

CITIZEN TRADE POLICY COMMISSION AGENDA

Thursday, November 3, 2011 at 1:00 p.m.
Washington County Community College, Calais
Main Hall – Assembly Room

1:00 pm Meeting Called to Order – Welcome and Introductions

- I. (1:05pm -1:40pm) State Consultation – How can Maine have more direct consultation with USTR? Joint presentation**
 - A. Rep. Peggy Rotundo – a historical perspective of the CTPC and the USTR (see Resolve)
 - B. Rep. Sharon Treat – the role of IGPAC and facilitating the relationship with USTR
 - C. Wade Merritt (CTPC member) – The role of the Maine International Trade Center

- II. (1:40-2:20) Recent developments regarding the Trans Pacific Partnership Agreement (TPPA)**
 - A. Rep. Sharon Treat – Pharmaceutical provisions of the agreement and the goal of affordable medicines
 - B. Professor Bob Stumberg – Regulatory provisions of the TPPA and the potential implications on domestic regulation

- III. (2:30 – 3:00) A local perspective Calais and St. Stephen New Brunswick**
 - A. Discussion with Diane Barnes, Calais Town Manager and John Ferguson, Chief Administrative Officer, St. Stephen, New Brunswick

- IV. (3:00 – 3:20) Trade Adjustment Assistance Program**
 - A. Briefing on the administration of TAA in Maine – Judy Pelletier, Trade Program Coordinator, ME Dept. of Labor

- V. (3:20 – 4:00) Bi-annual assessment**
 - A. Potential topics
 - 1. Member suggestion – Harry Ricker – interested in looking at the dollar value, volume and number of containers by product (shoes, lumber, apples) exported from Maine in 2009-10 compared to 1982 when the dollar was similarly weak.
 - 2. Trans Pacific Partnership Agreement
 - B. Process for completing assessment

Commission Adjourns

HP1152, , 125th Maine State Legislature
JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF THE UNITED STATES, THE
UNITED STATES CONGRESS AND THE UNITED STATES TRADE REPRESENTATIVE
REGARDING STATES' RIGHTS IN FUTURE INTERNATIONAL TRADE POLICY

PLEASE NOTE: Legislative Information **cannot** perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

**JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF
THE UNITED STATES, THE UNITED STATES CONGRESS AND
THE UNITED STATES TRADE REPRESENTATIVE REGARDING
STATES' RIGHTS IN FUTURE INTERNATIONAL TRADE POLICY**

WE, your Memorialists, the Members of the One Hundred and Twenty-fifth Legislature of the State of Maine now assembled in the First Regular Session, most respectfully present and petition the President of the United States, the United States Congress and the United States Trade Representative as follows:

WHEREAS, Maine strongly supports international trade when fair rules of trade are in place and seeks to be an active participant in the global economy; and

WHEREAS, Maine seeks to maximize the benefits and minimize any negative effects of international trade; and

WHEREAS, existing trade agreements have effects that extend significantly beyond the bounds of traditional trade matters, such as tariffs and quotas, and that can undermine Maine's constitutionally guaranteed authority to protect the public health, safety and welfare and its regulatory authority; and

WHEREAS, a succession of federal trade negotiators from both political parties over the years has failed to operate in a transparent manner and has failed to meaningfully consult with states on the far-reaching effect of trade agreements on state and local laws, even when obligating the states to the terms of these agreements; and

WHEREAS, the current process of consultation with states by the Federal Government on trade policy fails to provide a way for states to meaningfully participate in the development of trade policy, despite the fact that trade rules could undermine state sovereignty; and

WHEREAS, under current trade rules, states have not had channels for meaningful communication with the United States Trade Representative, as both the Intergovernmental Policy Advisory Committee on Trade and the state point of contact system have proven insufficient to allow input from states and states do not always seem to be considered as a partner in government; and

WHEREAS, the President of the United States, the United States Trade Representative and the Maine Congressional Delegation will have a role in shaping future trade policy legislation; now, therefore, be it

RESOLVED: That We, your Memorialists, respectfully urge and request that future trade policy include reforms to improve the process of consultation between the Federal Government and the states; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the President of the United States, the United States Congress and the United States Trade Representative seek a meaningful

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consultation system that increases transparency, promotes information sharing, allows for timely and frequent consultations, provides state-level trade data analysis, provides legal analysis for states on the effect of trade on state laws, increases public participation and acknowledges and respects each state's sovereignty; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the Federal Government reform the system of consultation with states on trade policy to more clearly communicate and allow for states' input into trade negotiations by allowing a state to give informed consent or to opt out if bound by nontariff provisions in a trade agreement and by providing that states are not bound to these provisions without consent from the states' legislatures; to form a new nonpartisan federal-state international trade policy commission to keep states informed about ongoing negotiations and information; and to provide that the United States Trade Representative communicate with states in better ways than the insufficient current state point of contact system; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that state laws that are subject to trade agreement provisions regarding investment, procurement or services be covered by a positive list approach, allowing states to set and adjust their commitments and providing that if a state law is not specified by a state as subject to those provisions, it cannot be challenged by a foreign company or country as an unfair barrier to trade; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the United States Congress fund a center on trade and federalism to conduct legal and economic policy analysis on the effect of trade and to monitor the effectiveness of trade adjustment assistance and establish funding for the Department of Commerce to produce state-level service sector export data on an annual basis, as well as reinstate funding for the Bureau of Economic Analysis's state-level foreign direct investment research, both of which are critical to state trade offices and policy makers in setting priorities for market selection and economic impact studies; and be it further

RESOLVED: That suitable copies of this resolution, duly authenticated by the Secretary of State, be transmitted to the Honorable Barack H. Obama, President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, to the United States Trade Representative Ambassador Ron Kirk and to each Member of the Maine Congressional Delegation.

10 §13. LEGISLATIVE APPROVAL OF TRADE AGREEMENTS

10 §13. LEGISLATIVE APPROVAL OF TRADE AGREEMENTS

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Commission" means the Citizen Trade Policy Commission established in Title 5, section 12004-I, subsection 79-A. [2009, c. 385, §1 (NEW).]

B. "Trade agreement" means an agreement reached between the United States Government and any other country, countries or other international political entity or entities that proposes to regulate trade, procurement, services or investment among the parties to the agreement. "Trade agreement" includes, but is not limited to, any agreements under the auspices of the World Trade Organization, all regional free trade agreements, including the North American Free Trade Agreement and the Central America Free Trade Agreement and all bilateral agreements entered into by the United States, as well as requests for binding agreement received from the United States Trade Representative. [2009, c. 385, §1 (NEW).]

[2009, c. 385, §1 (NEW) .]

2. State official prohibited from binding the State. If the United States Government provides the State with the opportunity to consent to or reject binding the State to a trade agreement, or a provision within a trade agreement, then an official of the State, including but not limited to the Governor, may not bind the State or give consent to the United States Government to bind the State in those circumstances, except as provided in this section.

