

CPATH ♦ Center for Policy Analysis on Trade and Health

Bringing a Public Health Voice to Trade and Sustainable Development

September 14, 2009

Ambassador Ron Kirk
United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20208

Re: Comments Concerning Free Trade Agreement with the Republic of Korea

CPATH thanks the Office of the United States Trade Representative for providing the opportunity to submit comment on the KORUS FTA.

CPATH has been involved in bringing a public health voice to the debate on trade and sustainable development through research, policy analysis, and advocacy for many years. We submitted written testimony to the Trade Subcommittee of the House of Representatives Ways and Means Committee at the March 20, 2007 hearing on the U.S.-Korea Free Trade Agreement Negotiations. In parallel to that testimony, we prepared a 'Public Health Report Card' to evaluate the impact of the proposed KORUS FTA on key public health issues (provided below). Because the language of the FTA itself has not changed, CPATH continues to be concerned about the impact of the KORUS FTA on the following issues, which were raised both in the report card and in the testimony:

1. Intellectual Property and access to affordable medicines
2. Tobacco control
3. Democratic participation by public health and transparency in trade policy
4. Protecting vital human services such as health care, water supply and sanitation
5. National, regional and local government sovereignty to protect population health
6. Sustainable economic development
7. Alcohol beverage control

Specifically, CPATH is concerned about that the implementation of the KORUS FTA would result in the following:

- Raise drug prices in Korea; many Koreans already cannot afford life-saving drugs, and the national health program's budget is strained.
- Affect reimbursement rates for hospital drugs covered by Medicare and drugs provided in community clinics in the U.S.
- Reverse recent tobacco controls in Korea, where 45% of men smoke and lung cancer is the leading cause of death.
- Subject health care, water and sanitation services to privatization and deregulation in Korea and the U.S.
- Strengthen NAFTA-style corporate rights that encourage frivolous trade challenges against public health protections, at a cost of millions of dollars to taxpayers.

In order to address these concerns, CPATH recommends the following changes to the FTA:

Access to Affordable Medicines:

1. Exclude TRIPS-plus provisions including data exclusivity, patent extensions and linkage, from the Korea agreement.
2. Exclude provisions calling for outside review of government drug purchasing determinations in Korea and in the U.S.
3. Integrate within the intellectual property chapter the recognition that nothing in the chapter affects the ability of Korea and the U.S. to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

Tobacco Control:

1. **Tariff and Nontariff Provisions:** Exclude tobacco products from all trade rules and in each relevant Schedule and Annex, including but not limited to Market Access, Most Favored Nation, National Treatment, Services, Intellectual Property, Investment and Dispute Settlement and tariff reduction schedules.
2. **Insert the following:** Notwithstanding any language to the contrary, nothing in this agreement shall block, impede, restrict, or modify the ability of any party to take or maintain any action, relating to manufactured tobacco products that is intended or expected, according to the party, to prevent or reduce tobacco use or its harms and costs or that is reasonably likely to prevent or reduce tobacco use or its harms, including tariffs and restrictions on the marketing of tobacco or tobacco products.
3. **Add:** Provisions of the Framework Convention on Tobacco Control shall govern, in the event of any conflict with this Agreement.
4. Eliminate the investor-state provision that gives foreign corporations greater rights than domestic investors to file trade challenges against tobacco control measures.

Participation by Public Health and Transparency in Trade Policy:

1. Congress should appoint additional public health representatives to trade advisory committees.
2. Authorize health-related Congressional committees to hold hearings on trade bills.

Although the FTA itself has not changed, CPATH is encouraged by the change of administration at the Office of the United States Trade Representative, and invites the Office to take a fresh look at the impact of trade agreements on public health.

In light of the negative public health impact that the KORUS-FTA would have if implemented in its current form, CPATH encourages the Office of the United States Trade Representative to seriously consider the proposed changes to the agreement.

Sincerely,

Ellen R. Shaffer

Ellen Shaffer
Co-Director, CPATH

Joe Brenner

Joe Brenner
Co-Director, CPATH

CPATH ♦ Center for Policy Analysis on Trade and Health*Bringing a Public Health Voice to Trade and Sustainable Development***KOREAN TRADE AGREEMENT: RISKS TO PUBLIC HEALTH
September 14, 2009**

The U.S.-Korea Free Trade Agreement (KORUS) continues the hijacking of global trade negotiations to the benefit of transnational drug and tobacco companies, and at the expense of people's health. It threatens core protections for public health, long under fire from NAFTA's notorious Chapter 11.

Despite mounting calls for democratic participation in trade policies relevant to public health, labor and the environment, the U.S. Trade Representative failed to involve its own advisory committees, members of Congress, and the public in negotiating key provisions of KORUS.

The agreement would:

- **Raise drug prices in Korea.** Many Koreans already cannot afford life-saving drugs, and the national health program's budget is strained.
- **Affect reimbursement rates for hospital drugs** covered by Medicare and drugs provided in community clinics **in the U.S.**
- **Reverse recent tobacco controls in Korea**, where 45% of men smoke and lung cancer is the leading cause of death.
- Subject **health care, water and sanitation** services to privatization and deregulation **in Korea and the U.S.**
- Strengthen NAFTA-style corporate rights that encourage frivolous trade challenges against public health protections, at a cost of millions of dollars to taxpayers.

“Public health, Congress and the public at large have a right to a voice on these critical trade policies before the ink is dry,” according to Dr. Ellen R. Shaffer, Co-Director of the Center for Policy Analysis on Trade and Health (CPATH). Instead, the US Trade Representative and the Bush Administration have championed a corporate agenda which fails America and endangers our future health.

