

**Comments on Adding Public Health to the Scope of Viewpoints Represented
on the Industry Trade Advisory Committees**

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Overview

We appreciate the opportunity to comment on the appropriate scope of representation on Industry Trade Advisory Committees (ITACs), on behalf of the Center for Policy Analysis on Trade and Health (CPATH).

We are however disappointed that there has been so little progress on the well-recognized need to include public health representation on all levels of trade advisory committees. It has been a full eight years since the Government Accountability Office documented this gap, five years from the day in 2005 that public health organizations formally approached the previous Administration on this topic, and almost a year since the expression of bipartisan support at the hearing by the Trade Subcommittee of the House Ways and Means Committee.

The Administration has the mandate and authority to take decisive action, and should do so.

We will discuss:

1. Public health views are essential to assure that the rapidly transforming global economy improves people's lives.

2. A public health presence on all three tiers of trade advisory committees is required for a legitimate balance of interests. Public health representatives on the Tier 1 ACTPN, a cross-cutting Tier 2 Public Health Advisory Committee on Trade (PHACT), and public health representatives on Tier 3 would improve the quality of information and advice provided to the USTR and the Secretary of the Department of Commerce. **Health-related industries are robustly represented on the trade advisory committees, including pharmaceuticals, tobacco, health insurance, processed foods, and alcohol beverages.**

3. How the public health perspective would add value and contribute to the ITACs' mission to provide information and advice to assist the USTR and the Secretary of the Department of Commerce in developing U.S. trade policy and negotiating positions.

4. The Administration must act to add public health voices to trade advisory committees.

In many respects the goals of trade and public health are harmonious. A great deal of contemporary discussion addresses the imperative to increase the wellbeing of individuals and communities while alleviating poverty. Trade policy can play an important role in achieving this agenda. To some degree the present submission illustrates areas of difference between public health and commercial interests, without delineating areas of agreement that do exist. We acknowledge the concern of some present trade advisory committee members that introducing other viewpoints would present barriers to the committees' work. To the contrary, we submit that to the extent that trade policies are controversial and unpopular, those policies are barriers to progress. Creating a regular forum that can include exploring and resolving mainstream concerns about current policies would be beneficial and is vital for discovering creative solutions.

1. Public health views are essential to assure that the rapidly transforming global economy improves people's lives.

In his State of the Union message in January of 2010, President Obama discussed the leadership imperative of advancing the prosperity of all people, including strengthening public health abroad, because “our destiny is connected to those beyond our shores.”¹

The trade landscape has changed dramatically since the 1980s. The pace and number of cross-border transactions have accelerated, though moderated by the current financial slowdown. The chain of production and consumption of goods frequently crosses borders. Services from finance to health care are major economic drivers in developed countries. Transnational corporations have become more concentrated. Millions in poor countries have emerged from poverty, at the same time that economic inequality is increasing among and within nations.

Trade agreements establish countries' mutual rights and obligations with regard to trade. Once focused on setting tariffs on goods, they now address rules that govern critical areas that are a matter of public debate at the national and international levels: intellectual property rules on access to medicines and to information; services ranging from banking to health care and water supply; government procurement for grants and contracts; and agriculture. They can provide a basis for altering domestic U.S. laws and policies, as well as those of our trading partners. Trade rules must balance between protecting corporations' ability to operate within uniform and predictable rules, and the obligations of governments to protect the public's safety and wellbeing.

Trade agreements can foster sustainable economic development, democracy, and peace, consistent with public health principles that prioritize achieving and protecting the health and wellbeing of individuals, communities and populations.^{2 3} They can also conflict with or subordinate policies that prioritize people's health, and equitable access to health-related services.⁴

Enforcement of a number of common trade rules requires balancing commercial and health concerns. For example, trade rules that allow nations to adopt and enforce measures necessary to protect human, animal, or plant life or health, also require that such measures cannot arbitrarily or unjustifiably discriminate between countries or be a disguised restriction on international trade. Domestic regulation rules regarding services similarly require that rules for licensing and qualifications, and technical standards, must be no more burdensome than necessary to ensure the quality of a service. Challenges before trade tribunals claiming that public health measures violate trade rules have been successful in almost all cases. Investor-state provisions that allow corporations to file charges against governments have enabled frivolous and damaging disputes. The Metalclad toxic waste site case against Mexico, and the Methanex/MTBE case against the U.S., are classic examples of charges that exposed populations to unjustifiable harm.

We discuss below issues of particular recent concern for both trade and health: access to

¹ President Obama Delivers State of the Union at US Capitol in Washington, D.C. , Jan. 27, 2010

² Institute of Medicine. The future of public health in the 21st century. National Academies Press, Washington, DC. November, 2002. <http://www.iom.edu/Object.File/Master/4/165/0.pdf>

³ World Health Organization. Constitution of the World Health Organization. http://www.who.int/rarebooks/official_records/constitution.pdf

⁴ United States Department of State. Metalclad Corporation v. United Mexican States. <http://www.state.gov/s/l/c3752.htm>.

affordable medicines, tobacco control, and services. Other public health concerns at issue, which we do not discuss here in detail, include the ability of local, state and national governments to regulate clean and safe air, water, food, consumer products; workplace environments, transportation systems; whether government procurement contracts can specify standards for medical and financial privacy, quality and performance, local economic development, and environmental protection; and the distribution of alcohol beverages

• **Intellectual Property Rules and Pharmaceuticals**

High prices restrict access to prescription drugs in lower income countries and also in developed countries which lack regulatory mechanisms to address drug pricing, such as the United States. Few useful innovative drugs are being developed, despite substantial revenue from drug sales. There is insufficient research into therapies for conditions prevalent in low-income countries.

Trade agreements enforce, extend, and progressively strengthen intellectual property (IP) rules internationally, such as patents, data exclusivity and linkage, that offer monopoly marketing rights to pharmaceutical companies which therefore exert tremendous influence over prices. The World Trade Organization's (WTO) Doha Declaration on Public Health notes that intellectual property protection is important for the development of new medicines. But it also states that IP rules "should not prevent [countries] from taking measures to protect public health." It reaffirms the right of WTO countries to use the flexibilities in TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights), including their right to issue compulsory licenses to produce brand name or generic equivalents of originator companies' drugs, and parallel importation. Respect for the Doha Declaration, and a fair balance of rights, was also stated as a Congressional objective in the Trade Act of 2002.

These rights were eroded in a number of U.S. bilateral and regional agreements with Jordan, Chile, Singapore, Morocco, Australia and Central America. Civil society organizations in the U.S. and in partner nations raised concerns, which frequently delayed negotiations. In May, 2007, with leadership by the Trade Subcommittee, Congress took action to limit negotiations with lower income countries on "TRIPS-Plus" IP rules.

• **CAFTA Raises Prices, Limits Availability of Life Saving Drugs for U.S. Trade Partners**

A recent report published in the peer-reviewed journal *Health Affairs* demonstrates how intellectual property rules in the U.S. - Central America Free Trade Agreement (CAFTA) keeps lower-priced generic versions of life-saving drugs off the shelves and out of the hands of some of the poorest people in our hemisphere.⁵ Guatemala is increasingly unable to produce or import affordable medicines because of intellectual property provisions in the trade deal that were demanded by the U.S. pharmaceutical industry and have been aggressively enforced by the U.S. Trade Representative (USTR). As a result, the cash-strapped Guatemalan public sector faces higher prices – up to 846 percent higher – for important drugs to fight diseases such as diabetes and HIV/AIDS. People with HIV/AIDS have reported cutbacks in access to needed drugs.⁶

The report focuses on **data exclusivity rules** and **patents** that are among the intellectual property provisions of CAFTA and other free trade agreements. Particularly alarming is that the rules not only

⁵ Shaffer, Ellen R. and Brenner, Joseph E., A Trade Agreement's Impact On Access To Generic Drugs, *Health Affairs*, op.cit.