[2009, c. 385, §1 (NEW) .]

3. Receipt of request for trade agreement. When a communication from the United States Trade Representative concerning a trade agreement provision is received by the State, the Governor shall submit a copy of the communication and the proposed trade agreement, or relevant provisions of the trade agreement, to the chairs of the commission, the President of the Senate, the Speaker of the House of Representatives, the Maine International Trade Center and the joint standing committees of the Legislature having jurisdiction over state and local government matters and business, research and economic development matters.

[2009, c. 385, §1 (NEW) .]

4. Review by commission. The commission, in consultation with the Maine International Trade Center, shall review and analyze the trade agreement and issue a report on the potential impact on the State of agreeing to be bound by the trade agreement, including any necessary implementing legislation, to the Legislature and the Governor.

[2009, c. 385, §1 (NEW) .]

5. Legislative approval of trade agreement required. Unless the Legislature by proper enactment of a law authorizes the Governor or another official of the State to enter into the specific proposed trade agreement, the State may not be bound by that trade agreement.

[2009, c. 385, §1 (NEW) .]

SECTION HISTORY

2009, c. 385, §1 (NEW).

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UPDATE ON RECENT TRADE NEGOTIATIONS BY REP. SHARON TREAT
Maine Citizen Trade Policy Commission
November 3, 2011

- Attended 9th round Transpacific Partnership negotiations in Lima, Peru. Presented at the stakeholder forum “Market Access, Transparency & Pricing: Does US Trade Policy in the TPPA Conflict with the Goal of Affordable Medicines?”
- Had the opportunity to meet with health care and medicines activists from other TPP countries including Peru, Chile, Malaysia and attend their strategy meetings and informational forums for journalists and the general public. These groups were extremely well organized and their forums were well attended, with huge press coverage, including a demonstration outside the negotiating site.
- The day before the all-day stakeholder forum where I presented along with many others, US negotiating text was leaked and publicly posted on the Internet. The leaked TPPA text is posted here: <http://www.citizenstrade.org/ctc/blog/2011/10/22/leaked-trans-pacific-fta-texts-reveal-u-s-undermining-access-to-medicine/>
- The leaked documents include:
 - Annex on Transparency and Procedural Fairness for Healthcare Technologies (June 22, 2011)
 - Proposed Technical Barriers to Trade (TBT) Annexes on Medical Devices, Pharmaceutical Products and Cosmetics Products (undated)
 - Regulatory Coherence text (undated)
 - Intellectual Property Rights Chapter (September 2011)
 - Previously leaked text includes a New Zealand negotiating paper on intellectual property (undated)
- Because this text was leaked, it was possible to review and discuss actual language with experts on trade and intellectual property (IP) law and to better understand the provisions. It is also possible for you to review the language and provide specific feedback to the USTR. Some of this text, but not all of it, was posted on the IGPAC secure advisors website. What I have now learned is that while the USTR will post proposed text for IGPAC comments, we do not always see the text the US actually offers in the negotiations, and sometimes the text is changed. I have never heard back from USTR that the text was changed in response to any of my or others’ comments, so we just don’t know what effect if any we (or others) have.
- Possibly because of these leaks, we have heard that the negotiations over the IP and transparency texts, which relate specifically to pharmaceutical, biologics and medical device pricing, generic introduction, and procedural restrictions on preferred drug list negotiations, did not go well for the US during the Peru round of talks. I have heard that at least the countries of **Australia, New Zealand, Chile** and **Peru** had many questions and “dug in their heels”, and possibly also **Malaysia** was in this group.

- Although Australia already has a FTA with the US which has a pharmaceuticals annex, this annex does not include the pricing language of the Korea FTA or the TPPA leaked text, and has many fewer procedural hurdles for PDL decisions than Korea. Also, drug prices in Australia's Pharmaceutical Benefits Scheme (PBS) increased after the US-Australia FTA and people blame the trade agreement.
- New Zealand has a program called Pharmac which is extremely popular and which assures that drugs are available at minimal cost, \$2-3 per script. They accomplish this through tough negotiating and not including every drug on their formulary but only those they deem effective. This is a hot political issue in New Zealand especially with elections coming up, and NZ politicians have stated they will not agree to anything that changes the "fundamentals" of Pharmac.
- We have also heard that NZ negotiators have told the US they will not sign a transparency text that does not apply to Medicaid. Rather than stopping these provisions from being agreed to, my fear is that the US will agree to the provisions without the Medicaid carve-out language in the Korea FTA. This fear is given some credence by the lack of clear carve-out language in the leaked text and the refusal by the US negotiators to answer the question of whether Medicaid and other programs (340B) will be carved out.
- Peru also already has an FTA with the US, which does not include the transparency and pricing language in the TPPA and Korea FTA, but which does have IP provisions. Generic drug costs have increased significantly after CAFTA went into effect, and in Peru since the Peru-US FTA, and it is a hot political issue in Peru, which has a brand-new government which has pledged to re-think its positions on trade. Peru's medicines agency has a preferred drug list that looks a lot like the US Medicaid PDLs.
- The cost of AIDS drugs is also a huge concern in many of these countries, including Malaysia, which has very active patient advocacy/AIDS groups. We also need to remember that the US government (US taxpayers) also pays for AIDS drugs in other countries and that trade deals that increase generic and other prices will also increase budget costs for these drugs.
- *Even if these provisions may be stalled for now, I don't have the sense that these countries will want the medicines provisions to get in the way of a final agreement, and the chief negotiators come from the trade side of the governments, not the health care side. But note that a number of other countries are interested in joining these talks, including Japan, which has a large pharmaceutical industry.*

- Some specifics to be concerned about in the leaked text:
 - Although much of the IP text is already US law, locking the US into this language and the lengthy timeframe for introducing generics (the data exclusivity provisions) may mean that US law cannot be changed, despite the huge abuses of the system we already see (Example, pay for delay which is under investigation by the FTC - deals between generic drugmakers and brand name companies that delay the introduction of generics and give one generic company an initial monopoly).
 - The so-called transparency provisions also lock US law into the status quo. Even if Medicaid is carved out, that does not help us move Medicare Part D to negotiated prices (as proposed by President Obama among others).
 - Few if any states comply with the procedural provisions of the text, and compliance will likely increase costs for state government and make it harder to negotiate prices for Medicaid
 - The new pricing provisions will tie pricing to “transparent and verifiable basis consisting of competitive market-derived prices in the Party’s territory” which could mean the over-the-counter cost to fill a prescription when you lack health insurance (which is not a big part of the US market)
 - There is no inclusion of “affordability” as an appropriate criteria in pricing decisions
 - Multiple opportunities for appeals are required
 - Agencies must *consider* including new uses for drugs on their PDLs even if no other country has approved the new use, just based on evidence from an industry-backed study
 - Internet posting of drug information by manufacturer must be allowed to be linked to any website, including social media which could undermine efforts in the US to regulate and enforce rules on off-label marketing
 - Unclear which of the provisions affecting medicines (TBT, IP, “transparency”) are enforced how- for example, are any of these enforceable through and investor-state dispute mechanism so that corporations could challenge state agency decisions?

