

TPP: High-Performance Trade Agreements To Advance Public Health

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CPATH

Center for Policy Analysis on Trade and
Health

Trans Pacific Partnership

September 10, 2011

CPATH Mission

Research, analysis and advocacy
to advance global economic policies
that improve and protect public
health

Introduction – On Public Health, Jobs, and the Global Economy

We are participating in Chicago in the semblance of a public forum on global trade, in an effort to put patches on economic and political systems that are increasingly incapable of fundamentally righting themselves and advancing the interests many of us came here to address. Outside of these walls, homeowners near Austin, Texas, are fleeing raging fires, as Philadelphia is flooding, a taste in the US of the climate change that has already brought melting glaciers in the Andes, and threatens the island and continental coasts in the Pacific.

“There hasn't been any rain in months, and the temperatures have been over 100°F (38°+ C) pretty much since May. Everything is as dry as a bone, and the Austinites are hoping for a hurricane to bring rain (the last one just brought more dry wind).”
Near Austin Texas, Sept. 5



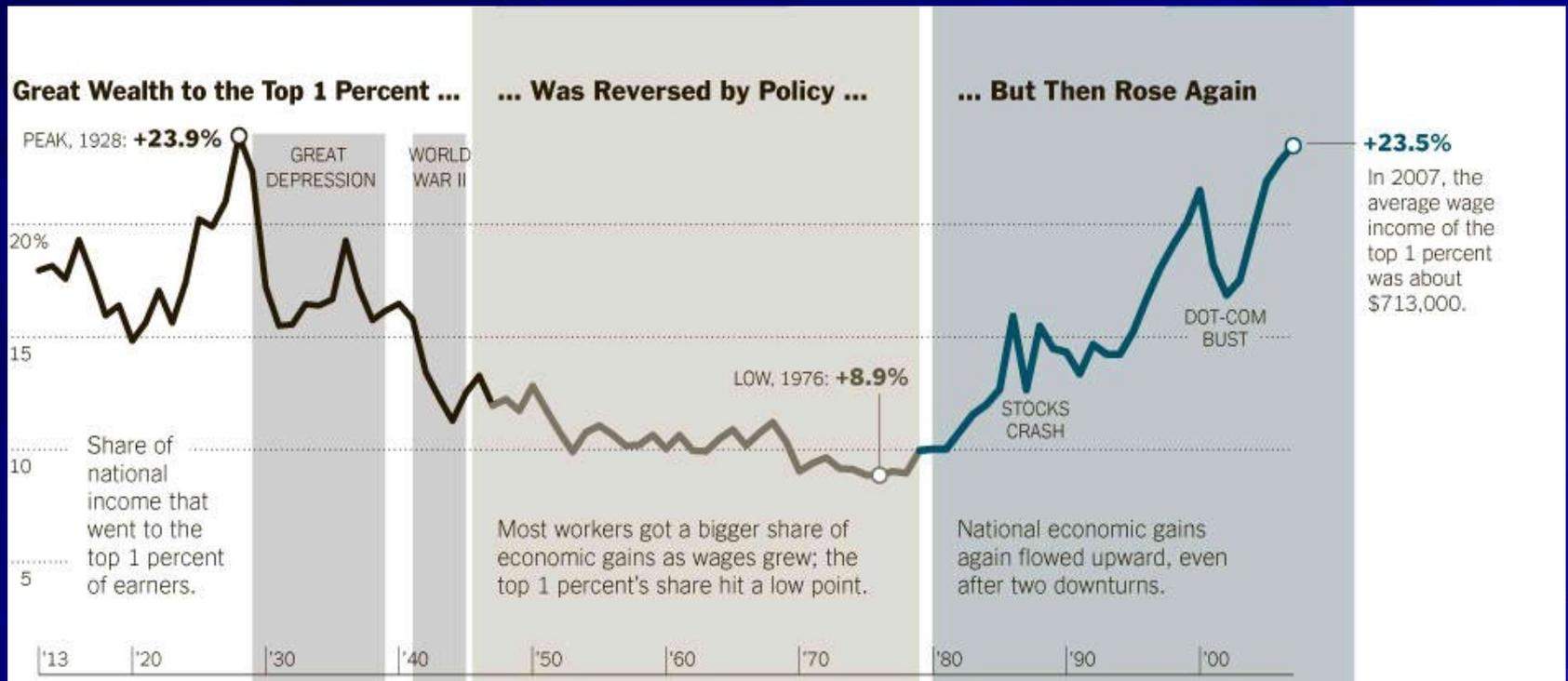
Inequality

The U.S. remains a strong, wealthy country. But we face serious challenges at the national and international levels. Income inequality in the U.S. is at the highest point it has stood at since the Great Depression in 1929: the top 1% of earners own 24% of the wealth. Public health research teaches us that individual and population health both improve with greater degrees of social and economic equality, and with democratic participation in making critical life decisions.

Finding Real Solutions: Jobs and the Economy

Too many of us are out of work. Like many of our trading partners, our political leaders, our residents, our businesses, are deliberating, charging forward, contesting for survival, for advancement, for standing in the world, for a road out of poverty, a roadmap to rewarding and fulfilling futures. We all want this. We are often frustrated. It is our privilege and our burden, as experts and advocates in the arena of the global economy, to make choices that will save lives and make progress, to challenge the imperatives of unmitigated accumulation and unrelenting poverty, and find a way forward.

