STATE OF MAINE

Citizen Trade Policy Commission

Addendum to 2012 Trade Policy Assessment

August 2012

The Citizen Trade Policy Commission (CTPC) provides an ongoing state-level mechanism to assess the impact of international trade policies and agreements on Maine's state and local laws, business environment and working conditions.

The CTPC was established by Public Law 2003, Chapter 699 during the Second special session of the 121st Maine State Legislature. The 22 member Commission includes six legislators, an Attorney General designee, five non-voting agency officials representing the Department of Labor, the Department of Health and Human Services, the Department of Environmental Protection, The Maine International Trade Center, the Department of Agriculture, Food and Rural Resources, and 10 public members representing business, labor, health, government and environmental interests.

The CTPC's statutory mandate was amended by PL 2007, Chapter 266 to require that the CTPC must hold regular meetings, gather information from the public through public hearings, to submit an annual report on its activities and to conduct a biennial assessment on the impacts of international trade agreements on Maine.

To comply with the requirement that the CTPC must conduct a biennial assessment on the impacts of international trade treaties on Maine, in early 2012 the commission started a process to conduct the required assessment:

- The CTPC considered 5 different individuals who were highly qualified in the subject of international trade;
- After a detailed review of the 5 candidates, the CTPC selected Professor Robert Stumberg, Professor of law at Georgetown University and Director of the Harrison Institute for Public Law, to conduct the 2012 CTPC Assessment;
- The CTPC contracted Professor Stumberg to conduct an assessment which focused on the following 3 subjects regarding the TransPacific Partnership Agreement (TPPA) and its possible effects on Maine:
    - Pharmaceuticals;
    - Procurement; and
    - Tobacco
- The contract with Professor Stumberg required him to:
    - Produce a first draft of the assessment by June 8, 2012;
    - Present the draft assessment in person at a Public Hearing by June 15, 2012;
    - Submit a final draft of the assessment by June 25, 2012

The printed document to which this addendum is attached represents the final version of the 2012 Assessment approved by the CTPC. A PDF version of this document can be downloaded from the CTPC website:

http://www.maine.gov/legis/opla/citpol.htm

A limited number of printed copies of this assessment are currently available at the Office of Policy & Legal Analysis.

HARRISON INSTITUTE FOR PUBLIC LAW
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2012

TRADE POLICY ASSESSMENT

Prepared for the Maine Citizen Trade Policy Commission

June 25, 2012

2012 Trade Policy Assessment

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Executive Summary

2012 Trade Policy Assessment
Prepared for the Maine Citizen Trade Policy Commission

The Obama Administration is leading negotiations to create a Trans-Pacific Partnership Agreement (TPPA), "a true 21st century trade agreement" that "will reflect U.S. priorities and values."[1] This 2012 Trade Policy Assessment[2] focuses on three topics of importance to the TPPA: treatment of tobacco trade, pharmaceutical trade, and government procurement.

The TPPA would be a trendsetter because of its size and scope. Starting with 11 countries,[3] the TPPA would likely expand to include most of the 22 members of APEC (Asia-Pacific Economic Cooperation) and potentially Japan, Korea, China and India.[4] It could exceed the size of the European Union. Whatever its innovations – more stringent trade rules or stronger safeguards for public interest regulations – the TPPA would have a significant impact on public policy.

I. Treatment of Tobacco in the TPPA

A. ***Introduction.*** Tobacco use is the "leading global cause of preventable death."[5] Should a 21st century trade agreement expand or restrict tobacco trade? Philip Morris International (PMI) asked USTR to extend to tobacco companies the same benefits that the TPPA would provide to all other sectors. These include increased market access for goods and services, stronger trademark protections, and expanded rights for foreign investors. Shortly after TPPA negotiations began, PMI used similar trade and investment rules to challenge tobacco controls in Ireland, Norway, Uruguay, and Australia. PMI has also targeted Singapore, another TPPA country, for legislation that tracks closely with the 2009 Tobacco Control Act in the United States. In other words, the TPPA could

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1 Remarks by Ambassador Ron Kirk at the Washington International Trade Association (December 15, 2009), available at http://www.ustr.gov/about-us/press-office/speeches/transcripts/2009/december/remarks-ambassador-ron-kirk-washington-inte (viewed August 11, 2010).

2 This report is part of a biennial assessment of trade policy that is likely to affect Maine's state laws, municipal laws, working conditions or business environment. *See* Maine Laws of 2007, c. 266, §2 (AMD).

3 The initial nine parties included Australia, Brunei, Chile, Hong Kong, Malaysia, New Zealand, Peru, the United States, and Viet Nam. Mexico and Canada have been approved to join the negotiations in the second half of 2012.

4 Inside U.S. Trade, TPP Partners Invite Mexico And Canada To Join TPP Talks, But Not Japan, 21 June 2012; Associated Press, Japan invited to meet with US-backed TPP members, Forbes.com (November 14 2010), available at http://www.forbes.com/feeds/ap/2010/11/14/business-as-japan-trade_8103664.html?boxes=Homepagebusinessnews (viewed November 15, 2010); Reuters, South Korea mulling U.S.-led TPP trade initiative: report (November 13, 2010), available at http://www.reuters.com/article/idUSTRE6AD05L20101114 (viewed November 15, 2010).

5 World Health Organization, World No Tobacco Day 2012: Tobacco industry interference (2012), available at http://www.who.int/tobacco/wntd/2012/industry_interference/en/ (viewed June 21, 2012); WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC 2009: IMPLEMENTING SMOKE-FREE ENVIRONMENTS (2009), available at http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=93&codcch=2220 (viewed June 21, 2012).

empower the tobacco industry's litigation strategy at a time when countries are striving to implement their obligations to restrict tobacco marketing under the Framework Convention on Tobacco Control (FCTC), the first global health treaty.
On the other hand, the TPPA could set a precedent by excluding tobacco from a trade agreement that provides greater market access and investor rights to challenge tobacco controls. Current TPPA countries are parties to FCTC, except for the United States, which signed but never ratified the treaty.

B. ***TPPA threats to tobacco control.*** If TPPA chapters follow the model of existing free trade agreements (FTAs), tobacco companies could use several of them to undermine or challenge tobacco controls. The chapters include:

1. *Investment* – would give greater rights to foreign investors to challenge regulations outside of domestic courts. PMI is using investor rights to seek compensation for "indirect expropriation" of its trademarks by Uruguay and Australia.
2. *Intellectual property* – would provide (as proposed by the United States) a new right to use elements of trademarks (e.g., non-origin names that refer to a place like Salem and Marlboro).
3. *Cross-border services* – would expand the number of laws covered by trade rules that limit regulation of tobacco-related services such as advertising, distribution and display of products.
4. *Regulatory coherence* – would create obligations to involve tobacco companies ("stakeholders") in policy-making, which could undermine an FCTC obligation to limit the influence of tobacco companies.
5. *Tobacco tariffs* – would reduce tariffs to zero (as proposed by the United States) for a range of tobacco products. Several TPPA countries have relatively high tobacco tariffs, which inhibit expansion by international tobacco companies.

C. ***U.S. proposal on tobacco.*** Caught between tobacco growers from key electoral states and a rising tide of global litigation by tobacco companies, the Obama Administration is seeking a compromise.

1. Three elements. USTR proposes to:
   a. Explicitly "recognize the unique status of tobacco products from a health and regulatory perspective."
   b. Eliminate tariffs on tobacco products.
   c. Provide a "safe harbor" for regulations that restrict tobacco marketing within the United States. This would be "language in the 'general exceptions' chapter that allows health authorities in TPPA governments to adopt regulations that impose origin-neutral, science-based restrictions on specific tobacco products/classes in order to safeguard public health."

2. Critique of the exception. As proposed, the exception for adopting regulations:
   a. Does not cover legislation.
   b. Does not cover enforcement of existing regulations (only adoption of new ones).
   c. Does not cover regulations adopted by license, tax and other non-health authorities.
   d. Does not apply to the investment and trade rules that are already being used to challenge tobacco controls (e.g., national treatment and indirect expropriation).

e. Introduces a "science-based" test that requires more stringent evidence than the existing health exception.

D. *Oversight questions*

1. *Exception or carve-out.* If each element of the proposed exception were fixed, the result would be a stronger exception. But it would still leave governments vulnerable to expensive challenges, which have become the tobacco industry's weapon of choice. The general question is, should TPPA governments create a "safe harbor" from threats to their tobacco controls? More specifically, should the Maine CPTC recommend whether the U.S. proposal should be a stronger safeguard? Options include:

   a. *As proposed* – a narrow exception for rules adopted by health authorities that does not apply to national treatment, indirect expropriation or transparency obligations.

   b. *A stronger exception* – e.g., one that covers legislation and all trade and investment rules.

   c. *A clear carve-out* – which would simply say that the TPPA does not apply to tobacco trade or investment. This option would minimize the threat of expensive litigation.

2. *Compliance with policy on tobacco trade.* With or without the proposed exception, are U.S. negotiators honoring the directives of the Doggett Amendment and the Executive Order, which prohibit promoting tobacco or undermining other countries' restrictions on tobacco trade?

II. Pharmaceutical Provisions in the TPPA

A. *Introduction.* Market-derived prices drove up state Medicaid reimbursements by an average of 13.1% per year for 15 years (1990 to 2005) until drugs accounted for 10% of state Medicaid payments. Most states, including Maine, responded with cost-containment strategies – including prior authorization (using preferred-drug lists), use of generics, and increased copayments – that reduced costs by as much as 50%. In response, drug companies sued Maine and other states, but U.S. courts upheld the state programs.

After years of consultation with the drug companies, USTR has proposed a Health Annex for the TPPA that requires reimbursement programs to shift to "market-derived" pricing rules and procedures that give drug companies an opportunity to litigate against the programs that are now working to contain costs. The proposal is drawing fire as a boon to drug companies that are seeking to roll back cost-containment in other countries and foreclose reforms in the United States.

B. *U.S. proposal on pharmaceuticals*

1. *Pricing rules*

   a. *Proposal* – The U.S. proposal requires reimbursement programs to set "competitive market-derived" prices, or in the alternative, prices that "recognize the value" of patents.

b. *Critiques* – The vagueness of these rules would undermine a government's ability to negotiate lower prices based on economy of scale from pooled purchasing. It would also enable drug companies to challenge the common practice of using *international* reference pricing. The impact would be to lock in prices where they are high and raise prices where they are low.

2. *Pricing procedures*

   a. *Proposal* – The U.S. proposal requires governments to disclose their methods for setting and negotiating reimbursement prices, enable drug companies to comment on pricing methods, give companies detailed written information about decisions on particular drugs, and provide companies with an individual appeal process.

   b. *Critiques* – The procedures will force governments to depart from established negotiating practices that private market actors use to contain their drug costs. The disclosure and appeal rights convert negotiations into a system of private company rights. As one critic says, the process is "a lawyer's dream."

3. *Coverage*

   a. *Proposal* – The U.S. proposal covers reimbursement programs of national health authorities. Unlike the last two trade agreements (Australia and Korea), it does not clearly state that Medicaid reimbursements are <u>not</u> covered by the pricing rules.

   b. *Critiques* – The omission of a carve-out for Medicaid appears with no explanation. Even if Medicaid is eventually carved out, states will see their Medicaid expenses increase if the pricing rules influence the federal 340B reimbursement program.

C. *Oversight questions*

1. *Cost to states.* Would the TPPA undermine cost-containment by states in Medicaid or by the federal government in the 340B program?

2. *Coverage or carve-outs.* The U.S. proposal does not clearly carve out several federal reimbursement programs on which state governments rely to constrain pharmaceutical costs. The question is whether or not they too should be carved out of the proposed Heath Annex. These federal reimbursement programs include:

   a. Medicaid, which is carved out of the Korea-U.S. FTA

   b. 340B

   c. Medicare Part B

3. *Pricing rules.* After decades of "market-derived" pricing, drug prices are six times higher than they were in 1990.

   a. Cost-containment strategies are working. How does replacing them with the U.S. proposal for market-derived prices benefit the public interest?

   b. What is the theory by which the proposed pricing rules would help states or consumers contain the cost of prescription drugs?

   c. Should the United States hold other countries to rules that it does not apply to its own reimbursement programs?

4. *Future cost-containment strategies.* Critics of the proposed Health Care Annex are concerned that it will foreclose options for cost-containment that are now on the table. They fear that market-derived price rules will lock in the highest market prices in the world. A constructive way to discuss the risk of trade conflict is to compare the U.S. proposal for the TPPA with pending cost-containment proposals. How would the U.S. proposal constrain future cost-containment strategies such as these:

   a. *Medicaid national pricing list* – As noted above, the Affordable Care Act will change the drug pricing approach of Medicaid from state-level rebate negotiations to a national list that is similar to the approach in Australia and New Zealand.

   b. *Medicare pool purchasing* – There are a number of proposals to make better use of the federal government's purchasing power to contain the cost of prescription drugs, particularly with respect to Medicare Part D.
      (1) The Obama Administration proposed a measure to reduce the deficit by limiting "excessive payments for prescription drugs by leveraging Medicare's purchasing power."
      (2) Senator Dick Durbin (D-Ill.) and Representative Jan Schakowsky (D-Ill.) proposed legislation to offer one or more Medicare Part D plans that would coexist with private plans. The bill would require the Secretary of HHS to negotiate with drug manufacturers for lower prices and establish formularies.

   c. *Marketing and consumer protection* – The Annex could undermine efforts to revise U.S. law regarding direct-to-consumer marketing during the initial period of sale when drugs have had limited use and when significant side effects are most likely to be exposed.

