

# PHACT ♦ Public Health Advisory Committee on Trade

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## TOWARDS A HEALTHY TRADE POLICY ALTERNATIVES TO THE PERU FREE TRADE AGREEMENT MAY, 2007

Global and bilateral trade negotiations present important opportunities to promote a healthy, safe and just global community. However, current U.S. trade policies have contributed to social and economic inequality, both within the U.S. and among our trading partners, factors strongly associated with poor health outcomes. Trade agreements provide a basis for altering domestic U.S. laws and policies that protect the public's health and access to health care and medicines.

The **Public Health Objectives for Global Trade** propose policies that would promote and protect health and sustainable economic development, including:

- **public health representation on trade advisory committees**
- **mutually beneficial trade relationships that create sustainable economic development**
- **domestic authorities' right and imperative to regulate in the interest of promoting and protecting population health**
- **public health protections for health services and health professional licensing**
- **tobacco control**
- **alcohol control, and**
- **access to affordable medicines.**

These Objectives should be used as a basis for amending pending trade agreements, to guide any future agreements, and to initiate a review of bilateral, regional and multilateral agreements for their adherence to public health principles.

The following statements outline each Public Health Objective, illustrate how the U.S.-Peru Trade Promotion Agreement fails to conform with each Objective, and present public health-compliant alternatives. The trade agreements with Peru, Panama and Colombia, with substantially similar provisions, have been signed by the President, and are undergoing reconsideration by Congress.

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## Public Health Objective for Global Trade #1:

### Assure democratic participation by public health and transparency in trade policy

**Objective: To assure democratic participation by public health and transparency in trade policy** by:

- a. Appointing to all relevant trade advisory committees representatives of organizations that work to assure equitable access to affordable health-related services and products, and promote the health of individuals, communities and populations,
- b. Opening all proceedings and documents of trade advisory committees to the public, and
- c. Requiring USTR's consultation with all relevant committees of the House and Senate in the development, implementation, and administration of U.S. trade policy, without renewing presidential trade promotion authority.

<b><u>Problems: Democratic Participation</u></b>	<b><u>Public Health Alternatives: Peru Trade Promotion Agreement</u></b>
<p><b>Fair Representation.</b> There are 19 advisory committee members from the pharmaceutical industry, and several from tobacco, alcohol, processed foods and health insurance, but not one voice representing the interest of public health. The absence of public health representation on the advisory committees has had tangible consequences. As only one example, providing access to affordable medicines as embodied in the Doha Declaration on Public Health is one of Congress' explicit objectives in the Trade Act of 2002. However, the perspective of the pharmaceutical industry predominates in trade policy on medicines, as is evident in the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) on the U.S.-Peru Trade Promotion Agreement (see further detail in #7 below).</p>	<p><b>Appoint</b> to all relevant trade advisory committees representatives of organizations dedicated to assuring equitable access to affordable health-related services and products, and promoting the health of individuals, communities and populations.</p> <p>Create a Tier 2 advisory committee on public health, similar to the labor and environmental committees.</p> <p>Authorize Congress to make appointments to advisory committees.</p> <p>Recognize jurisdiction of Congressional health committees on trade.</p>
<p><b>Transparency.</b> Trade advisory committees are influential in shaping US trade policy. Their written proceedings are not open to the public, and important aspects of their meetings are also closed to the public. The exceptions are the final advisory committee reports on each agreement, which are made public only after negotiations are completed, and cannot be changed. Further, trade agreements are not available to most members of the Congress or to the public until after they have been signed. As a result, there is virtually no opportunity for public comment on these agreements while they are still being negotiated.</p>	<p><b>Open all proceedings</b> and documents of trade advisory committees to the public.</p> <p><b>Publish</b> all proceedings of the meetings.</p>

**Public Health Advisors on the U.S.- Peru Trade Promotion Agreement and Democratic Participation**

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American Public Health Association (APHA) International Health Section  
APHA Trade and Health Forum  
California Public Health Association – North  
Center for International Environmental Law (CIEL)  
Global Health through Education Training and Service  
Health Alliance International  
Maquiladora Health and Safety Support Network  
Medical Mission Sisters Alliance for Justice  
Missionary Oblates Justice, Peace/Integrity of Creation Office  
National Legislative Association on Prescription Drug Prices  
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### Public Health Objective for Global Trade #2:

**Develop mutually beneficial trade relationships that create sustainable economic development** for the U.S. and our trade partners in an increasingly interdependent world.