CPATH's **“Public Health Report Card on KORUS”** (online: <http://www.cpath.org/id29.html>) details how KORUS undermines Public Health Objectives for Global Trade:

<u>Objective</u>	<u>Page</u>
1. Intellectual Property and Access to affordable medicines	4
2. Tobacco control	8
3. Democratic participation by public health and transparency in trade policy	10
4. Protect vital human services such as health care, water supply and sanitation	12
5. National, regional and local government sovereignty to protect population health	15
6. Sustainable economic development	17
7. Alcohol beverage control	18

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade #1: Intellectual Property and Access to Affordable Medicines

To eliminate intellectual property provisions related to pharmaceuticals from bilateral and regional negotiations, as these are more appropriately addressed in multilateral fora, and promote trade provisions which enable countries to exercise all flexibilities provided by the Doha Declaration on Public Health, including issuing compulsory licenses for patented pharmaceuticals, parallel importation, and other measures that address high prices and promote access to affordable medicines.

KORUS Diagnosis: KORUS presents significant threats to access to affordable medicines. For the U.S. it:

- Compromises the Medicare program's ability to set reimbursement rates for drugs and medical devices used in hospitals
- Hamstrings future efforts to negotiate outpatient drug prices for Medicare beneficiaries
- Threatens federal 340b programs that assist community clinics to purchase affordable medicines
- Discourages fair competition by lower-priced generics

Pharmaceutical prices could increase – to the benefit of the drug industry and at the expense of taxpayers and consumers. KORUS further complicates the chaotic market-driven U.S. health care system, in which millions of vulnerable Americans cannot afford adequate medicines, whether they are insured or not.

For Korea, the effects and consequences are more direct and profound. Most Koreans receive medicines through the National Health Insurance system, which relies on generic medicines to control drug costs. Drugs already account for 30% of Korea's health expenditures, more than other OECD countries, although the average annual income in Korea is \$20,000 a year. Too many Koreans do not receive life-saving drugs.

KORUS combines many of the worst features of “TRIPS-Plus” rules, recently abandoned by U.S. trade policy leaders, and the U.S.-Australia Free Trade Agreement of 2004. These provisions fail to properly balance incentives for innovation with guarantees for affordable access to medicines. Instead, KORUS gives transnational pharmaceutical companies extensive new monopoly patent rights, which are not linked to either innovation or access.

Analysis:

This report describes the impact of the three KORUS Chapters related to access to medicines:

5. Pharmaceuticals and Medical Devices

17. Government Procurement

18. Intellectual Property Rights

Chapter 5. Pharmaceuticals and Medical Devices calls for covered federal programs that create lists of covered drugs, or set reimbursement rates for them, to set reimbursement rates based on “competitive, market-derived prices.” If they do not base determinations on market prices, they still must “appropriately recognize the value of patented pharmaceutical products and medical devices” in setting reimbursement rates, and then give drug companies extensive rights to intervene in, challenge, and appeal determinations, and to re-apply for rate increases. Article 3, Transparency, requires countries to solicit comments from pharmaceutical makers about any proposed laws and regulations of general application that may affect the pricing, reimbursement and regulation of pharmaceutical products. (This provision does not exist in the

CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability

S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA

phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

Australia agreement.) Affected governments must also install an independent review board on government pricing and selection decisions related to both medicines and medical devices.

These rules would curb the Korea National Health System's new programs to implement a "positive list" of reimbursable prescription drugs with proven efficacy and price-competitiveness, in order to control drug expenditures. According to the Korea Policy Institute: "This would replace the existing 'negative list' system that only lists drug exclusions. Many U.S. states and HMOs are taking a similar approach of scrutinizing prescriptions drugs, encouraging the use of generics, and limiting reimbursements on brand name drugs."

These provisions would also subject to trade challenges several U.S. programs that use formularies and reference pricing (negotiated rates for a limited number of drugs in each therapeutic category). These U.S. programs include Medicare hospital drug purchases, and federally authorized 340b drug discount programs for other providers including community clinics. Should the federal government take action in the future to negotiate reimbursement rates for elderly and disabled Medicare beneficiaries' outpatient prescription drugs, that portion of Medicare would likewise be covered. These provisions were controversial in the U.S.-Australia trade agreement.

Medicaid, the federal health program administered by states for some low income patients, is explicitly excluded from coverage under this section, by footnote #3.

Chapter 17. Government Procurement Little will change for other U.S. federal programs that directly purchase and dispense drugs – as opposed to setting reimbursement rates - such as the Department of Defense and Veterans Affairs, which are covered under the Government Procurement chapter. The government procurement chapter of the U.S.-Australia agreement of 2004 was widely criticized for granting drug companies important new rights to challenge drug pricing systems for the VA and DoD, which have kept prices very low. KORUS, however, generally refers to the World Trade Organization's Government Procurement Agreement, which already covers both the U.S. and Korea.

Chapter 18. Intellectual Property Rights greatly expands drug company monopoly rights, discouraging fair competition by generic drug companies. According to Shawn Brown of the Generic Pharmaceutical Association, "The U.S. Korea agreement fails to fulfill the principle trade-negotiating objective of achieving an agreement that reflects a standard of intellectual property protection" similar to that in the U.S. "Rather, this agreement blatantly excludes provisions to ensure affordable access to safe and effective generic medicines. The standard of IP protection in U.S. law carefully balances fostering pharmaceutical innovation with ensuring access to affordable medicine...The implementation of laws, regulations and policies that are founded on unbalanced intellectual property principles will lead to the development of barriers to market access for U.S. generic manufacturers." (Advisory Committee Report of the United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3] April 24, 2007, p.16)

KORUS sets new terms for patent term restoration (Article 15.9.6), data exclusivity (Article 15.10.1) and "linkage" (15.10.2(a)).

