The Maine Citizen Trade Policy Commission

Maine was the first state to pass legislation to establish a **Citizen Trade Policy Commission**. This bi-partisan 22-member panel is charged with investigating the impact of international trade agreements on Maine workers, businesses, small farmers, and environment. Comprised of legislators and citizens representing a variety of constituencies, like farmers, labor, small business, manufacturers, and environmental non-profits, and representatives from Maine State Agencies, the Maine CTPC is a leader nationally in monitoring the impact of trade agreement on the state and speaking up to ensure change is made.

Since the Legislature established the coalition in 2003, the CTPC has helped to support bi-partisan legislation regarding trade gain unanimous support in the Legislature.

Currently, the CTPC works closely with the Governor and his staff to make sure Maine is weighing in together at the national level to change these undemocratic trade rules.

Why do states care about trade policy?

Free trade agreements like the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) contain provisions that allow foreign companies or countries to challenge local, state or federal laws or policies they don't like. They can claim the laws are "barriers to trade" and then sue for millions of dollars in lost *future* profits, or the money they claim they would have made had the law not been in place.

It gets worse. These cases are not heard in our domestic courts, but rather in closed door international trade tribunals.

Important environmental and public health and safety laws are all vulnerable to challenge. Countries and states that lose their case have to either overturn their law or pay a huge fine.

Examples of state sovereignty undermined by free trade agreements:

- California banned the additive MTBE from gasoline because it was contaminating groundwater. Methanex, a Canadian company that manufactures MTBE, sued the U.S. under NAFTA because of California's law.
- A state legislator in Maryland received a letter at his home from the People's Republic of China warning him that they would challenge his bill to limit lead in children's products. A state legislator in Vermont also received a letter at her home from the People's Republic of China, warning the same regarding her bill on the recycling of electronics.
- A town in Mexico tried to stop a toxic waste facility from polluting their water source, but they were sued under NAFTA by the company. They lost their case.
- ME laws about procurement, public health, and environmental protection are vulnerable.
 Maine policies on LNG, water extraction, pharmaceutical purchasing, kid's products, and insurance regulation are threatened by these trade rules.

Although we don't set trade policy at the state level, Maine is speaking out to fix trade policy so it better benefits our economy, workers, businesses, and state sovereignty.

International trade agreements

Compiled by Sarah Bigney Sources: WTO: <u>www.wto.org</u>, Forum on Democracy and Trade: <u>www.forumdemoracy.net</u>

NAFTA: North American Free Trade Agreement

Free trade pact between Mexico, U.S., and Canada. Went into effect in 1994. Removed tariffs and quotas and opened markets in all three countries to each other.

CAFTA: Central American Free Trade Agreement

Free trade pact between U.S., Costa Rica, Honduras, El Salvador, Nicaragua, Guatemala, and the Dominican Republic. Passed in 2005. Modeled after NAFTA.

WTO: World Trade Organization

Organization of 153 countries, designed to liberalize trade, eliminate taxes or tariffs and open borders for free flow of goods. Created in 1995 out of its predecessor the General Agreement on Taxes and Tariffs, or GATT. The WTO governs by completing "rounds" of negotiations and coming to a series of agreements that representatives of member nations agree to and each countries' parliament or Congress must ratify.

There are about **60 agreements of the WTO**. A few of the most significant are:

Agreement on Agriculture (AoA)

The AoA has three central concepts, or "pillars": domestic support, market access and export subsidies.

• General Agreement on Trade in Services (GATS)

The GATS was created to extend the multilateral trading system to service sector, in the same way the General Agreement on Tariffs and Trade (GATT) provides such a system for merchandise trade. This particularly effects state governments that oversee service licensing, etc.

Trade-Related Aspects of Intellectual Property Rights (TRIPs)

The Agreement on Trade-Related Aspects of Intellectual Property Rights sets down minimum standards for many forms of intellectual property (IP) regulation.

• Technical Barriers to Trade (**TBT**)

TBT attempts to ensure that technical negotiations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade.

Other bi-lateral free trade agreements modeled after NAFTA of which the U.S. is a party:

U.S Chile Free Trade Agreement (FTA)	U.S Bahrain FTA
U.S Peru Trade Promotion Agreement (TPA)	U.S Oman FTA
U.S Singapore FTA	U.S - Israel FTA
U.S Australia FTA	U.S Morocco FTA

Trade key terms

USTR: United States Trade Representative: The USTR is an ambassador level appointee of the Presidential administration designated to oversee international trade policy. The current USTR is Ron Kirk.

Doha Round: Current round of negotiations at the WTO. The round began in 2001 and has not been completed because an agreement cannot be reached. The talks collapsed in the most recent summit in 2008. Agricultural tariffs are one of the major sticking points.

Fast-Track: (Also called TPA- Trade Promotion Authority) The mechanism by which Congress gives up its constitutional right to negotiate trade policy and allows the Presidential administration to do the negotiating. After the agreements are negotiated, Congress gets an up or down vote on the agreement with no chance to amend. Once the President submits a trade agreement for ratification, Congress only has 90 days to get the bill through both chambers. There is a limit of floor debate to 20 hours in each chamber. Fast-Track expired in 2007 and has not been renewed, so there currently is no negotiating mechanism for trade agreements.

Federal/State Consultation: Although the current model of free trade agreements directly impacts state sovereignty and federalism, the process by which they are negotiated includes no meaningful consultation with states.

IGPAC: The Intergovernmental Political Advisory Committee is one of many advisory committees to USTR. IGPAC is the only advisory committee to represent the interests of state and local governments. It has neither funding nor staff, and is often unable to access important information on negotiations. It has 30 members, so not all states are represented.

Investor-State Rights: Found in NAFTA Chapter 11 and CAFTA Chapter 10, and in subsequent trade agreements, these provisions grant the right to foreign investors the right to challenge federal, state or local laws they think limits their right to future profits. They can sue a country for damages or a reversal of the law or policy they see unfit.

Dispute Mechanism: Under the WTO, if one country feels that another has broken one of the agreements it can bring forward a challenge. This dispute settlement is similar to investor-state rights disputes, but instead of foreign investors bringing the challenge, the country itself has to bring a challenge, so they are state-state disputes. These cases are not heard in domestic courts but rather are decided by an international tribunal. There can either be a fee levied, or the offending nation can offer up other sectors to open as a settlement.

Domestic Regulation: Proposed GATS provisions that would create major restrictions on the ability of sub-federal governments (i.e. U.S. states) to license, regulate, or govern the service sector.



States' Rights and International Trade

What do international trade agreements have to do with states? Isn't this a federal issue?

Trade is no longer simply a federal matter. Today's international trade agreements delve deeply into matters of state law. Pacts like the North American Free Trade Agreement (NAFTA) and various World Trade Organization (WTO) agreements contain numerous policy obligations and constraints to which U.S. federal, state and local governments are bound to conform their domestic policies. These types of "trade" agreements, which were passed in the United States using an extremely outdated trade negotiating process called Fast Track Trade Authority, undermine state regulatory authority in three major areas: government procurement, service-sector regulation and investment.

> Does the federal government ever consult with states on international trade?

While the federal government generally works cooperatively with states and state international trade offices in the area of export promotion, in other extremely important areas, consultation has been extremely limited or nonexistent. The Office of the U.S. Trade Representative (USTR), which is the cabinet-level, executive branch agency that negotiates U.S. trade agreements, relies on a severely flawed, outdated system for consulting states on trade-related matters. The current consultation system includes rare direct consultation only with governors on procurement issues; indirect consultation on services and other matters through a state Single Point of Contact (SPOC); and limited suggestions through the government-appointed Intergovernmental Policy Advisory Committee (IGPAC), who are required to have security clearances and are forbidden to share the information they receive with anyone else in the state government.

What are some specific examples of state laws that could be threatened by these agreements?

Many common state policies could be threatened under the procurement, investment and service sector rules of various trade agreements. Under procurement rules, jeopardized policies include measures to prevent offshoring of state jobs; "Buy Local" or "Buy America" policies; preferences for recycled content or renewable energy; and policies targeting companies' human rights, environmental and labor conduct. Under service sector rules, jeopardized policies include a variety of state gambling restrictions, health care policies, higher education subsidies, transportation policies, energy policies and many more. Under investment rules, an incalculable number of state regulations that might negatively impact a foreign investor's profitability could be challenged, including environmental and public health measures such as toxics bans and tobacco controls, adverse court judgments and more.

What happens if a state law is found as a "barrier to trade" under one of these agreements?

If another WTO nation challenges a state policy as a violation of one of the many WTO agreements, the case goes to a powerful, binding dispute resolution system built into the WTO. State and local officials have no standing before the WTO tribunals and must rely on the federal government to defend a challenged state or local policy. Tribunals are staffed by a rotating roster of trade lawyers who are not subject to conflict-of-interest rules and who may have no expertise in the matter at hand, yet are empowered to judge whether a local policy has resulted in a violation of a particular trade agreement – without reference to any U.S. law and jurisprudence on the matter. If a state law is ruled against in one of these trade tribunals, the policy must be eliminated or amended, or the federal government is subject to punitive trade sanctions until the violation is remedied.

