp (R-Mich.) set a goal of passing TPA this year.

Some Republicans complain the White House is not doing enough to build support for legislation among congressional Democrats, a charge that Froman rejects.

"I'm up on the Hill for a significant portion of every week, meeting with Democrats and Republicans in the House and the Senate, in groups and individually, precisely on that issue. I think we are certainly carrying our share of the weight on this one," Froman said.

"[But] it will be easier to have that kind of engagement when there's an actual bill, and that's really up to the Finance Committee and the Ways and Means Committee to produce."

Asked if the administration could finish the Trans-Pacific Partnership talks without TPA, Froman sidestepped the question, saying, "We're working on both tracks and expect and hope to see progress and success on both."

A "partnership" bill

In addition to shielding trade deals against amendments, TPA gives lawmakers the chance to set detailed negotiating objectives for trade agreements and to establish procedures for moving the deals through Congress.

"Trade promotion authority, you know, really is Congress's way of telling the administration what it should do with trade policy," Froman said. "It is a manifestation of the partnership between Congress and the executive on trade policy and really gives Congress a very important and meaningful role in both the substance and the process of trade negotiations."

(Also on POLITICO: Full trade policy coverage)

But even if Finance and Ways and Means leaders agree on a joint bill, history shows that winning approval of fast-track trade legislation can be a difficult fight.

In 2002, only about two dozen House Democrats voted for TPA legislation, which barely won approval after a bitter fight. In the late 1990s, former President Bill Clinton, a Democrat, was unable to win the legislation, even though the trade-friendly Republican Party controlled the House, as it does now.

Froman said he hoped the administration's focus on achieving a "higher standard" agreement in both the TPP talks and another proposed trade agreement with the European Union would attract strong Democratic support for TPA.

"I think we're all focused on ensuring that we're able to secure that authority and secure it with the broadest possible bipartisan support," Froman said.

Meanwhile, leaders from the 12 TPP countries — the United States, Japan, Canada, Mexico, Australia, New Zealand, Peru, Chile, Singapore, Vietnam, Malaysia and Brunei — reaffirmed at a recent meeting, in Bali, their desire to finish the pact this year, though the
government shutdown forced Obama to stay home from the event.

"Now that's an ambitious objective, we all recognize that. And certainly the substance of
the negotiations is going to ultimately dictate the timetable. But all the countries are
working, in some cases literally around the clock, at different levels and in different groups,
bilaterally, plurilaterally around various issues with that objective in mind," Froman said.

As the talks draw to a close, all the countries face difficult decisions balancing the new
business opportunities they hope to gain from the pact with the cries of sensitive domestic
interests that want to be shielded from increased competition.

"It's our jobs to weigh those interests and try to come up with a balanced package. And of
course each of the 11 other countries have their own perspective on these questions," Froman said. "What that means is that, you know, no one is going to get 100 percent of
what they are looking for in 100 percent of the chapters" of the agreement.

"Increasingly worried" about WTO talks

Meanwhile, Froman will return to Bali in early December for a meeting with top trade
officials from the other 158 members of the World Trade Organization. That has prompted
speculation TPP trade ministers could meet on the sidelines of the WTO ministerial
meeting to try to close the TPP deal. But Froman declined to give odds for that.

"It's possible that ministers will get together again between now and the end of the year,
but we haven't made any firm decisions as to when and where that might take place," he
said.

The United States' main focus at the December meeting is on a possible "trade facilitation"
deal among all 159 WTO members aimed at making it easier to move goods across
borders by reducing red tape and regulation, along with other components on agriculture
and development as part of a final Bali package, he said.

Froman praised new WTO Director-General Roberto Azevedo for "energizing"
negotiations at WTO headquarters in Geneva but expressed concern a deal might not be
reached.

"We are increasingly worried that not enough progress is being made [in the negotiations],
and the pace isn't sufficient to ensure that there is a completed, strong, binding trade
facilitation agreement by the time of Bali, and that has to be part of the core Bali package," Froman said.

Azevedo has cast the Bali meeting as a watershed moment for the WTO, whose full
membership has not agreed on any trade liberalizing package since it was created nearly
20 years ago.

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WASHINGTON, D.C. - Today, the U.S. Senate Finance Committee held a hearing on
negotiation of a U.S.-Europe trade deal, the so-called Transatlantic Trade and Investment
Partnership. The negotiating objectives for the TTIP agreement have little to do with free trade.
TTIP negotiations instead focus on removing perceived regulatory “barriers” and could result in
dangerous deregulation of environmental, climate, and public health safeguards. Erich Pica,
President of Friends of the Earth, had these comments:
“To today’s hearing in the Senate Finance Committee reveals the true objectives of industry
proponents of the EU-US trade deal -- to destroy the progress we have made over the last decade
in the EU and in states across the U.S. to protect human health from toxic chemicals, to undercut
food safety measures on both sides of the Atlantic, and to chill government action to address
global warming, including restrictions curtailing hydraulic “fracking” for natural gas. TTIP could
be a stealth attack on our health, our environment and our attempts to forestall climate
catastrophe.”