<b><u>Problems: Sustainable Economic Development</u></b>	<b><u>Public Health Alternatives: Peru Trade Promotion Agreement</u></b>
<p>The Peru agreement perpetuates an economic model that has exacerbated inequalities and insecurity. Government investment in infrastructure, including water, education and roads, have been an important element of Europe's more successful approach to the integration of new members of the EU which were lesser developed.. This is also the MERCOSUR model. US free trade agreements, from NAFTA to the present Peru/Colombia/Panama FTAs, take the opposite approach: they do not proactively promote international support to improve infrastructure and human resources, and they also erode governments' funding and authority to do so.</p>	<p>Implement trade policies and provisions that facilitate sustainable development, including <b>public investment in infrastructure and human resources.</b></p> <p>Examine <b>models to reduce economic and social asymmetries and inequalities</b>, including the EU and MERCOSUR.</p> <p><b>Assess the impact</b> of the U.S.-Peru Trade Promotion Agreement <b>on public health.</b></p> <p><b>Assess the comparative costs and benefits</b> of the U.S.-Peru Trade Promotion Agreement to the federal budget and US economy, particularly in terms of employment creation/retention and trade value, of the allocation of resources and trade protections to agricultural commodities, technology research and development, industrial goods, manufactured products, and services sectors, including international trade and investment data at the state level on services and merchandise imports and exports, and on international investment.</p> <p>Develop an economic program that <b>supports and trains workers</b> for the emerging high-tech economy, with strong social supports for valued community members who do not work including children, the elderly, caregivers, and people with employment limitations.</p>

### **Public Health Advisors on the U.S.- Peru Trade Promotion Agreement and Sustainable Development**

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## Public Health Objective for Global Trade #3:

**Recognize the legitimate exercise of national, regional, state and local government sovereignty to promote and protect population health,** and to ensure that countries do not weaken or reduce, as an encouragement for trade, sound policies that contribute to health and well being, including laws on public health, the environment and labor.

<b><u>Problems: Government Sovereignty</u></b>	<b><u>Public Health Alternatives: Peru Trade Promotion Agreement</u></b>
<p><b>The combination of Investment rules (Article 10) that grant greater rights to foreign private investors such as corporations, compared with domestic investors, and Government Procurement provisions (Article 9), undermine government regulatory authority necessary to promote and protect public health.</b></p> <p><b><u>Investment:</u></b></p> <p>The investment provisions of the U.S.-Peru Trade Promotion Agreement allow foreign corporations to bring enforceable trade disputes against governments, on terms that domestic corporations cannot use. The “investor-state” provisions in the Peru Agreement give even broader rights than NAFTA does to foreign private corporations, in ways that can compromise government sovereignty to promote and protect population health. These are noted by the Intergovernmental Policy Advisory Committee (IGPAC).<sup>1</sup></p> <p>The possibility that state or local laws may be challenged (by way of an action against the United States) is itself a chilling factor for those governments considering legislative and regulatory action.</p> <p>Ongoing investment disputes continue to present challenges to necessary regulatory authority. Important health-related examples are the NAFTA Chapter 11 arbitration claim filed by Glamis Gold Ltd. that challenges California’s environmental and extractive industry regulations, and the claim filed by Grand River Enterprises Six Nations Ltd., that implicates state and local regulation of the tobacco industry, including settlements of litigation.</p> <p>(Specific problems regarding government regulations on services, tobacco and alcohol control, and access to medicines, are shown in Sections 4 – 7 of this paper below.)</p>	<p>The U.S.-Peru Trade Promotion Agreement should be re-drafted, implemented, and interpreted, to <b>safeguard existing state and local level regulatory, tax, and economic development policies, and to support the social, economic, and environmental values that those policies promote.</b></p> <p><b>Eliminate “investor-state” provisions</b> that give foreign corporations the right to file trade disputes based on measures of state and local governments, and that give greater rights to foreign investors than to domestic ones.</p> <p>The U.S.-Peru Trade Promotion Agreement should state that statutes and regulations of states and local governments are afforded the same protection against preemption as those of the federal government, i.e. that nothing in the Agreement shall preempt any state or local law.</p> <p>Codify in the Agreement that: As a matter of general international law, a non-discriminatory regulation for a public purpose which affects a foreign investor or investment is not deemed expropriatory and compensable.</p> <p>Maintain the principle that the United States may not require states to alter their regulatory regimes in areas over which they hold constitutional authority. The U.S. must obtain approval from the legislature and executive of the implicated state or locality before a state or locality is bound by any trade provision or a rule, regulation, or statute is listed in – or otherwise implicated by – a trade agreement, offer or other binding commitment.</p>