U.S., 1929 and Now: 24% of Income to 1% of Population



Reich, NYT 9/3/11

Access to Medicines: The IP Stranglehold

- In the U.S., the corporate domination of our health care system is depleting our public coffers and our publicly financed health programs, and leaving too many Americans untreated, bankrupt or both. Unfortunate deals with the pharmaceutical industry like Medicare Part D that have not lived up to their promises. The industry grows more insistent with the expiration of every blockbuster's patent. It is a regime that cannot last. But they've turned to the complex and arcane world of extra-national authority embedded in trade rules to foreclose the world's options for access to affordable life-saving drugs, or to preclude someone else from discovering and distributing them.

CPATH on CAFTA and Access to Medicines in Guatemala

Shaffer, ER and JE Brenner. A trade agreement's impact on access to generic drugs. *Health Affairs*, Web Exclusive. Aug. 25, 2009. w957-w967.

Research Question

How do Intellectual Property provisions of **CAFTA-DR (Dominican Republic-Central America FTA)** affect access to lower-priced medicines, including generics, in Guatemala?

Methodology

- Reviewed relevant IP provisions in Guatemalan law, in TRIPS and in CAFTA

Tug of War

Data Protection in Guatemala

TRIPS (WTO)	Protects data against unfair commercial use
Guate 1999	DE, exceptions for access
Guate 2000	15 years DE
Guate 2003	5 years DE
Guate 2004	DE repealed
Guate 2005	5 years DE
CAFTA 2006	5 years DE

Methodology

(continued)

- Obtained lists of the drugs available through public and private drug purchasing systems in Guatemala
- Looked at medicines protected through CAFTA IP rules on data exclusivity and patents
- Compared prices with non-protected drugs
- Noted drugs removed from the market and/or denied entry due to conflicts with IP rules

Mujeres Positiva Guatemala City



CPATH: CAFTA-Protected Drug 856% Higher Cost

- All data-protected drugs are significantly more expensive compared to non-protected drugs in the same therapeutic class.