In the case of NAFTA, in addition to the tribunals that can authorize trade sanctions, there is an additional enforcement system with tribunals empowered to order that cash damages be paid to corporations that are permitted to directly challenge state laws as a violation of their NAFTA-granted foreign investor rights. Though it is the federal government that is technically liable for these cash damages, state governments could be held hostage for the funds. Simply defending one such corporate attack on a California law banning the gasoline additive and water pollutant MTBE has cost over \$3 million in legal fees alone.

Have any state laws ever been challenged as a barrier to trade?

One notable case occurred in 1997, when the European Union (EU) and Japan challenged a Massachusetts law banning purchases from companies that did business with the dictatorship in Burma (Myanmar). The EU argued that the state's

procurement policy had to conform to WTO rules and that the Burma law contravened the WTO procurement agreement by imposing conditions that were not "essential to fulfill the contract." While this WTO suit was withdrawn because the same business interests were pursuing a parallel suit in the domestic court system (that eventually succeeded in undermining the state law on narrow grounds that federal policy already existed on the Burma trade issue), this EU-Japan formal WTO attack on Massachusetts' law was then used by the U.S. State Department as Exhibit #1 when Maryland sought to pass similar legislation regarding the Nigerian dictatorship's brutal human rights violations. Federal government officials descended on the state capital lobbying to kill the proposal, which had been expected to pass easily. In the end, the bill was defeated by one vote.

After an initial wave of WTO cases and NAFTA foreign investor challenges, the enforcement of the NAFTA and WTO policy constraints has gotten more subtle – with challenges being threatened as a way to chill innovation or trigger federal government pressure against state initiatives. Although there is not a long list of formal WTO or NAFTA cases against U.S. state policies, the cases that have been launched are illustrative of the threats posed to normal governmental activity and legislative prerogatives by the NAFTA-WTO model.

What actions have states taken to safeguard their sovereignty from trade agreement incursion?

Many states have taken action in various ways to fight for fairer trade policies. Alarmed at the role the WTO's servicesector agreement has already had in accelerating the offshoring of service-sector jobs and worried about the problems the agreement could pose for quality health care and higher education, in 2006 four state governors took decisive action to safeguard their states from the worst aspects of the General Agreement on Trade in Services (GATS). Governors Baldacci of Maine, Kulongoski of Oregon, Granholm of Michigan and Vilsack of Iowa wrote to the USTR demanding that their states be carved out of prior and future U.S. GATS commitments.

Due to the growing awareness that states have much to lose and little to gain by signing up to the restrictive procurement rules of trade agreements, 31 states declined to sign onto the Central America Free Trade Agreement (CAFTA) procurement provisions in 2005. Also in 2005, two state legislatures took the extra step of clarifying the legal procedure at the state level regarding trade agreements' procurement provisions. Maryland and Rhode Island both passed laws that ensured the power to sign up to the procurement terms of any trade agreement rest exclusively with the state legislature.

> Does a state lose business opportunities overseas if it doesn't sign on to the procurement terms of a trade agreement? If a retroactive bill is passed, will these procurement contracts be invalidated?

Whether a state has signed on to the procurement chapter of a trade agreement or not, it still is qualified to bid for federal contracts in other countries in a trade agreement regardless of the state's signatory status. Thus, the only potential gain if a state signs on is the right to bid for *subfederal* contracts in other countries. Yet, the marginal benefit of additional business opportunities overseas depends on how many subfederal entities in other countries are bound to the procurement terms and how that other country deals with procurement vis-à-vis the portion of procurement conducted nationally versus locally. Second, the notion that most state businesses could take advantage of whatever marginal, additional subfederal overseas procurement opportunities might exist is in itself questionable, as mainly large and/or multinational firms, not smaller state businesses, have the capacity to undertake major international projects. If a state passes a law retroactively invalidating that state's participation in a procurement agreement with country X, this should not affect current state contracts made with overseas providers from country X. Whether or not a company was granted a contract probably has nothing to do with a state's participation in a specific trade agreement.

How can a state be a part of the fight to replace Fast Track?

States can take two actions as part of a nationwide effort to encourage the federal government to replace the failed Fast Track model. First, states can pass binding legislation like Maryland and Rhode Island did that formally clarifies and clearly provides that only an act of the state legislature – not just a governor's signature – can bind a state to the non-tariff terms included in any trade agreement that affects state regulatory authority. Second, to play a role in federal level reforms, states can pass nonbinding resolutions urging the replacement of the failed Fast Track model with a new mechanism that requires checks and balances, including by requiring federal trade negotiators to seek the formal consent from state legislatures prior to binding states to conform their laws to the terms of international trade pacts. If a large number of states were to pass such resolutions, it would send a powerful message to Congress that states expect their concerns about Fast Track running roughshod over state sovereignty to be addressed when Congress replaces Fast Track.



What's TRADE got to do with it? – Understanding the reach of new international agreements

The whole idea that rules found in international trade agreements could impact local governments seems far-fetched at first. How could an international agreement impact on the traditional powers vested in local governments? How could trade rules limit the scope of citizen input into democra-tic decision-making?

Trade rules are about lowering the barriers for companies trying to sell into foreign markets. Sellers of *goods* have worked for fifty years to lower the tariffs—the at-the-border taxes—that discriminate, on price, against foreign products.

But the latest generation of trade agreements propose much more comprehensive deals. It's not just about selling goods; it's also about selling *services*, and making *investments*. In most communities, the right to provide a service is dependent on the issuing of a permit or license. Foreign investors want assurances that they can get money into a country—and their profits out—with a minimum of red tape.

U.S. investors and local service suppliers understand how democratic traditions inform the way they do business. Rules may change; community values may need to be accommodated. Businesses also rely on the U.S. constitution's 'due process' protections to guard against unlawful seizure of assets. Obviously, businesses also try to make changes in local laws and procedures using the tools of local democracy available to them.

But here's the rub. Multinational sellers of services, and foreign investors, are seeking to change the way that state and local governments do business. They've done so not through the sorts of 'bottom-up,' grassroots efforts at democratic change that characterizes American politics. Instead, they've sought to impose changes 'from above.' And the mechanism for doing so has been through international trade rules, and arguments to the federal government that it should preempt states for the sake of harmonization international standards.

The rules are complex, and drenched in 'legalese.' Rather than pick apart these rules to try to parse out their meaning and applicability, consider instead the following two 'case studies,' modeled on real-life situations.

By following these two 'fact patterns,' it's possible to learn a lot about key provisions in the NAFTA (North American Free Trade Agreement) and the WTO (World Trade Organization) agreement on services.

The water district in a town in New England enters into discussions with a Canadian investor about withdrawing groundwater for use in a bottling plant. The investors present their plans to the state hydrologists, who say, "We'll have to run some tests on flow and recharge rates, but this seems okay to us." The investor gets a business license based on that exchange, and on the investor's submission of initial documents.

(Importantly, the investor documents this conversation with the state hydrologist. Maybe the investor even records it on tape. And puts that documentation in a file.)

Meanwhile, the municipal water district reviews the investor's plan, and decides that it is consistent with the municipality's comprehensive land-use document—that the water withdrawal isn't such a big deal and it should be considered a "low impact business."

But word of the plan gets out, so before the final permitting decisions are made, the water district is confronted with intense public opposition to the idea of the water withdrawal. And so the water district, together with the town planning board, holds a public hearing, hearing testimony from citizens—who, it turns out, are pretty much united in their opposition to the proposed project.

For some people, it's the loss of groundwater that's disturbing. For others, it's the proposed increase in truck traffic on their roads, resulting from the new bottling facility. In any case, it is now clear that the community doesn't consider the proposed water withdrawal to be a 'low impact business,' and so the planning board says, 'whoa, we better look at this.'

Three months later, the project permits are issued. However, the permit only allows for a modest volume of daily water withdrawal; the request to build a new truck-transfer station is denied; and limits on the time, size, and daily number of trucks moving through the town to the water-withdrawal site are imposed. In its decision, the town notes the importance of public input in finding the appropriate 'balance of interests.'

Knowing that U.S. domestic law limits the definition of the 'expropriation' of assets to physical occupation of the property, or the denial of ALL productive uses of the assets, the foreign investor does not challenge the modifications made to the permit, and moves ahead with the project at this smaller scale.

End of story, right? Well, not anymore. In the decade since NAFTA was signed and the WTO was created, there's the possibility that these investors might get a "second bite at the apple."

In this case, the Canadian investor has the option to sue—but not in the U.S. courts, where s/he would surely lose. Instead, as a result of NAFTA investment rules, the investor can file a claim to hear the case before an international investor tribunal. These tribunals are composed of three arbitrators, who themselves are usually commercial lawyers, rather than U.S. judges. The judges don't necessarily have to be American or Canadian citizens, or to have much legal background in the jurisdictions represented in the dispute.

The investor in the first case could claim that the state hydrologists made a promise that the permit would be granted. (Remember that meeting, where the investor took notes, and filed those notes away for possible future use? Did the state hydrologist also keep notes of the conversation? And so when they come before the NAFTA investment tribunal, one party has notes from that day, and the other doesn't—whose version of events can be documented?) The investor also could claim that testimony given at the public hearing was "anti-Canadian" (maybe some of it was); or that the loudest and angriest voices at the public hearing were able to dominate the proceedings—and that all

this resulted in a denial of justice, and a financial loss for the investor. If the arbitrators were to rule for the investors, then the U.S. government would have to pay them for their "lost profits."