**Government procurement Article 9:**

Problem 1. The plurilateral WTO agreement on government procurement does not currently cover Peru, or any other developing countries. The US-Peru Agreement applies to Peru's government procurement decisions while not recognizing the WTO's directions regarding benefits that should be accorded to developing countries.

In addition the agreement binds Peru to government procurement provisions which provide stronger rights to foreign investors than the WTO agreement does.<sup>2</sup>

Problem 2. Government procurement rules will apply to all **New York state agencies**, the state university system, and most public authorities and public benefit corporations. This could compromise procurement decisions related to state health facilities intended to promote or protect public health, or to stimulate local economic development.

Problem 3: The procurement rules apply to the Department of Health and Human Services.

Alternative 1: Remove government procurement rules from agreements with Peru and other developing countries.

At a minimum, restrict such rules to the rights granted investors in the plurilateral WTO Government Procurement Agreement.

Alternative 2. Exempt state laws on government procurement for health care services from trade rules.

Alternative 3. Exempt the Department of Health and Human Services.

**Public Health Advisors on the U.S. - Peru Trade Promotion Agreement and Government Sovereignty to Protect Health**

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## Public Health Objective for Global Trade #4: Services

**To exclude tariff and nontariff provisions in trade agreements that address vital human services** such as health care, water supply and sanitation, food safety and supply, and education, including licensing and cross-border movement of personnel in these fields.

<u>Problems: Services</u>	<u>Public Health Alternative: Peru Trade Promotion Agreement</u>
<p><b>Problem 1.1: The Agreement applies trade rules to vital human services such as health care, water supply and sanitation, food safety and supply, and education, including licensing and cross-border movement of personnel in these fields. Universal access to these services is a human right and a key to economic development. Assuring access, quality and affordability must take priority over encouraging market competition and protecting corporate rights.</b></p> <p><u>Problem 1.2</u> Trade rules also limit governments' ability to assure that these services are regulated in a manner that promotes and protects the public's health. <b>Article 11 on Services can challenge government regulations on services that are necessary to promote and protect public health.</b></p> <p>Article 11.7 on Domestic Regulations requires that in order to ensure that "measures relating to qualification requirements and procedures, technical standards, and licensing requirements do not constitute unnecessary barriers to trade in services, each Party shall endeavor to ensure, as appropriate for individual sectors, that such measures are:</p> <p>(a) based on <b>objective</b> and transparent criteria, such as competence and the ability to supply the service;</p> <p>(b) not <b>more burdensome than necessary</b> to ensure the quality of the service; and</p> <p>(c) in the case of licensing procedures, not in themselves a restriction on the supply of the service."</p> <p>A necessity test would be determined by trade authorities, not by public health officials. It could be used to challenge a range of important public health regulations.</p> <p>The IGPAC notes that: "To raise objectivity [in regulatory decision-making] to the level of an international obligation ... undermines the ability of domestic regulators to deal with the inherent complexity of service industries. An international objectivity test moves in the direction of standardized and technocratic regulation and away from regulation in the public interest by legislatures and utility commissions that are accountable for balancing diverse public interests."<sup>3</sup></p>	<p><u>Alternative 1.1:</u> Specifically <b>exclude</b> from trade agreements <b>vital human services</b> such as health care, water supply and sanitation, food safety and supply, and education, including licensing and cross-border movement of personnel in these fields.</p> <p><u>Alternative 1.2</u> <b>Remove requirements for a necessity test and an objectivity test in regulatory decision-making.</b> Trade tribunals should not be authorized to determine whether measures regarding essential services are objectively determined, or necessary to ensure the quality of services, public health and safety, environmental protection, and other important policy objectives.</p>