⁶ Report: *CAFTA Pushes Up Cost of Vital Medicines*, CAFTA puts lifesaving medicine out of reach for sick Guatemalans, *The story of a Guatemalan woman living with HIV*, Latino USA, Washington, DC, August 25th, 2009.

keep affordable new generics from entering the market; they also function retroactively to remove existing medicines from the shelves. While patents already allow brand name drug manufacturers like Novartis and Merck to suppress competition from generic drug makers in the U.S. and abroad, data exclusivity is an additional bonus for this multi-billion dollar industry. Securing data exclusivity is a simple process for these companies, but it places insurmountable bureaucratic burdens on generics manufacturers. Generic drug makers typically rely on the clinical trial data already generated by brand-name manufacturers to demonstrate the safety and efficacy of their products. But CAFTA prohibits generic drug manufacturers from using the brand-name clinical trial data for a fixed period of years, sometimes even after the brand-name drug is no longer under patent. Without these data, generic versions cannot be approved for market.

The report examined a total of 77 data-protected drugs. Detailed tables in the article illustrate the ways in which both patent and data exclusivity protections influence Guatemalan health officials to purchase brand name pharmaceuticals, often at hundreds of times the cost of their generic counterparts. They also provide examples of generic drugs that were blocked from being marketed in Guatemala in the first place.

- **U.S.-Australia FTA**

Provisions of the US-Australia Free Trade Agreement (FTA) from 2004 could result in higher prescription drug prices for U.S. and Australian consumers. The Agreement could block legislation authorizing reimportation of less expensive drugs into the U.S. New requirements for independent review of federal agency decisions about listing and pricing for drugs could lead to higher drug prices for the Medicaid program and for Veterans Administration health services, and necessitate changes to US law and current practices. The vagueness of key provisions places these important programs at risk.⁷

In 2009 there were 27 pharmaceutical industry representatives on 7 different trade advisory committees. Public health advocates have developed important proposals, ranging from easing the application of TRIPS-Plus rules to reformulating patent rules to incentivize innovation. These views should be included and incorporated in the trade advisory committee system.

- **Tobacco Control and Protection of Public Health**

Globally, tobacco use is expected to kill over 10 million people by 2030. Seventy per cent of the deaths are expected to occur in low and middle income nations. Worldwide, tobacco use is more prevalent among the poor, the uneducated, and those least informed about the effects of tobacco use.⁸

According to the Pan American Health Organization: “Transnational tobacco companies...have been among the strongest proponents of tariff reduction and open markets. Trade openness is linked to tobacco consumption.”⁹ Liberalization of trade in tobacco opens countries to competition from lower priced foreign tobacco products, leading to lower prices in the importing country.

⁷ Testimony to the Ways and Means Committee, U.S. House of Representatives: US-Australia Free Trade Agreement: Implications for Prescription Drug Prices in the US and Australia, Center For Policy Analysis on Trade and Health (CPATH), June 22, 2004.

⁸ E R Shaffer, JE Brenner, and T P Houston. Research Paper: International trade agreements: a threat to tobacco control policy. Tobacco Control 2005;14(Supplement 2).

⁹ 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.

Liberalization, and lower prices, are therefore associated with greater tobacco use.

A nation that imposes restrictions on tobacco imports, or on the distribution, labeling or advertising of cigarettes, may be challenged to prove that these restrictions are "necessary" for tobacco control, and are less restrictive on trade than alternative health protections—for example, consumer health warnings. The health protective alternatives can be hypothetical, and need not be demonstrably effective or politically feasible.

The Doggett Amendment to the Foreign Service Act, passed by Congress in 1997, banned the use of government monies from the Commerce, Justice, and State Departments to promote the sale or export of tobacco overseas or to seek the removal of any nondiscriminatory foreign-country restrictions on tobacco marketing. However, it is subject to annual renewal, and compliance is up to the USTR and other Agencies. Unfortunately, the Doggett Amendment has not been honored for the last 8 years. The U.S. has negotiated eliminating tariffs on tobacco products as well as leaf in bilateral and regional agreements, including the U.S. Singapore Agreement and CAFTA. It is time for a change. There is a single public health representative on one of the committees concerned with tobacco leaf, compared with **6 tobacco industry representatives on 3 different trade advisory committees**. A new Tier 2 public health advisory committee on trade as described in HR 2293/S 1644, would offer the opportunity for critical public health analysis and advice on the range of trade provisions at issue.

• **Trade in Services and the Nation's Health**

A range of vital human services such as water supply, health care, and education, as well as financial and commercial services, have been included in trade negotiations, and in some disputes. These issues call for public health leadership. Antigua's trade dispute challenging the U.S.' regulations on internet gambling came as a surprise to some U.S. negotiators, who stated they had not intended to include this activity in the commitment on recreation. A similar misunderstanding contributed to invalidating a Mexican surcharge on telecommunications under the WTO's General Agreement on Trade in Services.

In this case, again, it is imperative not only to include public health voices on individual Tier 3 committees, but also to comprise a Tier 2 committee composed of public health representatives. There are inevitably complex issues regarding the relationship of important public health protections, the concerns of domestic and foreign service suppliers, and the appropriate national and international locus for decision-making on a number of issues. A well-informed public health advisory committee would provide a valuable forum for analysis and consultation with other interests.

2. A public health presence on all three tiers of trade advisory committees is required for a legitimate balance of interests. Health-related industries are robustly represented on the trade advisory committees, including pharmaceuticals, tobacco, health insurance, processed foods, and alcohol beverages.

Legal Framework For Trade Advisory Process

The trade advisory committee system was established by Congress in Section 135 of the Trade Act of 1974 to institutionalize domestic input into trade negotiations from interested parties outside the federal government.¹⁰ Through the trade advisory committee system, U.S. trade negotiators receive information and advice with respect to U.S. negotiating positions before and during trade negotiations. Trade advisory committees are subject to the requirements of the **Federal Advisory Committee Act (FACA)**¹¹ **which requires that each advisory committee covered by the Act be fairly balanced in terms of points of view represented and committee functions performed.**¹² One of the primary purposes of FACA was to end industry domination of advisory bodies.¹³ Today, the structure of the US Trade Advisory Committees is extremely imbalanced, with domination by industries whose activities have an impact on public health, and notable and problematic absence of representation from the public health community.

