

# **THE U.S.-EU FREE-TRADE AGREEMENT: TIPPING OVER THE REGULATORY BARRIERS**

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## **HEARING BEFORE THE SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED THIRTEENTH CONGRESS**

**FIRST SESSION**

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**JULY 24, 2013**

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<sup>1</sup> Mr. Dooley did not respond to submitted questions for the record.

<sup>2</sup> Mr. Garfield did not respond to submitted questions for the record.

<sup>3</sup> Ms. Halloran did not respond to submitted questions for the record.

## **THE U.S.-EU FREE-TRADE AGREEMENT: TIPPING OVER THE REGULATORY BARRIERS**

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**WEDNESDAY, JULY 24, 2013**

**HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND  
TRADE,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.***

The subcommittee met, pursuant to call, at 9:45 a.m., in room 2123, Rayburn House Office Building, Hon. Lee Terry (chairman of the subcommittee) presiding.

Present: Representatives Terry, Lance, Blackburn, Harper, Guthrie, Olson, Kinzinger, Bilirakis, Johnson, Long, Schakowsky, Sarbanes, McNerney, Dingell, Matheson, Barrow, Christensen, and Waxman (ex officio).

Staff Present: Charlotte Baker, Press Secretary; Jerry Couri, Senior Environmental Policy Advisor; Kirby Howard, Legislative Clerk; Nick Magallanes, Policy Coordinator, CMT; Gib Mullan, Chief Counsel, CMT; Andrew Powaleny, Deputy Press Secretary; Shannon Weinberg Taylor, Counsel, CMT; Michelle Ash, Minority Chief Counsel; and Will Wallace, Minority Professional Staff Member.

### **OPENING STATEMENT OF HON. LEE TERRY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA**

Mr. TERRY. All right. I think we are all set now. And it looks like we will have a good morning, in the sense that the votes will not occur until 1:30. I am pretty confident that we are going to finish this panel before then.

So let's start the hearing. And I recognize myself for 5 minutes for the opening statement.

Good morning, and welcome to today's hearing, where we will examine the regulatory issues that we expect will come up during the negotiation of the Transatlantic Trade and Investment Partnership, also known as TTIP.

A trade agreement with the European Union should, in many ways, be a commonsense policy for the United States. Already, the bilateral trade relationship between the U.S. and the EU is the largest in the world, accounting for over \$1 trillion in trade, of which U.S. exports account for \$463 billion. According to the U.S. Trade Representative, this relationship supports over 13 million jobs in the United States and Europe, accounts for \$3.7 trillion worth of direct investment in both economies.

These are significant data points, and our subcommittee's legislative record thus far supports many of those figures. Our subcommittee's activity this Congress began by hosting an entire hearing series that focused on learning from our Nation's manufacturers. We heard time and time again from a variety of industries about the well-paid, middle-class jobs it could create if given the opportunity to expand their operations and the positive effects this type of growth has on various parts of our economy.

As the numbers suggest, foreign direct investment is a key element of our trade relationship with the EU. We want this piece of our trade portfolio to grow and strengthen, and not just with the EU. So Ranking Member Schakowsky and I crafted legislation aiming to lower barriers in the U.S. to inbound foreign direct investment that the full committee unanimously approved last week. And I am hearing solid rumors that it will be on the floor next week. I believe that when foreign companies want to initiate or expand their manufacturing footprint in the U.S., it is good for our long-term economic success.

Now we will turn our attention to TTIP, another potential job-creating addition for our economy. This trade agreement is unique for many reasons. Historically, tariffs on goods have been the single biggest barrier to trade, but because of how tariffs between the U.S. and the EU already exist, this isn't the case with this negotiation. Consequently, addressing non-tariff barriers is a substantial portion of the negotiation.

And, according to high-level working groups, as much as 80 percent of the so-called potential gains in the TTIP lie in addressing these so-called behind-the-border issues. TTIP represents a historic opportunity for both sides to create greater openness, transparency, and convergence in regulatory approaches and standards, while reducing unnecessary and redundant requirements.

It would seem to make sense that if the European Medicines Agency, EMA, just inspected a pharmaceutical manufacturer in Berlin for compliance with good manufacturing practices, that the U.S. FDA could rely on the findings of the European inspector instead of duplicating the effort by conducting its own inspection. But that is not the case.

It might also seem to make sense that, given our respective standards yield equivalent safety performance on vehicles, we should be able to find a certain level of uniformity or at least mutual recognition of the U.S. and European auto safety regulations. Remarkably, or maybe unremarkably, as the case may be, over the past 15 years only seven out of the hundreds of safety regulations have been harmonized.

There are countless more examples of areas where U.S. companies, workers, and consumers stand to gain from this type of collaboration. And we should use every tool at our disposal in an effort to maximize the potential benefits for Americans when it comes to this agreement.