<p><b>Problem 2.1. The Services rules can compromise governments' ability to provide vital human services in the public sector.</b> Trade rules on market access, national treatment, professional services, domestic regulation, and government procurement limit governments' ability to assure that they can finance and provide vital human services through the public sector</p> <p><b>Services</b> (continued)</p> <p>currently or in the future should they choose to do so.</p> <p>Provisions that could exclude some public services are too weak and general to provide ironclad exemptions. Article 11.1.6 excludes "services supplied in the exercise of governmental authority in a Party's territory," meaning "any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers." Health care programs that exclude some benefits, and nurse registries that serve public hospitals, could fail these criteria.</p> <p><u>Social services:</u> In Annex II: Non-Conforming Measures for Services and Investment, "the United States reserves the right to adopt or maintain any measure with respect to the provision of law enforcement and correctional services, and the following services <b>to the extent they are social services established or maintained for a public purpose:</b> income security or insurance, social security or insurance, social welfare, public education, public training, health, and child care."</p> <p>The definitions used to determine whether these important services are truly social services, and established or maintained for a public purpose, are unclear. Many such services involve both public and private payors, purchasers, and suppliers.</p> <p><u>Problem 2.2:</u> Social services are exempted from some trade rules, but not from market access (restricting the number or type of providers for a specific good or service, such as the number of liquor distributors on a block) and domestic regulation (regulations can't be more burdensome than necessary to trade).</p> <p>Peru exempts measures on potable water and sewage services from market access and local presence rules, but not from other rules</p> <p><u>Problem 2.3:</u> The list of social services does not include water supply and sanitation as exempted services.</p>	<p><b>Alternative 2.1: Exempt these services without any qualifications. Eliminate the requirement that they be established or maintained for a public purpose.</b></p> <p><u>Alternative 2.2:</u> Exempt these social services, and water and sewage, from all trade rules.</p> <p><b>Alternative 2.3: Include water supply and sanitation as exempted services.</b></p>
<p><b>Problem 3.</b> A negative list is used to determine which services will be covered by which trade rules. This method assumes that all services are covered by all trade rules, unless they are explicitly stated to be exempt.</p>	<p><u>Alternative 3:</u> Trade commitments should be derived via a process based upon "<b>positive lists</b>," that require the affirmative, informed consent from affected national, state and local entities, in consultation with public health representatives, to list each service.</p>

**Public Health Advisors on the U.S. - Peru Trade Promotion Agreement and Services**

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## Public Health Objective for Global Trade #5: Tobacco Control

**Exclude tobacco products**, which are lethal, and for which the public health goal is to reduce consumption, from tariff and nontariff provisions of trade agreements, including advertising, labeling, product regulation and distribution.