Medicine Price Comparison Protected and Banned Generic Brands in Guatemala

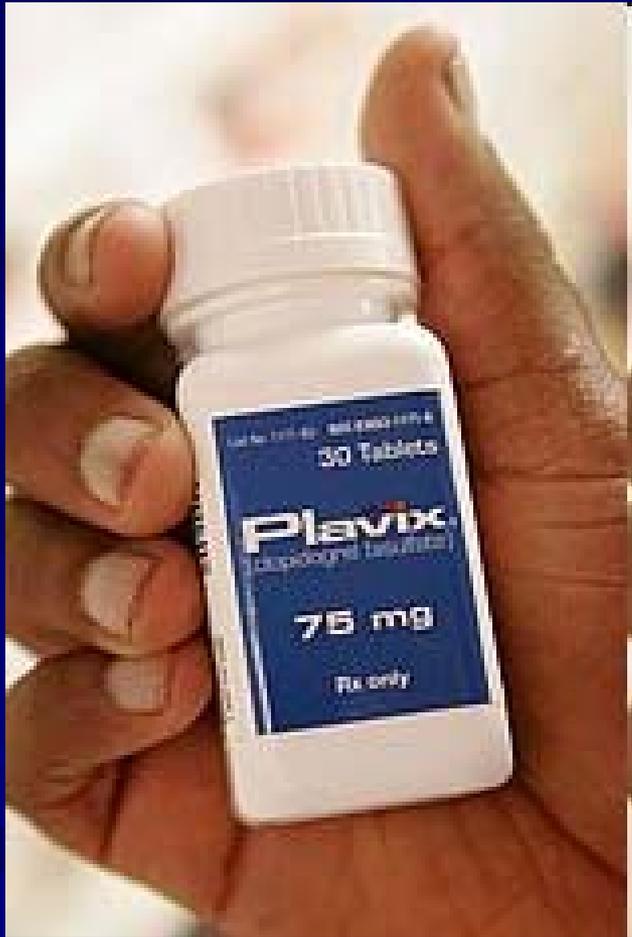


Protected Drug/Generic Equivalent*

* Drugs listed above are examples of different types of medication (insulin, statin, etc.).

Source: Author's analysis of data in Ellen Shaffer and Joseph Brenner (2009) "A Trade Agreement's Impact on Access to Generic Drugs."

Registered Generics Removed From Market



Registration revoked for 4 drug companies which sold generic version of Plavix (clopidogrel bisulfate)

Data Protected Brand-Name Drugs → Competing Generic Drugs Denied Market Entry

- Adefovir dipivoxil (Hepsera) - Chronic Hep B
- Pregabalin (Lyrica) - Fibromyalgia
- Levetiracetam (Keppra) - Epilepsy
- Ivabradine hydrochloride/ (Procoralan) -
Angina

Data Protection Expires Sooner in U.S. than in Guatemala

<u>Condition</u>	<u>Drugs Restricted in Guatemala & Not in U.S.</u>
■ Pneumonia & Respiratory Disease	1
■ Diabetes	4
■ Cardiac Disease	2
■ Cerebro Vascular Disease	1
■ Cancer	5

Basic Question

- Guatemala accounts for 0.14% of PhRMA annual sales
- Global pharmaceutical sales = 17 times Guatemala's GDP
- 56% of the population are poor
SO
- Why is big pharma fighting tooth & nail over the drug market in Guatemala?

Collateral Damage

- Several protected drugs are going off patent in U.S.
- A major objective for pharma TNCs is to keep prices high in the U.S. and prevent public awareness of more affordable solutions.
- Effect on Guatemala is collateral damage

Evidence: Funding Innovation Where?

- Poor countries used as marketing bases
- Transfer funds to brand name companies in rich countries
- Domestic generic industry under attack
- Few new innovative drugs in US
 - Mostly “me-too”

CPATH On Tobacco and Trade

- Shaffer, ER, JE Brenner and TPHouston. International trade agreements: a threat to tobacco control policy. *Tobacco Control* 2005;14;19-25.
- Shaffer, ER, H Waitzkin, J Brenner, R Jasso-Aguilar. Global Trade and Public Health. *American Journal of Public Health*. January, 2005

Teen Smoking: U.S.

- “About 30% of youth smokers will continue smoking and die early from a smoking-related disease.”
- “People who start smoking before the age of 21 have the hardest time quitting.”
- “Teen smokers are more likely to use alcohol and illegal drugs”

-Centers for Disease Control & Prevention



Global Concerns - Tobacco

- **Tobacco Consumption** fast becoming the leading preventable cause of illness and mortality
- Annual death toll worldwide: 5.2 million
- U.S. – tobacco use still kills more than 400,000 people each year

Use of Tobacco Products:

- Chile - 29% of population
- Singapore – 15% of population, up from 12.6%
- Vietnam – 18% of population, down from 25%

Tobacco – Philip Morris on TPP

1. Complete elimination of all tariffs on all goods.
2. Government-sponsored initiatives expropriate trademark rights.
3. Strong investor-state protections critical.