The scenario outlined here pulls different 'fact patterns' from actual NAFTA cases. In one notorious dispute, called *Metalclad*, the assurances given to the investor by officials at higher levels of government were taken as a significant factor in ruling *for* the investor, when the town itself wouldn't grant the necessary permits. In many other cases, investors faced with the choice of accepting the compromise given by government officials or resorting to international arbitration have chosen to hold out, to get a second bite at the apple by litigating their claim through an investment tribunal. And finally, in a case still pending that concerns the decision by California to try and prevent open-pit cyanide leach-heap gold mining after a federal permit to dig had been issued (*Glamis*), the Canadian investor actually said in an interview that he was taking his case to a NAFTA investment proceeding because the chance of "success" in that venue was better. He acknowledged that these tribunals represent a more investor-friendly forum for dispute resolution.

A major European property developer and banking consortium, working with a couple of big U.S. retailers as 'anchor tenants', proposes to build a new shopping mall on the outskirts of a [Massachusetts] city. The developer applies for the permits and licenses necessary to break ground on the new project.

The developer gets his permits. But there's a problem. Between the time the developer applied for the permit and its granting, the city changed its definition of what constitutes a 'Big Box' store. It used to be that the city—concerned with revitalizing its downtown, and with reining in 'sprawl'—zoned out any store with floor space greater than 200,000 square feet. Didn't allow them at all. The developer designed the shopping mall with this consideration in mind, and the 'anchor tenants' developed their store plans accordingly.

But the city has drafted new guidelines—maybe in response to this specific development application, maybe not. The city will allow stores with a square footage of between 100,000 and 200,000 square feet, but stores that big have to apply for special permits. Also, they are limited in how much land they can use for parking lots, what kind of lighting they can use, and the store also has to make promises about guaranteeing a certain percentage of managerial and floor jobs to local residents.

The 'anchor tenants' are just not willing to make those changes to the store design, and they pull out of the project. The property developer hasn't broken ground on the project, but all the work to date represents substantial 'sunk costs.' The developer sues the city.

Citing the precedent in the case of Kittery Retail Ventures LLC v. Town of Kittery—*in which the Maine Supreme Court ruled that towns and cities can change their permit-granting criteria even after a development permit is requested, so long as the permit hasn't been granted yet*—*the court in this case upholds the change in zoning laws.*

The developer is still free to find other tenants that conform to the new city guidelines, and to move ahead with the project accordingly.

This second case is constructed to illustrate something that's at stake in the global trade debate right now. Members of the WTO (including the U.S.) are currently negotiating new rules regarding the *permitted scope of domestic regulation*. Permitted by whom? That is, permitted by WTO rules. Applied to what? Applied to all levels of government. This is an example of a proposed international law that goes far beyond what we usually think of as the purpose of a trade rule—which is to prevent discrimination against foreign businesses. No, in the case of the domestic regulation rules, the WTO *seeks to impose limits on how governments can regulate in the public interest*, and it seeks to impose that limit on *governments at all levels: national, state, city, township, water district*.

Very briefly, the proposed rule that this case illustrates is called "pre-establishment". Proponents of these rules have argued that it should be very, very expensive for governments to change their minds —that is, once they've established the rules, that's it, they shouldn't be allowed to change them during the course of a permitting or registration process. Can't deny the license based on community opposition; can't change regulations while a license is pending; can't impose any new conditions as part of the licensing process; and can't even insert any new requirements at a later time when the license needs to be renewed.

Those rules aren't in place yet. They are still on the table. But the collapse of the 'Doha Round' of international trade negotiations didn't derail this negotiation. In fact, it didn't even really slow it down. Negotiators in the 'Working Party on Domestic Regulation' will return to work later this year to see if they can finalize this set of rules. And there are many voices at the table that are arguing for (among other intrusive rules) the inclusion of this "pre-establishment" test.

These scenarios illustrate that the WTO and NAFTA go well beyond what most of us consider to be the normal, legitimate scope of a trade agreement—which is to prevent discrimination against foreign commerce. The new global rules instead limit the democratic space available to states, cities, and communities—as well as to national governments, for that matter!

Discussion of the first case focused on NAFTA—the investor was Canadian. Individual investors can bring claims under NAFTA, regardless of whether the Canadian federal government thinks the case has merit or whether it might cause a diplomatic rift between the countries. NAFTA claims can be brought against the United States by *any investor* that has a substantial business presence in Mexico or Canada. That means that under certain circumstances, Wal-Mart Mexico could bring a claim against big-box store rules in New England states. It means *any North American subsidiary of a U.S. corporation* could avail itself of this trade-agreement provision.

The second case looked at a proposed WTO rule. The WTO only allows national governments to raise a claim. WTO cases have usually been filed after diplomacy and bilateral negotiations have failed. But such diplomacy and negotiation of a settlement is frequently accompanied by intense lobbying and pressure brought 'from above.' Two quick examples:

★ At the WTO, the European Union and Japan challenged the Massachusetts law that said, "if you do business with the slave-labor regime of Burma, you can't do business with us." The WTO challenge was suspended while a legal case wound its way through the U.S. courts. Eventually, the National Foreign Trade Council, a lobbying operation that acted as plaintiff in the domestic court case, won their case. If Massachusetts had won, there's no doubt that Europe and Japan would have reactivated their WTO challenge.

The Pharmaceutical Researchers and Manufacturers Association (PhRMA) *lost* three

different cases against state drug-purchasing laws in U.S. federal courts. The same language and arguments used by PhRMA in its unsuccessful bids soon thereafter found its way into U.S. trade negotiating positions. Sure, PhRMA argued that this language was now intended to constrain the drug-purchasing approaches used by U.S. trading partners—rather than to be used against the states. But it took a group of state legislators meeting with U.S. trade negotiators--demanding that an explicit carve-out of that language vis-à-vis the states be included in future trade agreements—to safeguard the rights of states to use preferred drug lists, and to clarify that this PhRMA-crafted language could not be turned against the states in future.

In general, Americans support the international trading system, so long as there's a 'level playing field' with clear rules to the game. Maybe it's time to look anew at the size of the playing field, rather than just whether it tilts this way or that. Maybe some issues are so important to our democracy that they simply don't belong on this negotiated field. Because when trade rules conflict with long-cherished traditions of local control and governance, most Americans would probably choose to safeguard their democracy.

What can State Oversight Commissions on International Trade Do?

International trade commissions set up at the state level can play important roles in raising issues of democracy and local control. How best to respond to international pressures on local decision-making? Among the ideas being discussed:

- State and local governments could do more to ensure that businesses applying for permits and licenses are aware of the rules regarding public hearings, comment periods, and other avenues for citizen input. While this may be 'second nature' to U.S. businesses, new investors in our economy may be less familiar with democratic rights of redress.
- States and cities have considered writing provisions into the permits they issue that would require corporations to waive their use of NAFTA Chapter 11's dispute resolution machinery. Obviously, this doesn't eliminate a company's right of redress; it simply ensures that those grievances are heard by domestic courts, not by NAFTA tribunals.
- Some states, and some of the national associations that represent state and local governments, have already lobbied Congress to call for a revision of existing investment rules, so that foreign corporations enjoy no greater right to compensation than do U.S. investors.
- States and cities are communicating to U.S. trade negotiators about the proposed WTO rules, like pre-establishment discussed above. (Collectively these proposed new rules are called the 'disciplines on domestic regulation.') States and cities have shown instances where citizen input led to modifications of permits and licenses. They wish to ensure that our trade negotiators will not agree to any new 'disciplines' that would prevent local governments from taking decisions based on the balance of input from all parties, including input through citizen petitions, hearings, and other democratic means of expression.
- Members of state oversight commissions can talk to their members of Congress about the proposed WTO rules. Even if the Congress decides that, on balance, a new trade agreement is in the best interests of the United States, right now Congress could make 'reservations' or modifications to any proposed agreement that comes before it for ratification.

CITIZEN TRADE POLICY COMMISSION AGENDA

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

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

I.

(1:05pm -1:40pm) State Consultation – How can Maine have more direct consultation with USTR? Joint presentation

- A. Rep. Peggy Rotundo a historical perspective of the CTPC and the USTR (see Resolve)
- B. Rep. Sharon Treat the role of IGPAC and facilitating the relationship with USTR
- C. Wade Merritt (CTPC member) The role of the Maine International Trade Center

II. (1:40-2:20) Recent developments regarding the Trans Pacific Partnership Agreement (TPPA)

- A. Rep. Sharon Treat Pharmaceutical provisions of the agreement and the goal of affordable medicines
- B. Professor Bob Stumberg Regulatory provisions of the TPPA and the potential implications on domestic regulation
- III. (2:30 3:00) A local perspective Calais and St. Stephen New Brunwick
 A. Discussion with Diane Barnes, Calais Town Manager and John Ferguson, Chief Administrative Officer, St. Stephen, New Brunswick

IV. (3:00 – 3:20)Trade Adjustment Assistance Program

A. Briefing on the administration of TAA in Maine – Judy Pelletier, Trade Program Coordinator, ME Dept. of Labor

V. (3:20 – 4:00) Bi-annual assessment

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

Commission Adjourns

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

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

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

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

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

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

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

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

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

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

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

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

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

HP1152, LR 2133, item 1, First Regular Session - 125th Maine Legislature, page 1

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

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

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

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

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

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

10 §13. LEGISLATIVE APPROVAL OF TRADE AGREEMENTS 10 §13. LEGISLATIVE APPROVAL OF TRADE AGREEMENTS

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

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

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

[2009, c. 385, §1 (NEW) .]