Over the years, Section 135 was amended several times to broaden the purposes for which trade advisory committees provide advice to executive branch officials. For example, the law expanded the scope of topics on which the President was required to seek information and advice, from “negotiating objectives and bargaining positions before entering into a trade agreement,” to the “operation of any trade agreements, once entered into,” and on other matters regarding the administration of U.S. trade policy.¹⁴ The law was also amended to include additional interests within the advisory committee structure, such as the services sector and state and local governments. Amended legislation also requires the executive branch to inform the advisory committees of “significant departures from their advice.”¹⁵

In regard to FACA’s requirement that each advisory committee covered by the Act be fairly balanced in terms of points of view represented and committee functions performed,¹⁶ the legislative history of FACA “shows that the fair balance requirement was intended to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee.”¹⁷ The FACA fair balance requirement applies to the trade advisory committees established under Section 135 of the Trade Act.¹⁸

Structure Of Trade Advisory Committees

As described by the House Trade Subcommittee: “The system is arranged in three tiers: the President’s Advisory Committee for Trade Policy and Negotiations (ACTPN), five policy advisory committees dealing with environment, labor, agriculture, Africa, and intergovernmental issues, and

¹⁰ GAO-02-876 International Trade p.4. P.L. No. 93-618, 88 Stat. 1996, codified at 19 U.S.C. § 2155

¹¹ Ibid; 5 U.S.C. App. §§ 1-14.

¹² Ibid. § 5(b)(2).

¹³ *Northwest Ecosystem Alliance v. USTR*, No. C99-1165R (W.D. Wash. Nov. 8, 1999); GAO-02-876, op.cit., p.62.

¹⁴ GAO-02-876 International Trade p.7; Pub. L. 96-39, 93 Stat. 308.

¹⁵ Ibid; 19 U.S.C. 2155(i).

¹⁶ Ibid. § 5(b)(2).

¹⁷ Ibid., p.57.

¹⁸ GAO-02-876, p. 58; *Northwest Ecosystem Alliance v. USTR*, No. C99-1165R (W.D. Wash. 1999).

22 technical advisory committees in the areas of industry and agriculture. The trade advisory committees have participated in the formulation of policy for all trade negotiations and provided advice to the Executive and Congress on concluded trade agreements prior to implementation.”

There is no formal relationship among the three tiers. The USTR assumes a leadership role, administering the advisory committees, along with the departments of Agriculture, Commerce, and Labor.

Working jointly with other relevant executive departments, USTR has the discretion to create, change, and terminate committees in tier 2 and tier 3. Legislative history of the 1979 amendments to section 135 of the Trade Act¹⁹ indicates congressional interest in broadening representation of the tier-2 and tier-3 committees to include other interests.

An extensive group of advisory committees now provide formal recommendations to the official U.S. trade negotiating agency, the Office of the U.S. Trade Representative (USTR). In 2002, the United States Government Accountability Office (then the General Accounting Office) examined the role, structure, and system of the trade advisory committee system. **The GAO Report found that “new stake holders in the trade process, such as public health...have limited or no participation in the formal committee system, even though topics such as intellectual property are of interest to them.”**²⁰

Lack of Public Health Representation on Trade Advisory Committees Is Endemic

In November, 2003, U.S. health leaders called for caution in negotiating international trade agreements. Former U.S. Surgeon General Dr. David Satcher, joining representatives from the American Medical Association, American Nurses Association, the American Public Health Association, and the Center for Policy Analysis on Trade and Health (CPATH), to issue an historic “Call for Public Health Accountability in International Trade Agreements.”

During the 2004 Congressional deliberations on the US-Australia Free Trade Agreement (FTA), members of the House and Senate expressed concerns about the extreme imbalance on trade advisory committees and lack of representation from public health. Congress raised objections to provisions in the agreement related to pharmaceuticals and intellectual property that they had been unaware of that could have an impact on Congressional efforts to authorize re-importation of drugs. They also expressed concern about the potential impact on current U.S. health care programs, including on Veterans Affairs, Medicare and Medicaid, and urged that such provisions should not serve as precedent for future trade agreements.

On the effect of the imbalance on the trade advisory committees on the American people, Rep Rahm Emanuel expressed his disappointment that:

...an otherwise strong Free Trade Agreement has been tainted by provisions designed to protect a captive market for the prescription drug industry in this country...Eli Lilly, Schering-Plough, PhRMA were all on the advisory board to the USTR when it came to negotiating this trade deal, and we are setting a precedent, forcing Americans again to continue to pay the highest pharmaceutical prices than anywhere in the world when we could have provided

¹⁹ GAO-02-876, p. 60; P.L. No. 96-39, 93 Stat. 308-10.

²⁰ Ibid, p. 40.

Americans the chance of a free trade agreement where we reopen markets, bring in competition, lower the prices around the world.²¹

Restructuring of the trade advisory committees in August, 2004, did not address this problem. There continued to be strong representation in the advisory committee structure from the industries with a direct financial stake in trade, including pharmaceuticals and tobacco..

An analysis by CPATH in 2005 found that the number of representatives from the health related pharmaceutical, tobacco, alcohol, processed food, and health services and products industries totaled 42 representatives on 25 committees. The pharmaceutical industry had 20 representatives, and the tobacco industry had 7. The Chair of the Advisory Committee on Consumer Goods (ITAC 4) was from the corporate tobacco giant Altria. The Chair of the Services and Finance Industry advisory committee (ITAC 10) was and today still is the president of the U.S. Coalition of Service Industries, the largest lobbying group in the U.S. of services companies, including health services.²²

The extent of the representation from the public health community in 2005 persisted: Zero.

Requests for Public Health Representation on U.S. Trade Advisory Committees

In May, 2005, public health organizations, including the Center for Policy Analysis on Trade and Health, American College of Preventive Medicine, the American Nurses Association, the American Public Health Association, the California Conference of Local Health Officers, the National Association of Community Health Centers, Physicians for Human Rights, and Physicians for Social Responsibility, sent a letter to USTR Rob Portman requesting the Administration to ensure that the concerns of the health of individuals, communities, and populations be taken into account in developing U.S. trade policy, and strongly encouraged appointment of public health representation on 7 relevant existing Tier 3 advisory committees, and the creation of a new Tier 2 public health advisory committee, to provide information, reports, and advice to and consult with the President, Congress, and the US Trade Representative.²³ Public health organizations cited issues considered by US trade advisory committees and provided analysis of the public health and health care interests and work affected. Issues considered by advisory committees which were cited in a report to the USTR as being of relevance and importance to public health included: agriculture; government procurement; health-related services; insurance; investment; intellectual property rights and pharmaceuticals; movement of personnel; regulations regarding hazardous substances including alcohol and tobacco; and transparency.²⁴

A concurrent letter was sent to the Ambassador Portman from seven tobacco control organizations urging advisory committee appointment of organizations working to ensure the ability of governments to regulate or control trade in, access to, and marketing of tobacco and tobacco products, citing the imbalance in the advice provided by advisory committees to the USTR.

In December, 2005, CPATH and others filed a lawsuit seeking representation on trade advisory

²¹ Congressional Record, July 14, 2004 House of Representatives debate on the U.S.-Australia Free Trade Agreement, H.R. 4759. <http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi>, H5708.

²² ITAC 10 Membership, <http://www.ita.doc.gov/itac/committees/services.asp>, accessed 7-15-09.

²³ Letter to USTR Robert Portman, May 2, 2005,

<http://www.cpath.org/sitebuildercontent/sitebuilderfiles/healthrequestustrdoc5-2-05.pdf>.