Review and comments by Maine Rep. Sharon Treat on leaked Trans-Pacific-Partnership Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies (June 22, 2011 text)

PARAGRAPH X.2: TRANSPARENCY RELATED TO HEALTHCARE TECHNOLOGIES

Article X.2.3: Concerns about the use of the term “*objective*” which is vague and could exclude regulatory criteria that are inherently subjective such as advancing the “public interest,” instead allowing only standards measured by physical, measurable quantities. It could similarly bar the use of tests that rely on balancing multiple criteria but that do not set a preordained weight for each criterion.

A better approach would be to define the term “objective” as simply meaning “*not arbitrary*” or “*nondiscriminatory*.” This alternative language is consistent with the standard of review in United States. *See, e.g.*, 5 U.S.C. § 706(2)(a) (scope of review under federal Administrative Procedure Act includes whether agency action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”).

PARAGRAPH X.3: PROCEDURAL FAIRNESS RELATED TO HEALTHCARE TECHNOLOGIES

This paragraph will impose procedural hurdles on parties that interfere with the effective administration of health care programs, and includes restrictions on how governments negotiate prices that will tie price to “competitive, market-derived prices” (whatever that is) even though these same restrictions are not imposed on private companies negotiating drug prices. The paragraph includes appeal rights and requires consideration of listing new uses for drugs even where those uses have not been approved by a party or by any other country.

X.3(a) requires formal applications for approval for reimbursement (payment) be completed “within a reasonable, specified period.” This is similar to KORUS but goes beyond AUSFTA [(a) ensure that consideration of all formal proposals for listing are completed within a specified time;] by requiring the time period to be “reasonable”. *This could be a grounds for appeal under the independent review and appeal provisions of X.3(i).*

X.3(b) requires procedural rules and methodologies to be disclosed “within a reasonable, specified period” but AUSFTA *does not require either a reasonable nor specified time period*. [AUSFTA: (b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal]. KORUS is similar to TPPA.

X.3(d): This whole paragraph is very, very problematic. *IT IS NOT IN AUSFTA AT ALL*. Nor do U.S. state comply with this when they negotiate prices for drugs.

- The language “*appropriately recognize the value*” is extremely broad and vague, and could preclude pricing benchmarks that consider affordability and access to health care. “Affordable access” is one of the agreed principles in Paragraph X.1(d), but this article

dealing with pricing ignores affordability and perhaps excludes consideration of affordability.

- Reference to "transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory" in X.3(d) is not found in AUSFTA Annex-2C.2. It is in KORUS.
- This language is intended to prevent any consideration of prices in other countries.
- This language holds governments to a different standard than private industry negotiating bulk drug purchases.
- The "transparent and verifiable" language means pricing negotiation details need to be public.

X.3(e): This paragraph says if a government uses any other method of pricing drugs instead of the market-derived prices in Paragraph (d), then it must provide the manufacturers with an opportunity to seek more reimbursement – essentially an appeal of the decision (in addition to the appeal guaranteed in X.3(i)).

X.3(f), (g), (h), (i): Taken together, these provisions appear to place a heavy substantive and procedural burden on a Party making a decision to deny reimbursement for any health care product, including for unapproved medical indications. These provisions are similar to KORUS, although they go beyond AUSFTA (for example, requiring "citations to any expert opinions or academic studies upon which a Party has relied" which is not in AUSFTA).

X.3(f) requires a government to establish a procedure for the manufacturer to seek reimbursement for (list drug for payment) new uses of drugs *even if those uses are not approved in any other country*; all the manufacturer must produce to trigger a review is "evidence" "on the product's safety or efficacy". This could be a single industry-sponsored study.

- This will waste agency time reviewing drugs that have not been approved for these other uses.
- This would be grounds for an appeal if denied.

X.3(h): How detailed must the "written information regarding its recommendations and determinations relating to the reimbursement of pharmaceutical products or medical devices" be?

- Is it grounds for appeal if not detailed enough?

X.3(g) seems to place a heavier burden of proof, and require higher quality of evidence, on the Party making a reimbursement recommendation or determination than on the manufacturer seeking reimbursement, even for unapproved uses. While the manufacturer must produce "evidence" the Party must include "citations to any expert opinions or academic studies."

X.3(i): Combined with the "independent appeal or review of recommendations or determinations relating to reimbursement" in X.3(i), the provisions of Paragraph X.3 seems a lawyer's dream, designed to create litigation opportunities that will make it difficult to defend a decision to deny reimbursement, and have a chilling effect on limited-budget government agencies whose mission is promoting health and insuring safety.

- **Important note:** In implementing the USFTA the Independent Review of PBAC decisions was established: <http://www.independentreviewpbs.gov.au/>
However, the Reviewer's decision is not binding on the Health Minister.

Resources:

AUSFTA Annex-2C Pharmaceuticals (http://203.6.168.65/fta/ausfta/final-text/chapter_2.html) and Side Letter 2 (http://203.6.168.65/fta/ausfta/final-text/letters/02_pbs.pdf).

*******Note that U.S. state Medicaid agencies making reimbursement decisions do not currently meet many of the standards in X.3. including detailed written decisions, appeals, public process for reimbursement, market-based pricing.*******

PARAGRAPH X.4: DISSEMINATION OF INFORMATION TO HEALTH PROFESSIONALS AND CONSUMERS

X.4 requires TPPA countries, even those without direct to consumer marketing, to allow a manufacturer's websites to post "truthful and not misleading" information about its products, and also requires that the countries allow the official manufacturer websites to link to *any* website they want to link to. This is similar to AUSFTA but goes beyond KORUS, *which only requires links to medical journal websites and does not mention communicating with consumers.*

This is a significant difference. It would prevent countries from regulating social media and other internet links to pharmaceutical websites, which currently are a loophole which allows companies to avoid off-label and deceptive marketing restrictions by linking to non-manufacturer websites which essentially market drugs without regulation.