Tobacco & Tariffs

- U.S. – Singapore FTA
 - Tobacco and tobacco products: zero duty
- U.S. – Chile FTA
 - Tobacco and tobacco products: progressive elimination of customs duties
- U.S.-Peru FTA
 - Tobacco and tobacco products: from reduced immediately to zero to reduction to zero over 5 years

Philip Morris on Australia

- Preventive Health Taskforce recommendation that Australia mandate plain packaging of cigarettes to reduce smoking:
 - Unduly limits commercial free speech
 - Breach of WTO TRIPS Agreement

Philip Morris on Singapore

- Smoking (Control of Advertisements & Sale of Tobacco) Act – discretionary power to ban tobacco products based on levels of harm:
- Breach of WTO Agreement on Technical Barriers to Trade (TBT) – discretionary authority to implement legislation and lack of proper implementation “may impact trade and violate the spirit and letter of the TBT Agreement.”

AMA Opposes Tobacco in TPP: Click to read: <http://bit.ly/n5iTH5>



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September 8, 2011

The Honorable Ron Kirk
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: Exclusion of Tobacco and Alcohol and Their Products from Negotiations on the Trans Pacific Partnership Trade Agreement

Dear Ambassador Kirk:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to comment on the proposed Trans Pacific Partnership Agreement (TPP).

The AMA strongly urges you to ensure that tobacco products and alcoholic beverages are excluded from all provisions of the TPP and any other Free Trade Agreements. Accordingly, tobacco control measures would be exempted from trade rules protecting intellectual property including trademarks as well as from any investor-state dispute resolution processes. Exclusion of tobacco and alcohol would also not force trading partners to reduce or eliminate their current applied tariffs on these products. US trade negotiators should not ask any nation to weaken its current anti-smoking or alcohol control strategies in the interest of promoting free trade. Moreover, in order to help your office safeguard health while promoting economic growth, the medical profession and our colleagues in public health would benefit from being well informed about trade policy such as by full public health representation on trade advisory committees.

Our request is consistent with longstanding AMA policy that "international trade agreements recognize that health and public health concerns take priority over commercial interests, and that trade negotiations be conducted in a transparent manner and with full attention to health concerns and participation by the public health community." The AMA has expressed similar concerns to your predecessors regarding the proposed agreements with Malaysia (2006) and Korea (2007).

Thank you for consideration of these public health concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'James L. Madara', is written over a horizontal dashed line.

James L. Madara, MD

Enclosure

Tobacco is Lethal It Is Legal Only Because It Is Addictive, and Therefore Profitable

- The American public has repeatedly demonstrated our familiarity with tobacco's deadly effects. Tobacco is profitable because it is addictive. Because it is profitable and addictive, it is still legal. Nevertheless, step by step, many of us in the US. and many more governments around the world have moved from ignorance to awareness, from big lies to compelling science, from truncated lives to a future of possibilities.
- The Framework Convention on Tobacco Control expresses the world's intention to take on the morbid machine that is the tobacco industry. Surely the road to the 21st century economy cannot depend on destroying the policy space to continue implementing this visionary agreement by constructing arcane, convoluted new legal constraints designed specifically to thwart the will of our national legislatures and the health of our youth.

No additives in our tobacco
does **NOT** mean a safer cigarette.

Winston Lights Box

9mg "tar", 0.7mg nicotine av.
per cigarette by FTC method.

**YEAH, I HAVE
A TATTOO.
AND NO,
YOU CAN'T
SEE IT.**



NO BULL



SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.







Canadian Cigarette Label

Australia

CAUSES OF DEATH IN AUSTRALIA*

TOBACCO - 19,019

Alcohol - 2,831

Motor Vehicle Accidents - 1,731

Illegal Drugs - 863

Murders - 203

**SMOKING -
A LEADING
CAUSE OF
DEATH**

Health Authority Warning

Brand Name

SMOKING - A LEADING CAUSE OF DEATH

Health Authority Warning

CAUSES OF DEATH IN AUSTRALIA*

TOBACCO - 19,019

Alcohol - 2,831

Motor Vehicle Accidents - 1,731

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**Quitline
131 848**

Smoking causes more deaths than murder, illegal drugs, motor vehicle accidents and alcohol combined. Smokers not only live shorter lives, they also live more years with disabling health problems.