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

[2009, c. 385, §1 (NEW) .]

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

[2009, c. 385, §1 (NEW) .]

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

[2009, c. 385, §1 (NEW) .]

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

[2009, c. 385, §1 (NEW) .] SECTION HISTORY 2009, c. 385, §1 (NEW).

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

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

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

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

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

PARAGRAPH X.2: TRANSPARENCY RELATED TO HEALTHCARE TECHNOLOGIES

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

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

PARAGRAPH X.3: PROCEDURAL FAIRNESS RELATED TO HEALTHCARE TECHNOLOGIES

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

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

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

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

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

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

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

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

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

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

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

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

• Is it grounds for appeal if not detailed enough?

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

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

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

Resources:

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

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

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

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

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

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

Resources:

- For a detailed report on off-label fraud settlements, see the report "Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010," (December 16, 2010) posted here: http://www.citizen.org/hrg1924.
- For information about digital marketing and the use of social media, unbranded websites and other tools that promote off-label and deceptive marketing, see "Questions Linger on Social Media Regulations for Pharma" by Michael Pogachar, iHealthBeat Associate Editor, <u>http://www.ihealthbeat.org/features/2011/questions-linger-on-social-media-regulations-forpharma.aspx#ixzz1blUpiIBG</u>
- And the petition to the US FDA from the Center for Digital Democracy, linked here: <u>http://www.centerfordigitaldemocracy.org/online-drug-marketing-fda-filing</u>

Comparison of FTA Texts:

TPPA

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

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

KOREA

Article 5.4: Dissemination of Information

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

AUSTRALIA

5. Dissemination of Information

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

PARAGRAPH X.7: DEFINITIONS

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

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

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

Article 5.8: DEFINITIONS

For purposes of this Chapter:

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

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

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

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

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

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

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

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

> Rep. Sharon Treat Maine Legislature

Executive Director, National Legislative Association on Prescription Drug Prices



October 23, 2011

Rep. Sharon Treat Stakeholder Presentation

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

□ Federalism: States & federal government jointly govern domestic policy as set forth in US Constitution

□ States have major role regulating and providing access to health care

□ States have limited role advising on trade policy

□ Formal state role: IGPAC

- □ Increasing state activism through state commissions on trade & sovereignty including ME,VT, NH, WA, UT, CA
- □ State laws: no commitment of states without state vote

State Health Care Role

- Medicaid jointly funded federal/state program for low income, disabled and children, largely implemented by state governments pursuant to federal rules
- 40 States Negotiate Medicaid Drug Prices
 through Preferred Drug List (PDL) State
 purchase price for branded drugs and many
 generics discounted through (1) federal rebate and
 (2) state rebates
 - □ Rebates can be significant In aggregate, Maine receives back 50% off "market price" in rebates

State-by-state rebate negotiation to be replaced by national reference price list under the Affordable Care Act in 2012



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

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

State Health Policy Role Goes Beyond Medicaid

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

□ 340B pricing is <u>below</u> Medicaid pricing



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

Veterans' Health Care – Reference pricing based on formulary

□ **Medicare Part B** – hospital drugs for elderly

Rep. Sharon Treat Stakeholder Presentation

US Government Share of Medicine Spending Significant

 Spending on prescription drugs in the US was \$234.1 billion in 2008. It has been one of the fastest growing components of health care spending – 6 times what was spent in 1990.

□ Government's share of prescription drug spending is 37% of the total.

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

□ 27.6 million enrolled in Medicare Part D

Rep. Sharon Treat Stakeholder Presentation

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

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

Rep. Sharon Treat Stakeholder Presentation



NO

☑ Public session negotiating rebates (price) and determining which drugs will be "preferred" on PDL

Detailed written explanation of transparent & verifiable basis for reimbursement decision

Opportunity for **independent appeal** or review of decision

Consistent administration in all 50 states, D.C. & territories

Rep. Sharon Treat Stakeholder Presentation



Medicaid Carve-Out in Korea-US FTA

□ **Footnote**: Medicaid is a regional level government program, FTA rules only apply to central level

□ No mention of 340B clinics and hospital prices

- Doesn't carve out Medicare Part D if President Obama succeeds in requiring government rebates in budget
- State Legislators & Governors: Footnote fails to carve out all public health programs, and ties hands for future changes such as Medicare Part D reference prices

Rep. Sharon Treat Stakeholder Presentation

Questions:

□ Will the TPPA include similar carve-out language?

Leaked text: NO FOOTNOTE

Should the TPPA require transparency and reimbursement standards that the United States does not itself fully comply with?

Other US states' concerns – reimbursement rules will increase prices

□ Reimbursement tied to market prices within territory will forever link US reimbursement to some of the highest market prices in the world and limit affordability

□ Where is the link to **affordability**?

- □ Waiting lists in US for AIDS drugs 7,299 in 10 states as of October 2011
- States cutting health care budget by limiting eligibility for public programs & increasing patient cost sharing – 15 states reducing or capping ADAP enrollment October 2011
- □ 60% of US bankruptcies cause by medical expenses and three-fourths had insurance

Rep. Sharon Treat Stakeholder Presentation

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Generic availability also an issue

Will US proposals in the TPPA prevent changes to current US policies that delay entry of generics to market?

"Pay for Delay" deals between patentholding manufacturer and generic manufacturer currently subject to investigation

Providing initial monopoly for first generic version on market delays competition and keeps prices high

Rep. Sharon Treat Stakeholder Presentation

Lima, Peru 10/23/11

Other state concerns loopholes in health & safety protections

Requiring Internet posting of information on drugs and devices for both consumers and medical professionals linking to any & all websites including social media will increase fraud and off-label marketing

 Between 2006-2010, 165 legal settlements by US states and federal government with pharma industry for \$19.8 Billion for off-label and deceptive marketing including Internet marketing and criminal violations
 YAZ deceptive ad lived on YouTube long after banned

Rep. Sharon Treat Stakeholder Presentation

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Lima, Peru 10/23/11



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

Recent example: metal hip joints generating "high volume of metallic debris ... absorbed into the patient's body." [NY Times]

Rep. Sharon Treat Stakeholder Presentation

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

Impossible in a secret process to seek and receive informed review of important health & safety public health rules that will bind future governments

□ There are many concerns with the marketing, transparency & pricing provisions of the TPPA even in the US

□ Irony: TPPA Transparency Provisions Developed in a Non-Transparent Process

Rep. Sharon Treat Stakeholder Presentation

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Lima, Peru 10/23/11 19

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



Contact Information

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

Twitter: @sharontreat

Rep. Sharon Treat Stakeholder Presentation

Lima, Peru 10/23/11

TRADE ADJUSTMENT ASSISTANCE REFORM ACT OF 2002

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

Has your job been adversely affected by foreign competition?

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

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

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

Benefits Available through the Trade Act

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

How can you qualify for these benefits?

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

Re-employment Services

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

Training - up to 104 weeks

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

Six criteria applied to program before training can be approved

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

Trade Readjustment Allowance (TRA) - Weekly Benefits

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

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

Duration of Training

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

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

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

Six specific situations when training can be waived

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

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

Health Coverage Tax Credit (HCTC)

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

Job Search Allowance

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

Relocation Allowance

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

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

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

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

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

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

AUGUSTA

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

BANGOR

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

BRUNSWICK

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

CALAIS

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

LEWISTON

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

MACHIAS

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

PORTLAND 185 Lancaster Street

Portland, ME 04I01-2453 771-5627 or 1-877-594-5627 TTY: 1-888-817-7113 Fax: 822-0221

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

ROCKLAND

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

SKOWHEGAN

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

SPRINGVALE

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

WILTON

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

From Troy Haines testimony

September 06, 2011

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

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

The FSPTCA took a series of unprecedented and bold measures to combat teenage smoking,



including the banning of many forms of flavored eigarettes. There is substantial evidence that tobacco companies produce and market these eigarettes as "starter" or "trainer" eigarettes in order to hook teenagers into a lifetime of nicotine addiction.

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

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

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

More on the details of the case after the jump.

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

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

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

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

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

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

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

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

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

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

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

Likeness is typically established by reference to:

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

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

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

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

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

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

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

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

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



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DISPUTE SETTLEMENT: DISPUTE DS406

United States - Measures Affecting the Production an Cigarettes

This summary has been prepared by the Secretariat under its own responsibility. The summary is for general information only and Panel report circulated on 2 September 2011 is not intended to affect the rights and obligations of Members.