I would like to thank our witnesses for appearing before us today. We have a broad cross-section of stakeholders before us that each have a unique perspective on what the TTIP could bring to their industries and, most importantly, into the United States.

I look forward to hearing from each of you and now recognize the ranking member, Jan Schakowsky from Illinois.

[The prepared statement of Mr. Terry follows:]

#### PREPARED STATEMENT OF HON. LEE TERRY

Good Morning, and welcome to today's hearing, where we will examine the regulatory issues that we expect will come up during the negotiation of the Transatlantic Trade and Investment Partnership, also known as the U.S.-EU free-trade agreement, or T-TIP.

A trade agreement with the European Union should in many ways be a common sense policy for the United States. Already, the bilateral trade relationship between the U.S. and the EU is the largest in the world—accounting for over \$1 trillion in trade-of which U.S. exports account for \$463 billion. According to the U.S. Trade Representative, this relationship supports over 13 million jobs in the United States and Europe and accounts for \$3.7 trillion worth of direct investment in both economies.

These are significant data points, and our subcommittee's legislative record thus far supports many of those figures. Our subcommittee's activity this Congress began by hosting an entire hearing series that focused on learning from our nation's manufacturers. We heard time and time again from a variety of industries about the well-paid middle class jobs they could create if given the opportunity to expand their operations and the positive effects this type of growth has on various parts of the economy.

As the numbers suggest, foreign direct investment is key element of our trade relationship with the EU. We want this piece of our trade portfolio to grow and strengthen, and not just with the EU, so Ranking Member Schakowsky and I crafted legislation aiming to lower barriers in the U.S. to inbound foreign direct investment that the full committee unanimously voted to approve last week. I believe that when foreign companies want initiate or expand their manufacturing footprint in the U.S. it's good for our long term economic success.

Now, we will turn our full attention to T-TIP, another potential job-creating addition to our economy. This trade agreement is unique for many reasons. Historically, tariffs on goods have been the single biggest barrier to trade. But because of how low tariffs between the U.S. and the EU, this isn't the case with T-TIP. Consequently, addressing non-tariff barriers is a substantial portion of the negotiation and, according to the High Level Working Group, as much as 80 percent of the overall potential gains in the T-TIP lie in addressing these so-called "behind the border" issues.

T-TIP represents a historic opportunity for both sides to create greater openness, transparency and convergence in regulatory approaches and standards while reducing unnecessarily redundant requirements.

It would seem to make sense that if the European Medicines Agency (EMA) just inspected a pharmaceutical manufacturer in Berlin for compliance with Good Manufacturing Practices, the U.S. FDA could rely on the findings of the European inspector instead of duplicating the effort by conducting its own inspection. Unfortunately, this is not the case.

It might also seem to make sense that given our respective standards yield equivalent safety performance of vehicles, we should be able to find a certain level of uniformity—or at least mutual recognition of—the U.S. and European auto safety regulations. Remarkably, or unremarkably as the case may be, over the past 15 years only seven out of the hundreds of safety regulations have been harmonized through participation in a United Nations working group.

There are countless more examples of areas where U.S. companies, workers and consumers stand to gain from this type of collaboration, and we should use every tool at our disposal in an effort to maximize the potential benefits for Americans when it comes to this agreement.

I would like to thank our witnesses for appearing before us today. We have a broad cross-section of stakeholders that each have a unique perspective on what the T-TIP could bring to the U.S. I look forward to hearing from each one of them.

I now recognize the ranking member, Ms. Schakowsky.

**OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS**

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I appreciate the hearing that you are holding, that we are holding here today on the Transatlantic Trade and Investment Partnership negotiations.

I look forward to hearing from all of our witnesses about this very important issue. I especially want to welcome Former Congressman Cal Dooley.

It is good to see you, Cal. Glad you are here.

American trade with Europe is vitally important to our economic outlook. One-fifth of all U.S. trade is conducted with Europe, accounting for \$1 trillion in trade of goods and services just last year. Some economists maintain that an agreement would increase trade by as much as 15 percent.

While I am committed to strengthening our economic ties to our European allies, I do have serious concerns that an agreement with inadequate safeguards could hurt American consumers, workers, public health, and the environment.

The High-Level Working Group on Jobs and Growth, in its February report on this issue, identified three objectives for a trade agreement with the EU. Among the three main objectives identified is the goal, quote, “to reduce unnecessary costs and administrative delays stemming from regulation,” unquote.

That objective, I have to tell you, raises many red flags for me. While we all agree that actual unnecessary trade barriers should be addressed, it is important to identify what qualifies as unnecessary.

For example, I don’t believe that the fuel economy standards that President Obama negotiated with auto manufacturers, which reduce greenhouse gas emissions by 6 billion metric tons over 8 years, saving the average U.S. driver \$8,000 over the life of her car, are unnecessary. I don’t believe that standards that keep the toys our children and grandchildren play with and the food we eat safe are unnecessary. I don’t believe that price limits for public programs like Medicare negotiation or Medicaid drug rebates are unnecessary, and, in fact, they save consumers billions of dollars and enable access to lifesaving medicine.

