

## **INTERNATIONAL TRADE ADVISORY COMMITTEE SYSTEM SHOULD INCLUDE PUBLIC HEALTH REPRESENTATION**

The United States has signed and is currently negotiating multilateral and bilateral trade agreements with significant implications for public health and health care. These agreements can provide a basis for altering domestic U.S. laws and policies, as well as those of our trading partners. Issues under negotiation which are directly related to health include: intellectual property, affecting access to affordable prescription drugs; trade in vital 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. In trade negotiations affecting the public's health, it is important for Congress and the U.S. Trade Representative (USTR) to receive information and guidance from the public health community, and to benefit from a transparent public debate.

The international trade advisory system was created by Congress in 1974 to institutionalize domestic input into trade negotiations from interested parties outside the federal government.<sup>1</sup> In 2002, the United States Government 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.”<sup>2</sup> Restructuring of the trade advisory committees in August, 2004 did not address this problem. In contrast, there continues to be strong representation in the advisory committee structure from the pharmaceutical industry, the tobacco industry, and other corporations with a direct financial stake in trade.

During recent Congressional deliberations on the US-Australia Free Trade Agreement, members of both chambers raised concerns and objections to provisions in the agreement related to pharmaceuticals and intellectual property that could have an impact on current Congressional efforts to authorize reimportation 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. Concerns were also expressed about the trade advisory process which lacks representation from public health.

To protect our nation's health and promote access to affordable medicines, it is imperative to take two steps: 1. Include public health representatives in the trade advisory process; and 2. Promote transparency and democratic accountability at all levels of trade negotiations.

This briefing paper addresses four issues, and concludes with Policy Recommendations:

- The Trade Negotiations Process: The Need for a Public Health Voice
- Legal Framework for Trade Advisory Process
- Structure of Trade Advisory Committees Related to Public Health Issues
- Recent Trade Provisions Related to Access to Affordable Drugs, Tobacco Control, and Other Public Health Concerns

---

<sup>1</sup> GAO-02-876 International Trade p.4.

<sup>2</sup> Ibid, p. 40.

## **THE TRADE NEGOTIATIONS PROCESS: THE NEED FOR A PUBLIC HEALTH VOICE**

U.S. Senator Charles Schumer recently noted, “The nature of international trade agreements is changing. They are not just about tariffs anymore.” For the first time, trade agreements treat health care, water, and other vital human services as tradable commodities. Under the complex rules of these trade agreement rules, foreign entities can challenge local, state, or national laws and regulations as “non-tariff” barriers to trade. This means that laws which safeguard public health and which address fundamental health policy issues, such as access to affordable health care, can be challenged and overridden.

Major agreements currently under negotiation include the US-Central American Free Trade Agreement (CAFTA), the General Agreement on Trade in Services (GATS) which covers all 147 nations belonging to the World Trade Organization, and the Free Trade Area of the Americas (FTAA) which covers the 34 nations of the western hemisphere except Cuba. The U.S. is also involved in negotiating a series of bilateral, nation-to-nation, trade agreements, such as the recently negotiated U.S.-Australia Free Trade Agreement.

Trade agreements are negotiated by government representatives. The U.S. Trade Representative (USTR), Ambassador Robert B. Zoellick, is authorized to negotiate trade agreements on behalf of the United States. Trade negotiations are not open to the public or to the press. The USTR consults with private sector advisory committees, established under federal law, which review trade agreements and issue advisory reports following completion of negotiations. Advisory committees are prohibited from sharing information with non-members. As Senator John McCain observed regarding the advisory committee process during recent U.S.-Australia Free Trade Agreement deliberations, “How many public health and consumer advocacy groups were included...? Zero.”

Over the past year, Congressional committees and representatives have sought advice from CPATH on the impact of trade agreements on health. The recent report by the American Medical Association notes that trade agreements require Congressional approval. Under the “fast-track” provisions of the Trade Promotion Act of 2002, Congress may vote up or down on each final agreement as a whole, without opportunity for amendment. Certain Congressional committees have jurisdiction over issues involved in trade negotiations, and hold periodic oversight hearings.

International trade tribunals enforce international trade agreements. They are appointed by the World Trade Organization (WTO) and meet in closed session. There is no requirement that trade tribunal members have expertise or background in public health or in U.S. jurisprudence. Trade tribunals have the authority to impose substantial financial penalties and authorize trade sanctions against countries found in violation of international trade rules. Trade tribunal decisions are not subject to U.S. constitutional law and cannot be appealed through U.S. courts. If foreign corporations or governments successfully challenge public health laws, these laws can be overridden without democratic representation.

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), warned the public that new trade rules threaten the ability of nations to protect public health. They issued the historic “Call for Public Health Accountability in International Trade Agreements.”