See also: > The basics: how disputes are settled in WTO > Computer based training on dispute settlement > Text of the Dispute Settlement

Complainant: Respondent: Third Parties: Understanding Other disputes involving: > Cigarettes Agreements cited: > Indonesia (as cited in request for > United States

Current status back to top

Key facts back to top

consultations) > General Agreement on Tariffs and Trade 1994 > Agreement on the Application of Sanitary and Phytosanitary Measures > Agreement on Technical Request for Barriers to Trade Consultations

Short title: US - Clove Cigarettes Indonesia United States Brazil; Colombia; Dominican Republic; European Union; Guatemala; Mexico; Norway; Turkey Sanitary and Phytosanitary Measures (SPS): Art. 3, 5, 7, 2 Technical Barriers to Trade (TBT): Art. 2, 12, 2.1, 2.2, 2.3, 2.5, 2.8, 2.9, 2.10, 2.12

GATT 1994: Art. XXIII:1(a), III:4, XX 7 April 2010

2 September 2011

Summary of the dispute to date back to top

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

Consultations

received:

Panel Report

circulated:

Find all documents from this case (Searches Documents Online most recent documents app on top)

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Complaint by Indonesia.

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

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

Panel and Appellate Body proceedings

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

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

Summary of key findings

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

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

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

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

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

As regards Indonesia's other claims under the TBT Agreement, the Panel found that the United States acted inconsistently with Article 2.9,2 (obligation to notify WTO Members of technical regulations) and Article 2.12 (obligation to allow reasonable interval between publication and entry into force of technical regulations). However, the Panel found that Indonesia failed to demonstrate that the United States acted inconsistently with Article 2.5 (obligation to provide an explanation of draft technical regulation), Article 2.8 (obligation to specify a technical regulation in terms of performance), Article 2.9.3 (obligation to provide particulars or copies of the proposed technical regulation) or Article 12.3 (obligation to take account of the special development, financial and trade needs of a developing country Member), and declined to rule on Indonesia's claim under Article 2.10 (obligation to notify in cases of urgency).

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

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

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CITIZEN TRADE POLICY COMMISSION DRAFT AGENDA

Thursday, December 15, 2011 at 1:30 P.M. Room 220, Burton M. Cross State Office Building Augusta, Maine

1:30 pm Meeting called to order

I. Welcome and introductions

- A. New member(s)
- B. CTPC session staff Lock Kiermaier

II. Consideration of annual report

III. Transpacific Partnership Agreement

- A. Bi-annual assessment -discuss scope and process to complete
 - 1. Overview of Transpacific Partnership Agreement (TPPA)
 - 2. Narrow areas of focus and how to create proactive positions on the TA
 - 3. Potential contractors to conduct the assessment
 - 4. Timeline for completion
- B. USTR request for comment on Canada, Japan and Mexico joining TPPA

IV. Response to Department of Treasury request for public Input on the Report to Congress On How to Modernize and Improve the System of Insurance Regulation in the United States

V. Financial report

VI. Schedule next meeting date and suggestions for agenda topics

Adjourn

Citizen Trade Policy Commission

Public Law 2003, Chapter 699

Wednesday, December 14, 2011

A _____ intment(s) by the Governor

John Palmer

P.O. Box 519 Oxford, ME 04270 207 539-4800

Harry Ricker

35 MacIntosh Drive Turner, ME 04282 207 754-3455

Appointment(s) by the President

Sen. Roger L. Sherman - Chair P. O. Box 682 Houlton, ME 04730 207 532-7073

Sen. John L. Patrick 206 Strafford Avenue Rumford, ME 04276 207 364-7666

Sen. Thomas Martin Jr. 1308 Clinton Ave. F on, ME 04901

Stephen Cole 80 Bristol Road Damariscotta, ME 04543

Michael S. Hiltz 45 Pleasant Ave. Portland, ME 04103

Joseph Woodbury 508 Gore Road Otisfield, ME 04270 **Representing Small Business'**

Representing Small Farmers

Members of the Senate

Senate Member

Members of the Senate

Representing Economic Development Organizations

Representing Health Care Professionals

Representing Maine-based Manufacturing Business' with More than 25 Employees

Appointment(s) by the Speaker

Rep. Joyce Maker - Chair 89 Lafayette Street Calais, ME 04619

Rep. Margaret Rotundo 446 College St. Lewiston, ME 04240 207 784-3259

Rep. Bernard L. Ayotte 1469 Van Buren Road Caswell, ME 04750 207 325-4905

Michael Herz P.O. Box 1462 Damariscotta, ME 04543

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Commissioner, Department of Health & Human Services

Barbara Van Burgel Director DHS Bureau of Family Independence 11 SHS Augusta, ME 04333 207 287-3106 Members of the House

House Member

House Member

Representing Nonprofit Environmental Organizations

Representing Nonprofit Human Rights Organizations

Representing Organized Labor

Attorney General or designee

Commissioner or designee

Commissioner or designee

Commissioner, Department of Labor

Michael Roland

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Representing Maine International Trade Center

Fox, Danielle

rom: Sent: To: Subject: Pistner, Linda Tuesday, December 13, 2011 4:35 PM Fox, Danielle; Guzzetti, Jean 2009 Assessment Recommendations

Hi, Danielle and Jean, would you please forward this to the members of the Commission? thanks!

Here is my attempt to provide some context for the "Options for the Commission to Engage on Trade Policy in 2010 and 2011" as included in the 2009 Assessment, which was done for the Commission by Bill Waren of the Forum on Trade & Democracy. Many of the options are directed at features of the trade treaty system that have the capacity to negatively impact on legitimate state regulatory efforts, and several address specific issues. The action steps involve issuing letters to Congress and the President highlighting these issues and suggesting reforms that will provide greater protection to states than do current treaty provisions. Rather than focus on the details, I've tried to provide a little background to help explain why these issues are important.

First, as a general matter, a question: why is it that international trade treaties, which have been around for several centuries, rather suddenly became important to states with the negotiation of the NAFTA?

Historically, trade treaties have generally been about identifying goods and appropriate tariffs to impose on their sale in international markets. Tariffs continue to be important to businesses and the economy. However, treaties now also cover services in addition to goods, and attempt to prevent so-called "non-tariff barriers" to trade, which include federal, state or local regulatory activities. Traditional areas of state regulation (by statute, agency rule, agency 'ecision, and even judicial decision) are now potentially the subject of challenge based on treaty provisions, not in our courts but before arbitration panels largely made up of international trade attorneys. The standards applied in a treaty dispute are not those of state and federal law and constitutions.

Preservation of State Sovereignty and Authority to Regulate in the Public Interest (pp. 47-49)

A. Reform of Measures Related to Federal Preemption & Unfunded Mandates (p.47 of the 2009 Assessment)

Trade treaties are enforced nation against nation; in the U.S., treaty challenges against state law are defended by the U.S. Secretary of State's Office. If the U.S. were to lose such a challenge, the federal government has the right to bring an action to preempt or invalidate a state law that has been found to be violative of a treaty. Some treaties also permit private investors to challenge state laws on various grounds including the taking of their property without compensation; if such a case is lost and compensation awarded against the U.S. based on a state law, the federal government may recoup those amounts from the state.

To my knowledge, no state has yet been penalized for either arbitration costs or compensation. However, costs alone can reach millions of dollars.

B. Reform of International Services Agreements (p.47)

Several key provisions common to the GATS and other treaties could be adjusted to provide greater protection to the traditional role of the states. The ideas presented in this section are not new, but have been raised by the states many times. The suggestions and their impact are summarized as follows.

An affirmative statement that states have the right to regulate, provided that regulation is in the public interest and is non-discriminatory, would bring treaty standards much closer to those that the Legislature, state agencies

1

and the courts use to determine the limits of regulation. One of the greatest concerns for states is the negotiation of the so-called Domestic Regulation rules that are proposed to create limits on regulation under the GATS, which has 153 nation members (listed here: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm). For example, one proposal would require that regulation be no more burdensome than necessary to the quality of the service, a standard that does not appear to take into account long-standing authority to regulate in the public interest to protect the health, safety and welfare of citizens. States have sought a commitment from the U.S. Trade Representative ("USTR") to oppose the "necessity rule." (The WTO's web page will give you a sense of the scope of issues that continue to be negotiated under the GATS; *see* "The Doha Agenda" at http://www.wto.org/english/thewto_e/whatis_e/tif_e/doha1_e.htm).

The USTR (under this and the prior administration) has met these concerns by pointing to the record of the U.S. Secretary of State in defending disputes involving state law. Nonetheless, states continue to press for more formal recognition of their legitimacy. In addition to the suggestion above (in the previous paragraph), states have sought to expand an existing defense in treaty disputes for legitimate national policy objectives to include state and local policy objectives.

Another area of particular concern is government procurement: the ability to choose when to obtain services from private contractors, when to provide them through public agencies, and when to make a change in either direction. Treaties do recognize the importance of this authority by giving state governors the right to opt in or out of contract procurement provisions in treaties. The suggestion here is that states should be able to opt in without putting their procurement decisions at risk as discriminatory (for ex., a claim that by selecting one contractor the state is discriminating against other providers).

C. Reform of International Investment Agreements and Treaties (pp. 47-49)

NAFTA and other trade agreements give individual investors the right to sue the U.S. based on a claim that a regulatory measure resulted in the expropriation of their property, for which compensation can be sought. The substantive standards applicable to these claims are more generous than their counterpart taking and due process claims under the U.S. judicial system. These claims are decided by a panel of arbitrators, wholly outside of the U.S. court system, who apply the terms of a treaty in a system that encourages trade in reaching a decision that has no precedential effect on subsequent cases. Lack of clarity in the standards for recovery adds to the difficulty of predicting the outcome of investor claims.