²⁴ <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/ustrcommitteeswarrantinghealthrep5-05.pdf>.

committees. In decisions in 2006 and 2008, both District and appellate courts found that although CPATH and public health have standing to claim injury due to lack of representation on trade advisory committees, the Trade Act's standards are insufficient for courts to determine a proper balance of membership.²⁵ In contrast, the court cited comparable statutes that designated at least broad groups of constituents to be included.²⁶ **The courts suggested that Congress and/or the Administration act to clarify further their intentions to address the obvious imbalance.**

In June of 2006, 6 key Senators and 9 Congressional Representatives, including Senator Kennedy, and Representatives Stark, McDermott, and Emanuel, urged the USTR to appoint a public health representative to the top Advisory Committee for Trade Policy and Negotiations, and to create a new Tier 2 advisory committee, specifically addressing public health, to provide advice, technical information, and guidance on policies affecting health care, global health, environmental health, and other important issues.²⁷

The absence of and continued need for public health representatives were chronicled in the September 2007 GAO Report entitled, "Intellectual Property – U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification."²⁸ The report found that input related to public health into U.S. trade negotiations had remained limited since Congress enacted the Trade Promotion Authority (TPA) in 2002. Two individuals associated with public health were appointed to two advisory committees that address pharmaceuticals, otherwise composed of 20 and 33 private sector representatives from the pharmaceutical and other industries. Eric Lindblom, representing the Campaign for Tobacco Free Kids, was appointed to an agricultural trade advisory committee on tobacco, cotton and peanuts. The report found little evidence that "USTR discussed the concerns submitted about the public health impact of FTAs with U.S. health agencies or other members of the public health community,"(p.55) and that there was little evidence that HHS or other U.S. agencies have determined whether FTAs affect public health, either positively or negatively.(p.52) As a possible explanation for the lack of consideration of public health concerns, the report notes that input USTR receives through informal channels (outside the trade advisory system) "may lack the weight of formal private sector input on public health issues in trade agreements."(p.57) The report proposes that if Congress is concerned over USTR's approach to date, it may wish to specify more clearly its intentions related to balancing public health concerns and the negotiation of IP protections in trade agreements.(p.6)

U.S. Trade Advisory Committees in 2009 - Increased Domination by Corporate Health Interests

In May, 2009, CPATH's updated analysis of the composition of U.S. trade advisory committees found that over the past five years, health-related industries have significantly increased their representation on advisory committees. The only decline is in tobacco industry representation. The number of representatives from health-related industries increased to 65, from 42 in 2005, and the breadth of representation from health-related industry representatives increased from a presence on 25 committees to presence on 31 committees. The pharmaceutical industry increased their representatives to 27. The change is illustrated in the table below.

²⁵ CPATH V OFFICE OF US TRADE (9th Cir. 2008), Federal Circuits, 9th Cir. (August 22, 2008), Docket number: 06-16682, Permanent Link: <http://vlex.com/vid/cpath-v-office-of-us-trade-41960551>.

²⁶ U.S. District Court, No. C05-05177 MJJ, Order Granting Motion To Dismiss, Case 3:05-cv-05177-MJJ Document 28 Filed 06/29/2006.

²⁷ Letter to USTR Susan Schwab, June 14, 2006, from U.S. Congress, http://www.cpath.org/sitebuildercontent/sitebuilderfiles/letter_ustrschwab_14june06.pdf.

²⁸ GAO-07-1198, Intellectual Property, <http://www.gao.gov/new.items/d071198.pdf>, p. 5.

Industry Represented	2005	2005	2009	2009
	No. of Advisory Committees	No. of Industry Representatives	No. of Advisory Committees	No. of Industry Representatives
Pharma	6	20	7	27
Tobacco	2	7	3	6
Alcohol	4	6	5	8
Food	13	4	13	7
Health Services, Products, Insurance	2	5	5	17
TOTAL:	27	42	33	65

* Does not include the industry-dominated APAC and 6 Agricultural Technical Advisory Committees

- 4 representatives from the pharmaceutical industry or representing pharmaceutical interests sat on the Advisory Committee for Trade Policy and Negotiations (ACTPN), the top advisory committee providing general advice to the President;
- 11 out of 35 members of the Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health Science Products and Services (ITAC 3) were from the pharmaceutical industry or representing pharmaceutical interests;
- The tobacco industry had 6 representatives on advisory committees including the advisory committee on Consumer Goods (ITAC 4);
- The alcohol industry had 8 representatives spread across 5 advisory committees.
- Representatives from the health services, health products, and health insurance industries totaled 17, serving on 5 committees, including 2 on the ACTPN.

3. How the Public Health Perspective Would Add Value and Contribute to the ITACs' Mission to Provide Information and Advice to Assist the USTR and the Secretary of the Department of Commerce in Developing U.S. Trade Policy and Negotiating Positions

The perspective of Public Health Advisers would add significant value and provide invaluable contributions to the information and advice to USTR and DOC in developing U.S. trade policy and negotiating positions which form a basis for altering domestic U.S. laws and policies, as well as those of our trading partners. The perspective from Public Health advisers can help ensure that our health and well-being and that of our trading partners is safeguarded and promoted, instead of possibly endangered.

The reasons for inclusion cited in the 2005 letter from public health groups are still powerful and merit attention: "It is important for Congress, the U.S. Trade Representative (USTR) and the Department of Commerce to receive information and guidance from the public health and health care community on trade negotiations which affect the public's health, and to benefit from a transparent public debate."²⁹

While there is no representation on the trade advisory committees for our point of view regarding the impacts of international trade on public health and health care...there is substantial representation from the pharmaceutical, tobacco, alcohol, food processing and health insurance industries. Vital issues in current international trade negotiations which are directly related to health include: intellectual property, affecting access to affordable prescription drugs; trade in essential human services such as health care and water, standards for health professional licensing, and alcohol and tobacco protections; standards for the safety of plants and food; and rules on how governments procure goods and services, such as affordable medicines for veterans and seniors.³⁰

Decisions affecting trade policy and negotiating positions made by USTR and DOC related to advice provided by federal trade advisory committees would have been qualitatively improved had the perspective from public health been considered in the trade advisory system.

The following statements and passages from the previous trade advisory committee reports demonstrate that they are of interest to and directly affect the work of the Public Health and Health Care community, and affect our health and well-being as a nation. These examples include all 3 levels of the trade advisory committees, including the ITACs.

The following examples illustrate areas of difference between public health and commercial interests. We understand the concern of present members that introducing other viewpoints would cause the committees' work to grind to a halt. To the contrary, we submit that the trade agenda has already become sufficiently controversial that creating a regular forum for mainstream concerns about current policies would only be beneficial.

- **Tier 1: Advisory Committee For Trade Policy And Negotiations (ACTPN)** – This is the top-level committee which provides overall trade policy advice. Members are appointed by the U.S. President. This committee has included representation from the tobacco, food, and pharmaceutical industries.

²⁹ Ibid.

³⁰ Ibid.

The ACTPN Report to the President on the **US-Australia Free Trade Agreement**, on March 12, 2004, stated:

“Agriculture --The agreement addresses sanitary and phytosanitary (SPS) issues and establishes a special working mechanism for bilateral cooperation and closer mutual engagement in regulatory processes with a view toward greater reliance on science-based measures.”³¹

Public Health and Health Care Interest and Work Affected: Public Health and Health Care organizations are centrally concerned with health promotion, and prevention of harm to the public. The Public Health and Health Care community offers significant expertise in the generation and evaluation of “science-based measures,” and is centrally concerned about discussion and consideration of sanitary and phytosanitary (SPS) issues and related regulatory processes. The absence of public health and health care representation has precluded discussion, for example, of the precautionary principle, an important consideration in developing standards that protect public health and health care.