According to the Labor Advisory Committee (LAC) on trade, "The scope of what is subject to patentability is sweeping, excluding only diagnostic, therapeutic and surgical procedures, as well as those inventions of which the prevention of commercial exploitation is necessary to protect public order or morality. A party cannot, however, exclude such commercial exploitation under the agreement simply because such exploitation is currently prohibited by law. Everything else, including the patenting of plants and animals, is covered." The Trade Advisory Committee on Pharmaceuticals (ITAC 15) asserts that this scope of coverage already exists in Korea, but hails its inclusion here as a springboard to future agreements with other countries.

KORUS provides for the granting of a new patent on products that are already known if a new use or

**CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability
S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA**

phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

method of using the product is discovered. The LAC notes, “This clause was excluded from past agreements over the obvious concern that a patent could be extended for decades beyond the initial inventive step. In essence, this clause grants additional monopoly rights without any innovation.”

”The pharmaceutical industry has lobbied for and obtained the right to extend the patent term to compensate for delays in granting marketing approval as well as delays in the examination of the patent application. No maximum period is provided for this extension. Moreover, the right to extend the term of the patent for delays in patent approval is triggered after four years under the KORUS FTA, not five as in previous FTAs, and there is no minimum defined period that will trigger patent extension for delays in granting marketing approval.

Footnote 20 defines a “new pharmaceutical product” as a “product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product” in each country.

Data protection. Original pharmaceutical patent holders must conduct clinical trials involving humans in order to establish the safety and efficacy of new drugs, and present the trial data to regulators in order to obtain marketing approval. Generic producers typically refer to the originator’s data when seeking marketing approval, but do not reproduce the clinical trials, which would be expensive and usually unethical (since most trials would involve withholding a treatment already known to be effective from some subjects). The WTO TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights) requires WTO member countries to protect undisclosed test data on pharmaceutical products against unfair competition, but it does not require members to grant originators exclusive rights over data.

However, the KORUS FTA obliges parties to grant exclusive rights to data for at least five years from the date of marketing approval in the country, regardless of whether it is patented or not or whether the data are undisclosed. The agreement also provides that data exclusivity extends to information used to obtain marketing approval for a new pharmaceutical product in a third country. The protection for data is also not affected by the expiration (or non-existence of) a patent (Article 18.9.3), potentially granting additional protection beyond the patent life or in absence of any patent. Finally, the agreement allows a producer to obtain consecutive periods of data exclusivity, which would extend the protection well beyond 5 years.

It also extends additional data protection to a producer when a second use is found for the original drug.

Subsections (a) and (b) of Article 18.9.2 require Korea to provide additional periods of data protection of three years from the date of marketing approval in Korea for new clinical information (other than information related to bioequivalency) or evidence of prior approval of the product in another territory that requires such new information, which is essential for the approval of a pharmaceutical product that uses a previously approved chemical component.

The KORUS FTA places restrictions, in Article 18.8.5, on how a third party may use a patented invention to generate data needed for the marketing approval of generic pharmaceutical products (so-called Bolar-type use). These restrictions limit the use of such data to use specifically for purposes related to meeting the marketing approval requirements; and if export of the generic pharmaceutical product is permitted, the product can only be exported outside the territory of the Party for purposes of meeting marketing approval requirements of that party.

The FTA requires a linkage between the drug registration and patent protection, which is not found in TRIPS. Such “linkage” gives any person or entity claiming a patent on a pharmaceutical the power to stop it from reaching the market, even if the patent is invalid. Linkage requires the agency responsible for drug safety to be responsible for verifying the patent status of the product and informing the patent holder, a function outside that agency’s mandate or expertise. Moreover, the government will be held liable if marketing approval is granted to a product that is later found to have a valid patent, rather than holding the violator liable (e.g. generics company).

The majority of trade advisory committee members, including a number of representatives of the drug

industry, “applaud the efforts of USTR that resulted in the very strong chapter on intellectual property rights included in this agreement. These members also fully support the important intellectual property provisions that this FTA contains regarding pharmaceutical products. In particular, Korea’s commitments regarding patent linkage, patent term restoration, and data protection appropriately recognize the critical nature of intellectual property rules as an engine for pharmaceutical innovation.” (Advisory Committee Report of the

United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3] April 24, 2007, Executive Summary of Committee Report, p.15)

ITAC 15 on Intellectual Property further lamented:

“The KORUS FTA fails to explicitly limit a country’s authority to grant compulsory licenses to situations that are needed to remedy anti-trust violations and to national emergencies or other circumstances of extreme urgency; and to govern situations of public non-commercial use.

“It was the objective of the U.S. government, of ITAC-15 and of the entire U.S. intellectual property community to use the opportunity offered by the FTA process (the Doha Round in the WTO will not be considering changes in the TRIPS enforcement text) to use our enforcement experience over this period to improve and strengthen these enforcement obligations, with the goal of having them adopted on a global basis.

“ITAC-15 notes that this task was particularly challenging since governments are most reluctant to bind themselves to specific performance standards in the area of enforcement.”

CPATH Recommendations:

1. Exclude TRIPS-plus provisions including data exclusivity, patent extensions and linkage, from the Korea agreement.
2. Exclude provisions calling for outside review of government drug purchasing determinations in Korea and in the U.S.
3. Integrate within the intellectual property chapter the recognition that nothing in the chapter affects the ability of Korea and the U.S. to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade # 2:

To exclude tobacco and tobacco products, which are lethal, and for which the public health goal is to reduce consumption, from tariff and non-tariff provisions of trade agreements, including advertising, labeling, product regulation and distribution.