Note that the U.S. Food and Drug Administration (FDA) is still considering how to regulate Internet-related marketing, including the relationship of social media to manufacturer-sponsored Internet sites, and it has no specific rules relating to children and drug. These are complex issues, with implications for the health and safety of minors as well as adult consumers. For example, in 2009, FDA sent a letter to Novartis warning that the drugmaker was improperly using a "Facebook Share" widget to promote the leukemia drug Tasigna. The letter to Novartis stated: "The shared content is misleading because it makes representations about the efficacy of Tasigna but fails to communicate any risk information associated with the use of this drug." The letter described how use of the Facebook application led to omitting risk information about the drug; and misleading statements suggesting a broader use of the drug other than what it is approved for. Novartis subsequently took down the Facebook widget. Meanwhile, in November 2010, four consumer advocacy groups filed a complaint with the Federal Trade Commission alleging that some websites are engaging in deceptive marketing tactics involving users' personal health information. Among other charges, the groups alleged that certain websites collect data on users' medical conditions, medications and treatment plans and that the data collection methods pose risks to the privacy and health of individuals.

Resources:

- For a detailed report on off-label fraud settlements, see the report “Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010,” (December 16, 2010) posted here: <http://www.citizen.org/hrg1924>.
- For information about digital marketing and the use of social media, unbranded websites and other tools that promote off-label and deceptive marketing, see “Questions Linger on Social Media Regulations for Pharma” by Michael Pogachar, iHealthBeat Associate Editor, <http://www.ihealthbeat.org/features/2011/questions-linger-on-social-media-regulations-for-pharma.aspx#ixzz1blUpjIBG>
- And the petition to the US FDA from the Center for Digital Democracy, linked here: <http://www.centerfordigitaldemocracy.org/online-drug-marketing-fda-filing>

Comparison of FTA Texts:

TPPA

PARAGRAPH X.4: DISSEMINATION OF INFORMATION TO HEALTH PROFESSIONALS AND CONSUMERS

Each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer’s Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, information that is truthful and not misleading regarding its pharmaceutical products that are approved for sale in the Party’s territory, provided that the information includes a balance of risks and benefits and is limited to indications for which the Party’s competent regulatory authorities have approved the marketing of the pharmaceutical products.

KOREA

ARTICLE 5.4: DISSEMINATION OF INFORMATION

Each Party shall permit a pharmaceutical manufacturer to disseminate through the manufacturer’s official Internet site registered in the Party’s territory and through medical journal Internet sites registered in the Party’s territory, that include direct links to the manufacturer’s official Internet site, truthful and not misleading information regarding the manufacturer’s pharmaceutical product, provided that the product has marketing approval in the Party’s territory and the information includes a balance of risks and benefits and is limited to indications for which the Party’s competent regulatory authorities have granted market approval for that product.

AUSTRALIA

5. Dissemination of Information

Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers through the manufacturer’s Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party’s territory as is permitted to be disseminated under the Party’s laws, regulations, and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party’s competent regulatory authorities have approved the marketing of the pharmaceuticals.

PARAGRAPH X.7: DEFINITIONS

This section defines to which health care programs the TPPA Annex for Procedural Fairness and for Healthcare Technologies would apply. The June 22, 2011 text does not clearly carve out Medicaid and other health care programs in the U.S. from the restrictions in this Annex. There is bracketed text in footnote 2 stating as follows:

[Negotiator's Note: Clarifying footnote regarding scope of application, such as with respect to central versus regional level healthcare programs.]

The Korea FTA clearly carves out Medicaid from its provisions in footnote 3 to the definitions in the Pharmaceutical Chapter. Here is the Korea FTA language:

Article 5.8: DEFINITIONS

For purposes of this Chapter:

health care authorities at a Party's central level of government means entities that are part of or have been established by a Party's central level of government to operate or administer its health care programs;

health care programs operated by a Party's central level of government means health care programs in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;³ and

pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product.

³ For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.

The Korea FTA has been criticized in the United States for failing to sufficiently carve out other health care programs that appear to come within these definitions, and state legislators have sought additional clarification that programs which appear to fall within the "central level of government," such as 340B of the federal Public Health Act and Medicare Part B, are not subject to the FTA provisions.

The leaked TPPA text leaves this issue very much up in the air. The bracketed text does not indicate whether the U.S. negotiators are seeking a similar footnote to that in the Korea FTA, broader language that makes clear 340B, Medicare Part B and/or other programs are also carved out, or weaker language that lacks the specificity and clarity of the Korea footnote.

While the Korea FTA footnote 3 is better than no footnote at all, it is inadequate because it fails to protect significant health care programs that currently do not comply with the pricing and procedural provisions of the Korea FTA also proposed in the TPPA, and also because it could restrict health reform efforts in the future, including requiring price negotiation under Medicare Part D. The latter proposal had been put forward by numerous members of Congress ever since Medicare Part D was enacted, most recently by President Obama as part of negotiations over the debt-reduction plan.

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**Market Access, Transparency &
Pricing: Does US Trade Policy in
the TPPA Conflict with the Goal of
Affordable Medicines?**

**Rep. Sharon Treat
Maine Legislature**

**Executive Director,
National Legislative Association on
Prescription Drug Prices**

Lima, Peru

October 23, 2011

Role of U.S. States Advising on Trade Policy & Implementing Health Care

- Federalism:** States & federal government jointly govern domestic policy as set forth in US Constitution
- States have major role regulating and providing access to health care**
- States have limited role advising on trade policy**
 - Formal state role: IGPAC
 - Increasing state activism through state commissions on trade & sovereignty including ME, VT, NH, WA, UT, CA
 - State laws: no commitment of states without state vote

State Health Care Role

- Medicaid** – jointly funded federal/state program for low income, disabled and children, largely implemented by state governments pursuant to federal rules
- 40 States Negotiate Medicaid Drug Prices through Preferred Drug List (PDL)** – State purchase price for branded drugs and many generics discounted through (1) federal rebate and (2) state rebates
 - Rebates can be significant** – In aggregate, Maine receives back 50% off “market price” in rebates
- State-by-state rebate negotiation to be replaced by national reference price list under the Affordable Care Act in 2012**

The US has significant income disparities and many people do not have health insurance

- More than 50 million people receive health care through Medicaid, an increase of 17% since the recession began in 2007 [Kaiser family Foundation].
- More than 50 million people in the US have NO health insurance and purchase medicines at the highest “market price.”
- 44% of US adults (80 million people) have either no insurance or inadequate insurance, much of which does not pay enough to cover prescription drug costs at an affordable level.

State Health Policy Role Goes Beyond Medicaid

- **340B – Federally Qualified Health Centers –**
Clinics provide sliding fee health care for rural, underserved urban, women, HIV/AIDS
- 340B pricing also in many hospitals (1,673 or one-third of all US hospitals)
- Some states use 340B to provide lower-cost drugs for corrections population (740,905 inmates in Texas alone!)
- **340B pricing is below Medicaid pricing**

Other U.S. Programs with Below-Market Drug Prices

- **Veterans' Health Care -**
Reference pricing based on
formulary
- **Medicare Part B - hospital**
drugs for elderly

US Government Share of Medicine Spending Significant

- Spending on prescription drugs in the US was \$234.1 billion in 2008. It has been one of the fastest growing components of health care spending – 6 times what was spent in 1990.
- Government's share of prescription drug spending is 37% of the total.