On the issue of drug pricing and accessibility, we are going to hear from Mr. Castellani—and I appreciate our meeting yesterday—about pharmaceutical issues and trade agreements. I want to make very clear my view that access to essential medicines should be debated out in the open, not in secret trade discussions where the public and even Members of Congress are excluded.

The pharmaceutical industry has put its significant weight behind efforts to protect the profits and intellectual property associated with its products. In many cases, those efforts fly directly in the face of efforts to expand access to lifesaving drugs for low-income individuals, both in the developing world and here at home. I am much more concerned about saving people’s lives than adding to the already large profits of the pharmaceutical companies.

We have made some progress to achieve more balance between the priorities of the pharmaceutical industry and those of the people in need of treatment through the Doha Declaration and the

May 10th Agreement, and I am deeply concerned about efforts to undo those improvements. I have heard from healthcare advocates and doctors from around the world and experts here at home that proposed changes to our trade agreements would not only raise the cost of drugs overseas but tie the hands of those who want to make medications more affordable here at home.

At the very least, I repeat, this issue should be considered in open, public forums, not closed-door trade negotiations.

Again, I support efforts to expand trade with Europe, but not at the cost of undermining our own or our partners' efforts to promote the growth of good jobs or protect the public health and the environment.

I look forward to hearing from all of our witnesses on these issues.

And, Mr. Chairman, I yield back.

Mr. TERRY. Thank you.

And now we recognize the vice chairman of the subcommittee, Mr. Lance, for 5 minutes.

**OPENING STATEMENT OF HON. LEONARD LANCE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. LANCE. Thank you, Mr. Chairman.

And I welcome our invited witnesses and everyone in the audience to this important hearing on the United States and European Union's negotiation of the Transatlantic Trade and Investment Partnership, also known as TTIP.

I am pleased that the United States and the European Union have entered into negotiations over TTIP. The economic relationship between the United States and the European Union is the world's largest and most prosperous. These negotiations have wide, bipartisan support because of the recognition that, should this trade agreement be completed, it will have a dynamic effect on the economies of all nations concerned.

In New Jersey's Seventh Congressional District, which I represent, the pharmaceutical and telecommunications industries stand to benefit from an agreement. On a broader scale, if successful, this agreement has the potential to serve as a template for which all future agreements between the United States, the European Union, and third parties could be negotiated.

From my perspective, I hope that the negotiations address some of the regulatory barriers that stand in the way of an agreement being reached, the so-called beyond-the-border barriers of regulations.

While tariffs between the United States and the European Union are lower compared to other standing trade agreements, the differences between the regulatory structure of the United States and the regulatory structure of the individual European states are, for the most part, different. And we must reconcile these differences in order to reach an agreement.

The other issue that I hope is addressed is that of intellectual property rights. This subcommittee highlighted the issues of intellectual property rights in trade agreements with India in a previous hearing, and I hope that the United States and the European

Union can agree to robust intellectual property-right protections in their trade agreement.

It is my ultimate hope that the United States and the European Union, the two largest trading markets in the world, will be able to come to a mutually beneficial agreement that strengthens this already great trading relationship. I look forward to the discussion among members of the committee and stakeholders on how to achieve this objective.

And, Mr. Chairman, I yield back the balance of my time.

Mr. TERRY. Is there anybody else on our side that wishes 2½ minutes?

Seeing none, the time is yielded back.

The chair recognizes the full committee ranking member, the gentleman from California.

**OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. WAXMAN. Thank you, Mr. Chairman.

Today we are holding a hearing on an important subject with major ramifications for U.S. policies, the U.S.-EU free-trade agreement.

The United States and the European Union, which together make up over 40 percent of global GDP, have entered into negotiations on what would be the largest free-trade agreement ever completed. Just for comparison, the EU market is more than five times larger than the combined markets of Canada and Mexico, our partners in NAFTA.

We have much in common. EU member states are democracies with general high levels of economic development. And, despite recent economic turmoil, they remain dedicated to policies supporting an open international economy. We both have engaged in austerity economic policies, which have failed there and are failing here.

In 2012, more than \$1.5 trillion in trade flowed between the U.S. and member states of the EU, nearly double the value of such trade 10 years earlier. The Transatlantic Trade and Investment Partnership, or TTIP, proposes to further strengthen our economic ties. I believe this is a worthy goal, and I applaud the Obama administration for pursuing it.

While traditional trade barriers between the U.S. and EU were already low, with average tariffs under 3 percent, they are still significant, particularly to small and medium-sized enterprises that want to become exporters. Lowering these tariffs will save these companies millions of dollars. We can also gain by cooperating on specific challenges, such as local content rules, state-owned enterprises, and customs policies.