KORUS Diagnosis: Public Health endangered because of increased risk of tobacco-related death.

- Korea's tobacco control measures are generally at risk under the KORUS rules on distribution services, and on Intellectual Property.
- **KORUS eliminates tariffs on tobacco and tobacco products, over a period of 10 -15 years.** (General Notes, Tariff Schedules, and TRQ Annexes, Annex 2-B: Tariff Elimination, Korea Agriculture Tariff Schedule) "Transnational tobacco companies...have been among the strongest proponents of tariff reduction and open markets. Trade openness is linked to tobacco consumption," according to the Pan American Health Organization.¹

Analysis:

Reducing tobacco consumption is a key public health goal of particular consequence for South Korea, where 45% of males smoke presently.

Korea currently attributes the majority of its deaths to cancer. Cancer-related deaths rose from 13.8% to 21.4% of all deaths between 1980 and 1994 – with cancer-related mortality for men changing from 49.5 to 134.2/100,000, and for women from 32.6 to 76.1/100,000. Since 1980, lung cancer has increased the most rapidly, and liver and lung cancer in men accounted for 65% of all cancer deaths from 1984-1998.²

In 1995, Korea passed the National Health Promotion Act (NHPA), which states that all public areas and facilities must assign smoking and non-smoking areas. The NHPA also restricts cigarette vending machines and selling to those under the age of 19. It requires health warnings on tobacco packaging and advertising.

These tobacco control measures appear to be achieving a slow decline in tobacco consumption in South Korea. Annual per capita consumption declined from 130 in 1990 to 116 in 2000. One goal of the NHPA was to reduce male smoking from 67% to 30%, and female smoking from 6.7% to 5%, by 2010.

However, all of these measures are at risk under the KORUS rules on distribution services, and on Intellectual Property.

Korea has a 40% tariff on imported tobacco products. Korea originally planned to levy a 40 percent tariff on imported tobacco as its lifting of the state monopoly on cigarettes became effective in July 1, 2001. But, driven by pressure from the U.S. government and multinational cigarette producers, the Korean government reluctantly consented to phase in the tariff by 10 percent a year, gradually raising it to 40 percent by 2004. This tariff will be eliminated by the agreement, which could increase consumption particularly among youth.

The proposed liberalization of tobacco markets under the KORUS FTA could also significantly hinder progress in tobacco control. Korea had import tariffs on foreign cigarettes until the 1980s, when the US

¹ (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.

² Sun Ha Jee, II Soon Kim, II Suh, Dongchun Shin and Lawrence J Appel (1998). Projected Mortality from lung cancer in South Korea, 1980-2004. *International Journal of Epidemiology*; 27;365-69.

exerted pressure to liberalize the tobacco industry under the Special 301 provisions. Smoking rates among male Korean teens rose from 18.4% to 29.8% in a single year, in 1988. The rates among female teens more than quintupled – from 1.6% to 8.7%.³ These rises were due to decreased prices and increased advertising.

NOTE: Services Annex I allows Korea to maintain or amend its following present rules on the distribution of tobacco, without interference from KORUS trade rules (p.4). However, similar new rules would not necessarily be allowed in the future:

Articles 12, 13, and 16 of the Tobacco Business Act (Law No. 8365, Apr. 11, 2007)
 Articles 4, 5 and 9 of its Enforcement Decree (Presidential Decree No. 18445, Jun. 29, 2004)
 Articles 5 through 9, and 11 of its Enforcement Regulations (Ordinance of the Ministry of Finance and Economy No. 512, Jul. 5, 2006)
 Notice of National Tax Service 2005-5 and 8

A person who supplies tobacco wholesale (including importation) or retail distribution services must establish an office in Korea.

Only designated tobacco retailers may sell tobacco to retail buyers. The sale of tobacco to retail buyers by mail or in electronic commerce is prohibited.

The distance between places of business of tobacco retailers must be at least 50 meters.

Agricultural Technical Advisory Committee for Tobacco, Cotton, Peanuts and Planting Seeds (ATAC, TCPPS) April 25, 2007

IV. Dissenting Opinion(s)

“One member of the TCPPS opposes the [FTA] for the following reasons:

“The agreement applies to manufactured tobacco products without providing adequate safeguards to ensure that it will not in any way interfere with either country’s laws, rules, or other measures or actions that are meant to, or are reasonably likely to, prevent or reduce tobacco use or the harms or economic costs caused by tobacco use.”

Member Dissenting from Committee Opinion:

Eric Lindblom, Campaign for Tobacco Free Kids

CPATH Recommendations:

1. **Tariff and Nontariff Provisions:** Exclude tobacco products from all trade rules and in each relevant Schedule and Annex, including but not limited to Market Access, Most Favored Nation, National Treatment, Services, Intellectual Property, Investment and Dispute Settlement and tariff reduction schedules.
2. **Insert the following:** Notwithstanding any language to the contrary, nothing in this agreement shall block, impede, restrict, or modify the ability of any party to take or maintain any action, relating to manufactured tobacco products that is intended or expected, according to the party, to prevent or reduce tobacco use or its harms and costs or that is reasonably likely to prevent or reduce tobacco use or its harms, including tariffs and restrictions on the marketing of tobacco or tobacco products.
3. **Add:** Provisions of the Framework Convention on Tobacco Control shall govern, in the event of any conflict with this Agreement.
4. Eliminate the investor-state provision that gives foreign corporations greater rights than domestic investors to file trade challenges against tobacco control measures.

