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Prescription Medicines

Changes to Peru and Panama FTA represent Democratic priorities and real progress

Dear Colleague:

I believe that the more facts are disseminated about provisions changing the previously negotiated Peru and Panama FTAs, the more it will be understood that they represented important breakthroughs and components of a new Democratic trade policy.

This is true of the provisions relating to prescription medicines. It is reflected in comments by several prominent organizations devoted to improving public health in developing countries who have recently expressed their appreciation and support for our efforts to improve access to medicines in developing countries, as described in the "New Trade Policy for America," introduced by the House Democratic leadership recently. The following are some important examples:

- Oxfam America, May 31 Letter to Speaker Pelosi:

"[W]e particularly welcome the significant achievement made in reducing the onerous requirements for intellectual property protections for pharmaceuticals[.] This will make a real difference in preserving access to affordable medicines, a critical need for the poor. We applaud your leadership in promoting a trade policy that places public health over private profits and recognizes that developing countries need more flexibility to ensure their populations access to affordable medicines."

- Generic Pharmaceutical Association (GPhA), May 31 Press Release:

The New Trade Policy for America "is proof that a balance between fostering drug innovation and ensuring access to affordable medicines can be achieved." It "is an important step forward in ensuring that our nation's Free Trade Agreements reflect U.S. law and ensure domestic and international access to affordable medicines." It "sends the message that our Free Trade Agreements should not unduly block generic competition abroad or include measures that delay timely access to affordable medicines."

- James Love, Director, Knowledge Ecology International (KEI), Web Post May 29, 2007:

“[House Democratic leaders] were able to deliver some substantial changes in trade policy on three highly technical but very important issues. As set out in this analysis, in every case, the new trade agreement reduces barriers to the use of generic medicines in poor countries. I agree with the groups that wanted more from the Democrats. But I was perhaps more impressed with how much was achieved in this first step toward a new trade agenda. ... The Bush administration made real concessions, and patients will benefit from this.”

To be sure, these and other public health groups would like to see additional changes made to U.S. policy. Nevertheless, they recognize that the changes in these agreements are substantial and will improve the lives of the poor and the sick in these developing countries.

Mistakenly, recent “Dear Colleague” letters state, among other things, that the New Trade Policy “would make it impossible for developing countries to access the affordable generic versions of the medicines needed to keep their people alive.” That statement is based on a number of misleading and inaccurate statements that need to be corrected.

First, the letter includes an estimate from the Peruvian Health Ministry regarding the harmful effect the FTA “as written” would have on access to medicines in Peru. A reader of this letter may have the mistaken impression that the quoted estimate relates to the New Trade Policy (the subject of the letter), rather than to the pre-existing text of the FTA, which the New Trade Policy is designed to fix. In fact, however, this estimate relates to the old provisions of the FTA – the ones that House Democrats successfully negotiated out of the text of the agreement.

Second, the letter asserts that the New Trade Policy “leaves in place the NAFTA patent rules that greatly undermine the ability of nations, through compulsory licenses and generic drugs, to ensure public access to affordable medicines permitted under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).” This statement is simply wrong. Consider the following examples:

- Unlike the NAFTA, the New Trade Policy affirms the commitment to the WTO Doha Declaration, including the right of each WTO Member to grant compulsory licenses and the right “to protect public health and, in particular, to promote access to medicines for all.”
- Unlike the NAFTA, the New Trade Policy includes an explicit exception to the data exclusivity rules “for measures to protect public health”.
- Unlike the NAFTA, the New Trade Policy clarifies that the chapter on intellectual property rights “does not and should not prevent the Parties from taking measures to protect public health”.

- Unlike the NAFTA, the New Trade Policy would require each country to “make best efforts to process patent and marketing approval applications expeditiously with a view to avoiding unreasonable delays.” The expeditious processing of these applications will ensure that patients in developing countries get access to life-saving medicines more quickly than they otherwise would.
- Unlike the NAFTA, the New Trade Policy would require each country to provide an expeditious procedure for challenging the validity of a patent. This provision will help to eliminate patents that serve no purpose other than to limit access to generic medicines.

In the instances where there are similarities between the New Trade Policy and some intellectual property provisions of the NAFTA, it is because the approach provides more not less access to needed medicines. For example, under both NAFTA and the New Trade Policy, a country would not be required to extend the term of a patent to compensate for unreasonable delays in the issuance of a patent or drug approval. This is in stark contrast to the existing text of the Peru and Panama FTAs, which does require patent extensions in those circumstances.

Also, the New Trade Policy would “start the clock” on data exclusivity in a country like Peru when it starts in the United States in some circumstances. This “concurrent period” provision, similar to a provision in NAFTA, will provide a major incentive for innovative pharmaceutical companies to quickly begin distributing their life-saving medicines in developing countries. And, if those companies do not distribute their products more quickly, they will lose some or all of the benefits of data exclusivity. Indeed, according to a recent study of medicines launched between 1982 and 2002, half of all medicines introduced in Peru are introduced five or more years after they are introduced in the United States. This means that, in the absence of a change in behavior by the innovative drug companies, there will effectively be **no data exclusivity period** for half of the drugs that are distributed in Peru under the New Trade Policy, and a much shorter period for the remaining medicines. This is a major change from the current text of the Peru FTA, which would require a full five years of data exclusivity for **all** medicines.

We are proud of these achievements and believe we have re-established a fair balance between promoting access to medicines in developing countries and protecting pharmaceutical innovation.

I would welcome the opportunity to discuss these provisions with you, as well as any of the other important changes that were secured for the Peru and Panama FTAs. Importantly, I would welcome the opportunity to discuss with you all of the action priorities to fully change the course of U.S. trade policy.

Sincerely,

Sander Levin
Member of Congress