For most major industries, the major focus of negotiations are behind-the-border barriers, which usually refers to domestic regulatory measures. While we should always work to avoid duplication, we must ensure that the push for regulatory compatibility does not create a race to the bottom. I have consistently believed that trade agreements negotiated by the United States should not compromise sensible standards in the United States or abroad. The

U.S. and EU member states should strengthen our competitiveness by raising the standards in our countries, not by weakening them.

The pharmaceutical industry is a good example of the complex issues this trade agreement raises. This agreement should not be used as a vehicle to, one, drive up drug prices in other countries or undermine efforts to reduce prices here; or, two, delay or impede access to less expensive generic drugs in developing countries, where too few can afford needed medicines; or, three, disrupt the delicate balance of innovation and access to medicines that we achieved in Waxman-Hatch. Yet this could be the result of some proposals that have been discussed.

International trade has the potential to raise the standard of living and quality of life for people in the United States, the European Union, and around the world. To uphold that vision, we must ensure that our citizens continue to have essential regulatory protections. Regulations keep automobiles, children's toys, our food supply safe. They support public health, privacy rights, and secure financial markets. And they are crucial to the global effort to combat climate change.

When TTIP negotiators reconvene, I encourage them to remember the importance of commonsense regulatory measures that enhance consumer wellbeing. Trade liberalization should not be just about reducing costs or enhancing efficiency. It is more fundamentally about improving people's quality of life, whether they live and work here in the United States or in the countries with which we trade.

Unless any of my colleagues wish to have additional time, what is left, I yield back the balance of my time.

Mr. TERRY. Thank you, Mr. Waxman.

The gentleman yields back. And I am going to introduce our—  
Mr. WAXMAN. Oh, Mr. Chairman, before you do—

Mr. TERRY. Yes?

Mr. WAXMAN [continuing]. May I apologize to the members that are testifying. I know it is a very good group, an important group of witnesses. But we have other subcommittees meeting at the same time, so—

Mr. TERRY. Almost all of them, by the way, all the subcommittees at one time, it seems like.

Mr. WAXMAN. Right.

Mr. TERRY. Thank you, Mr. Waxman.

I am now introducing our panel, and I will introduce the whole panel, and then we will start with you, Mr. Blunt, Governor Blunt, and move from my left to right.

So first on our panel, Governor Matt Blunt, president of the American Automotive Policy Council; then John Castellani, president and CEO of the Pharmaceutical Research and Manufacturers of America; one of our own, been on both sides of this table, honorable former Member Cal Dooley, president and CEO of the American Chemistry Council.

Then we are honored to have Dean Garfield, president and CEO of Information Technology Industry Council; and then Jean Halloran, on behalf of the Consumers Union and the Transatlantic Consumer Dialogue, U.S. liaison, Transatlantic Consumer Dialogue Secretariat, Senior Advisor, International Affairs, to the president

of Consumer Reports; and then last, Mr. Carroll Muffett, president and CEO of the Center for International Environmental Law.

Thank you all for taking time to be here to help educate us. As most of you know, you have 5 minutes for your statements. There are lights there that will be green when you start. When you start seeing the yellow, sum up, please.

So, at this time, I am honored to recognize Governor Blunt for your 5 minutes.

**STATEMENTS OF THE HON. MATTHEW R. BLUNT, PRESIDENT,  
AMERICAN AUTOMOTIVE POLICY COUNCIL; JOHN J.  
CASTELLANI, PRESIDENT AND CEO, PHARMACEUTICAL RE-  
SEARCH AND MANUFACTURERS OF AMERICA; THE HON.  
CALVIN M. DOOLEY, PRESIDENT AND CEO, AMERICAN  
CHEMISTRY COUNCIL; DEAN C. GARFIELD, PRESIDENT AND  
CEO, INFORMATION TECHNOLOGY INDUSTRY COUNCIL;  
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SUMER DIALOGUE SECRETARIAT, SENIOR ADVISOR ON  
INTERNATIONAL AFFAIRS TO THE PRESIDENT OF CON-  
SUMER REPORTS, ON BEHALF OF THE CONSUMERS UNION  
AND THE TRANSATLANTIC CONSUMER DIALOGUE; AND CAR-  
ROLL MUFFETT, PRESIDENT AND CEO, CENTER FOR INTER-  
NATIONAL ENVIRONMENTAL LAW**

**STATEMENT OF THE HON. MATTHEW R. BLUNT**

Mr. BLUNT. Thank you, Chairman Terry and Ranking Member Schakowsky and members of this committee.

Mr. TERRY. Is the microphone on?

Mr. BLUNT. It is now. And, again, thank you, Chairman.

I am Matt Blunt, president of the American Automotive Policy Council, which represents the common public policy interests of our member companies: Chrysler, Ford, and General Motors.