“Government Procurement -- The ACTPN is pleased with the provisions on government procurement, which provide U.S. firms competitive entry to Australian central government entities.”³²

Public Health and Health Care Interest and Work Affected: Government procurement relates to procurement of affordable medicines, for example, by the Department of Veterans’ Affairs. Under the US-Australia FTA, drug companies can challenge drug listing, purchasing and reimbursement decisions by the Department of Veterans Affairs, Medicare, Medicaid and other government authorities, which could lead to higher drug prices for the vulnerable populations affected. This issue was not addressed by the ACTPN report.

The March, 2004 ACTPN Report to the President on **the U.S.–Central America Free Trade Agreement (CAFTA)** stated: “...the CAFTA makes significant advances in protecting intellectual property, ensuring fair and effective protection for investors, ...greatly improving access for service providers...”³³

“Services -- The ACTPN is pleased that the agreement’s services commitments cover both the cross-border supply of services and the right to invest and establish a local service presence...”³⁴...the committee...wants to highlight particularly significant services industry accomplishments including the market opening achieved for U.S. telecommunications and insurance providers in Costa Rica –a major accomplishment.”³⁵

Public Health and Health Care Interest and Work Affected: The issue of cross-border supply of services, including direct investment and local service presence, are of considerable interest to the Public Health and Health Care community, as it directly impacts the provision and infrastructure of medical and health care services. CAFTA opens the insurance industry in Costa Rica, for

³¹ The U.S.-Australia Free Trade Agreement (FTA) – Report of the Advisory Committee for Trade Policy and Negotiations (ACTPN), March 12, 2004, p.4.

³² Ibid, p.6.

³³ U.S.–Central America Free Trade Agreement (CAFTA) – The Report of the Advisory Committee for Trade Policy and Negotiations (ACTPN), March 12, 2004, p.2.

³⁴ Ibid.

³⁵ Ibid.

example, which has direct implications for public health and health care provision of services and infrastructure, and indirectly affects conditions in the U.S.

“Investment -- The ACTPN applauds the full inclusion of investor-state provisions that provide access to impartial third-party arbitration of investor disputes with governments, which provide an important safety net and provide assurances of fair treatment of possible disputes.”³⁶

Public Health and Health Care Interest and Work Affected: “Investor-state provisions” may be and have been invoked to challenge US laws, rules, policies and programs that protect or enhance the public’s health, and that provide or regulate vital human services.

“Intellectual Property Rights (IPR) -- The ACTPN applauds and endorses the state-of-the-art IPR provisions in the Central America agreement. In the view of the ACTPN these provisions are the best that have been negotiated in any U.S. trade agreement, and should serve as the template for other agreements in the Hemisphere. The protection of patents...sets a new standard for free trade agreements that the committee hopes will be incorporated into additional agreements.”³⁷

Public Health and Health Care Interest and Work Affected: Intellectual property rights and patents for pharmaceutical products are integral to the work of the Public Health and Health Care community, which is concerned with access, affordability, safety and efficacy, as well as product innovation.

- ITACs - RELEVANT TIER 3 COMMITTEES INCLUDE:

Chemicals, Pharmaceuticals and Biotechnology (ITAC 3)

Consumer Goods (ITAC 4)

Distribution Services (ITAC 5)

Information and Communications Technologies, Services, and Electronic Commerce (ITAC 8)

Services and Finance Industries (ITAC 10)

Customs Matters and Trade Facilitation (ITAC 14)

Intellectual Property Rights (ITAC 15)

Standards and Technical Trade Barriers (ITAC 16)

Consumer Goods (ITAC 4) (formerly ISAC-4) – This committee has included representation from the alcohol industry, food industry, and tobacco industry. The committee has commented on the following issues related to public health and health care:

- **Regulations regarding hazardous substances including alcohol and tobacco**
- **Processed foods**
- **Intellectual property**
- **Investment**

The March 11, 2004 Report of the Industry Sector Advisory Committee on Consumer Goods (ISAC-4) on the **U.S.-Australia Free Trade Agreement (FTA)** stated:

“Market Access for Agricultural Products – ISAC-4 includes a number of processed

³⁶ Ibid, p.5

³⁷ Ibid.

food manufacturers, as well as wine and spirits producers... We commend negotiators for improving market access for processed foods, and the Committee is extremely pleased that the agreement incorporates explicit recognition that Bourbon and Tennessee Whiskey, which are the leading U.S. spirits exports, as products that may be produced only in the United States.”³⁸

Public Health and Health Care Interest: The public health and health care community is vitally interested in and devotes substantial work to addressing the public health and health care implications of alcohol consumption, and promoting alcohol control in the interest of Public Health and Health Care. Trade provisions which promote alcohol distribution and consumption are of the highest interest to the Public Health and Health Care community. Processed foods are also a major area of interest and work in the Public Health and Health Care community, especially with regard to efforts to address obesity.

The report on the **U.S.-Australia Free Trade Agreement** also stated:

“f. Regulatory Transparency – Consumer goods are subject to a wide range of regulation wherever they appear in commerce. We applaud negotiators for securing detailed disciplines on regulatory transparency. Our experience under the NAFTA has been that regulatory transparency is a critical factor in improving the business climate for all firms.”³⁹

Public Health and Health Care Interest: The Public Health and Health Care community is very interested in and directly involved in work regarding regulatory transparency, particularly as it impacts public measures which protect and promote health. Under the US-Australia FTA, new rules concerning transparency can challenge drug listing, purchasing and reimbursement decisions by the Department of Veterans Affairs, Medicare, Medicaid and other government authorities, which could lead to higher drug prices for the vulnerable populations affected.⁴⁰

The March 11, 2004 Report of the Industry Sector Advisory Committee on Consumer Goods (ISAC-4) on the **U.S.-Central America Free Trade Agreement** (FTA) stated: “...we generally support provisions on intellectual property and investment.”⁴¹

“c. Intellectual Property (IP) – In our estimation, the IP chapter of the U.S.-Central America FTA represents a major improvement in IP protection and a useful benchmark for future agreements.”⁴²

“d. Investment –The Investment chapter of the U.S.- Central America FTA appears to secure a predictable legal framework.”⁴³

Public Health and Health Care Interest: Intellectual property rights and patents in regard to pharmaceutical products are of a high level of interest and an integral aspect of the work of the Public Health and Health Care community, which is concerned with access and affordability, safety and efficacy, as well as product innovation.

³⁸ The U.S.- Australia Free Trade Agreement (FTA), Report of the Industry Sector Advisory Committee on Consumer Goods (ISAC-4), March 2004, p. 3-4.

³⁹ Ibid, p.4-5.

⁴⁰ U.S.-Australia Free Trade Agreement, Pharmaceutical Annex 2-C; Chapter 15 Government Procurement, Art.15.11.

⁴¹ The U.S.-Central American Free Trade Agreement (CAFTA) – Report of the Industry Sector Advisory Committee on Consumer Goods (ISAC-4), March 2004, p.2.

⁴² Ibid, p.3.

⁴³ Ibid, p.5.

The “Investment chapters” of CAFTA may be and have been invoked to challenge US laws, rules, policies and programs that protect or enhance the public’s health, and that provide or regulate vital human services.