III. Government Procurement

A. ***Introduction.*** TPPA negotiators are working on a procurement chapter, but no text is available. In the United States, procurement has been a more pro-democratic sector of trade policy. Beginning in the Uruguay Round of WTO negotiations in 1994, the U.S. Trade Representative invited governors to decide whether to commit their state to each successive procurement chapter of an FTA. Maine is among five states to open up the process further by requiring legislative approval of the decision to limit state procurement power under a trade agreement. A consequence of openness is that the number of participating states started with 37 (including Maine) in the WTO's Agreement on Government Procurement (GPA), then declined to 19 in CAFTA (2004), and more recently, to only 8 in the Peru FTA (2006). In addition to the GPA, Maine procurement is covered by the following procurement chapters of FTAs: CAFTA, Singapore, Chile, and Australia. Maine has declined to be bound by the more recent FTAs: Morocco, Peru, Colombia, and Panama.

USTR has yet to release a draft of TPPA procurement rules, so we summarize those from the GPA. In addition, the USTR has not indicated when states would be solicited to participate in TPPA procurement. In the meantime, there are developments outside of the TPPA that could significantly affect state procurement: a new GPA text has been negotiated; China is poised to join the GPA, and the EU and Japan are challenging procurement in Ontario with arguments that could subject state and local procurement to trade rules under trade agreements <u>other than</u> the GPA and procurement chapters.

B. ***Procurement rules.*** Procurement rules are a sensitive area of trade policy because they could be used to challenge preferences that favor local production or impose environmental criteria on government purchases. The most common procurement rules are contained in the WTO's GPA and procurement chapters of U.S. FTAs.

1. *Nondiscrimination rules* – prohibit preferential treatment of domestic goods, services or suppliers.
2. *Performance based standards* – require that technical specifications "in terms of performance rather than design or descriptive characteristics . . . ."
3. *International standards* – are required for procurement contracts if they exist.
4. *Procedural requirements* - include complete bid specifications and standards for evaluating proposals.

C. ***Recent developments – procurement negotiations***

1. *TPPA procurement chapter.* USTR is "delaying" asking for commitments from states to be covered under the TPPA. The text of the procurement chapter is not available to the public (June 2012).
2. *The proposed US–EU Agreement.* The United States and the European Union are discussing a potential US–EU trade agreement. The EU's Trade Commissioner recently said that it would be "crucial" for a US–EU agreement to cover state-level procurement, with no application of "Buy American" laws.
3. *Revised and expanded WTO GPA*. In March 2012, the Parties to the GPA signed a revised and expanded version of the agreement. The revised GPA provides for electronic commerce, domestic challenges for breach of GPA rules, more limits on qualification requirements, and disclosure of why bidders are rejected. Despite these changes, USTR intends to commit the United States to the revised GPA without congressional approval. By not asking Congress, it may be easier to also avoid asking states to recommit to the GPA, which would risk a significant drop in state participation.
4. *Accession of China and nine other countries to the GPA.* China has made its second major proposal to join the GPA; its export potential could transform the impact of GPA rules as a litigious country enters the market.
5. *GATS rules on procurement of services.* These negotiations could cover most state and local procurement of services, but they are not moving quickly.

D. ***Recent developments – procurement dispute.*** The EU and Japan are litigating a WTO dispute against Ontario's "feed-in tariff" (FIT) – a long-term procurement contract that pays above-market rates for electricity produced with wind or solar technology. Ontario requires that the technology must be produced in Ontario. The FIT clearly favors Ontario technology, so Canada's defense is that such a procurement contract is not covered by trade rules. Canada argues that trade rules do not apply here: provinces are not covered by Canada's GPA schedule, and the GATT non-discrimination rules do not apply to procurement for government purposes. Key EU arguments are that (1) "resale" of electricity to consumers does not qualify as government procurement, and (2) favoring local products cannot be a legitimate purpose of procurement. If the WTO adopts the EU's interpretations, many state and local procurement preferences and utility operations

would be covered by trade rules – notwithstanding the fact that states have avoided committing themselves to rules of the GPA and procurement chapters of FTAs.

E. *Oversight questions*

1. TPPA procurement

a. Would the TPPA include any innovations in its procurement chapter?

b. How would the TPPA safeguard state and local procurement preferences?

c. When will USTR invite states to decide whether to participate in the TPPA procurement chapter?

2. GPA revisions

a. How do provisions for domestic challenge work in the United States?

b. Will USTR submit the revised GPA for congressional ratification? Is there a legal basis for not seeking congressional ratification?

c. Will USTR invite states to participate in the revised GPA?

3. US-EU trade agreement

Considering that EU countries are already party to the GPA, what are the implications of including procurement within a US-EU trade agreement?

4. China as a party to the GPA

a. When is China expected to join the GPA?

b. Considering China's demonstrated export capacity, what is the likely impact (on U.S. states) of China becoming a party of the GPA?

5. GATS rules on procurement of services

a. What is the status of these negotiations?

b. Is there a scenario by which WTO nations would apply GATS rules to all procurement of services (i.e., all state and local governments) regardless of GPA commitments?

6. EU/Japan complaint against Ontario's FIT program

a. USTR filed a brief that criticizes Canada's defense. Does the United States support the complaint by the EU and Japan against Ontario's FIT program?

b. If the EU's interpretations prevail, what are the implications for coverage of state and local procurement under GATT prohibitions on discrimination or prohibited subsidies under the Agreement on Subsidies and Countervailing Measures (SCM) agreement?

c. If the WTO adopts the EU's interpretation – that the GATT exclusion does not apply to procurement that favors local content – then what meaning is there in asking states to participate in FTA procurement chapters?

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I. Treatment of Tobacco in the TPPA

2012 Trade Policy Assessment
Prepared for the Maine Citizen Trade Policy Commission

Robert Stumberg[6]

Introduction

Should a 21st century trade agreement expand or restrict tobacco trade? The impact of the TPPA on tobacco controls is important in several respects. It could empower the tobacco industry's litigation strategy at a time when countries are striving to implement their obligations to restrict tobacco marketing under the Framework Convention on Tobacco Control (FCTC), the first global health treaty. With one exception, all TPPA countries are members of the world's first global health agreement, the Framework Convention on Tobacco Control (FCTC).[7] The exception is the United States,[8] which is home to the world's largest tobacco company, Philip Morris International (PMI).[9]

In January 2010, the U.S. Trade Representative (USTR) sought public comments on the TPPA. In its comments, PMI urged U.S. negotiators to treat tobacco trade like any other sector, as they have in prior trade agreements.[10] In particular, PMI asked USTR to include investor-state arbitration, incorporate WTO rules to protect tobacco trademarks and brands, and expand restrictions on regulation of cross-border services, including distribution of tobacco.[11] Public

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[7] WHO, Framework Convention on Tobacco Control, WHO Doc. A56/VR/4 (May 21, 2003), available at http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r1.pdf. *See generally* Allyn L. Taylor, Ruth Roemer and Jean Lariviere, *Origins of the WHO Framework Convention on Tobacco Control,* 95 AM. J. PUB. HEALTH 936 (20050; U. of Maryland Legal Studies Research Paper No. 2005-50, available at SSRN: http://ssrn.com/abstract=818984.

[8] A White House spokesman said on November 11th that President Obama "hopes to submit" the FCTC to the Senate for ratification in 2011. Duff Wilson, Cigarette Giants in a Global Fight on Tighter Rules: Governments Are Sued, New York Times A1, at A6 (November 14, 2010) [hereinafter Wilson, NYT, Cigarette Giants in a Global Fight].

[9] PMI, Company overview, available at http://www.pmi.com/eng/about_us/company_overview/pages/company_overview.aspx (viewed August 2, 2010). In 2008, PMI spun off as a subsidiary from Altria, "becoming the world's leading international tobacco company and the fourth largest global consumer packaged goods company." PMI, Our History, available at http://www.pmi.com/eng/about_us/pages/our_history.aspx (viewed November 17, 2010). Philip Morris USA ("the largest tobacco company in the US") remains a subsidiary of Altria, Philip Morris USA, available at http://www.philipmorrisusa.com/en/cms/Home/default.aspx (viewed November 17, 2010). PMI has a much more aggressive litigation strategy than does Philip Morris USA. *See* Wilson, NYT, Cigarette Giants in a Global Fight, at A6.

[10] PMI, Submission of Philip Morris International in Response to the Request for Comments Concerning the Proposed Trans-Pacific Partnership Trade Agreement (January 22, 2010) 2, available at http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a81299 (viewed August 11, 2010) [hereinafter, PMI, Comments on TPP].

[11] *Id.*

health advocates urged USTR to reject PMI's request and carve out tobacco from the TPPA altogether.[12]

Just a few weeks later, PMI invoked investor-state arbitration and WTO trademark rules to challenge Uruguay's limits on tobacco brands and packaging.[13] PMI sought arbitration under the Switzerland-Uruguay bilateral investment treaty (BIT).[14] Like most BITs, this one provides the remedy of monetary compensation for an investor's losses.[15] Following the strategy used by oil companies under the U.S.-Ecuador BIT,[16] PMI has also asked arbitrators to "suspend" Uruguay's new regulations.[17] The challenged regulations do the following: (1) limit PMI to a "single presentation" of a brand in order to eliminate "light" tobacco brands and (2) require 80% of a package (the most anywhere) to depict the risk of death and disease from smoking.[18]

A year later, PMI filed a similar investment claim against Australia upon adoption of a national plain packaging law that restricts trademarks on a package and requires graphic warnings.[19]

PMI wants the TPPA to include the same legal tools that it is using against Uruguay and Australia. If successful, PMI will be able to influence a much larger set of countries that want to

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[12] Joseph Brenner and Ellen Shaffer, co-directors of CPATH, Comments to USTR: Proposed United States-Trans-Pacific Partnership Trade Agreement [Docket: USTR–2009–0041] (January 25, 2010), available at http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a83af2 (viewed August 9, 2010) [hereinafter, CPATH, Comments on TPP].

[13] Request for Arbitration, FTR Holdings S.A. (Switzerland), Phillip Morris Products S.A. (Switzerland) and Abel Hermanos S.A. (Uruguay) v. Oriental Republic of Uruguay, ICSID case no. ARB/10/7, noticed February 19, 2010 and registered March 26, 2010 available at http://ita.law.uvic.ca/documents/PMI-UruguayNoA.pdf (viewed March 5, 2011) [hereinafter, PMI v. Uruguay complaint].

[14] Agreement between the Swiss Confederation and the Eastern Republic of Uruguay relating to the Promotion and Reciprocal Protection of Investments, SR 0.975.277.6, 22 April 1991 [hereinafter, Switzerland-Uruguay BIT].

[15] Switzerland-Uruguay BIT, art. 5(1) (Dépossession, compensation).

[16] Like the Switzerland-Uruguay BIT, the U.S.-Ecuador BIT does not expressly limit arbitration awards to money damages or restitution of property. More recent U.S. BITs (e.g., Uruguay) and investment chapters of free trade agreements (e.g., Peru and Korea) do limit the scope of awards. This alone could explain why PMI chose to litigate under the Switzerland-Uruguay BIT rather than the U.S.-Uruguay BIT. *Compare* Treaty Between the United States of America and the Republic of Ecuador Concerning the Encouragement and Reciprocal Protection of Investment, art. VI (disputes and awards), S Treaty Doc No 103-15 (1993), 11 May 1997 [hereinafter, U.S.-Ecuador BIT] *with* Treaty Between the United States of America and the Oriental Republic of Uruguay Concerning the Encouragement and Reciprocal Protection of Investment, art. 31(1) (limiting arbitrators to awarding monetary damages and restitution of property), S Treaty Doc No 109-9 (2006), 1 November 2006 [hereinafter, U.S.-Uruguay BIT]. *See also* U.S.-Peru TPA, art. 10.26; proposed U.S.-Korea FTA, art. 11.26.

[17] PMI v. Uruguay complaint, ¶¶ 88-94 (relief sought). In Chevron's BIT claim against Ecuador, Chevron asked the arbitrators for interim measures, which include ordering Ecuador (1) "to use all measures necessary to enjoin enforcement of any judgment against Chevron" and (6) "to refrain from taking any action that would aggravate, exacerbate or extend the dispute in question." Chevron Corp. and Texaco Petroleum Co. v. Republic of Ecuador, Claimants' Request for Interim Measures (April 1, 2010) ¶ 14(a). In response, the arbitrators are monitoring domestic court proceedings against Chevron, and they ordered the parties to "maintain, as far as possible the status quo and not to exacerbate the procedural and substantive disputes." Chevron Corp. and Texaco Petroleum Co. v. Republic of Ecuador, Order on Interim Measures (May 14, 2010) ¶ 1(i).

[18] PMI v. Uruguay complaint, ¶¶ 20-38, 44-46 (single presentation), ¶¶ 39-42, 47 (demeaning pictographs and percent of package warning).

[19] Notice of Arbitration, Philip Morris Asia Ltd. v. Commonwealth of Australia, noticed Nov. 21, 2011 (hereinafter "PM v. Australia Notice of Arbitration"), *available at* http://www.ag.gov.au/Internationallaw/Pages/Investor-State-Arbitration---Tobacco-Plain-Packaging.aspx (viewed June 8, 2012).

exceed the "floor" of regulations required by the Framework Convention on Tobacco Control.[20] PMI candidly admits that it is targeting tobacco regulations in another TPPA country, Singapore. If the TPPA covers tobacco trade and investment, PMI would also have a platform to challenge future tobacco regulations in the United States (e.g., through a subsidiary in another TPPA country). In 2009, Congress delegated authority to the Food and Drug Administration to regulate tobacco products; this delegation is similar to the authority that PMI is targeting in Singapore.[21]

This report has three parts:

- *TPPA threats to tobacco controls.* First, we identify provisions in five TPPA chapters that could be used to undermine or challenge tobacco controls. These include:
  - *Investment,* a chapter that would expand investor-state arbitration among TPPA countries, and potentially, expand opportunities for treaty shopping.
  - *Intellectual property*, where the United States proposes new trademark protections that would benefit tobacco companies.
  - *Cross-border services*, a chapter that would expand application of trade rules that limit regulation of tobacco-related services such as advertising and distribution.
  - *Regulatory coherence*, a chapter that includes obligations for stakeholder participation that could undermine an FCTC obligation to limit the influence of tobacco companies.
  - *Tobacco tariffs*, where the United States proposes zero tariffs for a range of tobacco products.
- *The U.S. proposal for a tobacco exception.* Second, we explain the U.S. proposal to provide a "safe harbor" for tobacco regulations – and our assessment of shortcomings in that proposal.
- *Conclusion*. Third, we present an agenda of potential topics and questions for oversight of trade policy that affects tobacco controls.