On May 10th, AAPC and our European counterpart, ACEA, jointly submitted a detailed auto regulatory convergence proposal in response to the USTR Federal Register notice. This statement is based on that submission, which would provide a more thorough treatment of our proposal.

As the largest manufacturing and exporting sector in the United States, the auto industry has a major stake in the successful completion of a Transatlantic Trade and Investment Partnership, or TTIP. TTIP will represent the largest share of auto production and sales ever covered by a single free-trade agreement. And we believe that a well-negotiated TTIP that includes the elimination of tariffs and major non-tariff barriers in the auto sector has great potential to grow the transatlantic auto trade and investment relationship.

The global landscape for auto production and sales is changing. Global auto sales are expected to increase more than 50 percent by the end of the decade, equating to roughly a billion new automobiles on the road around the world. The concentration of this growth will be in emerging markets, with vehicle sales eventually surpassing the sales growth in mature markets such as the United States and Western Europe. It is essential to ensure that regulatory costs do not inhibit future growth in auto sales and exports

and the critical role they play in economies on both sides of the Atlantic.

The negotiation of the TTIP presents an opportunity to implement a regime that effectively breaks down regulatory barriers in the auto sector, recognizes regional integration of benefits both to the U.S. and the EU, reduces costs and increases commercial predictability, while respecting U.S. and EU sovereignty, and certainly without sacrificing vehicle safety or environmental performance.

Past efforts to harmonize have been ineffective and slow, and we are proposing a new approach: mutual recognition for existing automotive regulations and for future regulations that are deemed necessary, the establishment of a joint regulatory harmonization process that facilitates the development and adoption of common future new regulations.

Our proposal is guided by the following principles: We must have strong and sustained political support at the highest levels of government and the relevant regulatory authorities. There should be no net increase in U.S. or EU regulatory requirements as a result of this convergence; no new third regulations or additional certification requirements. And then, as I stated, mutual recognition shall permit an automaker to sell a vehicle built to either recognized standard in either market.

Recognizing the significant advancements that the regulations have provided in environmental and safety technologies in both the U.S. and the EU, acceptance of an existing regulation should be presumed unless the analysis of the data conducted by the responsible regulatory agency demonstrates that the regulation is deficient from either a safety or environmental perspective.

We recommend that the process begin immediately, in close cooperation with industry, in order to take advantage of the current increased existing political will and interest in regulatory convergence. Our May 10th submission provides a list of U.S. and EU safety and environmental regulations for mutual recognition consideration during the TTIP negotiations and a proposed data-driven process for purposes of completing the necessary assessment.

When a new regulation is needed, a joint U.S. and EU regulatory harmonization process that takes into account the differences and regulatory development and implementation timelines needs to be developed that promotes and facilitates the development and adoption of common future new regulations. This process should also include a mechanism to foster the development of common voluntary standards in the pre-regulatory environment.

Key elements of a U.S. and EU harmonized standards process must aim at strengthening the automotive industry in both regions with lower costs through reductions in regulatory complexity, reducing administrative burdens while maintaining flexibility and increased predictability, have strong and sustained political support at the highest levels of government, and engage industry to work together to develop the harmonized approach, and certainly should provide a timeline to complete the development of this harmonization process.

TTIP presents an opportunity to break down tariffs and regulatory barriers in the auto sector, promote regional integration, reduce costs, and increase commercial predictability, while respecting

U.S. and EU sovereignty, and, as I said earlier, without sacrificing vehicle safety and environmental performance.

Again, thank you for the opportunity to present our views on the TTIP, and we look forward to working with the subcommittee on this important negotiation.

Mr. TERRY. Thank you.

[The prepared statement of Mr. Blunt follows:]



**Summary of the Statement by Governor Matt Blunt,  
President of the American Automotive Policy Council**

As the largest manufacturing and exporting sectors in the United States (U.S.) and the European Union (EU), the U.S. and the EU auto industries have a major stake in the conclusion of an ambitious bilateral trade agreement. The TTIP negotiations present an opportunity to implement a regime that effectively breaks down regulatory barriers in the auto sector, recognizes regional integration based on existing free trade agreements that benefits both the U.S. and EU, reduces costs and increases commercial predictability, while respecting U.S. and EU sovereignty and without sacrificing vehicle safety or environmental performance.

To achieve regulatory convergence, AAPC is guided by the following principles: 1) strong and sustained political support at the highest levels of government, and relevant regulatory authorities, 2) no net increase in U.S. or EU regulatory requirements as a result of regulatory convergence of existing regulations, and 3) no new third regulations (in addition to the existing U.S. and EU regulations) or additional certification requirements. Mutual recognition shall permit an automaker to sell a vehicle built to either recognized standard in either market. The AAPC has prepared a non-exhaustive list of existing U.S. and EU regulations for mutual recognition during the TTIP negotiations.