It is important for U.S. policymakers and for the U.S. Trade Representative to receive guidance from the public health community on issues affecting the public's health and health care services, so that the U.S. can appropriately negotiate provisions in trade agreements in a transparent manner and with full attention to medical and health concerns.

## **LEGAL FRAMEWORK FOR TRADE ADVISORY PROCESS**

The trade advisory committee system was established by Congress in Section 135 of the Trade Act of 1974.<sup>3</sup> 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.<sup>4</sup> 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.”<sup>5</sup>

Trade advisory committees are subject to the requirements of the **Federal Advisory Committee Act (FACA)**.<sup>6</sup> **FACA requires that each advisory committee covered by the Act be fairly balanced in terms of points of view represented and committee functions performed.**<sup>7</sup> 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.”<sup>8</sup> The FACA fair balance requirement applies to the trade advisory committees established under Section 135 of the Trade Act.<sup>9</sup>

## **STRUCTURE OF TRADE ADVISORY COMMITTEES**

Section 135 of the Trade Act, as amended, established a three-tier structure which:

- 1) Required establishment of an Advisory Committee for Trade Policy and Negotiations (ACTPN) to provide overall trade policy advice (tier 1);
- 2) Authorized establishment of general policy advisory committees to provide general policy advice, which include the Intergovernmental Policy Advisory Committee (IGPAC), the Trade and Environment Policy Advisory Committee (TEPAC), the Labor Advisory Committee (LAC), and Agricultural Policy Advisory Committee (APAC) (tier 2);
- 3) Required establishment of industry sector and functional advisory committees, as appropriate, to provide technical advice and information about negotiations regarding products and other factors relevant to US positions in trade negotiations.

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.

<sup>3</sup> P.L. No. 93-618, 88 Stat. 1996, codified at 19 U.S.C. § 2155.

<sup>4</sup> GAO-02-876 International Trade p.7; Pub. L. 96-39, 93 Stat. 308.

<sup>5</sup> Ibid; 19 U.S.C. 2155(i).

<sup>6</sup> Ibid; 5 U.S.C. App. §§ 1-14.

<sup>7</sup> Ibid. § 5(b)(2).

<sup>8</sup> Ibid., p.57.

<sup>9</sup> GAO-02-876, p. 58; *Northwest Ecosystem Alliance v. USTR*, No. C99-1165R (W.D. Wash. 1999).

- USTR directly administers tier-1 ACTPN (whose members are appointed by the President), tier-2 IGPAC and TEPAC, and shares responsibility for administering the other committees.
- The Department of Agriculture co-administers the tier-2 APAC and six tier-3 Agricultural Technical Advisory Committees (ATACS).
- The Department of Commerce co-administers the rest of the tier-3 committees.
- The Labor Department co-administers the tier-2 LAC.

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 Act<sup>10</sup> indicates congressional interest in broadening representation of the tier-2 and tier-3 committees to include other interests. During the 2004 Congressional deliberations on the US-Australia Free Trade Agreement (FTA), members expressed concerns about the lack of representation from public health in the trade advisory process.

### **Restructuring of Trade Advisory Committees and Related Concerns for Public Health**

Effective, August, 2004, the advisory committees were restructured. Membership of ACTPN decreased from 34 members to 31. There continues to be representation associated with the tobacco industry. There is currently no labor representation on ACTPN as required by law.<sup>11</sup>

Tier 2 advisory committee membership decreased as follows: TEPAC, from 29 to 28; IGPAC from 41 to 40; LAC from 58<sup>12</sup> to 28. Also in the LAC: two labor organizations and two AFL-CIO departments were added; 10 labor organizations and five AFL-CIO departments were removed.

In tier 3, 17 industry sector advisory committees (ISACs) and four functional advisory committees (IFACs) were restructured as 16 Industry Trade Advisory Committees (ITACs). A sixth Agricultural Advisory Committee for Trade (ATAC) was added for “Processed Foods.”

**Industry Representation on Advisory Committees:** One of the primary purposes of FACA was to end industry domination of advisory bodies.<sup>13</sup> Trade advisory committees, however, are dominated by industries whose activities have an impact on public health.

**Pharmaceutical Industry** - Representatives associated with this industry serve on at least 6 advisory committees: ACTPN; Chemical, Pharmaceuticals, Health Science Products and Services (ITAC 3); 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).

**Tobacco Industry** - Representatives associated with this industry serve on at least 2 advisory committees: Tobacco, Cotton and Peanuts (ATAC); Consumer Goods (ITAC 4).

**Alcohol Industry** - Representatives associated with this industry serve on at least 4 advisory committees: Agricultural Policy Advisory Committee (APAC); Consumer Goods (ITAC 4); Distribution Services (ITAC 5); Intellectual Property Rights (ITAC 15).

