

# Leaked Trans-Pacific FTA Texts Reveal U.S. Undermining Access to Medicine

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Leaked Trans-Pacific Free Trade Agreement Texts Reveal U.S. Pushing Extreme Pharmaceutical Corporation Demands that Would Undermine Consumers' Access to Affordable Medicine

*Obama Administration Positions Roll Back Initial 2007 Reforms Made by Bush Administration on Medicines Patents, Abandon Access to Medicines Commitments*

Leaks of U.S. proposals for the Trans-Pacific Free Trade Agreement (FTA) reveal that the Obama administration has reversed reforms designed to enhance access to affordable medicines made during the George W. Bush administration and is instead demanding new rights for pharmaceutical firms to challenge pricing and other drug formulary policies used by many developed countries to keep down prices. The leaked draft text raises multiple concerns, including the following:

## EMPOWERING BIG PHARMA TO ATTACK COST-SAVING DRUG FORMULARIES

This is a new proposal to empower pharmaceutical firms to attack the medicine formulary systems that New Zealand, Australia and other developed countries have used so successfully to reduce sky-high drug prices. Governments use formularies to control health costs by listing medicines approved for government purchase or reimbursement and negotiating with drug firms to obtain the lowest prices. Using the Trans-Pacific FTA to undermine Australia's Pharmaceutical Benefits Scheme (PBS) and New Zealand's Pharmaceutical Management Agency (PHARMAC) is a goal U.S. pharmaceutical firms. U.S. states and some U.S. national programs also use formulary systems.

See the leaked U.S. proposal for a TRANSPARENCY CHAPTER – ANNEX ON TRANSPARENCY AND PROCEDURAL FAIRNESS FOR HEALTHCARE TECHNOLOGIES and see civil society groups' analyses of what it would mean below.

Also see the leaked U.S. proposal for TBT ANNEXES ON MEDICAL DEVICES, PHARMACEUTICAL PRODUCTS AND COSMETIC PRODUCTS.

#### NEW MONOPOLY PATENT RIGHTS FOR BIG PHARMA THAT WILL UNDERMINE ACCESS TO MEDICINE

The leaked texts show that U.S. officials' recently-announced medicines "access window" is window dressing for piling on monopoly privileges for Big Pharma that will in fact undermine access to medicine for millions. This U.S. intellectual property proposal, which rolls back initial reforms made in a trade pact that the Bush administration signed with Peru only four years ago, would lengthen pharmaceutical monopolies, eliminate safeguards against patent abuse, grant additional exclusive controls over clinical trial data and favor the giant pharmaceutical companies' monopoly interests at every stage.

See the leaked U.S. proposal for the INTELLECTUAL PROPERTY CHAPTER and see civil society groups' analyses of what it would mean below.

#### NEW CROSS-CUTTING LIMITS ON REGULATION OF GOODS AND SERVICES

The leaked draft text of the regulatory coherence chapter shows an attempt to impose a structure and set of procedures for domestic decisions on all forms of regulation in current and prospective Trans-Pacific FTA countries. It expands on Asian Pacific Economic Cooperation initiatives led by New Zealand, Australia and the U.S. that push deregulation and self-regulation. While some elements of the draft text are conducive to well-informed and consistent good decision making, it is inappropriate for a "trade" agreement to dictate to governments how they should structure their domestic regulatory agencies and procedures and make decision on domestic regulatory policy. Despite the procedural appearance of the proposal, it contains substantive biases in favor of light-handed regulation — a model that has proved highly problematic in many countries and sectors, not least the financial industry. Moreover, the chapter's links to regulatory constraint provisions in other proposed chapters of the agreement would confer undue corporate influence over national policy and regulatory decisions.

See the leaked text for the REGULATORY COHERENCE CHAPTER and see civil society groups' analyses of what it would mean below.