Acceptance of an existing regulation should be presumed, recognizing the significant advancements that the regulations have provided in environmental and safety technologies in both the U.S. and the EU, unless, the analysis of the data conducted by the responsible regulatory agency demonstrates that the regulation is deficient from a safety or environmental perspective.

With regard to new regulations, the AAPC recommends that the U.S. and EU implement a joint auto regulatory harmonization process that promotes and facilitates the development and adoption of common future new regulations. This approach will strengthen the U.S. and EU roles as worldwide auto standard setters, providing momentum for global auto regulatory convergence.

Eliminating tariffs and achieving greater regulatory convergence of current and future standards through the TTIP will increase trade, lower costs, create jobs, and improve the international competitiveness of the industry, strengthening the automotive industry and its economic contribution.



**Statement of Governor Matt Blunt,  
President of the American Automotive Policy Council**

**U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE**

**On**

**“The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory  
Barriers”**

**July 24, 2013**

I am Matt Blunt, President of the American Automotive Policy Council (AAPC). The AAPC represents the common international and domestic public policy interests of its member companies- Chrysler Group LLC, Ford Motor Company and General Motors Company. Thank you for the opportunity to share our views with the Subcommittee on this very important subject.

On May 10th, AAPC and our European counterpart, the European Automobile Manufacturers Association (ACEA), jointly submitted a detailed auto regulatory convergence proposal in response to the United States Trade Representative (USTR) Federal Register Notice, a Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement (TTIP); 78 Fed. Reg. 19566.

As the largest manufacturing and exporting sector in the United States, the auto industry has a major stake in the successful conclusion of a Transatlantic Trade and Investment Partnership Agreement (TTIP). The U.S. and the EU together account for 32% of global auto production and 35% of global auto sales.<sup>1</sup> U.S.–EU auto-related trade is also significant, accounting for 10% of all trade between the two economies. In 2012, in total, the value of bilateral U.S.–EU trade in autos and auto parts exceeded \$40 billion and 1.1 million passenger vehicles.<sup>2</sup> Although there is already robust automotive trade and investment between the U.S. and the EU, tariffs (import duties) and non-tariff barriers (divergences in automotive regulations), unnecessarily burden and constitute obstacles to free trade.

TTIP will represent the largest share of auto production and sales ever covered by a single free trade agreement and we believe that a well-negotiated TTIP, that includes the elimination of tariffs and major non-tariff barriers in the auto sector has great potential to grow the transatlantic auto trade and investment relationship.

The global landscape for auto production and sales is changing. Global auto sales are expected to increase more than fifty percent by the end of the decade, equating to roughly a billion new automobiles on the roads across the world. The concentration of this growth will be in emerging markets, with vehicles sales eventually surpassing the sales growth in more mature markets like the U.S. and Western Europe. It is essential to ensure that regulatory costs do not inhibit future

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<sup>1</sup> OICA.net (includes passenger and commercial vehicles)

<sup>2</sup> U.S. Exports-U.S. Dept. of Commerce & U.S. ITC / EU Exports- Eurostat

growth in auto sales and exports and the critical role they play in economies on both sides of the Atlantic.<sup>3</sup>

As the topic of this hearing is U.S. –EU regulatory barriers, this statement focuses on AAPC’s view on such matters. AAPC shall provide its views on appropriate tariff phase-out, rules of origin, trade facilitation and other auto-related matters regarding the TTIP negotiations at a later date.

#### **Auto Regulatory Convergence**

The negotiation of TTIP presents an opportunity to implement a regime that effectively breaks down regulatory barriers in the auto sector, recognizes regional integration that benefits both the U.S. and the EU, reduces costs and increases commercial predictability, while respecting U.S. and EU sovereignty and without sacrificing vehicle safety or environmental performance.

Past efforts to harmonize auto standards, were ineffective and slow. We propose a new approach: mutual recognition for existing automotive regulations and for future regulations that are deemed necessary, and the establishment of a joint regulatory harmonization process that facilitates the development and adoption of common future new regulations.

Our regulatory convergence proposal is guided by the following principles:

- Strong and sustained political support at the highest levels of government, and the relevant regulatory authorities;

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<sup>3</sup> Auto Alliance Submission to USTR’s request comments concerning proposed Transatlantic Trade Investment Agreement (TTIP); 78 Fed. Reg. 19566, May 10, 2013.

- No net increase in U.S. or EU regulatory requirements, as a result of regulatory convergence of existing regulations;
- No new third regulations (in addition to the existing U.S. and EU regulations) or additional certification requirements; and
- Mutual recognition shall permit an automaker to sell a vehicle built to either recognized standard in either market.

#### **Mutual Recognition of Existing Regulations**

Recognizing the significant advancements that the regulations have provided in environmental and safety technologies in both the U.S. and the EU, acceptance of an existing regulation should be presumed unless the analysis of the data conducted by the responsible regulatory agency demonstrates that the regulation is deficient from a safety or environmental perspective.