TPPA threats to tobacco controls

1. Investment

As a result of the PMI cases against Uruguay and Australia, the most publicized part of the TPPA is the investment chapter. This chapter provides a set of substantive and procedural rights that foreign investors can use to challenge regulatory measures that decrease the profitability of their investments.[22]

a. ***Right of foreign investors to litigate outside of domestic courts*** **–** In general, only nation-states ("states") have the ability to bring claims under international law against other states. Under some international investment agreements (IIAs), including both bilateral investment treaties and the investment chapters of free trade agreements (FTAs), foreign investors are given the right to challenge states directly in international arbitration proceedings. Known as "investor-state

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[20] WHO, Parties to the WHO Framework Convention on Tobacco Control, available at http://www.who.int/fctc/signatories_parties/en/index.html (viewed August 2, 2010).

[21] *See* "Number of brands and marketing terms," notes 38-39 below, with accompanying text.

[22] *See Outlines of the Trans-Pacific Partnership Agreement* (Nov. 12, 2011)*, available at* http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement.

dispute settlement" (ISDS), this process provides tobacco companies with three points of leverage against tobacco regulations:

i. *Monetary compensation* – Usually foreign investors use this process to seek monetary damages. PMI, for example, is using ISDS under the Hong Kong – Australia Bilateral Investment Treaty to seek "billions of Australian dollars" from Australia for its tobacco packaging laws.[23]

ii. *Injunctive intervention* – Increasingly, investors are also asking tribunals to order governments to stop enforcing regulations that they consider to be too burdensome. PMI is seeking such orders in its investment claims against Australia and Uruguay.[24]

iii. *Cost of arbitration* – The cost of international arbitration typically runs several million dollars (US), an amount that eclipses tobacco control budgets in most countries. Advocates assert that the industry pushes litigation to divert scarce funds and government resources away from anti-tobacco campaigns.[25] The industry has been remarkably candid in saying that one of its litigation tactics is to "spare no cost in exhausting their adversaries' resources."[26]

b. ***Foreign investor protections*** **–** The investment provisions of the TPPA will also provide tobacco companies with powerful substantive rights that can be used to undermine tobacco regulations. These include:

i. *Expropriation* – This provision has been interpreted to require countries to compensate foreign investors when laws have a "significant" or "substantial" adverse effect on the value of an investment. PMI is arguing that Australia's plain packaging legislation expropriates its investments by depriving it of intellectual property and decreasing the value of the shares of its subsidiary in Australia.[27]

ii. *Fair and equitable treatment (FET)* – This provision been interpreted to provide foreign investors with a right to a "stable and predictable regulatory environment" that protects their expectations concerning the profitability of their investments. PMI argues that Uruguay's tobacco labeling laws frustrate its "legitimate expectations" concerning its use of brands, trademarks and other investments in Uruguay. PMI suggests that Uruguay frustrated its expectations by, among other things, violating the

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[23] PMI v. Australia, Notice of Arbitration, para. 8.3.

[24] *See* PM v. Australia Notice of Arbitration, para. 8.2 ("PM Asia seeks an order for the suspension of enforcement of plain packaging legislation . . . ."); PM v. Uruguay Request for Arbitration, para. 88 ("the Claimants respectfully request that the Arbitral Tribunal order the suspension of the application [of the packaging laws]").

[25] J K Ibrahim and Stanton A Glantz, Tobacco industry litigation strategies to oppose tobacco control media campaigns, 15 Tobacco Control 50, 54 (February 2006), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563618/ (viewed Feb. 29, 2012).

[26] Robert L. Rabin, *A Sociological History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 857 (1992); *see also* Brief of Amici Curiae Tobacco Control Legal Consortium and Tobacco Control Resource Center, Howard A. Engle, M.D., et. al., Petitioners, vs. Liggett Group, Inc., et. al., Respondents. (Florida 2004), available at http://www.law.fsu.edu/library/flsupct/sc03-1856/03-1856amicus.pdf (viewed February 29, 2012).

[27] *See* PMA v. Australia, Notice of Arbitration, para. 7.3. *See also* PM v. Uruguay Request for Arbitration, paras. 82-83 (asserting that Uruguay's cigarette packaging regulations expropriate Philip Morris' intellectual property rights).

provisions of the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS).[28]

Several countries involved in the TPPA negotiations have previously attempted to constrain broad interpretations of FET by linking it to customary international law (CIL), which requires the investor to prove that its claim is based on a "general and consistent practice of States" that countries follow out of a sense of legal obligation (*opinio juris*).[29] In practice, however, arbitrators rarely examine actual state practice. Instead, they simply cite the awards of other tribunals[30] or the text of other investment treaties[31] in support of broad interpretations of FET.

2. Intellectual property

A central issue in tobacco investment disputes is whether companies have a right to use their trademarks – such that a government must compensate the company if government restricts the use of trademarks.

In February 2011, a draft of the U.S. Trade Representative's (USTR) proposed chapter on intellectual property (IP) in the TPPA was leaked to the public. Among many increased protections for IP, Article 2:22 of the draft contains language that requires that TPPA countries *shall permit the registration and use* of signs and indications that refer ro a geographic area that is not the true place of origin of a product. (There is no established term for this provision, so we refer to it as "Art. 2:22 protections").[32] This language creates and protects a new type of IP with a higher level of legal protection than what is

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[28] *See* PMI v. Uruguay Request for Arbitration, paras. 84-85. *See also* PM v. Australia Notice of Arbitration, paras. 7.6 -7.8 (assertion that failure to protect expectations concerning Philip Morris's investment in Australia).

[29] S*ee, e.g.,* Agreement Establishing the ASEAN-Australia-New Zealand Free Trade Area, ch. 11, art. 6(2)(c), Feb. 27, 2009, *available at* http://www.dfat.gov.au/fta/aanzfta/chapters/chapter11.html#fr6 ("[T]he concepts of 'fair and equitable treatment' and 'full protection and security' do not require treatment in addition to or beyond that which is required under customary international law, and do not create additional substantive rights."); U.S. Model Bilateral Investment Treaty, art. 5.2, 2004, *available at* http://www.ustr.gov/sites/default/files/U.S.%20model%20BIT.pdf ("The concept… of 'fair and equitable treatment' . . . do[es] not require treatment in addition to or beyond that which is required by [customary international law], and do[es] not create additional substantive rights").

[30] *See* Moshe Hirsch, *Sources of International Investment Law* at 27 (International Law Association Study Group on the Role of Soft Law Instruments in International Investment Law, Working Paper No. 05-11, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1892564 ("An examination of decisions rendered by investment tribunals indicates that investment tribunals that pronounce various customary rules are inclined *not* to discuss the existence (or lack of) of the separate components of 'practice' and '*opinion juris'*, and that they frequently rely on decisions of international courts and tribunals . . . ."); Stephan W. Schill, *From Sources to Discourse: Investment Treaty Jurisprudence as the New Custom?* at 2 (2011) ("Investment treaty tribunals . . . generate and implement a multilateral structure for international investment relations . . . not by reference to customary international law, but by referencing their own jurisprudence.")

[31] S*ee* Charles H. Brower, II, *Why the FTC Notes of Interpretation Constitute a Partial Amendment of NAFTA Article 1105,* 46 VA. J. INT'L L. 347, 358 **(**2006) ("[T]o the extent that treaties codify existing custom, their content should influence the application of [FET provisions] . . . . Alternatively, the widespread adoption of multilateral or bilateral treaties may reflect state practice sufficient to influence the development of custom . . . .")

[32] United States Trade Representative, Draft Trans-Pacific Partnership Intellectual Property Chapter, Chapt. 18, Art. 2:22, *available at* http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf [hereinafter Draft TPPA IP Chapt.]. While the draft IP Chapter refers to "products and services," this memo will focus only on products.

offered other types of IP.

Article 2:22 is included under a sub-heading, "geographical indications" (GIs), but it treats reference to a place differently than a GI does. GIs are a type of IP that allows a producer to market a product based on the reputation of a particular place so long as it originates in that place. Products like Champagne, Prosciutto di Parma and Parmigiano-Reggiano cheese are examples of GIs that are protected in the EU. Art. 2:22 protects products based on an opposite rationale.

The proposed Art. 2:22 protections would establish a right of producers to use place names that refer to products that do not actually come from that place, as routinely occurs with cheeses like parmigiano, romano, provolone and Swiss. The dairy industries of the United States, Australia, New Zealand, and several Latin American countries are pushing hard for inclusion of this language. They see the TPPA as an important battle in their on-going war with the EU over protections for names of cheeses and other products.[33] They assert that such names have become "common" or "generic" from repeated use outside of their home geographic area and therefore cannot be protected as IP.[34] Because the EU has attempted to expand the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to protect such names as GIs,[35] the dairy industry and its allies see these new Art. 2:22 protections as an opportunity to effectively block that expansion.

While they may have been intended to protect the dairy industry, Art. 2:22 protections could be easily exploited by the tobacco industry. There are numerous well-known trademarks that indicate geographical areas that are no longer the place of origin of the product: Camel Turkish Gold, Marlboro, Newport, Winston, Salem, Kent, Winfield, Chesterfield, Virginia Slims, Hollywood, and many others.

In late March 2012, the U.S. dairy industry announced a sweeping initiative to promote the protection of cheese names using the TPPA and Art. 2:22. The industry expressed its confidence that USTR is "very supportive." Intentionally or not, this provision could reinforce the litigation strategy of tobacco companies to challenge restrictions on use of trademarks. Even if PMI loses its investment claims based on current law, the U.S. proposal for the TPPA's IP chapter could spawn yet another round of litigation.

3. Cross-border services

Without trade in services, trade in goods cannot occur. Every sale of a good results from multiple services such as advertising, transport and distribution. Services once thought of as domestic may now be provided from almost anywhere in the world. The WTO's General Agreement on Trade in Services (GATS) created a system of trade rules to promote trade through "progressive liberalization" of domestic regulations.[36] In essence, a country agrees to restraints on its sovereign ability to regulate services. These trade rules have been echoed and expanded in subsequent free trade agreements (FTAs). The TPPA will include a chapter on cross-border trade in services, which will expand the

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[33] New Initiate Aims to Expand Reach of Fight to Counteract EU on GIs, Inside U.S. Trade, March 30, 2012.

[34] Id.

[35] *See* Bernard O'Connor, The Law of Geographic Indications 50 (2006).

[36] WTO, *The General Agreement on Trade in Services (GATS): objectives, coverage and disciplines*, http://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm (last visited Apr. 29, 2012).

reach of trade rules.

a. ***Coverage of tobacco-related sectors*** **–** From production through consumption, tobacco trade involves a variety of service sectors: advertising, packaging, wholesaling, and retail distribution, among others. Each of the TPPA countries has implemented tobacco control regulations that affect trade in these service sectors.[37] Countries can specifically *exclude* a service sector (or a particular regulation, e.g., a partial ban on tobacco advertising) by listing it in Annex II for non-conforming measures. If they do not, the country will be bound to follow the market access and national treatment rules for all regulations affecting that sector. For most countries, this would be a significant expansion of commitments (compared to GATS). The United States already has broad commitments under GATS for tobacco-related sectors. As a consequence, the TPPA does not pose a major expansion for the United States; its commitments are already in place.

b. ***Limits on regulation of tobacco***

i. *Market access rules* **–** GATS Article XVI, Market Access, prohibits certain types of quantitative regulations including quotas, limits on the number of suppliers, limits on the value of transactions, and limits on the participation of foreign capital, among others.[38] The WTO Appellate Body has ruled that an absolute ban on a service is inconsistent with the prohibition of quotas (i.e., a ban is a "zero quota").[39] Commentators are divided on whether a ban on tobacco-related services violates the prohibition on zero quotas. Some argue that any ban that allows zero services of a certain type or product is *quantitative*; it amounts to a zero quota. Others argue that a ban on service related to a product like tobacco is *qualitative* because of the product distinction. Hence, it is not covered by market access rules.[40] If a country wants to limit tobacco-related services, it can avoid the risk of a *market access* conflict by inserting in Annex II a broad reservation to safeguard all measures that affect tobacco-related trade or investments.

ii. *Disciplines on domestic regulation* **–** Recent free trade agreements such as the U.S.–Korea Free Trade Agreement (FTA) allow either party to

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[37] The schedule of GATS commitments for each TPPA negotiating country can be accessed though the WTO GATS Database, available at http://tsdb.wto.org/. For an overview of tobacco control laws, see Campaign for Tobacco Free Kids, Legislation, available at http://www.tobaccocontrollaws.org/legislation/.

[38] GATS Article XVI:2

[39] *See* Appellate Body Report, United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services, (WT/DS285/AB/R) (April 20, 2005) ¶¶ 238-239 ("a prohibition on one, several or all means of delivery crossborder" is a 'limitation on the number of service suppliers in the form of numerical quotas' within the meaning of Article VI:2(a) because it totally prevents the use by service suppliers of one, several or all means of delivery that are included in mode 1.").