You CAN quit smoking. Call **Quitline 131 848**, talk to your doctor or pharmacist, or visit www.quitnow.info.au

* Source: AIHW Quantification of drug caused mortality and morbidity in Australia, 1995 and ABS Causes of Death, 1998

Public Health Objectives for Global Trade

- 1. To assure democratic participation by public health and transparency in trade policy**
- 2. To develop mutually beneficial trade relationships that create sustainable economic development**
- 3. To recognize the legitimate exercise of national, regional and local government sovereignty to protect population health**

Public Health Objectives for Global Trade

4. To exclude tariff and nontariff provisions in trade agreements that address vital human services
5. To exclude tobacco and tobacco products
6. To exclude alcohol products
7. To eliminate intellectual property provisions related to pharmaceuticals from bilateral and regional negotiations... and promote trade provisions which enable countries to exercise all flexibilities provided by the Doha Declaration on Public Health

Carnegie: Trade and Wealth

- Trade is only one policy mechanism among many that must be pursued to lift people out of poverty, achieve economic growth and rising incomes.

Proceed from May 10 Agreement

- Peru FTA: compulsory license allowed
- Data exclusivity limited
- Expand labor rights, environmental protections
- Eliminate corporate challenges to public policy (investor-state disputes)
- Carve out tobacco, alcohol

Trade Advisory Committees 2005:

Business: 42 Public Health: 0

Pharma	20	Public Health	0
Tobacco	7	Public Health	0
Alcohol	6	Public Health	0
Food	5	Public Health	0
Health Insurance	4	Public Health	0

Taking Action: San Francisco

■ Trans-Pacific Partnership



City and County of San Francisco

Tails

Resolution

City Hall
1 Dr. Carlton B. Goodlett Place
San Francisco, CA 94102-4689

File Number: 100822

Date Passed: June 22, 2010

Resolution Calling on U.S. Trade Negotiators to Exclude lethal tobacco and tobacco products from the Trans-Pacific Partnership and other trade agreements negotiated by the United States, and urging the appointment of public health representatives to advise U.S. Trade Negotiators to protect public health.

June 22, 2010 Board of Supervisors - ADOPTED

Reps. Lewis, Ways and Means Members: For Public Health in TPP

Congress of the United States
Washington, DC 20515

September 8, 2011

The Honorable Ron Kirk
The U.S. Trade Representative
600 Seventeenth Street, NW
Washington, DC 20508

Dear Ambassador Kirk:

We write to express our expectation of an improved public health standard as you resume negotiations of the Trans-Pacific Partnership (TPP) trade agreement in Chicago, Illinois.

The standards established by this agreement should reflect our shared goals to improve global health and access to medicines. The terms agreed to by Congress and President Bush on May 10, 2007 should be considered a non-negotiable starting point for the TPP negotiations.

We appreciate USTR's continued updates and consultations regarding this new free trade agreement. In response to your request for guidance, we believe that all of the following principles should be incorporated into the core of the agreement:

- The 'May 10th' public health provisions should be improved with more flexible test data protections, and should eliminate provisions asking countries to enact patent linkage and patent extensions policies;
- The WTO Declaration on the TRIPS Agreement and Public Health principles should be clearly stated within the text of the TPP agreement and not addressed in side-letters;
- TPP standards should be flexible and reflect the diverse economies and public health systems among the developed and developing partner countries;
- The scope of patentability provisions should be voluntary, not mandatory;
- The TPP should not prohibit pre-grant patent opposition; and
- TPP should not undermine either U.S. or other member countries' current or prospective, non-discriminatory drug reimbursement policies and programs (e.g. Medicare, Medicaid, the VA, and other programs).

In general, we have long urged an improved and transparent interagency process and structured consultations with public health interests regarding the potential impact of IP and pharmaceutical provisions on U.S. and global public health efforts. The U.S. Agency for International Development, the U.S. Department of Health and Human Services, the U.S. Patent and Trademark Office, and other relevant agencies should be integrally involved in addressing TPP's potential public health impact.

The May 10, 2007 agreement created an improved model for labor, environment, public health, government procurement, and investment. We expect USTR to incorporate the May 10th text into this next generation of trade agreements, but trust that you will strive for an improved standard.

Network With CPATH

- Subscribe to CPATH's Globalization and Health listserv
- Send a blank email to join-G-H@list.cpath.org

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