³ Callard, Chitanondh, and Weissman. Why trade and investment liberalization may threaten effective tobacco control efforts. Tobacco Control, 2001; 10:68-70

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade #3:
Democratic Participation by Public Health and Transparency in Trade Policy

KORUS Diagnosis: Nation's health at risk from new KORUS trade rules. US trade negotiators failed to consult adequately with public health or Congress. Failed to respond to public health comments. Deliberations were not transparent.

Objective 3a: To assure democratic participation by public health and transparency in trade policy by appointing to all relevant trade advisory committees representatives of organizations that work to assure equitable access to affordable health-related services and products, and promote the health of individuals, communities and populations.

KORUS Diagnosis: Two trade advisory committee representatives registered caution in reports on access to medicines and tobacco control. One new member recently appointed to represent public health views on trade advisory committees for pharmaceutical issues, who has a background with the pharmaceutical industry, failed to record any comments in her committee's endorsement of KORUS.

Analysis:

Responding to public health demands to provide balance to the corporate interests represented by hundreds of industry representatives on trade advisory committees, the USTR has appointed three individuals to represent public health views plus a representative from the Generic Pharmaceutical Association. Trade advisory committees are subject to the requirements of the **Federal Advisory Committee Act (FACA)**.⁴ **FACA requires that each advisory committee covered by the Act be fairly balanced in terms of points of view represented and committee functions performed.**⁵

Where KORUS advisory committee reports note these minority voices, they serve as a warning signal to Congress and the public. In no case did minority views alter a committee recommendation. Here's the report:

Committee	Public Health Representative	Reported Public Health View	Influenced Committee Recommendation
ATAC on Tobacco, Cotton and Peanuts	Eric Lindblom, Campaign for Tobacco Free Kids	Opposed including lethal tobacco products	No
ITAC #3, Chemicals & Pharmaceuticals	Shawn Brown, Generic Pharmaceutical Association	Noted obstacles to affordable generic drugs	No
ITAC #3, Chemicals & Pharmaceuticals	Tine Hanson-Turton	None Listed	No
ITAC #15, Intellectual Property	Michele Forzley	No	No

Objective 3b. Open all proceedings and documents of trade advisory committees to the public

⁴ GAO-02-876 International Trade p.7; 5 U.S.C. App. §§ 1-14.

⁵ Ibid. § 5(b)(2).

KORUS Diagnosis: Failure to comply: Public Health representation at risk. – KORUS proceedings and documents were secret and closed to the public.

Objective 3c: Require USTR’s consultation with all relevant committees of the House and Senate in the development, implementation, and administration of U.S. trade policy, without renewing presidential trade promotion authority.

KORUS Diagnosis: Congressional role in development and oversight of KORUS trade agreement gravely absent.

- Five US Senators and many Representatives issued public complaints that they were not consulted or involved in the development or oversight of KORUS negotiations.
- Trade advisory committees on labor, the environment, and intergovernmental issues reported that they saw key provisions only after the agreement was signed, too late to inform Congress or the Administration.

Analysis:

U.S. Trade Advisory Committees are required to submit reports to the President, Congress, and USTR no later than 30 days after the President announces intention to enter into (sign) a trade agreement.⁶ In the KORUS Trade and Environment Policy Committee (TEPAC) report: “TEPAC... wants to make clear that it was not consulted about, and did not have the opportunity to review the new language of concern to the majority [regarding investments]... and the only way TEPAC learned about much of it was when it was posted on the secure website after negotiations were over and Congress had been notified.”

Intergovernmental Policy Advisory Committee (IGPAC) report: “While IGPAC appreciates the opportunity to comment on this FTA, IGPAC members recognize that an enhanced intergovernmental dialogue on this, and other trade policy issues, is necessary to strengthen future agreements and to help develop a broader consensus on our nation’s trade agenda. IGPAC has offered a number of recommendations to the USTR since 2004 that are designed to achieve this goal. IGPAC members respectfully and formally request that the USTR respond to these recommendations by indicating the steps the federal government would be willing to take to strengthen the intergovernmental consultation process. In the case of the Korea FTA, there was not even a full 30-day period allotted for review, as many KORUS chapters were made available after the 4/1/07 notification date. In view of the compressed schedule and the need to consult with a large number of constituent members, the representatives of the National Association of Attorneys General (NAAG) and the National Association of State Procurement Officials (NASPO) did not take a formal position on the Agreement.

CPATH Recommendations:

1. Congress should appoint additional public health representatives to trade advisory committees.
2. Authorize health-related Congressional committees to hold hearings on trade bills.

⁶ Trade Act of 2002, Division B – Bipartisan Trade Promotion Authority, Title XXI – Trade Promotion Authority, Sec. 2104 (e).

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade # 4: To exclude tariff and nontariff provisions in trade agreements that address vital human services such as health care, water supply and sanitation, food safety and supply, and education, including licensing and cross-border movement of personnel in these fields.

KORUS Diagnosis:

1. KORUS applies trade rules that encourage privatization and deregulation to a broad range of services, including some vital human services: environmental services in both the U.S. and Korea; hospitals and insurance in the U.S.; and some health care services in Korea.
2. All services are covered unless specifically excluded. This is a “negative list” approach. It benefits transnational services corporations, by including many services without deliberation by providers and users. However, people who use and provide services would benefit from a careful review of which services should be listed for greater privatization and deregulation.

Analysis:

U.S. Services:

Most federal laws and regulations on services that differ from KORUS trade rules are subject to trade challenges, unless specifically listed as exempt.