[40] *See e.g.,* Eric H. Leroux, *Eleven Years of GATS Case Law: What Have We Learned*, 10 J. Int'l Econ. L. 749 at 775 (2011) (suggesting that future disputes will consider the "purpose/rationale" of a nondiscriminatory measures before applying the market access rules); Lode Van Den Hende & Herbert Smith, *GATS Article XCI and National Regulatory Sovereignty: What Lessons to Draw From US-Gambling*, in THE WORLD TRADE ORGANIZATION AND TRADE IN SERVICES 466 (Kern Alexander and Mads Andenas eds., 2008) (Discussing the *US-Gambling* decision and the likely analysis of restrictions on advertising services).

limit its sector commitments to follow market access rules.[41] However, the FTA does not allow either party to deviate from "disciplines on domestic regulation." There are several such disciplines; the most significant one is found in the ASEAN-Australia-New Zealand Free Trade Area (AANZFTA), which requires that a regulation must be "not more burdensome than necessary to ensure the quality of the service."[42] This so-called "necessity test" requires governments to prove that their approach is less of a burden on trade than other approaches they considered, and it limits the regulatory objective to quality of the service, as opposed to protecting public health. Tobacco regulations are generally unconcerned with competence of distributors or ensuring the quality of the service; they are intended to stop the spread of tobacco use.

Regulatory coherence

The tobacco industry wants to limit governments to regulations that are "least impairing" of property rights, and "produce benefits that outweigh the costs … to the public or persons."[43] Several TPPA countries (Australia, New Zealand, Singapore, Chile and Brunei) have included a similar test in their FTA chapters on services, which require that regulations are "not more burdensome than necessary to ensure the quality of the service."[44] Australia and New Zealand, among others, have pushed the WTO to apply a necessity test to limit regulation of advertising, distribution, and other services.[45] In opposition, countries that usually support trade liberalization (Brazil, Canada, and the United States) argue that a necessity test "threatens the crucial discretion that regulators must maintain to … take into account legitimate policy objectives."[46] In fact, the United States has deleted the necessity test from the services chapter of its most recent FTAs.[47]

The draft TPPA chapter on Regulatory Coherence (RC) could support tobacco companies through stakeholder participation and a cost-benefit approach similar to necessity tests that have failed to reach consensus within the WTO negotiations as noted above.[48]

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41 U.S. – South Korea FTA, Chapter 12, Cross-Border Trade in Services.

42 AANZFTA Agreement, Chapter 8, Trade in Services.

43 *See, e.g.,* Imperial Tobacco New Zealand Limited, Submission to the Commerce Select Committee on the Regulatory Standards Bill, ¶¶ 3.4, 3.9, 3.10 (August 2011), in support of Hon Rodney Hide, Regulatory Standards Bill, § 7 Principles (2011).

44 Trans-Pacific Strategic Economic Partnership (the "P4" – New Zealand, Singapore, Chile, Brunei), art. 12.10.2(b).

45 Working Party on Domestic Regulation, Room Document from New Zealand, The Necessity Test in the Disciplines on Domestic Regulation, RD/SERV/39 (9 February 2011); Working Party on Domestic Regulation, Communication from Australia; Chile; Hong Kong, China; New Zealand and the Separate Customs Territory of Taiwan, Kinmen and Matsu, Article VI:4 Disciplines – Proposal for Draft Text, JOB(06)/193 (19 June 2006); *see generally,* Robert Stumberg, *GATS Negotiations on Domestic Regulation* (June 15, 2010).

46 Working Party on Domestic Regulation, Communication from Brazil, Canada and the United States, S/WPDR/W/44 (Mar. 22, 2011).

47 Compare the provisions on domestic regulation of the 2011 US-Korea FTA (Article 11.7.2) with the 2009 US-Peru FTA (Article 11.7.2(b)).

48 *See* Working Party on Domestic Regulation, Disciplines on Domestic Regulation Pursuant to GATS Article VI:4, Chairman's Progress Report, S/WPDR/W/45, 17-18 (April 14, 2011).

a. *Stakeholder participation*

i. *International coordinator* – The RC chapter would create a Committee on Regulatory Coherence that will monitor the efforts of TPPA countries to comprehensively reform their regulatory systems. The committee "shall establish mechanisms to ensure meaningful opportunities for interested persons to provide views on approaches to enhance regulatory coherence."[49] Historically, the "persons" with greatest interest have been highly regulated industries such as tobacco.

ii. *Threat to tobacco control* – The Framework Convention on Tobacco Control is the first global health treaty with 174 Parties.[50] For the TPPA countries other than the United States (the only one that has not ratified the FCTC), Article 5.2(b) of the FCTC obligates each party to "adopt … policies for preventing and reducing tobacco consumption." It further requires that "Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry." Contrary to these obligations, the RC chapter requires TPPA countries to directly "collaborate" with the tobacco industry as a stakeholder in the regulation of tobacco trade.[51]

b. *Cost-benefit approach*

i. *Regulatory impact assessment (RIA)* – The RC chapter encourages analysis of regulations based on an RIA method that roughly parallels the WTO jurisprudence for applying a necessity test.[52, 53] Among other things, the RIA method should –

- identify the "problem and policy objectives" of a new regulation;
- identify "potentially effective and reasonably feasible alternatives" (On this point, the WTO jurisprudence requires a challenging government to identify the alternatives; the RIA sets this as a task for a host government that is defending its measure.[54]);

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[49] TPP Regulatory Coherence, art. X.6

[50] WHO, Parties to the WHO Framework Convention on Tobacco Control, http://www.who.int/fctc/signatories_parties/en/ (viewed Feb. 28, 2012).

[51] The World Health Assembly formally urged its member nations "to be alert to any efforts by the tobacco industry to continue its subversive practice and to assure the integrity of health policy development in any WHO meeting and in national governments." World Health Assembly, Resolution 54.18: transparency in tobacco control, ¶ 2 (2001); *see also* WHO, *Tobacco industry interference with tobacco control*, 2 (2008) available at http://whqlibdoc.who.int/publications/2008/9789241597340_eng.pdf (viewed Feb. 28, 2012).

[52] *See generally,* WTO Secretariat, *"Necessity Tests" in the WTO*, S/WPDR/W/27 (Dec. 2, 2003).

[53] The RIA also reflects the national practice of Australia, New Zealand, and the United States, as well as methods promoted by the OECD and APEC. *See* Jane Kelsey, Preliminary Analysis of the Draft TPP Chapter on Domestic Coherence (Oct. 23, 2011), 3-5, available at http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific_RegCoherenceMemo.pdf (viewed Feb. 28, 2012).

[54] *See* Demitrios Delimatsis, *GATS and Public Health Care: An Uneasy Relationship*, TILEC Discussion Paper, DP 2012-005, 17 (2012), available at http://ssrn.com/abstract=2001918 (viewed February 29, 2012).

- identify how regulators conclude that a regulation "maximizes net benefits, including qualitative benefits, while also considering distributional impact;"
- assess "costs and benefits of each available alternative, including not to regulate"; and
- explain "why the alternative chosen is superior … through reference to the relative size of the net benefits of the available alternatives."

ii. *Threat to tobacco control* –Tobacco companies, as foreign investors, and TPPA governments could use evidence generated by an RIA to challenge tobacco control measures under other trade or investment rules:[55]

- *Investment* – New Zealand's Imperial Tobacco has already cited a government RIA to lobby against tobacco display regulations.[56] If Imperial were a foreign investor, it could reframe its alleged breaches of New Zealand's RIA process as a denial of fair and equitable treatment under the TPPA's investment chapter. If an RIA quantifies costs borne by investors, they could use it to challenge a measure as sufficiently burdensome to be an indirect expropriation.
- *Technical barriers to trade* – Tobacco controls have recently been challenged on grounds that they violate the WTO's Agreement on Technical Barriers to Trade (TBT), which requires measures to be "not more trade-restrictive than necessary."[57] A country could use evidence from an RIA to argue that a tobacco control fails this "necessity" test.
- *Services* – Based on recent FTAs of several countries, there might be a necessity test in the chapter on services. Even if there is not, a country might be able to use an RIA as evidence to challenge tobacco control measures under WTO disciplines on domestic regulation, which would be incorporated into the TPPA at a future date.[58]

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[55] *See* Jane Kelsey, International Trade and Investment Law Issues Relating to New Zealand's Proposed Tobacco Control Policies to Achieve an Effectively Smokefree New Zealand by 2025, § 3.7.2 Regulatory Coherence, 2012 (forthcoming).

[56] Imperial Tobacco New Zealand Limited, Submission to the Commerce Select Committee on the Regulatory Standards Bill, ¶ 2.6 (August 2011).

[57] WTO, Agreement on Technical Barriers to Trade (TBT), art. 2.2. The WTO dispute panel rejected Indonesia's challenge of the U.S. ban on clove flavoring in cigarettes on a number of grounds.

[58] *See, e.g.,* Korea-US Free Trade Agreement, art. 12.7.3.

4. Tariffs

All TPPA countries have limited their ability to use tobacco tariffs; each has limited the maximum tariffs that it may charge ("tariff bindings") upon joining the WTO.[59] Nonetheless, some TPPA countries have high WTO tariff bindings for tobacco. Singapore has a bound tariff for cigarettes of $115/kg, and Vietnam has a bound tariff for cigarettes of 135%.[60] When countries join a trade agreement like the TPPA after they join the WTO, the WTO tariff rates are enforceable among WTO members, and the lower TPPA tariffs would be enforceable among TPPA members.

a. ***The TPPA eliminates tariffs that are permitted under the WTO –*** Today, applied tobacco tariffs are almost always well below WTO tariff bindings. Some countries, such as Singapore and Brunei, do not apply tariffs to tobacco products.[61] Vietnam, Peru, New Zealand, Malaysia, and Chile each apply a tariff of at least 5% to cigarettes. Vietnam, Peru, Malaysia, and Chile apply a tariff of at least 5% to unmanufactured tobacco. As it stands, the TPPA would eliminate these altogether by binding countries to "zero" tariffs in their tariff schedules. It would also keep countries from raising tobacco tariffs in the future, even when it would be beneficial to their public health objectives. Members would not be able to apply tariffs to tobacco imported from other TPPA countries, even when doing so is consistent with their WTO commitments.

b. ***Eliminating tariffs can increase tobacco use and tobacco-related disease –*** In 1999, the World Bank published a landmark report on global tobacco control entitled *Curbing the Epidemic: Governments and the Economics of Tobacco Control*.[62] The report notes that trade liberalization, including the reduction or elimination of tariffs, can cause tobacco use to rise as much as 10%.[63] Greater competition among companies lowers prices and increases advertising and

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[59] TPPA countries joined the WTO in 1994, except for Viet Nam, which joined in 2007. World Trade Organization, *Goods Schedules: Members' Commitments*, http://wto.org/english/tratop_e/schedules_e/goods_schedules_e.htm (last accessed February 28, 2012); World Trade Organization, *Current Situation of Schedules of WTO Members*, http://wto.org/english/tratop_e/schedules_e/goods_schedules_table_e.htm (last accessed February 28, 2012).

[60] World Trade Organization, *WTO Tariff Analysis Online*, http://tariffdata.wto.org/ (last accessed February 28, 2012).

[61] Singapore, however, does levy excise duties on imported tobacco. *Singapore Customs: List of Dutiable Goods*, http://www.customs.gov.sg/leftNav/trad/val/List+of+Dutiable+Goods.htm, last accessed February 21, 2012. New Zealand, Australia, Brunei, and Singapore do not charge customs duties on unmanufactured tobacco. *World Trade Organization Tariff Analysis Online*, last accessed February 6, 2012.

[62] The World Bank, *Curbing the Epidemic: Governments and the Economics of Tobacco Control* 14, available at www.usaid.gov/policy/ads/200/tobacco.pdf. According to Professsor Frank Chaloupka's research, cigarette consumption per person in Japan, South Korea, Taiwan, and Thailand was nearly 10 percent higher after the elimination of tariffs and non-tariff trade barriers than they would have been if these measures had remained in place.

[63] *Id.* See also Chaloupka and Laizuthai, *US Trade Policy and Cigarette Smoking in Asia*, National Bureau of Economic Research (1996); Taylor, et al, *The Impact of Trade Liberalization on Tobacco Consumption* (2004).

product promotion, which leads to greater tobacco use overall.[64] The report also confirms that trade liberalization has the greatest impact on tobacco use in low and middle-income countries.[65] Other analysis shows that tobacco tariffs can reduce tobacco use in countries that import most of their tobacco products and in countries with significant competition between domestic and imported tobacco.[66]

c. ***Revenue from tobacco tariffs can support the fight against tobacco use*** – In the current economic climate, governments are cutting public health programs that target tobacco.[67] Yet the World Health Organization has called for an increase in government programs such as media campaigns and subsidies for products that help smokers quit.[68] While important for public health, these programs cost money. A corresponding increase in domestic taxes to substitute lost tariff revenue can be difficult, particularly in low- and middle-income countries. Middle-income countries generally recover only 45- 60% of lost tariff revenue through other sources. Low-income countries recover 30%. [69] Retaining the flexibility to generate revenue from tobacco tariffs can help governments keep needed public health programs that reduce tobacco-related disease.

The U.S. proposal for a tobacco exception

Caught between tobacco growers from key electoral states and a rising tide of global litigation by tobacco companies, the Obama Administration is seeking a compromise. The USTR proposes to treat tobacco in the TPPA as follows:[70]

1. Explicitly "recognize the unique status of tobacco products from a health and regulatory perspective."
2. Eliminate tariffs on tobacco products.
3. Provide "language in the 'general exceptions' chapter that allows health authorities in TPPA governments to adopt regulations that impose origin-neutral, science-based restrictions on specific tobacco products/classes in order to safeguard public health."

Leading tobacco-control advocates have commended the U.S. government's recognition that tobacco controls merit a safe harbor from trade litigation. They stress "that there is a global consensus that nations should act to reduce tobacco use, and that trade agreements should not

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64 The World Bank, supra note 3 at 14.

65 The World Bank, supra note 3 at 2, 14-15.

66 Campaign for Tobacco-Free Kids, *Public Health and International Trade Volume II: Tariffs and Privatization* 7-8 (2002).

67 *See e.g., States called on to restore anti-smoking funds*, The Wall Street Journal (February 25, 2012), http://online.wsj.com/article/AP78f5c536312b40d3b5cf4d67c0ca490d.html.

68 World Health Organization Regional Office for Southeast Asia, *Innovative Financing from Tobacco Taxation for Health Promotion*, (2011).