Several proposals are described that would narrow the circumstances under which compensation can be awarded to an investor based on the impact of a regulatory action. They include: requiring claimants to exhaust the remedies available to them in domestic and administrative agencies and courts so that a treaty dispute is a remedy of last resort; narrowing the categories of investment that are protected to those covered by the Takings Clause in the U.S. Constitution; and eliminating claims based on nondiscriminatory regulations.

State-Federal Consultation on Trade Policy (p. 51)

A. The Positive List Approach

One of the difficulties that states face in attempting to influence treaty negotiations is that they are entirely confidential; negotiators, such as the USTR, may generally describe issues under consideration, but there is generally little advance notice and rarely any release of language under consideration. A greater opportunity for input from the states would result if legislation were enacted that compelled the USTR to take particular positions on issues of importance to them.

B. A Center on Trade and Federalism

The USTR has a relatively small staff, and little or no resources to put to consultation with the states. The ssessment suggested that Congress create and adequately fund a center staffed to work with the states on their issues, studying legal and economic issues, and improving data collection to help increase exports and collaboration among the states.

The Decision Process for Initiating Trade Negotiations (p. 52)

Another way to make the negotiating process more transparent would be for Congress to legislate "readiness" criteria for future treaty partners, negotiating objectives that are truly binding, an effective process for consultation with state and local government, and a ratification process which requires that congress approve a treaty before the President signs it.

Developing the Maine Economy by Promoting Exports and by Preserving and Expanding the Number of Jobs, Particularly in the Manufacturing Sector (pp. 49-51)

A. Reform of Border-Adjusted Value Added Taxes (p. 49)

A value added tax applies to the sales price less the cost of production; under a VAT tax system, each party in the product supply chain pays tax on the value of its contribution to the product sold. So, for ex., the raw materials provider charges tax on the value of the raw materials, and the manufacturer of the end product charges tax on the difference between the sales price and the cost of purchasing raw materials, with the end result a tax on the total alue. Under European tax systems, exporters are allowed rebates on Value Added Taxes, but efforts by Congress to establish tax rules that would put U.S. exporters in a similar position to make them competitive were struck in WTO arbitrations as violative of the provisions against subsidies of exports.

B. Reform of Policy to Assist Small and Medium Sized Exporters (pp. 49-51)

More could be done at the federal level to assist small and medium sized businesses to benefit from international markets. Suggestions listed here include increasing the amount of export assistance loans and grants, and increasing the number of Small Business Administration export finance specialists in Export Assistance Centers.

C. Currency Manipulation Reform (pp. 50-51)

Artificially low currency values can amount to an illegal government subsidy of trade, and tend to cause a trade imbalance between countries. This problem has been addressed in some instances by bringing disputes to the WTO. The suggestion here is that Congress could legislate consequences for currency manipulation that would address the problem more quickly.

Linda M. Pistner Chief Deputy Attorney General 6 State House Station Augusta, ME 04333 (207) 626-8820

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POTENTIAL FRAMEWORK FOR CTPC 2011 ASSESSMENT FOR DISCUSSION PURPOSES ONLY

10 MRSA §11, sub-§9, ¶C, states that the commission:

C. Shall every 2 years conduct an assessment of the impacts of international trade agreements on Maine's state laws, municipal laws, working conditions and business environment. The assessment must be submitted and made available to the public as provided for in the annual report in paragraph D;

Question: If the Transpacific Partnership Agreement (in development) is to be the topic – What does the CTPC want from the assessment?

Some discussion at the conclusion of the Calais meeting on November 3rd supported using this assessment as a way for the CTPC to proactively make policy statements about the proposed trade agreement before it is finalized.

Below are some questions the commission may want to consider when determining a framework for the assessment:

- 1. Which industries in Maine might be disproportionately impacted by the TPPA? (fishing, agriculture)
- 2. What specific provisions of the TPPA being proposed are likely to place Maine vulnerable to allegations of trade violations?

Particularly if the lowest standard of regulation among member nations is the bar for NOT being a barrier to trade

- a. Procurement of goods and services by the state and local governments
- b. Workplace standards and safety
- c. Business subsidies and incentives (fishing, shipbuilding)
- d. Pharmaceuticals (pricing)
- e. Tobacco
- f. Liquefied natural gas
- 3. Are there steps the United States or Maine can take to minimize the infringement on federal/state sovereignty that the threat of trade violations (and judgments) might pose?
- 4. Since the TPPA may be modeled on previous trade agreements, are there continuing concerns about transparency, investor protection provisions, dispute mechanisms that should be addressed by the assessment? Are the more controversial aspects of these trade agreements being addressed in the development of the TPPA?

Other issues for the commission to consider:

- Commission should consider balancing the scope/subject of the assessment with what is doable by the potential field of candidates that can do this sort of work
- Timeframe for completion

Presented by D. Fox and J Guzzetti-Office of Policy and Legal Analysis December 2011 G:\STUDIES 2011\CTPC\misc\Notes on Assessment December 2011.docx

December 7, 2011

MEMORANDUM FOR ALL ADVISORY COMMITTEE MEMBERS

FROM:

Carlos H. Romero Assistant U.S. Trade Representative Intergovernmental Affairs and Public Engagement

SUBJECT: New Federal Register Notices on the Trans-Pacific Partnership

Today, USTR published three notices in the *Federal Register*:

- Request for Comments on Canada's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement
- Request for Comments on Japan's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement
- Request for Comments on Mexico's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

The comment period for each of these notices closes at noon on January 13, 2012. For questions related to Japan, please contact Michael Beeman at 202-395-5070. For questions related to Canada, please contact Mary Smith at 202-395-9404. For questions related to Mexico, please contact Kent Shigetomi at 202-395-9459.

marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character "P", followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http:// www.regulations.gov*, if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov*.

Douglas Bell,

Chair, Trade Policy Staff Committee. [FR Doc. 2011–31322 Filed 12–6–11; 8:45 am] BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Mexico's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative. **ACTION:** Request for comments.

SUMMARY: Mexican Economy Secretary Bruno Ferrari recently stated Mexico's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all

other elements related to Mexico's interest in the TPP negotiations. **DATES:** Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: http://www.regulations.gov. For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Kent Shigetomi, Director for Mexico, NAFTA, and the Caribbean, at (202) 395–3412.

SUPPLEMENTARY INFORMATION: On-December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a highstandard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at http:// www.ustr.gov/tpp.

On November 13, 2011, Mexican Economy Secretary Bruno Ferrari stated Mexico's intention to begin consultations with the current TPP participating countries towards joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Mexico. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Mexico. (b) Treatment by Mexico of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Mexico receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Mexican sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Mexico that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(ĥ) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues. (l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) "Mexico's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations." In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the http://www.regulations.gov Web site. Comments should be submitted under the following docket: USTR-2011-0020. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the http://www.regulations. gov home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the http://www. regulations.gov Web site, please consult the resources provided on the Web site by clicking on the "Help" tab.)



Public versions of all documents relating to the 2011 Annual Review will be made available for public viewing in docket USTR-2011-0015 at *www.regulations.gov* upon completion of processing and no later than approximately two weeks after the due date.

William D. Jackson,

Deputy Assistant, U.S. Trade Representative for the Generalized System of Preferences and Chair of the GSP Subcommittee of the Trade Policy Staff Committee, Office of the U.S. Trade Representative.

[FR Doc. 2011–31316 Filed 12–6–11; 8:45 am] BILLING CODE 3190–w2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Japan's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative. **ACTION:** Request for comments.

SUMMARY: Japanese Prime Minister Noda recently announced Japan's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Japan's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Japanese barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Japan's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: http://www.regulations.gov. For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Michael Beeman, Deputy Assistant U.S. Trade Representative for Japan, at (202) 395– 5070.

SUPPLEMENTARY INFORMATION:

On December 14, 2009, after consulting with relevant Congressional

committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malavsia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at http:// www.ustr.gov/tpp.

On November 11, 2011, Japanese Prime Minister Yoshihiko Noda announced Japan's intention to begin consultations with the current TPP participating countries towards joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Japan's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Japanese barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Japan. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Japan.

(b) Treatment by Japan of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Japan receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Japanese sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Japan that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.(i) Relevant competition-related

matters.

- (j) Relevant government procurement issues.
 - (k) Relevant environmental issues.
- (1) Relevant labor issues.
- (m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) "Japan's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations." In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the http://www.regulations.gov Web site. Comments should be submitted under the following docket: USTR-2011-0018. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the http://www.regulations. gov home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the http://www. *regulations.gov* Web site, please consult the resources provided on the web site by clicking on the "Help" tab.)

The http://www.regulations.gov Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment & Upload File" field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

[^]For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly



marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character "P", followed by the name of the person or entity submitting the comments.

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USTR strongly urges submitters to file comments through *http:// www.regulations.gov*, if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov*.

Douglas Bell,

Chair, Trade Policy Staff Committee. [FR Doc. 2011–31322 Filed 12–6–11; 8:45 am] BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Mexico's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Mexican Economy Secretary Bruno Ferrari recently stated Mexico's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all

other elements related to Mexico's interest in the TPP negotiations. **DATES:** Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: http://www.regulations.gov. For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Kent Shigetomi, Director for Mexico, NAFTA, and the Caribbean, at (202) 395–3412.