Last month President Obama proposed changing the Medicare Part D Program (prescription drugs for the elderly) to require price negotiation similar to Medicaid (currently private sector insurance companies negotiate prices).

□ 27.6 million enrolled in Medicare Part D

Concern: The US proposals in the TPPA and other TPAs will lock into place the current fractured US public health “system” that lacks the more effective medicines pricing controls such as in Canada, New Zealand, Australia, which are intended to broaden health access and increase affordability

QUESTION: Does the current State & Federal rebate negotiation process meet the “transparency” and procedural requirements in the Korea-US FTA and proposed by the US in the Trans-Pacific Partnership?

INO

- ☒ **Public session** negotiating rebates (price) and determining which drugs will be “preferred” on PDL
- ☒ **Detailed written explanation** of transparent & verifiable basis for reimbursement decision
- ☒ **Opportunity for independent appeal** or review of decision
- ☒ **Consistent administration** in all 50 states, D.C. & territories

Medicaid Carve-Out in Korea-US FTA

- Footnote:** Medicaid is a regional level government program, FTA rules only apply to central level
- No mention of 340B clinics and hospital prices
- Doesn't carve out Medicare Part D if President Obama succeeds in requiring government rebates in budget
- State Legislators & Governors: Footnote fails to carve out all public health programs, and ties hands for future changes such as Medicare Part D reference prices

Questions:

- Will the TPPA include similar carve-out language?
- Leaked text: NO FOOTNOTE
- Should the TPPA require transparency and reimbursement standards that the United States does not itself fully comply with?**

Other US states' concerns – reimbursement rules will increase prices

- Reimbursement tied to market prices** within territory will forever link US reimbursement to some of the highest market prices in the world and limit affordability
- Where is the link to affordability?**
 - Waiting lists in US for AIDS drugs – 7,299 in 10 states as of October 2011
 - States cutting health care budget by limiting eligibility for public programs & increasing patient cost sharing – 15 states reducing or capping ADAP enrollment October 2011
 - 60% of US bankruptcies cause by medical expenses – and three-fourths had insurance

Generic availability also an issue

- Will US proposals in the TPPA prevent changes to current US policies that delay entry of generics to market?
- “Pay for Delay” deals between patent-holding manufacturer and generic manufacturer currently subject to investigation
- Providing initial monopoly for first generic version on market delays competition and keeps prices high

Other state concerns - loopholes in health & safety protections

- Requiring Internet posting of information on drugs and devices for both consumers and medical professionals linking to any & all websites including social media will increase fraud and off-label marketing
- Between 2006-2010, 165 legal settlements by US states and federal government with pharma industry for \$19.8 Billion for off-label and deceptive marketing including Internet marketing and **criminal violations**
- **YAZ deceptive ad lived on YouTube long after banned**

Speeding up approval for
medical devices with
“priority review” & limiting
reconsideration of clinical
effectiveness could
jeopardize public health

- **Recent example:** metal hip joints
generating “high volume of metallic
debris ... absorbed into the patient’s
body.” [NY Times]

Does the US policy in the TPPA conflict with the goal of affordable medicines?

- Impossible in a secret process to seek and receive informed review of important health & safety public health rules that will bind future governments
- There are many concerns with the marketing, transparency & pricing provisions of the TPPA even in the US
- Irony: TPPA Transparency Provisions Developed in a Non-Transparent Process

Now that key pharmaceutical and device text under consideration for the TPPA is publicly posted, it is possible to answer this question with more complete analysis and to get feedback from state Medicaid program staff, regulators and prosecutors overseeing fraud and deceptive marketing, and advocates for affordable medicines.

Contact Information

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Email:

repsharon.treat@legislature.maine.gov

satreat@gmail.com

Trade & Impact on State Pharmaceutical Policy
information posted here:
www.reducedrugprices.org

Twitter: [@sharontreat](https://twitter.com/sharontreat)

For Trade Certifications numbered 50,000- 69,999 or 80,000+

Has your job been adversely affected by foreign competition?

The Trade Adjustment Assistance (TAA) Program includes among eligible workers those directly affected by increased imports or certain shifts of production to other countries. Eligible workers also include secondarily affected workers of an upstream supplier or downstream producer to a certified primary firm. When a layoff or work reduction occurs, a petition for TAA must be filed with the U.S. Department of Labor (USDOL) and the TAA Coordinator by:

- A group of 3 or more workers
- A certified union official or representative
- Official of the employer/firm
- One Stop operators or partner
- State dislocated worker unit staff

The petition and help completing the petition is available from CareerCenters and other State Workforce Agency offices. Filing a petition will trigger immediate rapid response and basic adjustment services to workers. Rapid reemployment is the goal. The USDOL has forty calendar days to complete its investigation and certify eligibility.

Benefits Available through the Trade Act

- Re-employment Services
- Training and Related Expense Reimbursement
- Trade Readjustment Allowance (TRA)
- Health Coverage Tax Credit
- Job Search Allowance
- Relocation Allowance
- Alternative Trade Adjustment Assistance (ATAA)

How can you qualify for these benefits?

- You must complete a TRA-26, "Request for Determination of Initial Entitlement to TAA/TRA"
- You must be pre-approved for all TAA/TRA services and benefits by a CareerCenter consultant
- You must be enrolled in training 8 weeks after the petition certification date or 16 weeks after separation
- You must complete an employability plan within 210 days of your company's first TAA certification, or, if later, within 210 days of your most recent layoff, to lock in additional TRA benefits

Re-employment Services

- Job search strategies
- Resume, cover letters, applications
- Referrals to jobs
- Labor Market Information
- Interview preparation

Training – up to 104 weeks

- On-the-Job Training
- Occupational Training
- Customized Training
- Remedial Training
- Other training related expenses
 - Tuition, books, fees, tools, and uniforms
 - Travel expenses (if beyond normal commute)
 - Subsistence allowance (if training is not available within your commuting area.)

Six criteria applied to program before training can be approved

1. Suitable employment is not available for you (Your CareerCenter consultant will match your skill level, salary, and commuting area to jobs listed)
2. You will benefit from training
3. You can reasonably expect to find employment following completion of your training program
4. Training is reasonably available to you (travel/subsistence)
5. You meet entry level education/training program requirements and have the financial resources to carry you through
6. Training is suitable for you and available at a reasonable cost

Trade Readjustment Allowance (TRA) – Weekly Benefits

(You must file a weekly claim and meet eligibility requirements to be paid.)