69 Baunsgaard and Keen, *Tax Revenue and [or?] Trade Liberalization* (June 2005), IMF Working Paper, http://www.imf.org/external/pubs/ft/wp/2005/wp05112.pdf.

70 USTR, TPP Tobacco Proposal (May 2012), available at http://www.ustr.gov/about-us/press-office/fact-sheets/2012/may/tpp-tobacco-proposal (viewed May 19, 2012).

undermine the authority of governments to do so."[71] The question is whether the U.S. proposal for a tobacco exception accomplishes this goal. The following is a summary of our preliminary analysis of shortcomings in the U.S. proposal. The USTR will not release the actual text, so this report is based on the written summary and several briefings by the staff of USTR.

1. Scope of the proposed exception

a. ***Domestic regulations*** – The proposal covers regulations adopted by a health authority. As proposed, the exception:

i. Does not cover legislation. While the exception would apply to rules that are issued to implement legislation, the exception would not block a challenge if a standard for regulation is initially adopted in the legislation itself.

ii. Does not cover regulations adopted by non-health authorities, some of which implement subnational regulations. These include tax, license, consumer, environment, intellectual property, and customs authorities. At the state and local level, these non-health authorities are more likely to issue tobacco regulations.

iii. May not cover enforcement of existing measures. It covers adoption of new measures. In WTO trade agreements, the exceptions are explicitly worded to cover adoption and enforcement of measures.

iv. If interpreted literally, the exception may be limited to regulations that directly regulate a product (e.g., not regulations that affect tobacco-related services like advertising or Internet sales).

- *Alternatives* – To foreclose the challenges already being litigated, an exception could cover adoption or enforcement of any measure that regulates or affects investment or trade in tobacco products.

b. ***TPPA rules*** – The proposal does not cover three trade or investment rules – national treatment, compensation for expropriation, and transparency – all of which are being used to challenge tobacco control measures. USTR staff says that compensation for indirect expropriation is not covered because it does not prohibit measures; it requires compensation. If it covers only rules that expressly prohibit certain measures, then the exception is much narrower than advertised. There are several other investor protections (e.g., fair and equitable treatment) that do not expressly prohibit certain measures.

- *Alternatives* – A truly general exception would apply to all rules in all chapters so as to foreclose the challenges already being litigated against tobacco control measures. A simple carve-out would be more effective; it would say that nothing in the TPPA applies to measures that affect tobacco trade or investment.

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[71] Letter to Amb. Ron Kirk, USTR, from the American Heart Association, the Cancer Action Network, the American Lung Association, and the Campaign for Tobacco-Free Kids (May 7, 2012), available at http://www.tobaccofreekids.org/content/what_we_do/federal_issues/trade/20120507_ngo_letter.pdf (viewed May 19, 2012). *See also* Letter to Amb. Ron Kirk, USTR, from the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American College of Physicians, the American College of Preventive Medicine, the American Medical Association, and the Center for Policy Analysis on Trade and Health (CPATH), (May 15, 2012), available at http://www.cpath.org/sitebuildercontent/sitebuilderfiles/med_pub_health_tpp_tobacco_16_may_2012.pdf (viewed May 19, 2012) (hereafter, medical associations' letter).

2. **Substantive tests**

   a. ***Origin-neutral*** – The term "origin-neutral" is open to interpretation and could enable an investor or government to challenge *de facto* discrimination, as Indonesia did in the clove cigarettes case.
      - *Alternatives* – A "facially neutral" (or origin-neutral on its face) test would prevent overt discrimination while preserving incremental regulation.

   b. ***Science-based*** – A "science-based" test would have to be interpreted by a dispute panel, which could draw upon a range of possible interpretations. The existing health exception in GATT applies to measures that are "necessary." The WTO's Appellate Body has ruled that a necessary measure must contribute to the health objective, but the contribution need not be proven with "science-based" evidence. In this regard, the proposed exception may be more stringent than the existing health exception.
      - *Alternatives* – To be parallel with the existing health exception, a tobacco exception could require only that a measure be rationally related to its health objective. A stronger exception would be self-judging: any measure that a party chooses to restrict tobacco trade or investment.

3. **Compliance with Executive Order 13193**

   A U.S. law (the Doggett Amendment) and Executive Order 13193 both prohibit federal agencies (i.e., USTR) from seeking the reduction of foreign governments' restrictions on tobacco marketing. In the briefings, USTR staff was asked how the U.S. proposal for treatment of tobacco (reducing tariffs and providing a narrow exception) complies with these prohibitions. Their response was that the prohibition had not been an obstacle in the past, and they view it as only a bar to direct marketing of tobacco products by the U.S. government. This does not square with the Executive Order, which explicitly applies to international trade policy.

Agenda for oversight of trade policy

1. **Exception or carve-out.** The proposed exception falls short of providing a brake on the trade or investment rules already being used to challenge tobacco control measures. If each element were fixed (as noted above), the result would be a stronger exception. But it would still leave governments vulnerable to expensive challenges, which have become the tobacco industry's weapon of choice. The general question is, how should TPPA governments adjust the "safe harbor" from threats to their tobacco controls under the FCTC, the first global health treaty? More specifically, the Maine CPTC could recommend whether the U.S. proposal should provide stronger safeguard from trade or investment disputes. Options include:
   a. ***As proposed*** – a narrow exception for rules adopted by health authorities that does not apply to national treatment, indirect expropriation or transparency obligations.
   b. ***A stronger exception*** – e.g., one that covers legislation and all trade and investment rules.
   c. ***A clear carve-out*** – which would simply say that the TPPA does not apply to tobacco trade or investment. This option would minimize the threat of expensive litigation.

2. ***Compliance with policy on tobacco trade***. With or without the proposed exception, are U.S. negotiators honoring the directives of the Doggett Amendment and the Executive Order, which prohibit promoting tobacco or undermining other countries' restrictions on tobacco trade?

HARRISON INSTITUTE FOR PUBLIC LAW
GEORGETOWN LAW

II. Pharmaceutical Provisions in the TPPA

2012 Trade Policy Assessment
Prepared for the Maine Citizen Trade Policy Commission

Robert Stumberg[72]

Introduction

If there is one thing that most Americans agree on, it is that true health care reform has to tackle the mounting costs of care. Yet cost-containment and affordability are not the theme of U.S. proposals for rules to govern pharmaceutical trade. In fact, the rules being proposed limit the options of government to use methods that are proven to work. Maine's progress in containing the cost of Medicaid prescription drugs is a case in point.

Prescription drug spending in the United States has pushed upwards of $250 billion – six times the level spent in 1990. The federal government paid $78 billion (38%) of this total.[73] Between 2006 and 2010, prices for the most commonly used drugs increased 70% faster than other health goods and services and 150% faster than generic drugs with the same active ingredients.[74] In 2010, Americans spent $220.3 billion at private pharmacies for an average of 12 prescriptions per person. Maine residents spent $1.18 billion of that total (15.1 prescriptions per person).[75]

State governments endured a dramatic jump in their share of Medicaid prescription drug costs, which increased 13.1% per year for 15 years (1990 to 2005) until drugs accounted for 10.1% of state Medicaid payments.[76] With Maine in a leadership role, the state governments responded by

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[73] Government Accountability Office, Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs (February 10, 2011) 1; Kaiser Family Foundation, Prescription Drug Trends (May 2010) 1. Available at http://www.kff.org/rxdrugs/upload/3057-08.pdf (viewed June 5, 2012).

[74] Stephanie Kirchgaessner, "Big Pharma faces challenge on drug prices," *Financial Times* (March 29, 2011), available at: http://www.ft.com/intl/cms/s/0/aadf4ef4-5a2d-11e0-86d3-00144feab49a.html

[75] Kaiser Family Foundation, Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2010, available at http://www.statehealthfacts.org/comparemaptable.jsp?ind=266&cat=5, Retail Prescription Drugs Filled at Pharmacies (Annual per Capita), 2010, available at http://www.statehealthfacts.org/comparemaptable.jsp?ind=267&cat=5 (viewed June 5, 2012).

[76] The 2005 cost of Medicaid prescription drugs, after accounting for manufacturer rebates, was $30.1 billion. Congressional Research Service, Prescription Drug Coverage Under Medicaid (February 6, 2008) 24. At the 10.1 percent average, Maine's Medicaid pharmaceutical spending would be $66.2 million (based on total 2009 Medicaid spending of $662,236,113). Medicaid.gov, Maine Medicaid Statistics, Medicaid Enrollments and Payments, ME, FY 2006-2010, available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-State/maine.html (viewed June 5, 2012).

developing a strategy that makes prescriptions more affordable (with supplemental manufacturer rebates to non-Medicaid participants). Maine was also a leader in using preferred drug lists (and prior authorization) to encourage – not require – doctors to use generic or alternative medicines when evidence points to their cost-effectiveness.[77] As a consequence of preferred drug lists, copayments, and other policies, the rate of increase in cost has gradually decreased to 3% (2008 data).[78]

There is a connection between the success of cost-containment by state and national reimbursement programs and trade rules being proposed in the Trans-Pacific Partnership Agreement (TPPA). The story begins in 2000 and 2002, when the Pharmaceutical Research and Manufacturers of America (PhRMA) filed lawsuits against programs in Maine, Michigan and Florida. PhRMA argued that federal Medicaid guidelines preempted Maine's supplemental Medicaid rebate, in part because the rebate to non-Medicaid participants did not serve a Medicaid purpose. The U.S. Supreme Court upheld the Maine law (and the others), holding that Maine's goal of promoting access and affordability was consistent with federal Medicaid objectives. The Court also noted that companies that chose not to offer a supplemental rebate were not unduly burdened because consumers could still gain access to their prescription drugs if their doctors used the prior authorization procedures.[79]

Within a few months of losing these cases, PhRMA began to work with U.S. trade negotiators to insert provisions in the U.S.-Australia Free Trade Agreement that could weaken cost-containment strategies for reimbursement programs in Australia, while providing new grounds for challenging cost-containment in Medicaid.[80] After intervention by legislators from Maine and other states, the U.S. Trade Representative (USTR) clarified that the new rules for reimbursement programs would apply to federal government programs except for Medicaid.[81]

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[77] *See* CRS, Prescription Drug Coverage, *supra* at 15-23. States continue to develop innovative cost-containment strategies including multi-state purchasing pools. *See* National Conference of State Legislatures, Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, http://www.ncsl.org/issues-research/health/bulk-purchasing-of-prescription-drugs.aspx (viewed June 5, 2012).

[78] In fiscal year 2012, 38 states imposed some kind of cost-containment strategy on Medicaid prescription drug purchases. These included subjecting more drugs to prior authorization, implementing or expanding preferred drug lists, and seeking new or enhanced supplemental rebates. Kaiser Family Foundation, Medicaid Cost Containment Actions Taken by States, FY2012, available at http://www.statehealthfacts.org/comparetable.jsp?ind=188&cat=4 (viewed June 5, 2012). Kaiser Family Foundation, Prescription Drug Trends (May 2010) 1. Available at http://www.kff.org/rxdrugs/upload/3057-08.pdf (viewed June 5, 2012). *See* Kosali Ilayperuma Simon Sharon L. Tennyson and Julie Hudman, *Do State Cost Control Policies Reduce Medicaid Prescription Drug Spending?*, 12 Risk Mgmt. and Ins. Rev., 39 (2009) (Analysis of state level annual spending growth shows that these restrictions have in general helped contain Medicaid prescription drug costs and that some approaches, such as the use of preferred drug lists (PDLs) and tiered copayment systems, may have been more effective than others.)

[79] *PhRMA v. Walsh*, 123 S. CT. 1855 (2003).

[80] *See* PhRMA, National Trade Estimate Report on Foreign Trade Barriers (Dec. 12, 2003) 4-6. PhRMA described Australia's regulatory and budgetary cost control schemes as "increasingly draconian," with particular reference to reference pricing and analysis of the cost-effectiveness of drugs. *Id.* at 6.

[81] Letter from State Senator Mark Montigny (MA), Chair of the National Legislative Association on Prescription Drug Prices, to Amb. Robert Portman, United States Trade Representative (May 25, 2005) 1. ("There are ambiguities in the Australia-U.S. Free Trade Agreement (AUSFTA) as well as a pattern in U.S. demands in ongoing negotiations that may expose ... state programs to [a trade] challenge. One of our main concerns in that in seeking compliance with trade rules the federal government will reject state cost-containment measures or seek to preempt state law.")

A leaked chapter of the Trans-Pacific Partnership Agreement (TPPA) shows that the USTR is proposing to retain and expand upon pharmaceutical trade rules that the United States first proposed in the Australia-U.S. FTA. The competing views sound like this:

- In the words of PhRMA, the industry association, the TPPA provisions are designed to reduce "…market access barriers, remedy inadequate consultative mechanisms and transparency concerns in countries like New Zealand, for which no US FTA currently exists…[in doing so] this would ensure that patients throughout the TPPA region receive safe, effective and innovative medicines."[82]
- According to health advocates in Australia, "This is coded industry/trade-speak which means, in effect, we want to replace Australia's PBS and New Zealand's Pharmac evidence-based, scientific cost-effectiveness evaluation systems with a market-based approach in which multinational corporations with market dominance can set whatever prices they feel appropriate."[83]

The debate concerns whether the TPPA should include provisions that weaken cost-containment strategies in New Zealand and Australia that are similar to but stronger than those developed for the state-run Medicaid programs in the United States. If the TPPA retains a carve-out for Medicaid, Maine's Medicaid strategy will not be threatened. However, the TPPA could influence other federal programs that save consumers and state governments tens of millions of dollars in pharmaceutical spending.

In the following section, we outline the following U.S. proposals and critiques –

- *Pricing rules.* The U.S. proposal sets trade rules to limit government cost-containment programs. These include vaguely worded obligations to set reimbursements according to either market-based prices or to the value of a patent.
- *Transparency rules.* The U.S. proposal sets trade rules to ensure that drug companies can participate in the decision-making process for reimbursement of prescription drugs.
- *Pricing appeals.* The U.S. proposal creates procedures that enable drug companies to challenge and appeal reimbursement decisions.
- *Coverage.* The U.S. proposal defines which federal programs are carved-in and carved-out of the TPPA.
- *Internet marketing.* The U.S. proposal prohibits governments from limiting Internet pharmaceutical marketing directly to consumers.