We recommend that the process begin immediately in close cooperation with the industry in order to take advantage of the current increased political will and interest in regulatory convergence.

Our May 10<sup>th</sup> submission provides a list of U.S. and EU safety and environmental regulations for mutual recognition consideration during the TTIP negotiations and proposed a data driven process for purposes of completing the necessary assessment.

#### **Treatment of Existing Regulations Not Included on the AAPC Mutual Recognition List**

The best possible outcome for the U.S. and EU auto sectors is comprehensive mutual recognition, where a vehicle certified as compliant with safety and environmental requirements in the U.S. is accepted as compliant in the EU, and vice versa.

However, even if this mutual recognition is a complete success, there will still be a number of U.S. and EU regulations that remain to be converged. AAPC therefore also recommends that the U.S. and EU include a provision in TTIP establishing a joint auto task force coordinated by the Office of the United States Trade Representative (USTR) and the Office of Information and Regulatory Affairs (OIRA) for the United States and the appropriate authorities for the European Union to continue to work towards comprehensive mutual recognition following the conclusion of the trade pact negotiations.

#### **Development of Common Future New Regulations**

When a new regulation is needed, a joint EU-U.S. auto regulatory harmonization process, that takes into account differences in U.S. and EU auto regulatory development and implementation timelines, needs to be developed that promotes and facilitates the development and adoption of common future new regulations. This process should also include a mechanism to foster the development of common voluntary standards in the pre-regulatory environment.

Key elements of a U.S.-EU harmonized standards development process must:

- Aim at strengthening the automotive industry in both regions, with lower costs through reductions in regulatory complexity, reducing administrative burdens while maintaining flexibility and increased predictability;
- Have strong and sustained political support at the highest levels of government;
- Engage industry to work together to develop each harmonized approach; and
- Provide a timeline to complete the development of each harmonized approach.

**Conclusion**

We believe that the TTIP presents an opportunity to break down tariffs and regulatory barriers in the auto sector, promote regional integration, reduce costs and increase commercial predictability, while respecting U.S. and EU sovereignty and without sacrificing vehicle safety and environmental performance.

We also believe that to achieve an ambitious outcome, especially with regard to regulatory convergence, there must be decisive and sustained political will at the highest levels of both the economic and regulatory agencies.

Again, thank you for the opportunity to present our views on the TTIP. We look forward to working with the Subcommittee on this important negotiation.

Mr. TERRY. Mr. Castellani, you are now recognized for your 5 minutes.

#### **STATEMENT OF JOHN J. CASTELLANI**

Mr. CASTELLANI. Thank you, Mr. Chairman, Ranking Member Schakowsky, and members of the committee. It is a pleasure to be here to talk about this very important proposed agreement.

To put the relationship of our industry between ourselves and Europe in context, in 2011 about 80 percent of the medicines and development around the world were being researched and tested in the United States and in the European Union. And this figure is a testament to the fact that the U.S. and EU generally provide the strongest global support for biopharmaceutical research and development.

Yet the continued strength of the innovative biopharmaceutical industry in both regions is far from guaranteed. The time and investment required to research and develop new medicines continues to increase, and the global ecosystem grows more hostile to that innovation.

And it is in this context that PhRMA and its member companies strongly support a high-standard, trade-liberalizing agreement between the EU and the U.S. and one that eliminates unnecessary non-tariff barriers between these regions and establishes a model for all future trade agreements.

PhRMA represents America's leading biopharmaceutical companies. Our members pioneer new ways to save lives, cure disease, and promote longer, healthier, and more productive lives.

In 2012, our members invested more than \$50 billion in research and development. And in 2011, the last year we have numbers, our sector employed more than 810,000 workers in the United States and supported 3.4 million jobs, in addition, across the country. That total activity contributed nearly \$790 billion in economic output, considering the direct, indirect, and induced effects of our industry.

PhRMA welcomes the expansion of the world's most dynamic trading relationship that already contributes significantly to creating jobs on both sides of the Atlantic. To be meaningful and comprehensive, the U.S. and EU negotiations should address not only regulatory compatibility initiatives but intellectual property protections, market access provisions, and customs and public pronouncement measures, as well.

Biopharmaceutical innovation does not happen in a vacuum. It requires significant intellect, time, resources, and an ecosystem that values and protects the resulting intellectual property that is created.

For this reason, our industry is particularly concerned about aspects of the current European environment.

First, shortsighted cost-containment measures, ostensibly proposed in response to financial crisis but too often implemented without predictable, transparent, and consultative processes, have significantly impacted our members' business in Europe. These measures raise serious concern regarding several EU member states' commitment to adequately reward innovation.