<b><u>Problems: Tobacco Control</u></b>	<b><u>Public Health Alternative: Peru Trade Promotion Agreement</u></b>
<p><b><u>Problem 1, Tariff Provisions:</u> The agreement reduces to zero a number of existing tariffs on tobacco products.</b></p> <p><b><u>Problem 2, Nontariff Provisions:</u></b> Unless explicitly excluded, tobacco products are subject to all trade rules, which have implications for tobacco control measures on distribution of tobacco products, trademarks, and advertising. Provisions of the Intellectual Property article on advertising, trademarks and labeling, Services rules on product regulation and distribution, and rules on market access, and national treatment, could all interfere with tobacco control measures. Tobacco control measures have been subject to trade challenges in the past, under the Investment provisions, and continue to be vulnerable in the Peru agreement, since they are not explicitly excluded.</p> <p><b><u>Problem 3:</u></b> Although tobacco products may be explicitly excluded in the future, dispute panels could construe them as subject to trade rules due to unforeseen circumstances. For example, although the US did not make a commitment on gambling under GATS, a WTO trade panel found that it was covered as a recreational service.</p>	<p><b><u>Alternative 1. Tariff and Nontariff Provisions:</u></b> <b>Exclude tobacco products</b> from all trade rules and in each relevant Schedule and Annex, including but not limited to Market Access, Most Favored Nation, National Treatment, Services, Intellectual Property, and tariff reduction schedules.</p> <p><b><u>Alternative 2: Insert</u></b> the following: Notwithstanding any language to the contrary, nothing in this agreement shall block, impede, restrict, or modify the ability of any party to take or maintain any action, relating to manufactured tobacco products that is intended or expected, according to the party, to prevent or reduce tobacco use or its harms and costs or that is reasonably likely to prevent or reduce tobacco use or its harms, including tariffs and restrictions on the marketing of tobacco or tobacco products.</p> <p><b><u>Alternative #3:</u></b> Add: Provisions of the Framework Convention on Tobacco Control shall govern, in the event of any conflict with this Agreement.</p>

## **Public Health Advisors on the U.S. - Peru Trade Promotion Agreement and Tobacco Control**

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## **Public Health Objective for Global Trade #6: Alcohol Beverage Control**

**To exclude alcohol products**, which present serious hazards to public health. Policies designed to reduce the harm caused by alcohol products should not be subject to compromise in exchange for other trade benefits.

<b><u>Problems: Alcohol Beverage Control</u></b>	<b><u>Public Health Alternative: Peru Trade Promotion Agreement</u></b>
<p>Alcohol beverage control measures are vulnerable to trade challenges in the Peru agreement, since they are not explicitly excluded from rules and including market access, and national treatment and intellectual property. These rules have implications for restrictions on distribution of alcohol beverages, trademarks, and advertising.</p> <p>Trade, transnational ownership of alcohol beverage production, sales, promotion and advertising, distribution and smuggling hinder the management and reduction of these problems and transcend national boundaries. Alcohol problems have proven difficult or impossible to mitigate by countries acting in isolation. There is illicit transnational trade in some regions and pressure by trading partners to reduce alcohol beverage control measures which are often characterized as barriers to trade. Adjudications of trade disputes and negotiations of trade agreements have constrained the abilities of national and sub-national governments to restrict the alcohol beverage market.</p>	<p>Insert the following language: Notwithstanding any language to the contrary, nothing in this agreement shall block, impede, restrict, or modify the ability of any party to take or maintain any action, relating to alcohol beverages that is intended or expected, according to the party, to prevent or to reduce harm to the public's health related to alcohol beverage use or that is reasonably likely to prevent or reduce alcohol beverage use or its harms, including tariffs and restrictions on the marketing of alcohol beverages.</p> <p>Encourage the World Health Organization to develop a legally binding international convention on alcohol beverages.</p>

## **Public Health Advisors on the U.S. - Peru Trade Promotion Agreement and Alcohol Control**

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## **Public Health Objective for Global Trade #7: Intellectual Property and Access to Medicines**

**Eliminate intellectual property provisions related to pharmaceuticals from bilateral and regional negotiations**, as these are more appropriately addressed in multilateral fora, **and promote trade provisions which enable countries to exercise all flexibilities provided by the Doha Declaration on Public Health**, including issuing compulsory licenses for patented pharmaceuticals, parallel importation, and other measures that address high prices and promote access to affordable medicines.

### **Public Health Alternative: Peru Trade Promotion Agreement**

It is time to turn to a new policy that truly provides incentives for innovative medicines, and makes them accessible to the millions in the U.S. and around the world who cannot afford them. The U.S. pays the highest prices in the world to the drug industry, which invests only 15% of revenues in research and development and 37% in marketing and administration, and reaps 19% in profit.