- Up to 26 weeks of regular unemployment benefits
- Up to 26 weeks of basic TRA
- Up to 52 weeks of additional TRA
- Up to 26 weeks of TRA benefits if in remedial training

Duration of Training

- Regular training is available for up to 104 weeks
- Remedial education is available for up to 26 *additional weeks* for a maximum total of 130 weeks.

Additional TRA Allowances – You may be able to collect up to 52 weeks of additional TRA if you use up your unemployment insurance and Basic TRA benefits. If you need more time and financial help to complete your training, you can apply for the additional TRA benefits. The additional benefits can only be paid to you if you applied for your training program within 210 days of your company's first TAA certification, or, if later, within 210 days of your most recent layoff.

Break in Training – If you have more than a 30-day break in your TAA training (not counting National and State holidays and weekends), TRA benefits are not payable. TRA payments will resume when your approved TAA training starts again.

Six specific situations when training can be waived

1. You have a written note that you will be recalled within 6 months (specific recall date is required)
2. You have marketable skills (determined by assessment)
3. You are within 2 years of qualifying for Social Security or a privately sponsored pension
4. You are in poor health but can actively seek and accept full time work
5. You are determined eligible for training but the first available enrollment date is delayed (training must begin within 60 days)
6. Training is not available at a reasonable cost or funds are not available under TAA or other Federal laws

Job Search Requirements – If you complete training or receive a waiver from training, you must actively seek full time employment to receive Basic TRA benefits. CareerCenter staff will help you through your work search. Re-employment is the goal!

Health Coverage Tax Credit (HCTC)

- You must be covered under a TAA certification of eligibility for TAA benefits.
- Your HCTC eligibility may begin on the 61st day after the date the petition was filed.
- You must be entitled to UI benefits.
- You must be enrolled in approved training, have completed a training program or have obtained a waiver. (This requirement is applicable during the period that you are receiving TRA as well as UI.)
- You must have received TRA or UI benefits on any day of the month to qualify for HCTC that month.
- You are eligible for an additional month after ceasing to be an eligible TAA recipient and as such remain eligible for the advanced tax credit for one more month.
- You must call toll free **1-866-628-4282** to apply for an advance tax credit – if eligible, the HCTC office will pay 80% of your health insurance premium – you pay 20%.

Job Search Allowance

- You must be pre-approved by your CareerCenter Consultant to seek work beyond your normal commuting area
- 90% of the cost of expenses for meals, lodging, and mileage may be refunded to you to the nearest suitable employment opportunity with a maximum amount of \$1,250

Relocation Allowance

- You must be pre-approved by your CareerCenter Consultant to seek suitable work beyond your normal commuting area (Certain deadlines apply – see your Consultant)
- You must live 50 miles or more from your new place of work
- You must have a written offer of employment

- Your new job must be within the continental United States
- 90% of the total cost of the following to the nearest suitable employment opportunity
 - Cost of meals, lodging, and mileage
 - Cost of moving your household goods and personal and family effects (lesser of 2 estimates)
 - Up to 2 months storage
- A lump sum payment equal to 3 times your average weekly wage (maximum \$1,250)

Alternative Trade Adjustment Assistance (ATAA) Demonstration Project for Older Workers Wage Supplement

- Criteria must be met for group certification
- You must be at least 50 years old
- You must start a new job within 26 weeks of layoff from the TAA certified company
- You may receive 50% of difference between reemployment wages and wages earned at separation
 - Payments may not last more than 2 years
 - Total payments may not exceed \$10,000 over 2 year period (whichever of these runs out first)

REMINDER: CareerCenter staff must approve training programs, job search allowances and relocation allowances in advance. The HCTC toll free number is 1-866-628-4282.

For more information and help with the TAA Program, contact one of our staff at your local CareerCenter.

AUGUSTA

21 Enterprise Drive, Suite 2
109 SHS
Augusta, ME 04333-0109
624-5120 or 1-800-760-1573
TTY- (207) 624-5134 or 1-800-633-0770
Fax- (207) 287-6236

BANGOR

45 Oak Street, Suite #3
Bangor, ME 04401-6667
561-4050 or 1-888-828-0568
TTY: 1-800-498-6711
Fax: 561-4066

BRUNSWICK

275 Bath Road, Suite #3
Brunswick, ME 04011
373-4000 or 1-888-836-3355
TTY: 1-800-697-2871
Fax: 373-4004

CALAIS

One College Dr., PO Box 415
Calais, ME 04619-0415
454-7551 or 1-800-543-0303
TTY: 1-888-697-2883
Fax: 454-0349

LEWISTON

5 Mollison Way
Lewiston, ME 04240-5805
753-9000 or 1-800-741-2991
TTY: 1-877-796-9833
Fax: 783-5301

MACHIAS

15 Prescott Drive, Suite 1
Machias, ME 04654-9752
255-1900 or 1-800-292-8929
TTY: 1-800-381-9932
Fax: 255-4778

PORTLAND

185 Lancaster Street
Portland, ME 04101-2453
771-5627 or 1-877-594-5627
TTY: 1-888-817-7113
Fax: 822-0221

PRESQUE ISLE

66 Spruce Street, Suite #1
Presque Isle, ME 04769-3222
760-6300 or 1-800-635-0357
TTY: 1-888-697-2877
Fax: 760-6350

ROCKLAND

91 Camden Street, Suite 201
Rockland, ME 04841-2421
596-2600 or 1-877-421-7916
TTY: 1-888-212-6229
Fax: 594-1428

SKOWHEGAN

98 North Avenue
Skowhegan, ME 04976-1923
474-4950 or 1-800-760-1572
TTY: 1-888-697-2912
Fax: 474-4914

SPRINGVALE

9 Bodwell Court
Springvale, ME 04083-1801
324-5460 or 1-800-343-0151
TTY: 1-888-697-2913
Fax: 324-7069

WILTON

865 US Route 2E
Wilton, ME 04294-6649
645-5800 or 1-800-982-4311
TTY: 1-888-697-2895
Fax: 645-2093

From Troy Haines' testimony

September 06, 2011

U.S. measures to reduce teenage smoking deemed WTO violation

U.S. measures to reduce teenage smoking violate World Trade Organization (WTO) rules, according to a panel ruling released late last week. Indonesia successfully argued that the U.S. Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009 violated WTO rules. The ruling opens the door to more teenage tobacco addiction, while further imperiling the legitimacy of a WTO that rules against environmental, health and other national policies 90 percent of the time.



The FSPTCA took a series of unprecedented and bold measures to combat teenage smoking, including the banning of many forms of flavored cigarettes. There is substantial evidence that tobacco companies produce and market these cigarettes as "starter" or "trainer" cigarettes in order to hook teenagers into a lifetime of nicotine addiction.