Distribution Services (ITAC 5) – Among the purposes of the Industry Trade Advisory Committee on Distribution Services are, “To hear about and discuss various trade matters that impact distribution services, including GATS [General Agreement on Trade in Services]...regional and country distribution services issues, FTAs.”⁴⁴ Related public health and health care issues include distribution of:

- **Hazardous products including alcohol and tobacco**
- **Pharmaceuticals**

Public Health and Health Care Interest: Health care and health-related services are significant issues in the GATS negotiations and of fundamental interest to Public Health and Health Care. The Public Health and Health Care community is vitally interested in and devotes substantial work to addressing the Public Health and Health Care implications of alcohol consumption, and promoting alcohol control in the interest of public health and health care. Trade provisions which promote alcohol distribution and consumption are of the highest interest to the Public Health and Health Care community. Current US restrictions in market access rules regarding tobacco and alcohol distribution mean the US can respect minority community efforts to limit the number of liquor stores in their neighborhoods, and enforce state laws on tobacco distribution. In GATS negotiations, the European Community has requested removing these restrictions.

Information and Communications Technologies, Services, and Electronic Commerce (ITAC 8) (formerly IFAC-4) – This committee includes representation from the health services and health insurance industries. Health-related subjects include:

- **Privacy of data, including medical records**
- **Health-related communications including advertising**

The March 2004 report on the **US-Australia Free Trade Agreement** from the Industry Functional Advisory Committee on Electronic Commerce (IFAC-4) states:

“IFAC-4 members provide advice on trade policy matters on a range of issues, including: electronic commerce negotiating priorities, data privacy,...standards, consumer protection,...and security and content.

“...Given the rapidly changing nature of electronic commerce, the IFAC-4 believes U.S. negotiators should focus on adoption of broad electronic commerce objectives or ‘principles.’ ...These principles include:

“3. Governments should refrain from enacting trade-related measures that impede ecommerce.

“4. Where legitimate policy objectives require domestic regulations that affect e-commerce, such regulations should be least trade restrictive, nondiscriminatory, transparent, and promote an open market environment.

“7. trade commitments in services necessary to the conduct of electronic commerce transactions.

⁴⁴ 2004 Current FY Report: Review of Federal Advisory Committee, ITAC 5, Industry Trade Advisory Committee on Distribution Services, U.S. Department of Commerce, 2004, <http://www.fido.gov/facadatabase/rptannualreport.asp>.

“10. data privacy and security issues that impact electronic commerce.”⁴⁵

Public Health and Health Care Interest: Data privacy and security, and government safeguards that protect patient and medical privacy are of significant interest to the Public Health and Health Care community, especially as electronic commerce raises new issues of concern regarding privacy and security. Negotiations objectives that call for regulations that are “least trade restrictive” raise serious issues concerning patient and medical privacy protections. Privacy protections are also of concern to researchers and to health care providers who bill using electronic commerce.

The recent GATS decision limiting the U.S.’ internet gambling regulations illustrates the wide area of public health and health care concern in this area.

Services and Finance Industries (ITAC 10) (formerly ISAC 13) – This committee reports that its “overall goal is to liberalize trade in the wide range of services...”⁴⁶ It includes representation from the health services and health insurance industries. It is chaired by the president of the U.S. Coalition of Service Industries (CSI), which represents major financial, banking, and insurance companies, including health insurance.

The March 2004 **US-Australia Free Trade Agreement** Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) stated: “[The US-Australia FTA] has provided commitments above those made in the GATS, including...medical and hospital services, data base services, R&D services on natural sciences...”⁴⁷

Movement of Personnel

The February, 2003 Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) on the **U.S.-Chile Free Trade Agreement (FTA)** stated:

“On December 7, 2001, ISAC 13 proposed to the United States Trade Representative the inclusion of a *special visa* to facilitate personnel mobility as one of the negotiating objectives of this Agreement. The *special visa* would have permitted multiple entries of the holders of the visa for a period as long as three years. ISAC 13 acknowledged that this special temporary entry visa would require a change in U.S. immigration law but believe then, as it does now, that it is desirable to do so to further facilitate the temporary movement of professionals and other essential company personnel between the United States and Chile.”⁴⁸

The March 2004 report on the **US-Australia Free Trade Agreements** from the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) stated:

“It would seem appropriate...that the responsible committees of Congress develop guidelines for future bilateral and multilateral trade agreement so that USTR has the flexibility to negotiate

⁴⁵ US-Australia Free Trade Agreement - Report of the Industry Functional Advisory Committee on Electronic Commerce (IFAC-4), March 2004, p.3-5; U.S.-Central America Free Trade Agreement – Report of the Industry Functional Advisory Committee on Electronic Commerce (IFAC-4), March 2004, p.4-5.

⁴⁶ Ibid, p.3.

⁴⁷ The U.S.-Australia Free Trade Agreement (FTA) - Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13), March 12, 2004, p.2.

⁴⁸ The U.S.-Chile Free Trade Agreement (FTA) – Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13), February 28, 2003, p.5.

temporary entry provisions for highly skilled individuals, senior corporate executives, professional personnel (...health care personnel, as examples)⁴⁹

“At a minimum, a bilateral trade agreement should include, in the case of business visitors, a binding for access to the most common short-term business activities and a prohibition of prior approval procedures, petitions, labor certification tests or numerical limitations...Particular attention should be given to the temporary entry of professionals.”⁵⁰

“The agreement does contain language found in other FTAs that requires the formation of a Joint Committee that will report in three years on progress made toward establishing standards and procedures for mutual recognition of licensing for professionals. The goal is admirable, and we applaud the framers of the agreement for encouraging medical societies in both Australia and the United States to work toward this goal.”⁵¹

“ISAC 13 looks forward to working with USTR and other agencies to fashion commercially meaningful and politically feasible temporary entry/personnel movement proposals.”⁵²

The March 2004 **US-Central America Free Trade Agreement** Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) stated:

“CAFTA breaks new ground concerning the temporary licensing of physicians and surgeons that will be helpful for US hospitals engaged in international medical care to gain market presence. The committee encourages negotiators to continue to refine temporary licensing language for inclusion in all future Free Trade Agreements.”⁵³

Public Health and Health Care Interest: The movement of personnel, including the migration of health clinicians, is of fundamental interest to the Public Health and Health Care community, and raises several important questions, including international agreement on standards for professional training and practice, adequate availability of trained clinicians and service providers in countries that “import” and “export” such workers, and issues of fair working conditions. Increased hiring of immigrant nurses in the US, for example, may mask poor working conditions, and drain important clinical resources away from countries of origin. These issues should be examined in a process which includes public health and health care representation.

The issue of standards and procedures for mutual recognition of licensing for professionals is one of ongoing interest, dialogue and work in the Public Health and Health Care community, as recognized by the comments in the advisory committee report above, and should be involved in the advisory process.

Healthcare Services

The March 2004 report on the **US-Australia Free Trade Agreement** of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) stated:

“Regarding the provision of health care services, such as patient care, hospital

⁴⁹ The U.S.-Australia Free Trade Agreement (FTA) – Report of the Industry Sector Advisory Committee on Services for Trade Related Matters (ISAC 13), February 28, 2003, p.7; The U.S.-Central America Free Trade Agreement – Report of the Industry Sector Advisory Committee on Services for Trade Related Matters (ISAC 13), March 17, 2004, p.7.

⁵⁰ The U.S.-Australia Free Trade Agreement (FTA) – Report of ISAC 13, op.cit., p. 7.