Most future state laws and regulations on services that differ from KORUS trade rules will be subject to trade challenges. Current state measures on services are exempted, but only from some trade rules, and only temporarily; future such laws will be covered. U.S. Annex I: Non-Conforming Measures for Services and Investment, notes that “non-conforming measures of all states of the United States, the District of Columbia, and Puerto Rico” - laws that differ from trade rules - are exempt from some trade rules, for now.

Problems:

1. Even state measures on services are still subject to some trade rules like Domestic Regulation, which says that regulations should not present unnecessary barriers to trade.
2. State measures adopted in the future will be subject to all trade rules.
3. Local laws and regulations are not exempted.

Some additional services are exempt from some trade rules, now and in the future. These services are listed in U.S. Annex II.

Problem: Even these Annex II services are still subject to some trade rules like Domestic Regulation, which states that regulations should not present unnecessary barriers to trade.

Problem: Social Services at risk

Annex II exempts federal measures with respect to income security or insurance, social security or insurance, social welfare, public education, public training, health, and child care, but only if they are social services established or maintained for a public purpose, without any competition.

Problem: US Water and sanitation services at risk:

US Annex II-A, p.8, commits the following services to Market Access rules. Market Access rules prohibit restrictions on the number or type of service providers:

Environmental Services

Wastewater Management, excluding Water for Human Use (Wastewater services (contracted by
CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability
S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA
 phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

private industry))
 Solid/hazardous waste management (contracted by private industry)
 Refuse disposal services
 Sanitation and Similar Services

Referring to terminology used in the WTO General Agreement on Trade in Services (GATS), KORUS commits these Environmental Services to coverage by Market Access rules in modes 1-3 (cross-border delivery of services, and foreign direct investment). Mode 4, cross-border movement by personnel, is “Unbound, except as indicated in the horizontal section” of the GATS schedule. **The U.S. has not included these services in GATS or in any previous trade agreement.**

The U.S. also covers all services in KORUS that it has already agreed to under the WTO General Agreement on Trade in Services (GATS), including hospitals and health insurance.

Korea Services:

Annex I (present measures, but not future ones, exempted from some trade rules):

Korea would be able to maintain most present rules requiring that businesses open an office in Korea in order to import or do business in certain types of pharmaceuticals, medical devices, Asian medicines, blood products and veterinarian or aquatic animal disease inspection services must establish an office or otherwise obtain authorization in Korea.

A company that supplies the following environmental services must establish an office in Korea. But future measures in these areas are subject to trade rules:

Environmental Services - Waste Water Treatment Services, Waste Management Services, Air Pollution Treatment Services, Environmental Preventive Facilities Business, Environmental Impact Assessment, Soil Remediation and Groundwater Purification Services, and Toxic Chemical Control Services

Annex II Services Korea:

1. Environmental Services at risk.

Both future and current laws are protected relating to the following services in the public sector. However, private sector services are not protected; they are covered by KORUS trade rules, to the extent private supply of such services is permissible under relevant laws and regulations:

Environmental Services - Treatment and Supply Services for Potable Water; Collection and Treatment Services for Municipal Sewage; Collection, Transportation and Disposal Services for Municipal Refuse; Sanitation and Similar Services; Nature and Landscape Protection Services (Except for Environmental Impact Assessment services)

2. Social Services at risk:

Current and future laws related to social services are exempted from trade rules, but the definition of social services is not precise. It is not clear which services are considered to be social services established or maintained for public purposes, meaning any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers. The Agreement exempts “law enforcement and correctional services, and the following services to the extent that they are social services established or maintained for public purposes: income security or insurance, social security or insurance, social welfare, public training, health, and child care.”

3. Health Care at risk: KORUS incorporates the special privileges granted by legislation creating Free Economic Zones and the Jeju Special Self-Governing Providence. Human health service organizations are not subject to licensing and investment regulations that apply elsewhere in Korea. In the FEZ zones and Jeju

CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability
 S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA

phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

Island, U.S. human health service organizations may establish hospitals, pharmacies and certain other health care centers, and U.S. licensed physicians may in fact practice medicine in these areas. Removing licensing requirements can reduce the quality and accountability of health care services and of service providers.

According to the industry-dominated U.S. Industry Trade Advisory Committee on Services and Finance, “Inclusion into the FTA strengthens the rights of U.S. health care organizations and practitioners by making it more difficult for the Korean legislature and executive branch to remove those benefits through changes in domestic legislation.”

4. Insurance and retirement security: According to the U.S. trade advisory committee on services and finance (p.14-16): “The KORUS FTA will permit greater expansion, competition and business opportunities for all insurance providers. Korea is the largest insurance market subject to a USFTA. South Korea is the world’s eighth largest insurance market with total premium volume of more than \$65 billion. The South Korean insurance and **retirement security** market would be by far the largest insurance market to be included in an FTA with the United States...”

“The KORUS FTA commits Korea to Most Favored Nation (MFN) and national treatment provisions across the sector, including expanded application to self-regulatory organizations (SROs), non-governmental entities that nonetheless perform a de facto regulatory role.

“On market access, the KORUS FTA permits the full range of establishment rights, including joint ventures, wholly-owned subsidiaries, or branches. It also does not place any quantitative or geographic restrictions on the number of licensed insurers in the market. For cross-border provisions, the FTA permits the standard range of services provided on a cross-border basis, including ... services auxiliary to insurance.

“Korea’s agreement to move to a “negative list” approach to financial sector regulation means insurers will be allowed to provide any product or service unless specifically prohibited or curbed by regulation. The FTA also contains provisions for expedited regulatory approval for new insurance products within one year after entry into force.