In the conclusion, we offer an agenda of topics and questions for oversight of trade policy by the Maine CTPC.

Likely TPPA provisions

The likely TPPA provisions quoted below are taken from the U.S. proposal for a "Transparency Chapter – Annex on Transparency and Procedural Fairness for Healthcare Technologies," dated June 22, 2011 (hereafter, Healthcare Annex).

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[82] PhRMA, Comments to USTR on the Trans-Pacific Partnership Agreement, Docket ID: USTR-2009-0041, 2, available at http://www.regulations.gov/search/Regs/home.html#docketDetail?R=USTR-2009-0041 (viewed June 5, 2012).

[83] Thomas Faunce and Ruth Townsend, Potential Impact of the TPPA on Public Health and Medicine Policies, Australian National University, College of Law (April 14, 2010) 7.

1. Pricing rules

a. *U.S. proposal*

Several provisions limit the substantive (not procedural) terms of government reimbursement programs. Paragraph X.3 provides that "… a party shall:[84]

> (d) ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue;
>
> (e) where a Party provides for a determination of the reimbursement amount on a basis other than competitive market-derived prices in that territory, that Party shall permit a manufacturer of the pharmaceutical product or medical device in question, before or after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product or device based on evidence the manufacturer provides on the product's superior safety, efficacy or quality as compared with comparator products;
>
> (f) establish procedures that allow a manufacturer of a pharmaceutical product or medical device to apply for reimbursement for additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy;"

b. *Purposes*

(1) As stated in the Healthcare Annex, the price proposals are designed to promote "access to high-quality pharmaceutical products" and "sound economic incentives and the operation of competitive markets, or … procedures that appropriately value objectively demonstrated therapeutic significance" of pharmaceutical products.[85]

(2) One government official observed that PhRMA's aim is to increase the number and rates of reimbursement for "high-quality" or "innovative" drugs.[86]

(3) A university study in Australia infers that the price proposals are designed to shift the character of pharmaceutical reimbursement regulations from a public good to a private rights-oriented system.[87]

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[84] Healthcare Annex, para. X.3, Paragraph X.3: Procedural fairness related to healthcare technologies.

[85] Healthcare Annex, para. X.1 (a) and (c) (Agreed Principles).

[86] *See* Knowledge Ecology International, *In Poland, an Ambassador (and former George W Bush roommate) demolishes PhRMA's 2009 Special 301 filing*, available at http://keionline.org/node/1250 (viewed June 5, 2012). ("While pharmaceuticals companies often assert that they would be happy with a transparent process, even if it led to decisions not to fund their drugs, in practice they seem to resent all government measures aimed at cost containment, as these also inevitably limit drug companies' sales.")

[87] Thomas Faunce, Evan Doran, David Henry, Peter Drahos, Andrew Searles, Brita Pekarsky and Warwick Neville, *Assessing the impact of the Australia-United States Free Trade Agreement on Australian and global medicines policy* (2005), available at http://www.globalizationandhealth.com/content/1/1/15 (viewed June 5, 2012).

c. ***Critiques***

(1) *Competitive market-derived prices in a Party's territory* – In effect, this rule replaces a bargaining process with a legal process to determine which price is "market-derived." The vagueness of the term "market-derived" enables drug companies to use the appeals process (see below) to push for an interpretation that increases the price. This undermines a government's ability to bargain using its economy of scale from pooled purchasing. The reference to market prices "in a Party's territory" would enable drug companies to challenge the common practice by health authorities of using *international* reference pricing.[88]

As Todd Tucker observes, "[i]t is not clear that any U.S. healthcare cost containment program would meet this standard, as most involve statutory price controls or the use of government contracting to lower costs."[89] His view is that the purpose of the Health Annex is to clarify, in light of recent WTO subsidy disputes, that "market-derived" prices do not factor in the impact of governments as market participants.[90] For example, in the softwood lumber case, the WTO's Appellate Body observed that "[w]henever the government is the predominant provider of certain goods, even if not the sole provider, it is likely that it can affect through its own pricing strategy the prices of private providers for those goods."[91] Thus, the lack of any guidance leaves it to future dispute settlement or formal interpretation to determine the logical relationship between a reimbursement price and a market from which it is "derived."

Sean Flynn summarizes his critique in blunt terms:

> "This is a radical proposal that would move trade agreements completely beyond any pretense to regulate trade and instead directly regulate domestic regulation itself. If such an agreement is desired by countries, it should be negotiated in an open forum where public health experts and advocates are well represented, e.g., the World Health Organization. This is a completely inappropriate subject for closed door trade negotiations."[92]

Over 40 states participate in the Medicaid reimbursement program and share costs with the federal government. These states use a process of negotiating prices based on preferred drug lists that compare a variety of factors, including cost-effectiveness.[93] Maine has reduced the average cost of pharmaceuticals to 50% of list

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88 Sean Flynn, Statement – Leaked U.S. Proposal for a Pharmaceutical Chapter (October 22, 2011) 4 (hereafter, Flynn, Lima Round presentation) *See also* Sean Flynn, Analysis of the Potential TPP Pharmaceutical Chapter, Program on Information Justice and Intellectual Property, American University Washington College of Law (September 14, 2011) 5-6. (Hereafter, Flynn, Chicago Round presentation)

89 Todd Tucker, *TPP could undermine Medicare, Medicaid and Veterans' Health - hurting seniors, military families and the poor* (June 14, 2012) 8, available at http://citizen.typepad.com/eyesontrade/2012/06/tpp-could-undermine-medicare-medicaid-and-veterans-health-hurting-seniors-military-families-and-the-.html (viewed June 25, 2012). (hereafter, Tucker, Proposed TPP rules)

90 Tucker, Proposed TPP rules, 9.

91 Appellate Body Report, *US – Softwood Lumber IV*, ¶ 100.

92 Flynn, Chicago Round presentation, 8.

93 California State Senator Liz Figueroa explained the potential for coverage of Medicaid under the Australia FTA: "Given that California's Medi-Cal program operates under federal guidelines and that California must submit a State plan for federal approval in order to change or expand that program, it is certainly with the scope of reason to conclude that a close-door, FTA dispute panel could potentially interpret the federal guidelines and approval process as a 'decision,' thereby making state programs 'federal' and covered by the provisions of the trade

prices.[94] Rep. Sharon Treat describes the U.S. proposal as seeking to "require governments to act more as if they are individual patients going to pharmacies to fill prescriptions, rather than as giant purchasing agents using market power to negotiate a good deal based on volume."[95]

(2) *Recognize the value* – In their respective FTAs, Australia and Korea resisted the U.S. proposal for market-derived prices. The resulting compromise was to set lower-than-market prices so long as these prices "appropriately recognize the value" of patents. In Sean Flynn's view, the vagueness of this phrase "invites litigation and promotes uncertainty."[96] Lacking a market reference, it is difficult to predict how "value" would be interpreted. Todd Tucker observes that the federal TRICARE program (for military personnel and their families) could run afoul of this rule because TRICARE allows administrators to privilege drugs for reimbursement based on cost-effectiveness and how quickly their patent is likely to expire, regardless of the value that the manufacturer considers should be attributed to the drug.[97]

(3) *Superior safety, efficacy or quality* – These criteria could produce prices that are more rational than market value, but the list fails to include cost. It is detached from the capacity of a government to afford a product.

(4) *Additional medical indications* – This criterion provides for reimbursements with no reference to prior government approval of a drug for its intended use. As Sean Flynn observes, it "suggests that the safety and efficacy information would be submitted directly to the reimbursement entity, side stepping regulatory authorities."[98]

2. Pricing procedures

a. *U.S. proposal*

Several provisions create procedural obligations for government reimbursement programs. Paragraph X.3 provides that "… a party shall:[99]

> (b) disclose to applicants within a reasonable, specified period all procedural rules, methodologies, principles, criteria (including those used, if any, to determine comparator products), and guidelines used to determine the eligibility for, and amount of, reimbursement for pharmaceutical products or medical devices;
>
> (c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the decision-making process related to reimbursement for pharmaceutical products or medical devices;

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agreement." California Senator Liz Figueroa, Letter to Ambassador Robert Zoellick (February 16, 2005), available at http://www.wcl.american.edu/pijip/go/figuera-kuehl2005 (viewed June 7, 2012).

94 *See* Rep. Sharon Anglin Treat (ME), Stakeholder Presentation, Lima Round Trans-Pacific Partnership Agreement (October 23, 2011) 3. (hereafter, Treat, Lima Round presentation)

95 Rep. Sharon Treat, Trans-Pacific Partnership Leaked Text on Transparency for Health Marketing and Reimbursement (May 24, 2012) 1. (hereafter, Dallas Round presentation)

96 Flynn, Lima Round presentation, 4.

97 Tucker, Proposed TPP rules, 12, 28-30.

98 Flynn, Lima Round presentation, 4.

99 Healthcare Annex, para. X.3, Paragraph X.3: Procedural fairness related to healthcare technologies.

(g) within a reasonable, specified period, provide detailed written information to applicants regarding the basis for recommendation or determination relating to their applications for reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies upon which the Party has relied;

(i) make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices;"

b. *Purpose*

A USTR white paper states that the general goal is to "ensure the fairest possible opportunity for both generic and innovative medicines to enter TPP markets, require respect for basic norms of transparency and procedural fairness in the operation of national government healthcare reimbursement programs."[100]

c. *Critiques*

(1) *Disclose to applicants ... methodologies, principles, criteria* – Private health insurance companies and hospitals do not disclose their drug pricing methodologies to their suppliers. This rule precludes governments from using the same successful methods that private market participants use to negotiate drug prices.[101] Rep. Sharon Treat explained why state governments do not disclose their methods to drug companies: "States revise their drug list on a regular basis and at times, on short notice, to take advantage of market changes and the availability of new generics, or to promptly reassess safety and efficacy based on new evidence. Most do not allow drug companies to sit on committees deciding which drugs are on the list, rejecting this as a major conflict of interest …"[102]

(2) *Opportunities to provide comments* – Same critique as above; this rule converts a negotiation into a rule-making process.

(3) *Make available an opportunity for independent appeal* – Similar to the prior critique, this obligation converts a negotiation process into a contested rule-making process. As it creates an option to appeal where none now exists, it enables drug companies to threaten litigation and thus enhance their bargaining power.[103] Again, in the words of Sharon Treat, "[t]aken together, these provisions will turn the formulary development process into a lawyer's dream with multiple opportunities to challenge state decision-making."[104]

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[100] U.S. Trade Representative, Trans-Pacific Partnership Trade Goals to Enhance Access to Medicines (September 11, 2011) 2, available at http://keionline.org/sites/default/files/USTR_11sep2011_TPP_Trade_Goals_Medicines.pdf (viewed June 7, 2012).

[101] *See* Flynn, Lima Round presentation, 3.

[102] Treat, Lima Round presentation, 3.

[103] *See* Flynn, Lima Round presentation, 4.

[104] Treat, Dallas Round presentation, 2.

3. Coverage

a. *U.S. proposal*

(1) The U.S. proposal applies to "the extent that health care authorities of a Party's central level of government maintain procedures for listing pharmaceutical products … for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government[1] …"

> Footnote 1 provides that "Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for health care agencies that engage in government procurement. Chapter X (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products."

(2) *Health care authorities* are defined as "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"[105]

(3) *Health care programs* are defined as those "in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies[2] …"

> Footnote 2 says: "[Negotiator's Note: Clarifying footnote regarding scope of application, such as with respect to central versus regional level of government healthcare programs.]"

b. *Purpose*

(1) By covering "reimbursement" programs, the U.S. proposal avoids coverage of drug pricing for direct purchasing under U.S. federal programs (e.g., VA hospitals, GSA, DoD).

(2) The U.S. proposal appears to cover two important federal reimbursement programs, the 340B program (where prices for pharmaceuticals are set through a federal statutory formula), and Medicare Part B (covering reimbursements in hospitals). This coverage of certain federal reimbursement programs, while excluding Medicaid, appears to be a deliberate decision since the Australia-U.S. FTA.[106]

c. *Critiques*

(1) *State Medicaid programs* – Absent footnote 2, the Health Annex appears to cover state Medicaid programs. This footnote did not exist in the Australia-U.S. FTA until the National Legislative Association on Prescription Drug Prices pressed USTR to explicitly exclude Medicaid programs.[107] As a result, footnote 2 in the

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[105] Health Annex, para. X.7 (Definitions).

[106] *See also* U.S. Trade Representative, "Remarks of U.S. Trade Representative Rob Portman and Australian Deputy Prime Minister and Minister for Trade Mark Vaile, March 7, 2006, available at http://www.ustr.gov/sites/default/files/uploads/speeches/2006/asset_upload_file478_9124.pdf

[107] *See* Letter from State Senator Mark Montigny (MA), Chair of the National Legislative Association on Prescription Drug Prices, to Amb. Robert Portman, United States Trade Representative (May 25, 2005) 1. ("There are ambiguities in the Australia-U.S. Free Trade Agreement (AUSFTA) as well as a pattern in U.S. demands in ongoing negotiations that may expose ... state programs to [a trade] challenge. One of our main concerns in that in

pharmaceutical provisions of the Australia and Korea FTAs reads as follows: "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 same footnote does not appear in the U.S. proposal for a TPPA Health Annex; instead, there is a placeholder. Conceivably, the reason is that the Affordable Care Act will change Medicaid to use a national pricing list that resembles the approach used by reimbursement programs in Australia and New Zealand.[108]

(2) *Covered federal programs* -

(a) *340B reimbursement program.* The purpose of the 340B drug pricing program[109] is to "to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[110] The program allows qualifying providers to purchase drugs for outpatient use at significantly reduced rates: approximately 20 percent below the Medicaid price. State governments save money when Medicaid participants become patients of facilities that purchase outpatient drugs on their behalf at the discounted 340B price.[111] As of October 2011, 16,869 health facilities participated in the program.[112] Covered facilities include disproportionate share hospitals, family planning clinics, and federally qualified health centers, among others.[113] Numerous states have adopted programs to expand their ability to benefit from the 340B program: California, Connecticut, Florida, Kansas, Pennsylvania, Utah, Vermont, and Virginia.[114]

(b) *Medicare Part B reimbursement program*. Medicare Part B reimburses doctors and hospitals for pharmaceuticals used in medically necessary services for Medicare beneficiaries.[115] Medicare reimbursements under Part B amounted to one-third of spending on the Medicare Part D program for reimbursement of pharmaceutical purchases in 2007.[116] While Part B reimbursements tend to reflect average prices, there has been litigation in the past because the program

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seeking compliance with trade rules the federal government will reject state cost-containment measures or seek to preempt state law.")