However, as the U.S. noted in its defense in the WTO case, the U.S. did not ban all types of cigarettes. In particular, regular tobacco and menthol cigarettes were excluded from the ban. The justification for these exclusions was that, unlike candy flavored or clove cigarettes, large numbers of adults are also hooked on regular and menthol cigarettes. To abruptly pull these products out of the market could cause a strain on the U.S. healthcare system (as lifetime addicts would instantly seek medical treatment for wrenching withdrawal symptoms) and might lead to a rise in illicit black market sales and associated crime. Nonetheless, various studies were ordered on the feasibility of banning menthol cigarettes in the future.

The FSPTCA banned candy and clove cigarettes regardless of where they were produced or who produced them. But Indonesia successfully argued that, since its exporters are the primary providers of clove cigarettes to the U.S. market, the FSPTCA constituted de facto discrimination in violation of WTO rules under the Agreement on Technical Barriers to Trade (TBT). The WTO panel accepted this argument, despite the fact that the FSPTCA was totally non-discriminatory and many U.S. cigarette makers (such as those that make cola-flavored cigarettes) were also blocked from making these harmful products.

This severe blow to consumer protection comes on the heels of two other WTO rulings against America's dolphin-safe tuna and beef country-of-origin labels, and are likely to put a significant damper on the Obama administration's efforts to pass trade deals with South Korea, Colombia and Panama that contain similar anti-consumer rules.

More on the details of the case after the jump.

This trio of cases have been the first real "road testing" of the TBT, which has only been the subject of a few previous (and much less controversial) completed WTO cases. Prior to the creation of the WTO in 1995, there was a fairly limited basis under international trade rules for challenging labeling measures. For the last 15 years, the implications of TBT rules have been uncertain, but governments and corporations have invoked TBT requirements as a reason to not implement or to water down consumer protection policies. This happened several years ago, for instance, when the Bush administration pushed back on Maryland's tough proposed toy safety rules, out of concerns that China might push a WTO case. (See, for instance, page 12 of this report.)

But this trio of cases helps fill in the blanks as to why the TBT rules are so dangerous. Here are just a few of the problematic conclusions and implications:

Rare progressive achievement overturned. The FSPTCA was one of the top achievements of the Obama administration and 111th Congress. Indeed, it was one of the few accomplishments that hasn't been whittled away by preemptive carving in, selective implementation of statute, industry pressure, regulatory capture, non-implementation of regulatory recommendations, U.S. court challenge or GOP pressure. Tobacco companies would have been hard-pressed to beat the FSPTCA in the domestic context, both because they have few political allies and probably no legal basis for doing so. The WTO did the dirty work for them, and the U.S. will have to water down the teenage smoking measure or face trade sanctions.

Legitimate consumer safety policy deemed WTO-illegal. The WTO panel noted approvingly many aspects of the U.S. policy, but still ruled against it. The panel:

- acknowledged that the FSPTCA was "legitimate" (para 7.286);
 - approvingly cited scientific studies that concluded that "the clove cigarette is nearly ideal in design as a 'trainer' cigarette for capturing young people as smokers" (para 7.403);
 - concluded that the ban on clove cigarettes reflected "at least the majority view, and potentially the unanimous view," among scientists (para 7.401);
 - determined that Indonesia had failed to prove that there was a "less-trade restrictive alternative" measure "that would make an equivalent contribution to the achievement of the [public health objective] sought by the United States" (para 7.421);
 - found that alternatives suggested by Indonesia appeared to be riskier for public health (para 7.424); and finally
 - noted that the U.S. executive branch and Congress went out of their way over many years to take Indonesia's views into account when designing the FSPTCA (para 7.645).
- Nonetheless, the panel ruled that the FSPTCA violated WTO rules. (The fact that the U.S. government even engaged in these consultations with Indonesia before protecting

Americans' health would likely outrage many citizens: the fact that this wasn't even enough to avoid a WTO challenge calls into serious question the usefulness of having done so in the first place.)

The fact that a policy could still be ruled WTO-illegal despite being so reasonable is likely to turn even more of the public against the WTO.

Despite major differences between clove and menthol cigarettes, the WTO rules that these are "like products." Indonesia brought its major successful claim against the U.S. under ITRT Article 2.1, which states that

"Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country."

As the WTO panel stated, three elements are traditionally required for such a claim to prevail:

"The Panel considers that the essential elements of an inconsistency with Article 2.1 of the TRT Agreement are, as a minimum, that the measure at issue is a 'technical regulation'; that the imported and domestic products at issue are 'like products' within the meaning of that provision; and that the imported products are accorded 'less favourable' treatment than that accorded to like domestic products." (para 7.77)

Likeness is typically established by reference to:

- (a) the properties, nature and quality of the products;
- (b) the end-uses of the products;
- (c) consumers' tastes and habits – more comprehensively termed consumers' perceptions and behaviour – in respect of the products; and
- (d) the tariff classification of the products.

The WTO panel ruled that menthol and clove cigarettes are "like", even though:

- clove and menthol cigarettes have different additives present in substantially different quantities (para 7.180);
- clove cigarettes may have higher toxicity levels (para 7.184);
- different types of consumers may have different patterns of consumption of each type of flavored cigarette (para 7.232); and
- the U.S. has classified cloves separately from other cigarettes in its tariff schedule (para 7.235).

Indeed, a key part of the U.S. argument was that menthol cigarettes (because so many adults smoke them) are fundamentally different from clove cigarettes, and a sudden ban on the former may not be practical or wise. This does not appear to have been given any weight by the WTO panel for the purposes of its likeness analysis.

Similarly, the U.S. noted that U.S. companies that manufacture candy-flavored and clove-flavored cigarettes were also impacted by the ban. Despite this fact, the WTO panel arbitrarily determined that it would compare U.S. menthol to Indonesian clove cigarettes (para 7.274), rather than U.S. candy to Indonesian clove cigarettes. If it had done the latter, the panel would have been much less likely to have found a violation.

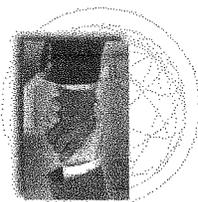
Indeed, the WTO panel utilized any interpretive flexibility it had in order to find that the TRT had been violated (see paras 7.104 and 7.187), rather than deferring to consumer protection. This, despite the ritual nod to national sovereignty (para 7.2) that is increasingly without much meaning.

The WTO, not the U.S. Congress, gets to decide how to balance competing interests. The U.S. had a reasonable and logical reason for not banning menthol cigarettes, and Congress had over many years weighed the pros and cons of banning all cigarettes, or just those that presented unique challenges to reducing teenage smoking. Banning menthol cigarettes was deemed to come with significant costs. The panel determined that the U.S. should have gone ahead and incurred that cost (including all the health emergencies and black market threats) rather than impact Indonesian exporters in any way. (para 7.289-7.291). Again, the only way to come to this conclusion is to willfully ignore that candy cigarettes produced in the U.S. were also banned.