**Exclude TRIPS-plus provisions** from the Peru agreement.

**Provide technical, political, and economic support to Peru to enact and enforce TRIPS public health safeguards**, as reaffirmed by the Doha Declaration on TRIPS and Public Health, in Peru's national legislation

#### **Short-term damage control:**

The concept paper "Peru FTA Changes" released by Congressional leaders and the Administration on May 10 could mitigate some of the damage caused by TRIPS-Plus trade rules. But to alleviate this damage, Congress must carefully craft the legislative language for new intellectual property provisions on pharmaceuticals. The concept paper could remedy past problems with undue patent extensions, and with cumbersome requirements that government drug registration offices link drug approvals to patent status.

**Data exclusivity** rules set a time during which a drug regulatory authority cannot reference the originator company's clinical trial data, or rely on the fact of the prior registration, to confirm the safety and efficacy of a follow-on (generic) product. During this time, generics cannot be registered, and the rules could prevent governments from issuing a compulsory license. These rules are an unnecessary barrier to access in low and middle income countries, and should not apply to them.

As an interim step, the Peru agreement must clarify that: 1. The exclusivity period will last only five years. 2. The clock starts when the originator product is registered anywhere in the world. 3. To benefit from #1 and #2, countries do not need to adhere to a time limit for granting approval of an application for marketing by an originator. 4. Data exclusivity measures will not obligate generic competitors to repeat clinical trials on humans, since the repetition of such experiments violates medical ethics. 5. Parties are authorized to declare a public-health exception to data exclusivity for purposes of issuing a compulsory license to register a drug, or to implement any of the multiple alternative means of authorizing production or importation of a competing product authorized under the TRIPS Agreement, the Doha Declaration, and their subsequent protocols.

**These improvements are at best only a first step toward a trade policy that truly advances access to medicines.**

## **Problems: Intellectual Property and Access to Medicines**

### **Intellectual Property:**

**Article 16 of the Peru agreement, on intellectual property, includes the full range of TRIPS-Plus measures which would inhibit or eliminate the competition for pharmaceutical products, thus raising the price of life-saving medicines to unaffordable levels in poor countries. They buttress the legal architecture to prop up high prices in the US.**

These measures include:

- extension of patent terms, including by definitions of new products eligible for patent protection.<sup>4</sup>
- processes to prevent generic drug approvals during the term of the patent covering the pharmaceutical product (i.e., “linkage”).
- lack of effective measures that would enable generic competitors to have market-ready products at the time that patents do expire.
- data exclusivity, which would prevent generic drug approvals for a number of years, even after a patent has expired or where there is no patent. Regulators could not rely upon clinical test data submitted for a drug’s first approval when considering marketing approval for generic versions during this period. They could bar the use of compulsory licenses.

This is in direct contradiction to Congress’ stated trade objective, to facilitate access to affordable medicines by supporting the Doha Declaration on Public Health and encouraging the use of flexibilities provided under that Declaration. It exceeds the patent protections provided by the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).<sup>5</sup>

The Peruvian Health Ministry estimates that if these measures are enacted, **700,000 to 900,000 people each year will lose access to medicines** in the first five years, with particular consequences for the growing number of people with tuberculosis, malaria and HIV/AIDS. **By 2020 the Peruvian health system will pay an additional \$130 to \$170 million per year to cover the cost of medicines.**

Members of the Trade and Environment Advisory Committee noted in its report on Peru:

“The Congress has been grappling with the issue of **affordability of medicines for American consumers**. A succession of bilateral trade agreements, expanding patent rights and introducing new limitations on the ways generics can be marketed, may well have a preemptive effect, intruding on the prerogatives of the Congress to define national and global policy. Questions have already been raised about the interference of such provisions with the authority of Congress to enact drug re-importation legislation.”