[108] Treat, Lima Round presentation, 3.

[109] Veterans Health Care Act of 1992, P.L. 102-585 § 602; PHS Act § 340B; 42 U.S.C. § 256b.

[110] H.R. Rep. No. 102-384, at 12 (1992)(Conf. Rep.).

[111] *See* Kory Mertz, *An Oldie but Goodie": The 340B Program,* Volume 28, Issue 491 (May 14, 2007), available at http://www.ncsl.org/issues-research/health/archive-an-quotoldie-but-goodie-quot-the-340b.aspx (viewed June 5, 2012).

[112] National Conference of State Legislatures, States and the 340B Drug Pricing Program, http://www.ncsl.org/issues-research/health/340b-drug-pricing-program-and-states.aspx (viewed June 5, 2012).

[113] 42 U.S.C. § 256b(a)(4).

[114] Rep. Sharon Anglin Treat, Stakeholder Presentation, Chicago Round Trans-Pacific Partnership Agreement (September 10, 2011) 4. (hereafter, Treat, Chicago Round presentation)

[115] *See* Department of Health and Human Services, Medicare Part B (Medical Insurance), available at http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-b.aspx (viewed June 7, 2012).

[116] Amanda Cassidy, "Coverage and Payment for Prescription Drugs Under Medicare Part B: A Complex Patchwork," National Health Policy Forum, Background Paper No. 70 (August 31, 2009) 6-7, available at http://www.nhpf.org/library/details.cfm/2755 (viewed June 7, 2012).

does not always "pass through" (authorize) reimbursement for a new and more expensive drug if a less expensive alternative is on the market.[117]

(3) *Covered programs in other countries* - Vermont Governor Peter Shumlin wrote to President Obama:

> "U.S. Federal government agencies and state governments use the same policy tools as foreign governments for public medicine purchasing and reimbursement, and they pay similar prices. [Examples cited: 340B and Medicare Part B] … Even if a chapter was proposed that did include a Medicaid carve-out, state leaders believe it is inappropriate for U.S. trade policy to advance restrictions on pharmaceutical pricing programs that U.S. programs do not meet but for technical carve outs."[118]

4. Internet consumer marketing

a. *U.S. proposal*

Paragraph X.4 provides that "Each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site … and on other Internet sites … 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."

b. *Purpose*

This proposal would create a right of drug companies to market patented drugs to doctors and directly to consumers via their own websites and indirectly through other websites, including social media.

c. *Critiques*

(1) Direct consumer marketing is contrary to the drug marketing laws of many countries.[119]

(2) Creating a right to use Internet marketing would permit marketing of drugs through links to unregulated social media at a time when the states are pursuing billion dollar settlements with the pharmaceutical industry for off-label marketing.[120]

(3) The provision appears to conflict with a proposal by Representative Henry Waxman that companies not be allowed to engage in certain kinds of direct to consumer promotion in the first three years of a drug's time on the market.[121]

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[117] *See* Tucker, Proposed TPP rules, 31; Amgen v. Smith, 357 F.3d 103 (2004).

[118] Letter from Gov. Peter Shumlin to President Barak Obama, 2-3 (June 1, 2011), available at http://www.forumdemocracy.net/downloads/Letter%20from%20VT%20Gov.%20Shumlin%20to%20President%20Obama%20-%20June%201,%202011.pdf (viewed June 7, 2012).

[119] Flynn, Lima Round presentation, 4.

[120] Treat, Dallas Round presentation, 2.

[121] Treat, Dallas Round presentation, 2.

Agenda for oversight of trade policy

In order to provide an agenda for the CTPC as a forum and link to state and federal government, we conclude with a summary of the issues identified above.

1. **Cost to states.** Would the TPPA undermine cost-containment by states in Medicaid or by the federal government in the 340B program?

2. **Coverage or carve-outs.** The U.S. proposal does not clearly carve out several federal reimbursement programs on which state governments rely to constrain pharmaceutical costs. The question is whether or not they should be carved out of the proposed Heath Annex. These federal reimbursement programs include:
    - Medicaid, which is carved out of the Korea-U.S. FTA
    - 340B
    - Medicare Part B

3. **Pricing rules.** The legacy of "market-derived" pricing is one of prices that are six times higher than they were in 1990.
    - Cost-containment strategies are working. How does replacing them with the U.S. proposal for market-derived prices benefit the public interest?
    - What is the theory by which the proposed pricing rules would help states or consumers contain the cost of prescription drugs?
    - Should the United States hold other countries to rules that it does not apply to its own reimbursement programs?

4. **Future cost-containment strategies.** How would the U.S. proposal constrain future cost containment strategies in federal reimbursement programs? Critics of the proposed Health Care Annex are concerned that it will foreclose options for cost-containment that are now on the table. They fear that market-derived price rules will lock in the highest market prices in the world. A constructive way to discuss the risk of trade conflict is to compare the U.S. proposal for the TPPA with pending cost-containment proposals. In the United States these include:

    - *Medicaid national pricing list* – As noted above, the Affordable Care Act will change the drug pricing approach of Medicaid from state-level rebate negotiations to a national list that is similar to the approach in Australia and New Zealand.
    - *Medicare pool purchasing* – There are a number of proposals to make better use of the federal government's purchasing power to contain the cost of prescription drugs, particularly with respect to Medicare Part D.
        - The Obama Administration proposed a measure to reduce the deficit by limiting "excessive payments for prescription drugs by leveraging Medicare's purchasing power."[122]
        - Senator Dick Durbin (D-Ill.) and Representative Jan Schakowsky (D-Ill.) proposed legislation to offer one or more Medicare Part D plans that would

[122] *See* White House, The President's Framework for Shared Prosperity and Shared Fiscal Responsibility (April 13, 2011), available at: http://www.whitehouse.gov/the-press-office/2011/04/13/fact-sheet-presidents-framework-shared-prosperity-and-shared-fiscal-resp (viewed June 7, 2012).

coexist with private plans.[123] The bill would require the Secretary of HHS to negotiate with drug manufacturers for lower prices and establish formularies.[124]

- *Marketing and consumer protection* – The Annex could undermine efforts to revise U.S. law regarding direct-to-consumer marketing during the initial period of sale when drugs have had limited use and when significant side effects are most likely to be exposed.[125]

[123] Office of Senator Dick Durbin, "Durbin, Schakowsky Introduce Bill Requiring HHS to Negotiate Drug Pricing in Medicare Part D," Press Release, March 11, 2011, Available at: http://durbin.senate.gov/public/index.cfm/pressreleases?ID=555cc1e8-cc54-4ead-9d85-d5e6275b3789

[124] H. R. 999, Medicare Prescription Drug Savings and Choice Act of 2011, Sec. 2(b) and Sec. 2(e)(2), available at http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.999 (viewed June 7, 2012). *See* Tucker, Proposed TPP rules, 19-20

[125] Treat, Dallas Round presentation, 2.

HARRISON INSTITUTE FOR PUBLIC LAW
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III. Government Procurement

2012 Trade Policy Assessment
Prepared for the Maine Citizen Trade Policy Commission

Robert Stumberg[126] and Matthew Porterfield[127]

Introduction

Procurement remains a focus of negotiations on the Trans-Pacific Partnership Agreement (TPPA).[128] Once completed, the TPPA could significantly expand from 9 countries initially to over 20, a free-trade area that would be larger than the European Union.[129]

There are also developments outside of the TPPA that could significantly affect state procurement: a new GPA text has been negotiated; China is poised to join the GPA, and the EU and Japan are challenging procurement in Ontario with arguments that could subject state and local procurement to trade rules under trade agreements other than the GPA and procurement chapters.

Historically, trade negotiations are criticized as anti-democratic because they set policy that limits the traditional domain of national and state legislatures.[130] They do it behind closed doors, with an advisory system that invites "industry capture."[131] The TPPA sets a new record on secrecy in negotiations: the draft chapters are stamped "classified" for a period of four years after the close of negotiations – enough time to pass the next election cycle for governments that draft the agreement.[132]

Yet in the United States at least, procurement has been a more pro-democratic sector of trade policy. Beginning in the Uruguay Round of WTO negotiations in 1994, the U.S. Trade Representative invited governors to decide whether to commit their state to each successive

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[128] USTR, Trans-Pacific Partnership (TPP) Talks Advance in Texas (May 16, 2012) 2.

[129] *See* Jane Kelsey, *Investment Developments in the Trans-Pacific Partnership Agreement*, Investment Treaty News (January 12, 2012), available at http://www.iisd.org/itn/2012/01/12/investment-developments-in-the-trans-pacific-partnership-agreement/ (viewed June 8, 2012); Jane Kelsey, *The Trans-Pacific Partnership As A Lynchpin Of Us Anti-China Strategy*, available at http://www.converge.org.nz/watchdog/28/06.htm (viewed June 8, 2012).

[130] *See* SUSAN AARONSON, TAKING TRADE TO THE STREETS: THE LOST HISTORY OF PUBLIC EFFORTS TO SHAPE GLOBALIZATION (University of Michigan Press, 2004).

[131] Margot E. Kaminskii, *The U.S. Trade Representative's (USTR's) Democracy Problem*, 35 SUFFOLK TRANSNATIONAL L. REV. (forthcoming 2012) Parts IV-V, available at http://ssrn.com/abstract=2043605 (viewed June 8, 2012). (hereafter, Kaminsii, USTR's Democracy Problem)

[132] *See e.g.,* Trans-Pacific Partnership, Intellectual Property Rights Chapter, Draft (February 10, 2011), available at http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf (viewed June 8, 2012).

procurement chapter of a free trade agreement (FTA). Maine is among five states to open up the process even further by requiring legislative approval of the decision to limit state procurement power under a trade agreement.[133]

As a consequence of this openness, the number of states participating in procurement agreements started with 37 (including Maine) in the WTO's Agreement on Government Procurement (GPA),[134] then declined to 19 in CAFTA (2004),[135] and more recently, to only 8 in the Peru FTA (2006).[136]

In addition to the GPA, Maine procurement is covered by the following procurement chapters of FTAs: CAFTA, Singapore, Chile, and Australia. Maine has declined to be bound by the more recent FTAs: Morocco, Peru, Colombia, and Panama.[137]

While active state decision-making addresses the democracy deficit, the trend is stoking efforts of the European Union and other trade partners to expand the scope of international procurement rules by means other than negotiation. If successful, the EU's strategy could undermine the assumption of Maine and other states that their decisions on procurement chapters are meaningful.

In this report, we –

- review important procurement rules in the GPA and procurement chapters of FTAs,
- provide an update on procurement negotiations including the TPPA and the WTO,
- explain the EU's litigation strategy to expand coverage of procurement outside of the GPA, and
- conclude with an agenda for trade policy oversight.

Procurement rules

The GPA and FTA procurement chapters apply to purchases by government agencies over specified dollar thresholds. The GPA is a "plurilateral" rather than a "multilateral" agreement, meaning that it does not bind all 155 Members of the WTO, but rather only those countries that specifically have agreed to be covered. Currently, there are 42 countries signed on to the GPA,

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[133] *See* Maine Rev. Stat. Ann. Title t 10, Part 1, Chapter 1-A, §13, Legislative approval of trade agreements, *available at* http://www.mainelegislature.org/legis/statutes/10/title10sec13.html (viewed June 8, 2012). The other states are Maryland, Rhode Island, Hawaii, and Minnesota. *See* Public Citizen, Trade Policy and Government Procurement, available at http://www.citizen.org/Page.aspx?pid=1204 (viewed June 8, 2012). (hereafter, Public Citizen, Trade and Procurement)

[134] The other states covered by the GPA are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, New York, Nebraska, New Hampshire, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin and Wyoming. Government Procurement Agreement, Annex 2 of Appendix 1, reprinted in H.R. Doc. 103-316, 103d Cong., 2d Sess., Vol. 1, at 330-336 (1994).

[135] CAFTA Annex 9.1.2(b)(i) § B Schedule of the United States (covering procurement of twenty-two states). Several states have attempted to withdraw from coverage. *See* Public Citizen, Trade and Procurement, available at http://www.citizen.org/Page.aspx?pid=1204.

[136] *See* U.S. - Peru Trade Promotion Agreement, Annex 9.1, available at http://www.ustr.gov/sites/default/files/uploads/agreements/fta/peru/asset_upload_file937_9528.pdf. *See* Public Citizen, Trade and Procurement.

[137] Public Citizen, States Bound to International Trade Agreement Government Procurement Provisions, available at http://www.citizen.org/documents/states%20procurement%20chart.pdf (viewed June 8, 2012).

including the United States.[138] Parties to the GPA and FTA procurement chapters are bound only regarding those specific agencies at the national and subnational (i.e., state and local) levels that they have listed in appendices.