⁵¹ The U.S.-Australia Free Trade Agreement (FTA) – ITAC 13 Report, op.cit., p.13.

⁵² Ibid, p.8.

⁵³ Ibid p.13.

management and consulting services, clinic ownership, licensing of health professionals and continuing health care education, we find the Free Trade Agreement breaks no substantial new ground, but also offers no new barriers to trade.”

Public Health and Health Care Interest: The provision of health care services, such as patient care, hospital management and consulting services, clinic ownership, licensing of health professionals and continuing health care education are core issues of interest and work of the Public Health and Health Care community.

Investment. The March 2004 **US-Central America Free Trade Agreement** Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13) stated:

“Foreign direct investment is particularly important for trade in services...and includes high standard protections for such investment, including investor-state arbitration, the free transfer of capital and protections related to expropriation and fair and equitable treatment.”⁵⁴

“ISAC 13’s objective is to ensure high levels of protections for U.S. investors abroad, including protections related to...expropriation,...no performance requirements, investment agreements and investor-state dispute settlement.⁵⁵ ...Very importantly, the Agreement includes the investor-state dispute settlement mechanism...”⁵⁶

Public Health and Health Care Interest: The “Investment chapters” of CAFTA and other trade agreements, which including provisions that relate to expropriation and investor-state dispute settlement, are of vital interest to the Public Health and Health Care community, as such provisions have been and may be invoked to challenge US laws, rules, policies and programs that protect or enhance the public’s health, and that provide or regulate vital human services. Under NAFTA, a private Canadian corporation is challenging an executive order by the State of California to remove the additive MTBE from gasoline. MTBE is known to leak into ground water, and acts as a carcinogen.

Insurance

“While these countries already have fairly open insurance markets, in most cases these insurance commitments are significant improvements over current WTO obligations. Perhaps most significantly, Costa Rica’s insurance sector, which is currently dominated by a monopoly, will be opened for the first time under this agreement, albeit slowly.”⁵⁷

Public Health and Health Care Interest: Insurance, including health insurance, is of primary interest to the Public Health and Health Care community, as it affects standards for performance and patient protections. Programs and rules that can be challenged under trade rules involving insurance, which are of interest to the Public Health and Health Care community, include Medicare, Medicaid, and workers compensation; extending coverage for health care (restricting the number of competing insurers could violate CAFTA); restrictions on genetic and gender discrimination, and patient protection laws.

In the case of Costa Rica, market opening of the insurance industry has direct implications for public health and health care provision of services and infrastructure, with implications for other CAFTA countries, including the U.S.

⁵⁴ The U.S.-Central America Free Trade Agreement (CAFTA) – Report of the Industry Sector Advisory Committee on Services for Trade Policy Matters (ISAC 13), March 17, 2004, p.2.

⁵⁵ Ibid, p.4. ⁵⁵ Ibid, p.6.

⁵⁶ Ibid, p.6.

⁵⁷ Ibid.

Transparency. Regarding CAFTA, the ISAC said:

“The overarching provisions in the introductory chapter on transparency require the essentials: ...the requirement for prompt publication; the requirement that ‘to the extent possible’ measures that each Party proposes to adopt are published in advance... Further, the chapter provides that parties at interest to proceedings receive reasonable notice of such proceedings, and that they are allowed to present their case prior to final administrative actions. Each Party must establish independent tribunals or procedures for prompt review of administrative actions, and has the right to a decision based on evidence.

“This chapter also provides for the Parties to reach agreements mutually recognizing their qualifications and standards for professional practice.”⁵⁸

Customs Matters and Trade Facilitation (ITAC 14) (formerly IFAC 1) – The March 2004 **US-Australia Free Trade Agreement** Report of the Industry Functional Advisory Committee on Customs Matters (IFAC 1) stated: “The Industry Functional Advisory Committee (IFAC 1) on Customs Matters is concerned with all aspects of the process of importing and exporting goods through customs services, both domestic and foreign, and, with facilitation of the movement of such goods into and out of customs.”⁵⁹

The March 2004 **US-Central America Free Trade Agreement** Report of the Industry Functional Advisory Committee on Customs Matters (IFAC 1) stated: “The functions of the import process and how it is administered can make the agreement more successful for the benefit of traders or it can maintain non-tariff barriers to that trade.”⁶⁰

Public Health and Health Care Interest: Customs matters and trade facilitation, including issues related to facilitation of the movement of goods into and out of customs and non-tariff barriers to trade, are of significant interest to the Public Health and Health Care community, particularly as they relate to goods which impact injury control (tobacco, alcohol, and firearms) and government ability to safeguard public health and health care.

Intellectual Property Rights (ITAC 15) (formerly IFAC-3) – This Committee addresses provisions that affect intellectual property rights for pharmaceuticals, as well as communications media and information technology.

The March 2004 **US-Australia Free Trade Agreement** Intellectual Property Provisions Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) stated:

“IFAC-3 strongly supports the chapter on intellectual property and believes that, on the whole, it establishes key precedential provisions to be included in the other FTAs now being negotiated, including the FTAA.”⁶¹

⁵⁸ Ibid, p.8.

⁵⁹ The U.S.-Australia Free Trade Agreement – Report of the Industry Functional Advisory Committee on Customs Matters (IFAC 1), March 2004, p.2.

⁶⁰ Ibid, p.3.

⁶¹ The U.S.-Australia Free Trade Agreement (FTA) – The Intellectual Property Provisions Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), March 12, 2004, p.2-3.

“Specifically, IFAC-3’s objectives and priorities seek to further promote the adequate and effective protection of intellectual property rights on a global basis... Finally, the Committee seeks to establish strong precedents in these FTAs in order to raise the global level of protection and enforcement, nationally and in regional and multilateral agreements.⁶²

“IFAC-3 is particularly gratified that AFTA preserves these strong precedents set forth in these other agreements and now, with high-level agreements with both small developing countries in the CAFTA and a strong and mature developed country like Australia, it will prove much easier to convince future FTA countries that strong intellectual property protection is in the interest of all countries regardless of their economic circumstances.⁶³

“The resultant level of intellectual property protection that it contains should set a new baseline for future FTAs, including the FTAA.⁶⁴

“IFAC-3 also wishes to highlight its expectation that the U.S. will insist, in any future FTA negotiations with countries that have yet to implement fully their TRIPS obligations, that they not only do so before the launch of the negotiations but also provide a standstill specifically with respect to the approval of generic copies of pharmaceutical products.⁶⁵

“IFAC-3 is also pleased to see that provisions were included in the FTA to enhance the ability of patent owners to prohibit international exhaustion of patent rights. IFAC-3 believes that it is critical that the FTAs include provisions that restrict the authority of countries to provide for international exhaustion of patent rights, including, as was done in the Australian agreement, by protecting the right of the patent owner to prevent the unauthorized importation of goods subject to the patent put on another market by the patent owner or its agent. AFTA [Australia FTA] does so by providing a right of action to enforce contractual provisions that are violated outside the territory of each Party.⁶⁶

“AFTA imposes restrictions on a country’s authority to grant compulsory licenses to situations that are needed to remedy anti-trust violations, national emergencies or other circumstances of extreme urgency, and for public non-commercial use.”⁶⁷

The March 2004 US-Central America Free Trade Agreement Intellectual Property Provisions Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) stated:

“IFAC-3 views the TRIPS Agreement as reflecting minimum international norms of intellectual property protection that most countries should already have in place. The role of the FTAs is to clarify, where necessary, those obligations and to improve upon them by enhancing the level of intellectual property protection in the negotiating partner.⁶⁸

“The patent section of CAFTA provides a number of clarifications and improvements to the protection standards articulated in the TRIPS Agreement. Once implemented, these standards will improve the effectiveness of patent protection in the CAFTA countries.

