

# TPP: High-Performance Trade Agreements To Advance Public Health

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# CPATH Mission

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

# TPP and Health 2010

- Global Economy and Development
- Investor-State Rules
- Tobacco Control: Ag, IP, Investment
- Affordable Medicines: IP, Investment
- Services: Right to Regulate
- Public Health in the Trade Policy Process

# Threats to Global Health

- Widespread threats to global health persist
  - Infectious diseases: AIDS, TB, Malaria
  - Chronic illnesses: Hypertension, diabetes
  - Environmental: Cancer, respiratory
- Coexisting with both unprecedented wealth and economic inequality

# Advancing Public Health

- Sustainable development
- Social and economic justice and equality
- Accountable, democratic governments
  - Democratic participation in setting policy
- Access to affordable health care, water, medicines, education and other vital human services

# Global Economy and Development

- Investment spurs economic growth
- Does open trade increase investment?
  - Sometimes!
  - Also: Government actions and policies
- Does economic growth promote health?
  - Sustainable economic development can play a role

# 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.

# Which Comes First: Wealth or Health?

## Infant Mortality Rates

	<b>Higher Income Growth</b>	<b>Lower Income Growth</b>
<b>Better IMR</b>	Many East Asian countries	Many Latin American Countries
<b>Worse IMR</b>	Many South Asian countries	Many African countries

Nishan de Mel, Trinity College, Oxford

*Health Without Wealth*



# Carnegie Policy Proposals

1. Reject proposed trade policy changes that are likely to worsen poverty
2. Reject trade policy changes likely to produce benefits for only small numbers of firms and households while inflicting economic harm on larger numbers
3. Sequence liberalization
4. Strengthen trade adjustment assistance.

# Trade and Health 2010

- Global Economy and Development

- **Investor-State Rules**

- Tobacco Control: Ag, IP, Investment

- Affordable Medicines: IP, Investment

- Services: Right to Regulate

- Public Health on Trade Advisory Committees

# Investor-State Rules and Public Health

- Permit corporations to bring trade challenges against country governments for range of infractions
- Threaten to pre-empt a wide range of laws, regulations, policies, and programs in the U.S., and federal, state and local authority to prevent disease and promote health

# Laws and Regulations At Risk

- Environmental health
- Public subsidies for safety net
- Affordable medications
- Water and Food safety/GMO foods
- Quality standards for health care services and products & allocation based on need
- Clinician licensing
- Health insurance & patient protection
- Distribution of alcohol, tobacco, firearms
- Occupational safety & health
- Public administration of water & sanitation

# NAFTA Challenge to Health: Metalcad



- State of San Luis Potosí - permission to re-open waste disposal facility denied.
- Geological audit - **waste disposal site would contaminate local water supply**. Community opposed re-opening.
- Metalclad Company- local decision was an **expropriation** of its future potential **profits**.
- Metalclad successfully sued Mexico.  
Awarded **\$16.7 million**.

# NAFTA Suit: MTBE

- **Methanex** Corporation of Canada sued the United States for approximately **\$1 billion**, because the state of **California** banned the use of methyl tertiary butyl ether (**MTBE**), a gasoline additive, due to **suspected carcinogenicity**.
- Due to the possible sanctions from this case, other states withdrew their plans to prohibit this product from use in gasoline.

# Public Health Protections Can Be Trumped

- Disputes must be pursued at the government-to-government level

# Trade and Health 2010

- Global Economy and Development

- Investor-State Rules

## ■ Tobacco Control

- Affordable Medicines: IP, Investment

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# Tobacco Is A Hazardous Substance

- When used exactly as intended, manufactured tobacco products cause serious harm, including disease and preventable death.

# 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 – Free Trade Candidate?

## **A Goal of Liberalizing Trade:**

**Make products more  
readily available,  
at lower prices,  
worldwide.**

# World Bank: How liberalizing trade in tobacco products affects use

- More competition for market share
- More aggressive advertising
- Lower prices
- Aspirational goods – “sexy” international brands, and easier to smoke

Joy de Beyer, World Bank, Tobacco Trade Issues

# Open Markets for Tobacco... Increase in Death and Disease

“Given the inverse relationship between price and consumption ... cigarette smoking and other tobacco use will likely increase...as tobacco markets become more open. As a result, deaths and diseases from tobacco use will also increase.”

“The Impact of Trade Liberalization on Tobacco Consumption,” [World Bank](#), 2000.

# WHO/PAHO on Tobacco and Trade

“Transnational tobacco companies...have been among the strongest proponents of tariff reduction and open markets. Trade openness is linked to tobacco consumption.”

D. Woodward, N. Drager, R. Beaglehole, D. Lipson. Globalization, global public goods, and health. In: Trade in Health Services: Global, Regional and Country Perspectives. N. Drager and C. Vieira, Eds. Washington, DC: PAHO, 2002. pp 6-7.

# Tobacco Liberalization

- Agriculture
  - Tariffs on tobacco leaf and products
- Intellectual Property
  - Advertising
  - Trademarks
- Investor-State Rules
- Services, Domestic Regulation
  - Distribution of cigarettes
  - Smoke-free regulations



# Previous Trade Agreements

- NAFTA
- U.S.-Singapore FTA
- U.S.-Chile FTA
- U.S.-Peru FTA

# CHILLING EFFECT ON PUBLIC HEALTH REGULATIONS

- Canada proposes "plain" packaging for cigarettes.
- American tobacco companies threaten NAFTA challenge for "expropriation" of their intellectual property - their trademarks.
- Canada withdraws proposal.