<sup>10</sup> GAO-02-876, p. 60; P.L. No. 96-39, 93 Stat. 308-10.

<sup>11</sup> GAO-02-876, p. 59. 19 U.S.C. § 2155(b).

<sup>12</sup> The size of the Labor Advisory Group which provided advice regarding CAFTA.

<sup>13</sup> A Federal Court found that FACA’s requirement that advisory committees be fairly balanced does not mean that membership of an industry sector advisory committee is broadly representative of the industry sector for which the committee was established. GAO-02-876, p.62. No. C99-1165R (W.D. Wash. 1999).

**Food Industry** - Representatives associated with this industry serve on at least 13 advisory committees: ACTPN; APAC; TEPAC; 6 ATACs; Chemical, Pharmaceuticals, Health Science Products and Services (ITAC 3); Consumer Goods (ITAC 4); Distribution Services (ITAC 5); Customs Matters and Trade Facilitation (ITAC 14).

**Health Services and Health Insurance Industries:** Representatives associated with these industries serve at least on the following advisory committees: Information and Communications Technologies, Services, and Electronic Commerce (ITAC 8); Services and Finance Industries (ITAC 10).

**Specific Advisory Committees:**

**The Tobacco, Cotton and Peanuts ATAC** – Appointments for representatives from the tobacco industry continue through May, 2005. Last year, the ATAC Advisory Report stated: “The Free Trade Agreement with Singapore appropriately covers all agricultural products, including tobacco.”<sup>14</sup>

**Chemicals, Pharmaceuticals, Health Science Products and Services (ITAC 3)** – Membership has increased from 27 to 29. Representation from the pharmaceutical industry has increased. There are no advocates for importation of medicines. The recent Advisory Committee report on US-Australia FTA stated: “...the resultant level of intellectual property protection that [a free trade agreement] contains should not be viewed as setting any ceilings for the intellectual property chapters for future FTAs. Rather, each individual FTA should be viewed as setting a new baseline for future FTAs.”<sup>15</sup>

**Consumer Goods (ITAC 4)** – Membership decreased from 26 to 24. This advisory committee is chaired by a representative of the tobacco industry,<sup>16</sup> and has other representation from the tobacco industry, as well as from the alcohol industry. There is no consumer or public health representation.

**Distribution Services (ITAC 5)** – This new committee includes representation from the fast food industry and from the alcohol industry. There is no representation from public health.

**Services and Finance Industries (ITAC 10)** – This advisory committee is chaired by the president of the U.S. Coalition of Service Industries (CSI). CSI represents major financial, banking, and insurance companies, including health insurance. **The US Coalition of Service Industries has explicitly identified regulations that restrict licensing of health care professionals and excessive privacy and confidentiality regulations as serious barriers to trade** in health care services.<sup>17</sup>

**Intellectual Property Rights (ITAC 15, formerly IFAC-3)** – At least 9 of the 15 members are associated with the pharmaceutical industry. There is no public health representation. The recent Advisory Committee report on US-Australia Free Trade Agreement (FTA) stated:

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

<sup>14</sup> Members of Agricultural Technical Advisory Committee representing tobacco interests, to US Trade Representative, February 2003.

<sup>15</sup> ISAC 3 Advisory Committee Report to USTR on US-Australia FTA, March 12, 2004, p. 9. There is one environmental representative who is there as a result of a 2001 settlement of *Washington Toxics Coalition v. USTR*, Civ. No. C00-0730R(W.D. Wash. 2001).

<sup>16</sup> Mr. Donald M. Nelson, Jr. also serves on the Tobacco, Cotton and Peanuts ITAC.

<sup>17</sup> Coalition of Service Industries. Response to Federal Register Notice of March 28, 2000. Solicitation of public comment for mandated multilateral trade negotiations on agriculture and services in the World Trade Organization and priorities for future market access negotiations on non-agricultural goods. P. 65.

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. IFAC-3 notes that the underlying right being protected is implicitly acknowledged to be the right of the patent owner to exercise its exclusive right to prohibit importation of products subject to the patent. While IFAC-3 welcomes the formulation found in AFTA, it continues to urge that future agreements explicitly provide this understanding. (Article 17.9.4)<sup>18</sup>

### **Confidentiality of Trade Proposals**

The USTR can authorize advisory committees to operate in a transparent, public manner. For a number of years, however, the USTR has chosen impose a blanket closure rule, requiring that advisory committee members maintain complete confidentiality regarding proposed trade agreement provisions until after each agreement is signed. This restriction limits debate by Committee members' own constituencies, by the public, and by policy-makers, on public health matters of significant domestic concern. A more transparent mechanism is imperative.