“For the first time in any trade agreement, the KORUS FTA contains in the financial services annex specific reference to data transfer, enabling U.S. companies to freely transfer customer data into and out of Korea.

“Finally, the KORUS FTA creates an Insurance Working Group, a flexible arrangement allowing both governments to review future developments in the insurance sector on an ongoing basis, taking into account changes in the marketplace and in competitive conditions affecting the sector.”

CPATH Recommendations:

1. **Replace the negative list opt-outs for making commitments on trade in services with “positive lists” of commitments in order to assure protecting vital human services.**
2. **U.S. Annex I - If a “negative list” is maintained, exempt current and future state and local measures from all trade rules for services in U.S. Annex I which affect health, human, and environmental services, including Domestic Regulation.**
3. **U.S. Annex II - Eliminate the restriction that in order to be exempt from trade rules, federal measures relating to social services must be established or maintained “without any competition.”**
4. **Rescind the commitment of water and sanitation services to Market Access rules.**
5. **Revisit Annex II Services Korea to require human health service organizations in the FEZ zones and Jeju Island to be subject to licensing and investment regulations that apply elsewhere in Korea to protect quality and accountability of health care services and service providers.**

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade # 5: To recognize the legitimate exercise of national, regional and local government sovereignty to protect population health, and to ensure that countries do not weaken or reduce, as an encouragement for trade, sound policies that contribute to health and well being, including laws on public health, the environment and labor.

KORUS Diagnosis: Protection of the health of the population in Korea and in the U.S. face increased risk due to challenges to national, regional, and local government sovereignty.

KORUS expands the rights of transnational corporations (referred to as “investors”) to challenge sound policies in the U.S. and Korea that contribute to health and well being, including laws on public health, the environment and labor. For the first time in a U.S. investment treaty or free trade agreement, all contract rights are declared to be property rights, and subject to trade dispute charges (in side letter to Chapter 11). Numerous public regulations are subject to challenge by foreign corporations.

Analysis:

The KORUS Labor Advisory Committee Report states (p.4): “The agreement’s provisions on investment, procurement, and services constrain both governments’ ability to regulate in the public interest, pursue legitimate social objectives through responsible procurement policies, and provide affordable and high quality public services...In many cases, provisions on these issues worsened.”

According to the Trade and Environment Trade Policy Advisory Committee report:

“In Investment (Chapter 11), Paragraph 3(b) of Annex B creates two new tests for what constitutes an indirect expropriation: (1) whether the regulatory action is “extremely severe” and (2) whether the regulatory action is “disproportionate in light of its purpose or effect.” These tests have no antecedent in international law, provide great discretion to arbitrators to strike down good faith laws and provide foreign investors greater rights than U.S. investors have under U.S. laws. These new tests are inconsistent with the Trade Act of 2002’s admonition not to provide foreign investors with greater rights than United States investors have in the United States.

“A side letter to Chapter 11 declares all contract rights to be property rights, and subject to trade dispute charges through investor-to-State arbitration, for the first time in a U.S. investment treaty or free trade agreement.”

The Labor Advisory Committee report further notes that Article VI of the WTO’s Government Procurement Agreement (GPA) prohibits the preparation, adoption or application of technical specifications if they have the intent or effect of “creating unnecessary obstacles to international trade.” While KORUS Article 17.7 provides an exception for technical specifications to promote the conservation of natural resources or protect the environment, numerous other public interest regulations could still be challenged.

“The Government Procurement Annex, Section C, incorporates the procurement of services under Appendix I of the World Trade Organization’s Government Procurement Agreement. Annex 2 of Appendix I of the GPA is a list of the *states’* commitments on procurement, undertaken in 2002, that are intended to be covered under the rules of the GPA. Thus, it appears that USTR may have bound 37 states to the additional rules on procurement under the KORUS FTA. Further clarification of this provision is needed.”

InterGovernmental Policy Advisory Committee reports:

“IGPAC members support expanding trade and market access, but only as long as there is a simultaneous commitment to ensuring that our nation’s trade initiatives, trade laws, enforcement efforts and the dispute settlement process respect the authority of states and local governments to regulate, legislate and interpret land-use, labor, health, safety, welfare, and environmental measures.” (P. 17)

CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability

S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA

phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

“Statutes and regulations that states and local governments have validly adopted, that are constitutional, and that reflect locally appropriate responses to the needs of our residents, should not be overridden by provisions in trade agreements.

IGPAC members would strongly prefer that trade commitments be derived via “positive lists”...rather than upon a system of “negative list” opt-outs. The recent WTO tribunal ruling against the US in the GATS internet gambling case brought by Antigua & Barbuda illustrates the inherent peril of the “negative list” approach, which risks covering matters that were expected to be excepted, either by inadvertence or by lack of knowledge of relevant laws and regulations.

Unlike other recent FTAs, Article 18 of the Korea-US (KORUS) FTA does not provide sovereignty protection to US courts by precluding certain cases pending in the U.S. from being subsequently raised before a trade tribunal.