SUPPLEMENTARY INFORMATION: On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a highstandard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at http:// www.ustr.gov/tpp.

On November 13, 2011, Mexican Economy Secretary Bruno Ferrari stated Mexico's intention to begin consultations with the current TPP participating countries towards joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Mexico's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Mexican barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Mexico. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Mexico. (b) Treatment by Mexico of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Mexico receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Mexican sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Mexico that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) "Mexico's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations." In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the http://www.regulations.gov Web site. Comments should be submitted under the following docket: USTR-2011-0020. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the http://www.regulations. gov home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the *http://www*. regulations.gov Web site, please consult the resources provided on the Web site by clicking on the "Help" tab.)

The http://www.regulations.gov Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment & Upload File" field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

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Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www. regulations.gov,* if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

Douglas Bell,

Chair, Trade Policy Staff Committee. [FR Doc. 2011–31318 Filed 12–6–11; 8:45 am] BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Canada's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Canadian Prime Minister Stephen Harper recently stated Canada's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Office of the United States Trade Representative (USTR) is assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Canada's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: http://www.regulations.gov. For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Mary T. Smith, Director for Canada, at (202) 395–3412. SUPPLEMENTARY INFORMATION:

On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at http:// www.ustr.gov/tpp.

On November 13, 2011, Canadian Prime Minister Stephen Harper stated Canada's interest in joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Canada. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Canada.

(b) Treatment by Canada of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Canada receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Canadian sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Canada that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(h) Relevant investment issues.

(i) Relevant competition-related

matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.

(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to

innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) "Canada's Expression of Interest in the The http://www.regulations.gov Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment & Upload File" field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character "P", followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

USTR strongly urges submitters to file comments through *http://www. regulations.gov,* if at all possible. Any alternative arrangements must be made with Donald W. Eiss in advance of transmitting a comment. Mr. Eiss should be contacted at (202) 395–3475. General information concerning USTR is available at *http://www.ustr.gov.*

Douglas Bell,

Chair, Trade Policy Staff Committee. [FR Doc. 2011–31318 Filed 12–6–11; 8:45 am] BILLING CODE 3190–W2–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on Canada's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments.

SUMMARY: Canadian Prime Minister Stephen Harper recently stated Canada's intention to begin consultations with the Trans-Pacific Partnership (TPP) countries towards joining the TPP negotiations. The Óffice of the United States Trade Representative (USTR) is assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. In conducting its assessment, USTR is seeking public comments on these concerns and all other elements related to Canada's interest in the TPP negotiations.

DATES: Written comments are due by noon, January 13, 2012.

ADDRESSES: Submissions via on-line: http://www.regulations.gov. For alternatives to on-line submissions please contact Donald W. Eiss at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For questions concerning requirements for written comments, please contact Donald W. Eiss at (202) 395–3475. All other questions regarding this notice should be directed to Mary T. Smith, Director for Canada, at (202) 395–3412. SUPPLEMENTARY INFORMATION:

On December 14, 2009, after consulting with relevant Congressional committees, USTR notified Congress of the President's intent to initiate negotiations on a TPP trade agreement. These negotiations aim to achieve a high-standard, 21st century agreement with a membership and coverage that provides economically significant market access opportunities for America's workers, farmers, ranchers, service providers, and small businesses and that can expand to include additional countries across the Asia-Pacific region. Currently, the negotiations include Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam, as well as the United States. Further information regarding the TPP negotiations can be found at http:// www.ustr.gov/tpp.

On November 13, 2011, Canadian Prime Minister Stephen Harper stated Canada's interest in joining the TPP negotiations. The Chair of the interagency Trade Policy Staff Committee (TPSC) invites interested persons to provide written comments that will assist USTR in assessing Canada's expression of interest in the TPP negotiations in light of the TPP's high standards for liberalizing trade and specific issues of concern to the United States regarding Canadian barriers to agriculture, services, and manufacturing trade, including non-tariff measures. Commenters may address these issues or any other specific barriers affecting U.S. exports to or investment in Canada. The TPSC Chair invites comments on all of these matters, and, in particular, on the following:

(a) Economic costs and benefits to U.S. producers and consumers of eliminating tariffs and eliminating or reducing non-tariff barriers on goods and services traded with Canada.

(b) Treatment by Canada of specific goods (described by HTSUS numbers), including product-specific import or export interests or barriers.

(c) Adequacy of existing customs measures to ensure that only qualifying imported goods from Canada receive preferential treatment, and appropriate rules of origin for goods entering the United States.

(d) Canadian sanitary and phytosanitary measures or technical barriers to trade that should be addressed.

(e) Existing barriers to trade in services between the United States and Canada that should be addressed.

(f) Relevant electronic commerce issues.

(g) Relevant trade-related intellectual property rights issues.

(ĥ) Relevant investment issues.

(i) Relevant competition-related matters.

(j) Relevant government procurement issues.

(k) Relevant environmental issues.

(l) Relevant labor issues.

(m) Relevant transparency issues.

(n) Relevant issues related to

innovation and competitiveness, new technologies and emerging economic sectors, the participation of small- and medium-sized businesses in trade, and the development of efficient production and supply chains.

Public Comment: Requirements for Submissions

Persons submitting written comments must do so in English and must identify (on the first page of the submission) "Canada's Expression of Interest in the



Trans-Pacific Partnership Trade Negotiations." In order to be assured of consideration, comments should be submitted by noon, January 13, 2012.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the http://www.regulations.gov Web site. Comments should be submitted under the following docket: USTR-2011-0019. To find the docket, enter the docket number in the "Enter Keyword or ID" window at the http://www.regulations. gov home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notices" under "Document Type" on the search-results page, and click on the link entitled "Submit a Comment." (For further information on using the http://www. regulations.gov Web site, please consult the resources provided on the Web site by clicking on the ''Help'' tab.)

The http://www.regulations.gov Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type comment & Upload File" field. USTR also prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Comments" field.

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Douglas Bell,

Chair, Trade Policy Staff Committee. [FR Doc. 2011–31317 Filed 12–6–11; 8:45 am] BILLING CODE 3190–W2–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Denial of Motor Vehicle Defect Petition

AGENCY: National Highway Traffic Safety Administration, (NHTSA), Department of Transportation. **ACTION:** Denial of a petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition Defect Petition (DP) 10–004 submitted by Ms. Lalitha Seetharaman (petitioner) with the assistance of Emerick Bohmer to NHTSA by a letter received on November 5, 2010, under 49 CFR part 552. The petitioners request an investigation of brake failure in model year 2005 Honda Accord Hybrid vehicles.

FOR FURTHER INFORMATION CONTACT: Mr. Derek Rinehardt, Vehicle Controls Division, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone (202) 366–3642. Email *derek.rinehardt@dot.gov*.

SUPPLEMENTARY INFORMATION:

Section-1.0 Introduction

Interested persons may petition NHTSA requesting that the agency initiate an investigation to determine whether a motor vehicle or item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 CFR 552.1. Upon receipt of a properly filed petition the agency conducts a technical review of the petition, material submitted with the petition, and any additional information. § 552.6. After considering the technical review and taking into account appropriate factors, which may include, among others, allocation of agency resources, agency priorities, and the likelihood of success in litigation that might arise from a determination of a noncompliance or a defect related to motor vehicle safety, the agency will grant or deny the petition. § 552.8.

Petition Review—DP10-004

Section—2.0 Background Information

Ms. Lalitha Seetharaman of Newton. Pennsylvania (sometimes referred to as "Petitioner"), with the assistance of Mr. Emerick Bohmer, a friend of about a year, filed a petition on November 5, 2010 with NHTSA alleging that she was the driver of a model year (MY) 2005 Honda Accord Hybrid (subject vehicle), VIN JHMCN36425C005487, that experienced a brake failure. The petition states that the incident allegedly occurred on July 23, 2005, while braking and, at the same time, driving over rumble strips adjacent to her lane of travel on highway I-195 in New Jersey. In her petition, Ms. Seetharaman further alleges the brake failure resulted in a crash, fatally injuring her husband, Mr. Gautama Saroop (the front seat passenger), severely injuring the petitioner (the driver), and severely injuring the two occupants of a MY 1990 Ford Tempo vehicle that was struck by the petitioner's vehicle.

In March of 2005, four months prior to the crash, Ms. Seetharaman purchased the subject vehicle as a birthday present for her husband. On the evening of the crash, Ms. Seetharaman, who also owns a 1999 Mazda Protégé as her normal usage vehicle, was driving the subject vehicle with her husband as the passenger from their home in Newtown, PA to Bellmawr, NJ. The events leading to the crash and the crash itself are described by Ms. Seetharaman in the petition document and in a vehicle owner questionnaire (VOQ) 10329383 submitted to NHTSA. The two documents contain similar summaries of the event. The Defect Petition, at page 39, states:

While traveling East on I-195, I saw that a Police Officer had a vehicle pulled over on the right shoulder of the highway. I moved over to the left lane in order to decrease any chance of an accident with the stopped vehicles. When I did, I crossed onto the rumble strip on the left side of the highway. I applied the brakes while on the rumble strip to bring the vehicle under control, and nothing happened (no brakes) and the vehicle accelerated uncontrollably.