# 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

# Tobacco - TPP

## Philip Morris International

- Leading international tobacco company
- 7 of the world's top 15 cigarette brands
- Operates in all TPP countries

## Goals:

- Freer trade in goods
- Increase services and investment across national borders
- Protect investor and intellectual property rights

# 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.

# 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.”

# Toward a Higher Trade and Health Standard

- Exclude tobacco from international trade agreements
  - Trade agreements exclude other legal products and services that are hazardous or critical to public safety: weapons, airline safety
- Involve Health Ministries in trade negotiations
- Regional agreements to regulate tobacco/  
implement Framework Convention on Tobacco  
Control



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- **Affordable Medicines**
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# TRIPS

- Trade-Related Aspects of Intellectual Property Rights
- WTO Agreement
- All WTO members must give patent holders rights as stated in TRIPS
- Phased in

# Compulsory Licensing

- Article 31 of TRIPs states governments “may be permitted” to issue compulsory licenses for “public non-commercial use”
- This may be done *after* the government has “made efforts to obtain authorization.... on reasonable commercial terms”

# TRIPS Challenge to ARVs in South Africa, 2000

- Pharma files TRIPS suit to force SA to change drug laws
- Withdraws due to international outcry, 2001
- Led to Doha Declaration, 2001

# International Response to Crisis: Doha Declaration on the TRIPS Agreement and Public Health

Paragraph 4. “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”

- **World Trade Organization Ministerial Meeting, Doha.** Adopted November 14, 2001

# “TRIPS-Plus” Rules

- Debate: Is TRIPS Floor or Ceiling?
- Can bilateral and regional agreements give patent holders greater monopoly rights than they enjoy under TRIPS?
- Yes: CAFTA
- Limited: Australia

# TRIPS-Plus Conditions in Bilaterals

- Data Exclusivity
  - Can't use originator's clinical trial data to establish safety and effectiveness of drugs for 5 years, even if no patent in place
- “Evergreening” rules extend patents
- Requiring licensing authorities to verify complex patents
- Barriers to generic competition, compulsory licenses
- Include plants and animals as patentable

# TRIPS-Plus Rules

- CAFTA

- Peru

Pending/Attempted:

- Korea

- Thailand

- Southern African Customs Union



# Trade Rules Prop Up Drug Prices: Australia and Korea FTAs

- Forbids reimporting lower priced drugs from Australia to US
- Challenges effective Pharmacy Benefit Scheme for controlling drug prices in Australia

# CPATH Case Study: Guatemala

- Compared prices for a sample of 5- and 15-year data protected drugs with non-data protected drugs listed on the Open Contract, for statins, insulins, antibiotics, oncology drugs, and protease inhibitors.
- Data-protected drugs are significantly more expensive compared to non-protected drugs in the same therapeutic class.

# CAFTA IP rules affect the price of medicines

- New protected drugs introduced under IP rules targeted to wealthy
- Some (not all) are clinical improvements
  - Fewer side effects
  - Less resistance
- **Clinical substitutes** for protected drugs, both branded and generic, **are less expensive than the protected products**
- Strain on government funds

# 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”

# Most Profitable Industry in World: Justified by R&D?

- 15% Research and Development
- 19% Profits
- 37% Marketing and Administration

2007:

## New Congress Changes the Rules

- Peru FTA: compulsory license allowed
- Data exclusivity limited

# Threat of Investor Suits

- Threat of Investor Suits Depresses Use of Flexibilities
- Legal AIDS drugs intercepted in Holland

# Australia Concerned Re: Investor-State Disputes on Drugs

- “One issue that flared was whether the TPP would include a mechanism allowing companies to sue a government if it introduced laws that hindered trade interests.” — March 16, Jacob Saulwick
- Pharmacy Benefits Scheme (PBS)  
popular, inexpensive



# Policy Recommendations

1. Preserve national programs that provide affordable medicines: Australia PBS; US VA, Medicaid
2. Ensure that needed medicines are sold at affordable prices and delivered to low-income countries
3. Technology transfer programs
4. Adopt trade negotiating objective: prioritize the human right to health and access to affordable medicines, while advancing innovative research and development of new medicines.

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# Bargaining Away Services

Can bargain away regulatory “protections” for services, affordable medicines vs. economic “protections” for local goods, agriculture

# Grounds for Pre-Emption: Domestic Regulation, Investment

Laws and regulations that are “**more burdensome than necessary** to ensure the quality of a service” can be challenged as barriers to trade.



# WTO Trade Disputes on Services

- Trade dispute panel banned Mexico telecommunications surcharges intended to fund wider access to phone services, because unfair to foreign companies
- U.S. internet gambling prohibitions overturned
  - Intended to protect youth, the public, from online abuses related to gambling addiction
  - Found to discriminate against online gambling companies in Antigua

# Caution Warranted in Services Commitments

- Countries can question benefits of commitments
- Health care, sanitation, education, energy
- Commitments should be “bottom up” – only covered if affirmatively committed
  - In “top down” commitments, all services are covered unless explicitly excluded

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- **Public Health Voice in Trade Policy**

# Campaign for Public Health Representation

- Mechanisms for domestic input into trade negotiations
- Provide formal and informal advice to trade policy makers



# Trade Advisory Committees:

**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

# Van Hollen/Doggett/Stabenow Bill: Representation

- HR 2293/S 1644
- Public Health and Consumer Representatives

# Getting Specific: Public Health Objectives

- 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**

# Getting Specific: Public Health Objectives

- 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**

Thanks for the opportunity  
to present

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