Click here to read the statement on TTIP and toxic chemicals submitted to the Senate Finance
Committee by the Center for International Environmental Law, Friends of the Earth, U.S, Center
for Biological Diversity, and Sierra Club.

Click here to read a TTIP policy analysis prepared by Friends of the Earth: see “Deregulatory
disappointment: transatlantic free trade agreement negotiations"

Click here and read more in this blog post, “Chevron fracks Europe: Transatlantic trade and
investment agreement favors big energy companies and threatens the environment”
weaken-regulations#sthash.XsB4FNbf.dpuf
President Barack Obama  
The White House  
1600 Pennsylvania Ave NW  
Washington, D.C. 20500  

October 30, 2013  

Dear President Obama,

We write to express our disappointment in the tobacco provisions proposed by the United States during the most recent round of Trans-Pacific Partnership (TPP) trade negotiations in Brunei. They are a step backward from the approach described by the United States last year, which included a clear “safe harbor provision to preserve regulations that protect the public from the dangers of tobacco products. These weaker provisions, combined with concessions to lower tariffs on tobacco products, would likely lead to greater consumption of a deadly product, particularly in developing countries.

Tobacco companies have a history of using trade law to subvert tobacco control measures. Indonesia, on behalf of Kretek International, an Indonesian tobacco company that sells a clove-flavored cigarette that is attractive to children, used provisions in the World Trade Organization Agreement to challenge a provision in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that banned candy-like flavorings that appeal to youth smokers. Philip Morris International filed a Bilateral Investment Treaty dispute against Uruguay because of Uruguay’s graphic warning labels. The company is also using Australia’s Bilateral Investment Treaty with Hong Kong to challenge an Australian ban on color and images on tobacco packages. These efforts by tobacco companies to use trade law to subvert public health measures are deplorable.

The language described by representatives of the Office of the United States Trade Representative (USTR) last year would provide some certainty that regulations implementing the Tobacco Control Act and other similar regulations throughout the TPP region would be protected from country-to-country challenges. But instead of providing this certainty, USTR put forth much weaker language stating that tobacco control measures are measures that “protect human health,” and as such would be analyzed under the “general exceptions chapter of the TPP, analogous to Article XX(b) of the General Agreement on Tariffs and Trade (GATT). The specific reference to tobacco is a positive development, but the new language does not provide the certainty of the prior proposal and its tobacco-specific safe harbor. For example, despite the new language, a tribunal may still take too narrow of a view as to what health measures are “necessary,” second-guessing public health authorities and striking down a health measure where the tribunal is able to envision an alternative measure that may be less restrictive of trade. Surely, tobacco control measures addressed in the Framework Convention on Tobacco Control should be protected from challenge.

USTR also proposed that the health ministers of the two countries have an opportunity to discuss any challenged tobacco control measure. This is helpful, but it is not a substitute for the safe harbor language.
We are also concerned that the USTR position be consistent with the letter and spirit of the Doggett Amendment, which prohibits the United States government from promoting tobacco exports. With tobacco tariffs subject to duty reduction, and with uncertainty as to whether tobacco control measures are adequately protected, the TPP could result in greater use of a deadly product. This is what happened in South Korea and other countries when tariff reductions opened local markets to imports of cigarettes by multinational tobacco companies. Vietnam is a particular concern. It is a developing country, currently has low rates of smoking among women, and is not prepared to combat Western-style tobacco marketing by the multinational tobacco companies.

The United States should be leading the fight against death and disease from tobacco products, which are a uniquely dangerous threat to public health. We urge you to direct USTR to reconsider its position.

Thank you for considering our views.

Henry A. Waxman
Member of Congress

Lloyd Doggett
Member of Congress

Lois Capps
Member of Congress

Sander M. Levin
Member of Congress

Charles B. Rangel
Member of Congress

Frank Pallone, Jr.
Member of Congress

John Lewis
Member of Congress

Allyson Y. Schwartz
Member of Congress

Gene Green
Member of Congress

John Conyers, Jr.
Member of Congress

Earl Blumenauer
Member of Congress

Adam B. Schiff
Member of Congress

Janice D. Schakowsky
Member of Congress

Jim McDermott
Member of Congress

Chris Van Hollen
Member of Congress