I tried to bring the vehicle back on the highway. Both my husband and myself were hoping something would bring the vehicle under control. In a desperate attempt to bring the vehicle under control my husband pulled the emergency brake. Upon pulling the Sen. Roger Sherman, Chair Sen. Thomas Martin Jr. Sen. John Patrick Rep. Joyce Maker, Chair Rep. Bernard Ayotte Rep. Margaret Rotundo

Heather Parent Stephen Cole Michael Herz Michael Hiltz Connie Jones



Wade Merritt John Palmer Linda Pistner Harry Ricker Michael Roland Jay Wadleigh Joseph Woodbury

Staff: Lock Kiermaier

STATE OF MAINE

Citizen Trade Policy Commission

December 15, 2011

Secretary Tim Geithner U.S. Department of the Treasury Federal Insurance Office MT 1001 1500 Pennsylvania Avenue, NW Washington, DC 20220

Re: Input on the Report to Congress on How to Modernize and Improve the System of Insurance Regulation in the United States

Dear Secretary Geithner,

We are writing on behalf of the Maine Citizen Trade Policy Commission in response to the Department of Treasury's request for comment on How to Modernize and Improve the System of Insurance Regulation in the United States.

When the Restoring of Financial Stability Act of 2010, later amended in conference committee to the Dodd-Frank Wall Street Reform and Consumer Protection Act, was first proposed, it included provisions that preempted state insurance laws if such laws are perceived to be inconsistent with international trade agreements. At that time, the Commission expressed strong opposition to those provisions in a letter to Senator Dodd (see enclosure).

The Commission maintains its opposition and would like to take this opportunity to encourage the Treasury to recommend against any similar provisions for future insurance regulation. The Commission's letter to Senator Dodd is attached and outlines our rationale for opposition.

Thank you for your consideration.

Sincerely,

Senator Roger Sherman, co-chair

Representative Joyce Maker, co-chair

cc:

Senator Susan M. Collins Senator Olympia J. Snowe Representative Michael Michaud Representative Chellie Pingree Governor Paul LePage

> Citizen Trade Policy Commission c/o Office of Policy & Legal Analysis State House Station #13, Augusta, ME 04333-0013 Telephone: 207 287-1670 http://www.maine.gov/legis/opla/citpol.htm

Sen. Troy Jackson, Chair Sen. Stan Gerzofsky Sen. Roger Sherman Rep. Margaret Rotundo, Chair Rep. Jeffery A. Gifford Rep. Sharon Anglin Treat

Jane Aiudi Malcolm Burson Leslie Manning Wade Merritt Linda Pistner Barbara VanBuroel



Sarah Adams Bigney Carla Dickstein Michael Herz John Palmer John L. Patrick Cynthia Phinney Paul Volckhausen Joseph Wodbury

Curtis Bentley, Legislative Analyst

STATE OF MAINE

Citizen Trade Policy Commission

April 16, 2010

The Honorable Christopher J. Dodd, Chairman Committee on Banking, Housing, & Urban Affairs United States Senate 448 Russell Senate Office Building Washington, DC 20510

Re: Restoring American Financial Stability Act of 2010

Dear Senator Dodd:

We are writing on behalf of the Maine Citizen Trade Policy Commission which by unanimous vote today expressed its strong opposition to the Office of National Insurance (ONI), created by Title V, Subtitle A of the Restoring American Financial Stability Act of 2010 (Chairman's Mark, Senate Standing Committee on Banking, Housing, & Urban Affairs). Subtitle A would establish a new federal bureaucracy (ONI) and give one person the power to invalidate state insurance laws that are perceived as "inconsistent with" international agreements.

We are concerned that this legislation bypasses the trade negotiation and implementation process and vests in one person in the Treasury Department the power to preempt validly enacted state laws – without waiting for a specific allegation of a trade violation, and based on a vague and expansive definition of potentially affected trade agreements. All of this would be done without any of the protections provided by the U.S. Constitution when international treaties are negotiated and Congress preempts state law. Disturbingly, even a treaty that has been submitted for ratification and defeated could be considered an "agreement" with preemptive force.

The Maine Citizen Trade Policy Commission (CTPC) is a bipartisan commission established in 2003 to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment, and to make policy recommendations to the Legislature and the Governor concerning the impact of trade agreements

and trade-related policies. In our view, the preemption provisions of Subtitle A reach well beyond the scope of current trade policy and constitute an unprecedented intrusion into matters reserved to the states.

We are cognizant that international agreements can have an impact on state policies, and indeed the CTPC has an advisory role within Maine to insure that policy makers are aware of the parameters of trade policy. Subtitle A goes well beyond any trade policy we are aware of and vests within one agency employee the power to sweep aside state insurance laws regulating purely domestic markets, such as licensing laws or laws requiring the use of U.S. statutory accounting principles. Any "international insurance agreement" with a foreign government or regulatory entity (even a non-governmental entity) could be used by this federal employee as the rationale for an action to preempt state-based standards, overturning the actions of state legislatures without resort to the courts or to international trade dispute resolution tribunals.

We urge you to strike the preemption provisions and the authority given to Treasury to negotiate and enter into new international insurance agreements in Title V, Subtitle A.

Thank you for your consideration.

Sincerely,

Senator Troy Jackson, co-chair

Representative Peggy Rotundo, co-chair

cc:

Senator Susan M. Collins Senator Olympia J. Snowe Senator Harry Reid The Honorable Michael Michaud The Honorable Chellie M. Pingree Mila Kofman, Superintendent of Insurance Janet Mills, Attorney General

Pl 2003, C. 699 (LD 1815), as amended

Ti : An Act to Establish the Maine Jobs, Trade and Democracy Act

010-30A-0081-01 - Legislature

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Citizen Trade Policy Commission (ongoing Title 5 Commission)

Budget (as amended)

	FY 12 ADJUSTED BUDGET	FY 12 Expenditures (through 12/13/11)	Unspent Balance (as of 12/13/11)
Emergency Legislation: Yes Number of Meetings (at least twice annually specified + PHs Meetings During Session: None budgeted	8 ;)		
Report Date(s): annual (evaluation by 12/31/09) Extension Provision: N/A			
 # of Persons Eligible for Per Diem Legislators Others # of Persons Eligible for Per Diem 	6		
# ersons Eligible for Expenses but not Per Diem	10		
Number of Department/Agency Personnel or Others for whom per diem and expenses are not calculated Total Number of Members	6 22		
Personal Services Costs		550.00	2 000 00
	2,640.00	550.00	2,090.00
All Other Costs Contractual Services Member Expenses/mtgs & 2 public hearings Staff Travel Postage, Printing and Miscellaneous Assessment Public Hearings (2 annually) FY 12 @\$500 each Total - All Other	10,150.00 6,400.00 210.00 750.00 10,000.00 1,000.00 28,510.00	2,273.85 2,273.85	10,150.00 4,126.15 210.00 750.00 10,000.00 1,000.00 26,236.15
Total Cost	31,150.00	2,823.85	28,326.15

NOTE: The Legislative Council approved the Commission's request to carry over unspent FY 11 assessment funds. Therefore, the FY 12 budget has been increased by \$5,000 on a one-time basis.

NOTE: The Legislative Council further approved the carry over of an additional \$13,780 in unspent FY ¹¹ funds to enable the Commission to hold up to a total of 8 meetings in FY 12 and for contracted st support.

Sen. Roger Sherman, Chair Sen. Thomas Martin Jr. Sen. John Patrick Rep. Joyce Maker, Chair Rep. Bernard Ayotte Rep. Margaret Rotundo

Heather Parent Stephen Cole Michael Herz Michael Hiltz Connie Jones



Wade Merritt John Palmer Linda Pistner Harry Ricker Michael Roland Jay Wadleigh Joseph Woodbury

Danielle Fox, Legislative Analyst Jean Güzzetti, Legislative Analyst

STATE OF MAINE

Citizen Trade Policy Commission

Ambassador Ron Kirk Office of the United States Trade Representative 600 17th Street NW Washington DC, 20508

December 2, 2011

Dear Ambassador Kirk,

For the Maine Citizen Trade Policy Commission (CTPC), 2011 has been a year of transition, including changes in membership. As chairs of the CTPC, we recognize that organizations and offices with which the commission communicates often experience transitions as well. It is our understanding that for the purposes of clear and direct communication, the Office of the USTR has agreed to identify and maintain communication with a single point of contact in the State of Maine. It is important to the CTPC that we are clear who the contact point is in the state. In an effort to keep our contacts current, we would greatly appreciate confirmation from your office that you have a single point of contact in Maine as well as the name and contact information for that person. Thank you for your time and consideration of our request.

Sincerely,

Roger L. Sherman

Senator Roger L. Sherman, Co-chair Maine Citizen Trade Policy Commission

ve Joyce A. Maker, Co-chair

Représentative Joyce A. Maker, Co-chair Maine Citizen Trade Policy Commission

Citizen Trade Policy Commission c/o Office of Policy & Legal Analysis State House Station #13 Augusta, ME 04333-0013 (207) 287-1670 http://www.maine.gov/legis/opla/citpol.htm