IGPAC members also noted: 1) the problematic and overly broad Article 28 definition of investment is far more expansive than NAFTA, includes concepts of “investment authorization”, licenses and permits, and is less linked to business enterprises; 2) the Article 5 “minimum standard of treatment” language seems to codify the *Loewen* case holding that state court actions are subject to review by international investment tribunals; and 3) the Article 5 due process standards, based on unclear international norms that could grant foreign investors greater rights than US investors, rather than reflecting US constitutional norms of substantive due process. Investors from nations with well-developed legal systems appear to have abused these provisions to improperly and frivolously challenge the authority of state and local governments. In particular, the *Methanex* and *Loewen* cases stemming from NAFTA Chapter 11 reinforced concerns that the provision would be abused by investors intending to circumvent established legislative and judicial procedures. (p. 19)

CPATH Recommendations:

1. **Investment (Chapter 11), Paragraph 3(b) of Annex B – Revisit and eliminate the two new tests for what constitutes an indirect expropriation, which are inconsistent with the 2002 Trade Act objective of not providing foreign investors greater rights than U.S. investors in the United States.**
2. **Chapter 11 Side Letter - to Chapter 11 – Revisit and eliminate the new and unprecedented language that declares all contract rights to be property rights, and to be subject to trade dispute charges through Investor-to-State arbitration.**
3. **Government Procurement Annex, Section C – Clarify that 37 U.S. states are would not be bound to the additional rules on procurement under the KORUS FTA, and if so, provide an opt-out for states from this provision.**
4. **Replace the negative list opt-outs for making commitments on trade in services with “positive lists” of commitments in order to assure protecting vital human services.**
5. **Intellectual Property Rights (Article 18) - Revisit and clarify to provide sovereignty protection to US courts by precluding cases pending in the U.S. from being subsequently raised before a trade tribunal.**

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade #6: To develop mutually beneficial trade relationships that create **sustainable economic development** for the U.S. and our trade partners in an increasingly interdependent world.

KORUS Diagnosis: **Promotion of Economic and Social Progress at Increased Risk due to narrow and restrictive rules on government procurement.** KORUS's rules on Government Procurement could challenge how the federal government directs funds to achieve public policy aims including government subsidies, prevailing and living wage laws, sweat-free purchasing, domestic sourcing preferences, project-labor agreements, and responsible contractor requirements.

Analysis: Korea and the U.S. are already members of the World Trade Organization (WTO) Government Procurement Agreement (GPA), on which many U.S. FTA procurement chapters are based. It requires national treatment, non-discriminatory treatment, transparent notice and bidding procedures, non-discriminatory technical specifications, penalties for corrupt procurements, and objective domestic review of procurement decisions. The Industry Trade Advisory Committee #10 on Services and Finance notes (pp. 6-7): "This Agreement expands the coverage of those commitments by Korea to nine additional Central government agencies and lowers the [financial] threshold by nearly half for Central government goods and services procurements to which U.S. suppliers will have non-discriminatory access." The Agreement also incorporates several of the changes agreed to by the WTO GPA Committee in December 2006, including language reducing the tendering period where procurement notices and information are made available electronically and for off-the-shelf items and promoting the use of electronic procurements.

The Trade and Environment Trade Policy Advisory Committee report noted (p.16-18) that: "KORUS FTA's rules on procurement have the potential to restrict public policy aims that may be met through procurement policies at the federal level. These rules could be used to challenge a variety of important procurement provisions including domestic sourcing preferences, prevailing wage laws, project-labor agreements, responsible contractor requirements...and the ability of governments to use procurement dollars to promote local employment and to discourage outsourcing of the goods and services upon which the government relies. Article III of GPA, National Treatment, would prevent any discrimination to be made between two bidders on a procurement contract based upon where those goods or services came from. In other words, a government could not prefer a bidder that employed only local employees or used U.S.-made goods, or discriminate against a bidder that proffers outsourced goods or services.

"Government assistance in the form of subsidies is not excluded, although it has been in numerous previous agreements."

The Labor Advisory Committee reports that the supplier qualifications in Article VIII of the GPA and Article 17.5 of the KORUS FTA could prohibit sweat-free procurement rules that require a company to certify its production does not utilize sweatshop labor, and the exclusion of companies based on their international human rights and environmental records. Other conditions, such as the payment of a prevailing or living wage, could be put in jeopardy. It is unclear whether articles 17.5 (3)(c) or (d) are sufficient to bar bidders that have seriously or repeatedly violated federal labor laws.

CPATH Recommendation:

1. **Government Procurement (Article 17) - Revise and clarify rules on procurement to ensure that federal, state, and local procurement policies, provisions, and regulations which promote local economic development, support labor standards, enforce human rights and protect environmental standards cannot be challenged under trade rules of the U.S.-Korea FTA.**

CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ Thoreau Center for Sustainability
S.F. Presidio, P.O. box 29586, San Francisco, CA 94129 USA

phone: 415-922-6204 ♦ fax: 415-885-4091 email: cpath@cpath.org ♦ www.cpath.org

US-Korea Free Trade Agreement: Public Health Report Card

Public Health Objective for Global Trade #7. To exclude alcohol products, which present serious hazards to public health. Policies designed to reduce the harm caused by alcohol products should not be subject to compromise in exchange for other trade benefits.

KORUS Diagnosis: Alcohol beverage control measures in the U.S. and Korea are generally at risk under the KORUS rules on distribution services, and on Intellectual Property. They are not exempted from trade rules.

Analysis:

Services Annex I allows Korea to maintain or amend the following present rules on the distribution of alcohol (p.4):

Articles 8, 9, 10, 40 and 43 of the Liquors Act (Law No. 7841, Dec. 31, 2005)

Articles 9, 45 and 56 of its Enforcement Decree (Presidential Decree No. 19336, Feb. 9, 2006)

Notice of National Tax Service 2005-5 and 8

A person that supplies liquor wholesale distribution services must establish an office in Korea and obtain authorization from the head of the relevant tax office, which is subject to an economic needs test. Liquor may not be sold through electronic means or by phone.

CPATH Recommendation:

1. **Exempt beverage control measures in the U.S. and Korea from trade rules under the U.S.-Korea FTA.**