“IFAC-3 welcomes the pledge made by the CAFTA countries to “undertake all reasonable

⁶² Ibid, p.3.

⁶³ Ibid, p.4.

⁶⁴ Ibid, p.5.

⁶⁵ Ibid, p.5-6.

⁶⁶ Ibid, 11-12. Nearly identical language is found in the Advisory Committee’s report on the U.S.-Singapore FTA.

⁶⁷ Ibid, p. 12.

⁶⁸ Ibid, p.5.

efforts” to make patent protection for plants available by the date the agreement enters into force.⁶⁹

“CAFTA also imposes a second set of obligations that...prohibits generic drug approvals during the term of the patent covering the pharmaceutical product (i.e., “linkage”); and requires the mandatory disclosure of the identity of the generic applicant that seeks marketing approval to enter the market during the patent term. (Article 15.10.3)”⁷⁰

Public Health and Health Care Interest: Intellectual property rights and patents in regard to pharmaceutical products are of a high level of interest and an integral aspect of the work of the Public Health and Health Care community, which is concerned with increasing access and affordability of safe and efficacious prescription drugs.

The US-Australia Free Trade Agreement prohibits drug reimportation from Australia without the consent of patent owner.⁷¹ This implicitly applies to importing drugs into the U.S. from any nation where the patent owner has contractual restrictions.

Similarly, the US-Singapore FTA grants patent owners have the right to block reimportation through contractual provisions in the market.⁷²

The US-Morocco FTA also prohibits drug reimportation without consent of patent owner. Parties may limit this section to cases where patent owner has placed restrictions on reimportation by contract or other means.⁷³

In addition, the Public Health and Health Care community have substantial interest in the issue of intellectual property rights as they may impact protection of patents on plants. Patents of plants may directly impact the economic livelihood and health of local farmers who have traditionally depended on their knowledge of and access to medicinal and nutritional plants but may be required to pay transnational corporations that patent plants.

Standards and Technical Trade Barriers (ITAC 16) (formerly IFAC 2) – The March, 2004 Reports of the Industry Functional Advisory Committee on Standards (IFAC 2) on the **U.S.-Australia Free Trade Agreement (FTA)** and the **U.S.-Central America Free Trade Agreement** stated:

“In particular, the Committee provides detailed policy and technical advice, information, and recommendations to the Secretary and the USTR regarding trade barriers and implementation of trade agreements negotiated under Sections 101 or 102 of the Trade Act of 1974, as amended, and Sections 1102 and 1103 of the 1988 Trade Act, which affect the products of its sector;”⁷⁴

“IFAC 2 supported U.S. negotiations, which would seek an opportunity for direct participation on a non-discriminatory basis in the development of Standards-Related Measures (not covered by WTO rules; cf NAFTA 909.7).”⁷⁵

⁶⁹ Ibid, p.13.

⁷⁰ Ibid, p.16-17.

⁷¹ U.S.-Australia Free Trade Agreement, Chapter Seventeen Intellectual Property Rights, Article 17.9.4, p.17-15.

⁷² U.S.-Singapore Free Trade Agreement, Article 16.7.2 p. 194.

⁷³ U.S.-Morocco Free Trade Agreement, Chapter Fifteen Intellectual Property Rights, Article 15.9.4, p.15-19—15-20.

⁷⁴ The U.S.-Australia Free Trade Agreement (FTA) – Report of the Industry Functional Advisory Committee on Standards (IFAC 2), March 9, 2004, p.3; The U.S.-Central American Free Trade Agreement (CAFTA) – Report of the Industry Functional Advisory Committee on Standards (IFAC 2), March 9, 2004, p.3.

⁷⁵ Ibid.

Public Health and Health Care Interest: Standards and technical trade barriers are of direct interest to the work of the Public Health and Health Care community, including in the areas of environmental health and safety, agricultural and processed food safety, tobacco and alcohol products. In the absence of internationally recognized standards, public health and health care measures may be subject to challenge under trade agreements.

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4. How Public Health Viewpoints Can and Should Be Effectively Incorporated Into Other Fora Also Within the Trade Advisory System

- **Create a New Tier-2 Public Health Advisory Committee**

Proactive action to protect and promote health should be taken now by providing formal representation from the Public Health Community on ITACs and as a stand alone Tier 2 Committee as proposed in HR 2293 and SB 1164.

On May 6, 2009, Congressman Chris Van Hollen (D-MD) joined Congressman Lloyd Doggett (D-TX) to introduce the Public Health Trade Advisory Committee Act. The legislation amends the 1974 Trade Act by requiring that a Public Health Advisory Committee be added to the influential Tier 2 level of Federal Trade Advisory Committee System. A new tier-2 public health advisory committee would to provide information, reports, and advice to and consult with the President, to Congress, and to the U.S. Trade Representative (USTR). Giving public health concerns proper consideration in the trade advisory system will ultimately make America safer and healthier.

As noted by Mr. Van Hollen: “Global trade agreements can greatly influence all aspects of American health. By establishing a Trade Advisory Committee charged with the task of protecting and preserving the health of Americans, we can potentially prevent health threats before they happen.”

“We need more inclusion in what has been largely a closed process. Too often there has been no effective presentation of environmental and public health concerns,” said Mr. Doggett.

Public health officials have praised the proposed legislation, introduced by Senator Stabenow with Senator Kennedy as SB 1164 in the Senate, which would allow increased public health participation in the formation of trade bills. “Trade agreements have become a product of secrecy and smoky back-room deals. This bill lets in the sunlight, as the Obama Administration has pledged,” stated Ellen R. Shaffer, Co-Director of the Center for Policy Analysis on Trade and Health (CPATH).

“Trade and commerce shape our increasingly interconnected world,” said Georges Benjamin, Executive Director of the American Public Health Association (APHA). “Done right, trade policies can not only expand economic opportunity, but can help promote and protect the health and wellbeing of the public and communities. We will all benefit from this important initiative and by including the public health community in these critical decisions.”

“The United States can and should use trade negotiations to improve the health of people worldwide. Good trade policy can diminish trade in hazardous or unhealthy commodities, improve access to medicines, and ensure that governments worldwide can make laws that protect their own health and environment. The creation of the Public Health Advisory Committee on Trade is an important step toward U.S. leadership on trade and health,” said Susanna Bohme, Deputy Editor, International Journal of Occupational and Environmental Health and Chair, American Public Health Association Forum on Trade and Health.

- **Appoint Public Health Representatives to the Advisory Committee for Trade Policy and Negotiations (ACTPN), which provides overall trade policy advice (tier 1).**

In early 2010, USTR committed to placing public health advisers on the Advisory Committee for Trade Policy and Negotiations (ACTPN). While other advisers have been appointed to the ACTPN, public health advisers have not. It is time to make such appointments.

- **Promote transparency and democratic accountability at all levels of the trade negotiation process, including enabling public access to all trade advisory committee meetings, proceedings and submissions related to multilateral and bilateral trade negotiations.**