#### LEAKS SHOW WHY CIVIL SOCIETY DEMANDS FOR REGULAR ACCESS TO NEGOTIATING TEXTS IS CRITICAL

The leaks highlight the need for regular release of Trans-Pacific FTA negotiating texts, which has been a repeated demand of civil society organizations in the involved countries. Twenty-two U.S. labor, consumer, faith, environmental and human rights organizations — including the Citizens Trade Campaign, AFL-CIO, Sierra Club, Presbyterian Church (USA) and Public Citizen — again wrote U.S. Trade Representative Ron Kirk in October 2011

calling on the U.S. government to implement the administration's transparency pledges and release draft negotiating texts. Past demands have been rebuffed. In September at the Chicago round of negotiations, Trans-Pacific FTA negotiators admitted that they had signed a special pact to keep all documents relating to these trade talks secret. The U.S. organizations' letter, as well as letters from civil society groups in the other involved countries to their governments can be viewed at <http://bit.ly/nmiw4v>.

#### CIVIL SOCIETY'S ANALYSES OF LEAKED U.S. PROPOSALS

Public Citizen's Memo on Obama Administration Backtracking from Bush Era Access to Medicine Commitments

Professor Sean Flynn's Analysis of Leaked U.S. Proposal for a Trans-Pacific FTA Pharmaceutical Chapter

Public Citizen's Comparative Analysis of the U.S. Intellectual Property Proposal and Peruvian Law

Professor Jane Kelsey's Preliminary Analysis of the Draft Chapter on Domestic Coherence

Doctors Without Borders' Release and Memo on How the Trans-Pacific FTA Undermines Access to Medicines

"New leaked texts proposed by the United States to the Trans-Pacific Free Trade Agreement show that the Obama administration has again increased demands on developing countries to trade away access to medicines. The new leaked proposals on intellectual property roll back even modest Bush era commitments to safeguard public health in trade pacts."

— *Peter Maybarduk, Public Citizen* [see full analysis]

"The leaked text confirms the worst fears of health officials. The Obama White House is walking back the core concessions on patent extensions, patent linkage and test data protection that were negotiated with the Bush White House in May 2007. Obama is now objectively much worse than Bush on these issues. It may help the White House raise campaign money from big drug companies, or help USTR officials find their next high paying job working as lobbyists for the drug companies. It is a huge disappointment for us. The texts cover complex issues, and it is hard to summarize all that is important. Even as regards to the reference to the WTO Doha Agreement, the White House tries to sneak in text that makes it appear as though it is limited to only some diseases or emergencies. Collectively, the provisions are designed to strengthen IPR monopolies on drugs, and make it harder to regulate prices. The consequences of stronger monopolies and higher prices are less access to medicine."

— *James Love, Knowledge Ecology International*

"All countries negotiating the Trans Pacific Partnership agreement should reject the US proposal regulating pharmaceutical reimbursement programs. This is an extreme proposal that has no place in a trade negotiation,

particularly one with some of the poorest countries in the world.”

— *Prof. Sean Flynn, Program on Information Justice and Intellectual Property, American University Washington College of Law* [see full analysis]

“Despite the apparent focus on procedures, the [regulatory coherence] proposal also has substantive biases in favour of light-handed regulation — a model that has proved highly problematic in many countries and sectors, not the least the financial industry.”

— *Prof. Jane Kelsey, School of Law, University of Auckland* [see full analysis]

“The leaked draft intellectual property proposals by the United States for the Trans-Pacific Free Trade Agreement have confirmed our fears that the Obama administration is walking away from previous efforts to ensure that developing countries can access affordable medicines, setting a dangerous new standard that will likely be replicated in future trade agreements with developing nations. The administration is touting a so-called ‘access window’ as a mechanism to boost access to medicines. In fact, the administration is confusing access with affordability. The ‘access window’ is all about getting brand-name drugs to market faster, and giving their producers longer monopoly rights that prevent price-lowering competition and keeping medicines out of the hands of the millions of people who need them. Our doctors who work across the developing world rely on affordable generic medicines to trade patients. For example, competition among generic manufacturers is what brought down drug prices for HIV/AIDS by 99 percent, from US\$10,000 per person per year to roughly \$100 today. Trade agreements of the type being pushed this week in Peru threaten these types of crucial gains in access to life-saving medicines.”

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