Obama administration does not use all defenses available to it. As with the tuna-dolphin case, the Obama administration did not invoke all of the defenses available to it. The WTO panel seemed prepared, for instance, to determine whether the flavored cigarette ban were "necessary to protect human... health" under GATT Article XX, but the U.S. didn't even utilize that defense. (See para 7.296) This is a worrying pattern. It suggests that the Obama administration is overly concerned with avoiding the precedent of environmental and health defenses being invoked when the tables are turned and the U.S. is the complainant country, rather than defending U.S. interests. Members of Congress will take note of this omission the next time that an administration official cites a so-called "exception" provision in a trade deal.

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In sum, this latest WTO ruling shows yet again that current trade agreements systematically put the corporate interest before that of consumers. Democracy, public health, science and logic better get out of the way. These anti-consumer provisions should be amended at the first possible opportunity, and stripped from the pending trade deals.



DISPUTE SETTLEMENT: DISPUTE DS406 United States – Measures Affecting the Production and Cigarettes

This summary has been prepared by the Secretariat under its own responsibility. The summary is for general information only and is not intended to affect the rights and obligations of Members.

Current status [back to top](#)

Panel report circulated on 2 September 2011 ⁽¹⁾

Key facts [back to top](#)

See also:	
> The basics: how disputes are settled in WTO	US – Clove Cigarettes
> Computer based training on dispute settlement	Indonesia
> Text of the Dispute Settlement Understanding	United States
Other disputes involving:	Brazil; Colombia; Dominican Republic; Mexico; Norway; Turkey
> Cigarettes	
> Indonesia	
> United States	
> General Agreement on Tariffs and Trade 1994	
> Agreement on the Application of Sanitary and Phytosanitary Measures	
> Agreement on Technical Barriers to Trade	
Request for Consultations received:	7 April 2010
Panel Report circulated:	2 September 2011

Summary of the dispute to date [back to top](#)

The summary below was up-to-date at 21 October 2011 ⁽¹⁾

Consultations

Complaint by Indonesia.

On 7 April 2010, Indonesia requested consultations with the United States with respect to a provision of the Family Smoking Prevention Tobacco Control Act of 2009 that bans clove cigarettes. Indonesia alleged that Section 907, which was signed into law on 22 June 2009, prohibits, among other things, the production or sale in the United States of cigarettes containing certain additives, including clove, but would continue to permit the production and sale of other cigarettes, including cigarettes containing menthol. Indonesia alleged that Section 907 is inconsistent, *inter alia*, with Article III:4 of the GATT 1994, Article 2 of the TBT Agreement, and various provisions of the SPS Agreement.

On 9 June 2010, Indonesia requested the establishment of a panel. At its meeting on 22 June 2010, the DSB deferred the establishment of a panel.

Panel and Appellate Body proceedings

At its meeting on 20 July 2010, the DSB established a panel. Brazil, the European Union, Guatemala, Norway and Turkey reserved their third-party rights. Subsequently, Colombia, the Dominican Republic and Mexico reserved their third-party rights. On 9 September 2010, the parties agreed on the composition of the panel. On 8 March 2011, the Chairman of the panel informed the DSB that the timetable adopted by the panel after consultations with the parties to the dispute envisages that the final report was to be issued to the parties by the end of June 2011 and that the panel expected to conclude its work within that timeframe.

On 2 September 2011, the panel report was circulated to Members.

Summary of key findings

This dispute concerns Section 907(a)(1)(A) of the *Federal Food, Drug and Cosmetic Act* (“FFDCA”), which was added to the FFDCA by Section 101(b) of the *Family Smoking Prevention and Tobacco Control Act*. This measure bans the production and sale of clove cigarettes, as well as most other flavoured cigarettes, in the United States. However, the measure excludes menthol-flavoured cigarettes from the ban. Indonesia is the world’s main producer of clove cigarettes, and the vast majority of clove cigarettes consumed in the United States prior to the ban were imported from Indonesia.

Indonesia’s main claims were that the ban on clove cigarettes is discriminatory, and that it is also unnecessary. Indonesia further claimed that the United States acted inconsistently with a number of procedural and/or other requirements under the TBT Agreement in the context of preparing and implementing Section 907(a)(1)(A). Indonesia did not argue its claims under the SPS Agreement.

The first step in the Panel’s analysis was to determine whether the challenged measure falls within the scope of the TBT Agreement. The Panel found that it does, on the basis that Section 907(a)(1)(A) is a “technical regulation” within the meaning of Annex 1.1 of the TBT Agreement. The Panel then examined Indonesia’s claims under Articles 2.1, 2.2, 2.5, 2.8, 2.9, 2.10, 2.12, and 12.3 of the TBT Agreement.

In one of its key findings, the Panel found that the ban is inconsistent with the national treatment obligation in Article 2.1 of the TBT Agreement because it accords clove cigarettes less favourable treatment than that accorded to menthol-flavoured cigarettes. The Panel found that clove and menthol-flavoured cigarettes are "like products" within the meaning of Article 2.1 of the TBT Agreement, based in part on its factual findings that both types of cigarettes are flavoured and appeal to youth. Having found a violation of Article 2.1 of the TBT Agreement, the Panel declined to rule on Indonesia's claim under Article III:4 of the GATT 1994, or on the United States' defence under Article XX(b) of the GATT 1994 (invoked only in respect of the claim under Article III:4 of the GATT 1994).

However, the Panel rejected Indonesia's second main claim, which was that the ban is unnecessary. In this regard, the Panel found that Indonesia had failed to demonstrate that the ban is more trade-restrictive than necessary to fulfil a legitimate objective (in this case, reducing youth smoking) within the meaning of Article 2.2 of the TBT Agreement. The Panel's conclusion was based, in part, on its finding that there is extensive scientific evidence supporting the conclusion that banning clove and other flavoured cigarettes could contribute to reducing youth smoking.

As regards Indonesia's other claims under the TBT Agreement, the Panel found that the United States acted inconsistently with Article 2.9.2 (obligation to notify WTO Members of technical regulations) and Article 2.12 (obligation to allow reasonable interval between publication and entry into force of technical regulations). However, the Panel found that Indonesia failed to demonstrate that the United States acted inconsistently with Article 2.5 (obligation to provide an explanation of draft technical regulation), Article 2.8 (obligation to specify a technical regulation in terms of performance), Article 2.9.3 (obligation to provide particulars or copies of the proposed technical regulation) or Article 12.3 (obligation to take account of the special development, financial and trade needs of a developing country Member), and declined to rule on Indonesia's claim under Article 2.10 (obligation to notify in cases of urgency).

On 15 September 2011, Indonesia and the United States requested the DSB to adopt a draft decision extending the 60-day time period stipulated in Article 16.4 of the DSU, to 20 January 2012.

The World Trade Organization (WTO) deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible.

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Key areas
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