**These TRIPS-Plus measures directly correspond to the priorities of the pharmaceutical industry**, as expressed in the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) on The U.S.-Peru Trade Promotion Agreement (TPA), The Intellectual Property Provisions, February 1, 2006:

“Specifically, ITAC-15’s objectives and priorities seek to further promote the adequate and effective protection of intellectual property rights on a global basis... **The FTA process has become the principal process through which the IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments.**” (p.4)

On page 3 of the same report, the advisory committee encourages US interference into the domestic regulations of our trading partners, a practice that has drawn criticism from Congress, as well as from those partners: “Finally, ITAC-15 urges the United States not only to monitor very closely the implementation by Peru (and our other FTA partners) of their FTA obligations but also to ensure that Peru and our other FTA partners have in place, before the entry into force of the FTAs, national legislation that faithfully reflects their FTA obligations.”

**The side letter on public health provides no protection from these distortions of the market for pharmaceutical products.** Side letters do not override language in the official text, and the language of the side letter itself is also ambiguous. This view that the side letter is essentially of no effect is echoed by ITAC 15:

**“ITAC-15 believes that the (side) letter serves only to clarify the Understanding and does not impose any additional obligations beyond those already found in the Understanding.”**

## **Public Health Advisors on the U.S. - Peru Trade Promotion Agreement and Access to Medicines**

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Physicians for Social Responsibility

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<sup>1</sup> The US-Peru Trade Promotion Agreement (TPA). Report of the Intergovernmental Policy Advisory Committee, February 1, 2006. [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Reports/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Reports/Section_Index.html)  
For example:

1) The Article 10.5 “minimum standard of treatment” language seems to codify the *Loewen* trade dispute case holding that **state court actions** are subject to review by international trade tribunals.

2) The Article 10.5 due process standards are based on unclear international norms rather than reflecting US constitutional norms of substantive due process, as required by the Trade Act of 2002. The Trade Act directs that trade agreements be negotiated so as to not “weaken or

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reduce the protections afforded in domestic environmental and labor laws” and includes as a negotiating objective “ensuring that foreign investors in the United States are not accorded greater substantive rights with respect to investment protections than United States investors in the United States.”

<sup>2</sup> For example, on the important issue of appealing procurement decisions, the Peru Agreement gives challenging corporate bidders more specific rights, and gives governments less flexibility, than the WTO:

WTO Article XX , Challenge Procedures

7. Challenge procedures shall provide for:

(a) rapid interim measures to correct breaches of the Agreement and to preserve commercial opportunities. Such action may result in suspension of the procurement process. However, procedures may provide that overriding adverse consequences for the interests concerned, including the public interest, may be taken into account in deciding whether such measures should be applied. In such circumstances, just cause for not acting shall be provided in writing;

US Peru agreement

Article 9.11: Domestic Review of Supplier Challenges

3. Each Party shall provide that an authority established or designated under paragraph 1 may take prompt interim measures, pending the resolution of a challenge, to preserve the supplier’s opportunity to participate in the procurement and to ensure that the procuring entities of the Party comply with measures implementing this Chapter. Such interim measures may include the suspension of the award of a contract or the performance of a contract that has already been awarded.

<sup>3</sup> Annex I-US-13 exempts non-conforming state laws on services and investments from some trade rules, but not from Domestic Regulation rules.

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<sup>4</sup> The PTPA seeks to ensure that the term “new product” that is used in Article 16.10 is not confused with the “novelty” requirement for patentability found in Article 16.9.1 that an invention must be “new.”

“ITAC-15 welcomes, as an important clarification of the term “new chemical entity” found in TRIPS Article 39.3, the regulatory-related definition of a “new product” contained in Article 16.10.1(c) as being a product that does not contain a chemical entity that had been previously approved in Peru for use in a pharmaceutical or agricultural chemical product.

<sup>5</sup> The data exclusivity measure, for example, exceeds TRIPS in effectively barring the ability of generic competitors to refer to the clinical trial data used by an originator company in preparing for marketing approval. TRIPS 39.3 states:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

In contrast, the Peru agreement imposes an obligation of “non-reliance” on either the originator’s approval or the originator’s data package itself for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in Peru. (Article 16.10.1(a))

In addition, the PTPA explicitly provides protection in cases where regulatory approval is conditioned on the demonstration of prior marketing approval in another territory by requiring the deferral of the date of any marketing approval to third parties not having the consent of the party providing the information in the other territory for a period of at least five years from the date of approval for a pharmaceutical product.