### **RECENT TRADE PROVISIONS RELATED TO ACCESS TO AFFORDABLE DRUGS, TOBACCO CONTROL, AND OTHER PUBLIC HEALTH CONCERNS**

Earlier CPATH briefing papers have addressed the possible effects of trade agreements on the reimportation of affordable prescription drugs into the U.S. Following is a brief sample of provisions in current and pending trade agreements that present public health concerns:

#### **Parallel Importation (Reimportation Of Pharmaceuticals)**

**Singapore FTA:** Patent owners have the right to block reimportation through contractual provisions in the market.<sup>19</sup>

**Australia FTA:** Prohibits drug reimportation from Australia without consent of patent owner.<sup>20</sup> Implicitly applies to importing drugs into the U.S. from any nation where the patent owner has contractual restrictions.

**Morocco FTA:** 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.<sup>21</sup>

**Andean FTA (under negotiation):** Proposed language - At minimum, reimportation into U.S. or into Andean countries from another country can be blocked where the patent owner has placed restrictions on importation through a contract or by other means.

#### **Pharmaceutical Provisions, Government Procurement, and Public Health Objectives**

**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.<sup>22</sup>

<sup>18</sup> 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. 11-12. Nearly identical language is found in the Advisory Committee's report on the U.S.-Singapore FTA.

<sup>19</sup> U.S.-Singapore Free Trade Agreement, Article 16.7.2 p. 194.

<sup>20</sup> U.S.-Australia Free Trade Agreement, Chapter Seventeen Intellectual Property Rights, Article 17.9.4, p.17-15.

<sup>21</sup> U.S.-Morocco Free Trade Agreement, Chapter Fifteen Intellectual Property Rights, Article 15.9.4, p.15-19—15-20.

<sup>22</sup> U.S.-Australia Free Trade Agreement, Pharmaceutical Annex 2-C; Chapter 15 Government Procurement, Art.15.11.

**Central American FTA (CAFTA):** CAFTA rules undermine important capabilities of local, state and national governments' procurement contracts to specify standards for medical and financial privacy, quality and performance, local sustainable economic development, environmental protection, public health and safety, gender and racial equity, labor practices, and human rights. Under CAFTA, government actions to favor local companies or service suppliers, or to impose technical specifications, can be challenged as barriers to trade. The U.S. has agreed to include health care services in this chapter.<sup>23</sup>

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

**Singapore FTA:** The Pan American Health Organization has stated: "Transnational tobacco companies...have been among the strongest proponents of tariff reduction and open markets. Trade openness is linked to tobacco consumption."<sup>24</sup> Under the Singapore FTA, tariffs on tobacco and tobacco products are to be progressively reduced.<sup>25</sup>

**CAFTA:** Tobacco companies would be granted the ability to directly challenge national and state tobacco control laws under CAFTA's investment provisions.<sup>26</sup>

### **POLICY RECOMMENDATIONS**

Trade agreements are increasingly being used to shape social and health policy in the U.S. and internationally, with no official representation by public health, and little notice by Congress and the public. The Center for Policy Analysis on Trade and Health (CPATH) together with other public health organizations recently issued a letter to Congress with the following policy recommendations:

- 1. Public health, health care, and tobacco control representatives should be appointed to relevant existing tier-3 advisory committees,** such as: Tobacco, Cotton and Peanuts; Chemicals, Pharmaceuticals, Health Science Products and Services; Consumer Goods; Distribution Services; Services and Finance Industries; and Intellectual Property Rights.
- 2. A new tier-2 public health advisory committee should be created, consisting of public health representatives** to provide information, reports, and advice to and consult with the President, Congress, and the U.S. Trade Representative (USTR), in accordance with the Trade Act of 1974, as amended.
- 3. Transparency and democratic accountability should be promoted at all levels of the trade negotiation** process, including enabling public access to trade advisory committee meetings, proceedings and submissions related to multilateral and bilateral trade negotiations.
- 4. As an important first step, establish the Congressional Public Health Advisory Committee on Trade (PHACT).** This committee will be accountable to Congress, rather than to the Administration, and can therefore be constituted and begin to provide information and analysis immediately. While serving temporarily outside of the Administration's formal trade advisory process, the PHACT would provide guidance and advice, and consult with Congress and the USTR on issues related to current and prospective trade agreements and health, through briefings and discussions, written analysis, and reports.

<sup>23</sup> US-Central American Free Trade Agreement, Chapter 9: Government Procurement.

<sup>24</sup> 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.

<sup>25</sup> U.S.-Singapore Free Trade Agreement, (Annex 2B-Schedule-83-85).

<sup>26</sup> US-Central American Free Trade Agreement, Chapter 10 Investment, Article 10.7: Expropriation and Compensation.