While there are some differences between the GPA and FTA procurement chapters, the principal trade rules are very similar. For sake of brevity, we summarize the GPA's restraints on government procurement, including the following:

- ***Nondiscrimination.*** The GPA contains "most favored nation" (MFN) and "national treatment" (NT) provisions that prohibit Parties from implementing procurement policies that prefer domestic products, services or suppliers over those of another Party, or that fail to treat the products and services of other Parties equally. Impermissible discrimination under WTO rules can include measures that have discriminatory effects as well as those which intentionally discriminate in order to favor domestic producers.

- ***Performance based standards***. Article VI of the GPA contains language stating that "where appropriate," technical specifications for procurement shall be prescribed "in terms of performance rather than design or descriptive characteristics . . .."[139]

- ***Use of "relevant international standards."*** Article VI also indicates that "where appropriate," technical specifications for procurement contracts shall "be based on international standards, where such exist; otherwise, on national technical regulations, recognized national standards, or building codes."

- ***Procedural requirements.*** The GPA contains various procedural provisions, including a requirement in Article XII:2 that "[t]ender documentation provided to suppliers shall contain all information necessary to permit them to submit responsive tenders . . .." The specific information that must be provided includes "a complete description of the products or services required or of any requirements including technical specifications, conformity certifications . . . [and] any factors other than price that are to be considered in the evaluation of tenders . . .."[140]

These procurement rules have long been a sensitive area of trade policy due to concern that they could be used to challenge procurement preferences that favor local production or impose environmental criteria on government purchases.[141] It is common for governments to use their purchasing power to not only buy goods or services, but in so doing, to also to promote economic development, create economies of scale for environmentally friendly products, comply with human rights obligations (e.g., avoiding goods produced with forced or child labor), and lead by example in other ways. (Examples are reviewed in the 2009 Assessment.)

Accordingly, government purchasing is partially exempted from the WTO non-discrimination rules that apply to all WTO countries. These are contained in Article III of the General Agreement on Tariffs and Trade (GATT).[142] The widely held view is that government

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[138] *See* World Trade Organization, *Briefing Note: Government Procurement Agreement Parties (GPA)* (accessed June 7, 2012), available http://www.wto.org/english/thewto_e/minist_e/min11_e/brief_gpa_e.htm.

[139] GPA Art. VI:2(a).

[140] GPA, art. VII(2)(g) & (h).

[141] *See generally* Ben Stafford, *Caveat Emptor: How CAFTA Imperils State Recycled Procurement Preferences,* 82 WASH. L. REV. 175 (2007).

[142] *See* GATT, art. III(8)(a): ("The provisions of this Article shall not apply to laws, regulations or requirements

procurement is bound only by the WTO's GPA, which enables each country to decide whether to participate at all, and if so, to specifically list each agency or unit of subnational government that it chooses to commit.[143]

Recent developments – Procurement negotiations

- ***TPPA procurement chapter.*** Recently, USTR has indicated that it is "delaying" seeking commitments from states to be covered under the proposed Trans-Pacific Partnership Agreement (TPPA).[144] The text of the procurement chapter is not available.

- ***The proposed US–EU Agreement.*** The United States and the European Union have been engaged in discussions over a potential US–EU trade agreement. The EU's Trade Commissioner, Karel De Gucht, was recently quoted as saying that it would be "crucial" for a US–EU agreement to cover state-level procurement, including exemptions from "Buy American" laws.[145]

- ***Revised and expanded WTO GPA.*** In March 2012, the Parties to the GPA signed a revised and expanded version of the agreement.[146] The revisions include provisions to accommodate electronic commerce, expanded commitments of agencies by Parties, and a set of work programs on issues including participation of small and medium enterprises in procurement to be addressed by the Parties in the future. Other revisions include: [147]
    - Domestic challenges based on breach of the GPA
    - Award to lowest-bidder
    - More limits on contractor qualifications
    - More limits on technical specifications with respect to brand names and prohibitions of technical barriers to trade
    - Notice of why bidders are rejected
    - Transparency obligations including Internet publication of contract terms

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governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale.")

[143] *See* WTO, *WTO Regime on Government Procurement* (2011). In the foreword to this publication WTO Director General Pascal Lamy explains that although government procurement composes as much as 15-20 % of global GDP, "much of this is not yet covered by current international disciplines." The forward is available at http://www.wto.org/english/res_e/publications_e/gproc_regime_e.htm (viewed June 8, 2012).

[144] *See* "U.S. Seeks Delay In Addressing Sub-Central Procurement In TPP Talks," World Trade Online (May 14, 2012). USTR's lead negotiator on the TPPA, Barbara Weisel, announced this policy during a stakeholder briefing in response to a question from Rep. Sharon Treat.

[145] *See* "De Gucht Says U.S.-EU Trade Deal Must Yield New Access At State Level," World Trade Online (May 17, 2012).

[146] *See* World Trade Organization, *Committee on Government Procurement adopts revised Agreement* (March 30, 2012), available at http://www.wto.org/english/news_e/news12_e/gpro_30mar12_e.htm.

[147] *See* WTO Committee on Government Procurement, *Adoption of the Results of the Negotiations under Article XXIV:7 of the Agreement on Government Procurement, and Action Taken by the Parties to the WTO Agreement on Government Procurement at a Formal Meeting of the Committee*, GPA/112 (Dec. 15, 2012), *available at* http://www.wto.org/english/tratop_e/gproc_e/negotiations_e.htm. *See also* Robert D. Anderson, Steven L. Schooner, and Collin D. Swan, *The WTO 's Revised Government Procurement Agreement - An Important Milestone Toward Greater Market Access And Transparency In Global Public Procurement Markets,* Volume 54, Number 1, THE GOVERNMENT CONTRACTOR (Jan 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1984216.

USTR apparently intends to commit the United States to this revised agreement without seeking congressional approval.[148] This decision may in part reflect pressure from the European Union, which has pressed for coverage of more state and local governments in the United States – at a time when fewer and fewer states are accepting the invitation to be covered by procurement chapters in U.S. FTAs. By not asking Congress to ratify the amended GPA, it may be easier for USTR to also avoid asking states to recommit to the GPA. Independent of its desire to avoid asking states to participate, USTR is increasingly prone to avoid seeking congressional ratification.[149]

- ***Accession of China and other countries to the GPA.*** Currently, nine WTO Members are in the process of "acceding" to the GPA (joining as a party). China is by far the most significant addition; the others include Albania, Jordan, the Kyrgyz Republic, Moldova, Oman, Panama and Ukraine.[150] Accession by another country does not change the rules that apply to Maine or other jurisdictions, but it does expand the number of countries that compete for procurement contracts and hence the number of countries that might take exception to procurement policies under rules of the GPA.

- ***GATS rules on procurement of services.*** Negotiations continue at the WTO on the need for rules on procurement of services. The forum is a working party on rules that could be adopted under the General Agreement on Trade in Services (GATS). If adopted, GATS rules would have a much broader scope of coverage than the GPA. In 2011, the working party studied several topics, including the services aspects of the Procurement (GPA) and the latter's impact on international procurement markets.[151] It does not appear that the working party is close to agreement on whether GATS rules on procurement are needed, and if so, how they would differ from the GPA.

Recent developments – Procurement dispute

In 2009, the Province of Ontario adopted a "feed-in-tariff" (FIT) program that provides guaranteed, above-market, long-term pricing for the generation output of wind and solar energy facilities.[152] To qualify, Ontario requires a minimum percentage of the energy to be produced with equipment manufactured in the province. The FIT is implemented through public procurement contracts for purchase of wholesale electricity.[153] Ontario's provincial procurement is not covered by Canada's schedule of commitments to the GPA.[154]

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[148] *See* World Trade Online, *Parties Adopt Updated GPA; U.S. Sees Entry Into Force Within A Year* (April 5, 2012) (subscription required) ("most GPA parties except the U.S. need to have their legislatures formally ratify the [revised GPA] deal before they can submit their instruments.")

[149] *See* Kaminsii, USTR's Democracy Problem, Parts V-VI.

[150] WTO, Accession to the agreement, available at http://www.wto.org/english/tratop_e/gproc_e/overview_e.htm (viewed June 8, 2012).

[151] WTO, Annual Report of the Working Party on GATS Rules to the Council for Trade in Services (2011), S/WPGR/22 (10 November 2011) 2.

[152] S.O. 2009, c. 12.

[153] Ontario Power Authority, FIT Rules, Version 1.5.1 (31 October 2011), and the microFIT Rules, Version 1.6.1 (10 August 2011); OPA, FIT Contract, Version 1.5.1 (31 October 2011), and microFIT Contract, Version 1.6.1 (31 October 2011).

[154] Foreign Affairs and International Trade Canada, Explanatory Note Regarding Canada's Annex 2, Sub-Central Government Entities, and Annex 3, Government Enterprises, of Appendix I (August 2002) ("For the WTO Agreement on Government Procurement, Canada does not have Annex 2 or Annex 3 commitments."), available at http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/wto-omc/entity.aspx?view=d (viewed June 8, 2012).

Nonetheless, the European Union and Japan filed WTO claims against Canada. They are seeking to block Ontario's procurement strategy by arguing that Ontario's FIT program violates trade agreements other than the GPA, including the General Agreement on Tariffs and Trade (GATT) and the Agreement on Subsidies and Countervailing Measures (SCM).[155] If the EU and Japan are successful, their interpretation of WTO agreements could also be used to challenge procurement measures of U.S. states, or for that measure, any jurisdiction that is not covered by the GPA. This could be a wake-up call for the states that have sought to avoid trade conflict by saying "no" to being covered by the GPA or procurement chapters of FTAs.

In several negotiations at the WTO, the EU has tried without success to convince WTO Members to negotiate procurement rules that would apply to all 155 WTO countries, not just the 42 parties to the GPA. If the WTO adopts the EU's arguments in the Canada-FIT dispute, the EU would achieve through dispute settlement what it has failed to achieve through negotiation.

The EU's most far-reaching argument is probably that the FIT program violates rules in GATT Article III that prohibit discrimination. Canada does not dispute Ontario's intent to favor of its own producers of green technology. Instead, Canada argues that Article III:8(a) excludes the FIT program from the non-discrimination rules.

- *The GATT exclusion of procurement.* Article III:8(a) provides, "(t)he provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale."
- *EU argument – government purposes.* The EU responds that the language in Article III:8(a) is much narrower than Canada's interpretation. The EU seeks to limit what it means to purchase goods "for governmental purposes," arguing that the GATT exclusion does not apply to the FIT program because the electricity is ultimately sold to all consumers in Ontario, not used only by government. If this interpretation is accepted by the WTO, it could mean that GATT rules apply to municipal water, roads for public use, book purchases by university libraries, and other traditional types of procurement.
- *EU argument – local content as an illegitimate purpose.* The EU argues further that "the protection and encouragement of its domestic industry" cannot be an acceptable governmental purpose under the procurement exclusion.[156] If adopted by the WTO, this interpretation would shrink the GATT exclusion from non-discrimination rules to virtually no exclusion at all. Procurement preferences – even those not covered by the GPA schedules – could be challenged as violations of GATT prohibitions on discrimination.
- *The U.S. brief.* The United States has submitted a brief in the dispute criticizing Canada's arguments regarding the application of GATT Article III to procurement measures.[157] For example, the United States argues that exclusion from GATT rules of procurement of electricity under Article III:8(a) does not justify "a local content requirement covering private purchases of a different class of goods" [wind or solar

[155] WTO, Request for the Establishment of a Panel by the European Union, Canada – Measures Relating to the Feed-In Tariff Program, WT/DS426/5 (10 January 2012). (hereafter, Canada – FIT)

[156] Canada – FIT, Submission of the EU, ¶ 36.

[157] Canada – Measures Affecting the Renewable Energy Generation Section (WT/DS412) & Canada – FIT (WT/DS426), Executive Summary of the Third Party Submission of the United States of America (April 2, 2012).

technology used by electricity generators]. This argument implies that electricity can be purchased without production by technology, or that water can be purified without technology, or that food can be processed without technology. If Article III:8(a) applies only to a single good, regardless of how it is produced, the exclusion has little value for goods like electricity or water that are necessarily produced by a technological process.

Agenda for oversight of trade policy

The CTPC could build upon its role of providing a public forum and engaging in meaningful oversight of procurement policy in a number of ways:

- Submit letters to USTR requesting written responses to the oversight questions below.
- Write to Maine's congressional delegation informing them of the recent developments concerning the status of state procurement under trade rules and requesting their assistance in engaging with USTR.
- Encourage the Maine legislature to hold hearings on international trade rules and state procurement policies.

To summarize our review of recent developments, here are some oversight questions that the Maine CTPC could pose to USTR, Members of Congress, and others:

1. **TPPA procurement**
   a. Would the TPPA include any innovations in its procurement chapter?
   b. How would the TPPA safeguard state and local procurement preferences?
   c. When will USTR invite states to decide whether to participate in the TPPA procurement chapter?
2. **GPA revisions**
   a. How do provisions for domestic challenge work in the United States?
   b. Will USTR submit the revised GPA for congressional ratification? Is there a legal basis for not seeking congressional ratification?
   c. Will USTR invite states to participate in the revised GPA?
3. **US-EU trade agreement**

   Considering that EU countries are already party to the GPA, what are the implications of including procurement within a US-EU trade agreement?
4. **China as a party to the GPA**
   a. When is China expected to join the GPA?
   b. Considering China's demonstrated export capacity, what is the likely impact (on U.S. states) of China becoming a party of the GPA?
5. **GATS rules on procurement of services**
   a. What is the status of these negotiations?
   b. Is there a scenario by which WTO nations would apply GATS rules to all procurement of services (i.e., all state and local governments) regardless of GPA commitments?

6. EU/Japan complaint against Ontario's FIT program

a. USTR filed a brief that criticizes Canada's defense. Does the United States support the complaint by the EU and Japan against Ontario's FIT program?

b. If the EU's interpretations prevail, what are the implications for coverage of state and local procurement under GATT prohibitions on discrimination or prohibited subsidies under the SCM agreement?

c. If the WTO adopts the EU's interpretation – that the GATT exclusion does not apply to procurement that favors local content – then what meaning is there in asking states to participate in FTA procurement chapters?