Another issue of concern to the industry is the EMA's current and proposed data disclosure policies. The biopharmaceutical industry is firmly committed to enhancing the public health through responsible reporting and publication of clinical research and safety information. However, the disclosure of non-public data submitted in clinical and preclinical dossiers and patient-level data sets risks that damage both public health and patient welfare.

PhRMA and its members urge the U.S. Government to engage with the EU in every available avenue to ensure responsible data-sharing.

We also recommend that the biopharmaceutical market access commitments be included in the EU and the U.S. agreements, with the Korean form of the basis for similar commitments included in any EU–U.S. agreement.

Key principles should be built into potential pharmaceutical chapters that we believe should include recognizing the value of biopharmaceuticals and the value they can play in reducing more costly medical interventions and improving the life of patients; respecting the right of physicians and other healthcare providers to prescribe appropriate medicines for their patients based on clinical need.

Further, both the EU and the U.S. recognize that IP is the life-blood of innovation, and providing IP rules within the legal and regulatory regimes. Any agreement between the U.S. and EU must not dilute those protections.

Finally, on the already high level of cooperation between the FDA and EMA, PhRMA has proposed a number of regulatory compatibility initiatives to reduce the regulatory burden for both the sponsors and the agencies. These include reducing redundant testing, seeking mutual recognition of our general manufacturing principles and our good clinical principles, inspections, and establishing a procedure for the development of therapeutic area-specific regulatory guidelines.

In summary, PhRMA and its members strongly support the proposed agreement and look forward to being an active stakeholder throughout the negotiations.

Thank you very much.

Mr. TERRY. Well done. Thank you very much.

[The prepared statement of Mr. Castellani follows:]

TESTIMONY SUMMARY OF JOHN J. CASTELLANI, PRESIDENT AND CEO OF  
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)  
BEFORE THE HOUSE ENERGY & COMMERCE SUBCOMMITTEE  
ON COMMERCE, MANUFACTURING & TRADE  
HEARING OF JULY 24, 2013

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients live longer, healthier, and more productive lives.

PhRMA and its member companies strongly support the negotiation of a comprehensive and ambitious trade liberalizing agreement between the U.S. and the EU, and welcome the expansion of the world's most dynamic trading relationship. The proposed agreement will provide an important opportunity for the two sides to demonstrate international economic leadership, and to establish minimum benchmark standards that the U.S. and the EU should seek in all future trade agreements with third parties.

The U.S. innovative biopharmaceutical industry provides significant benefits to our economy. PhRMA's member companies invested almost \$50 billion in R&D for new medicines in 2012. The industry supported 3.4 million jobs across the United States in 2011 and generated over \$50 billion in exports in 2012. Yet our industry faces substantial expense and risk in the course of bringing innovative medicines to market, with only 2 out of every ten approved medicines recouping their development costs.

PhRMA believes it is critical that the Transatlantic Trade and Investment Partnership (TTIP) agreement include robust provisions that further collaboration and create new opportunities for the innovative biopharmaceutical industry to thrive, contributing to growth in the U.S. and EU and benefiting patients around the world. To be meaningful and comprehensive, the U.S.-EU negotiations should address market access provisions, intellectual property protections, and regulatory compatibility initiatives.

Short-sighted cost containment measures have severely impacted our members' businesses in Europe. A U.S.-EU agreement should recognize the value biopharmaceuticals can provide in reducing other more costly medical interventions and in improving the lives of patients. Agreed-to principles should include respect for the right of health care providers to prescribe appropriate medicines based on clinical need. Other market access provisions should ensure transparent, timely, and predictable pricing and reimbursement processes that provide applicants with meaningful due process.

Strong intellectual property protections are critical to the biopharmaceutical industry. A U.S.-EU agreement should be a standard-setting agreement that places a high value on IP as the lifeblood of innovation and highlights countries like India, with weak and deteriorating IP regimes, as outliers in the global market. To that end, an agreement should, among other things, ensure 12 years of regulatory data protection for biologics, clarify patentability standards, implement patent term adjustments necessary to incentivize further investment in biopharmaceutical R&D, and secure effective patent enforcement systems that allow for early patent dispute resolution.

Finally, addressing unnecessary and duplicative regulatory requirements can help enhance efficiency of drug development, optimize deployment of limited agency resources, and expedite patient access to new, innovative, and life-saving medicines. Regulatory compatibility initiatives that can achieve these goals include reducing redundant testing, seeking mutual recognition of Good Manufacturing and Clinical Practices inspections, and establishing a procedure for the development of scientific and other regulatory guidelines for specific therapeutic areas.



950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

**TESTIMONY OF THE PHARMACEUTICAL RESEARCH  
AND MANUFACTURERS OF AMERICA (PhRMA)**

**BEFORE THE**

**HOUSE ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE,  
MANUFACTURING AND TRADE**

**“The U.S.-E.U. Free Trade Agreement:  
Tipping Over the Regulatory Barriers”**

**July 24, 2013**

Chairman Lee Terry, my name is John J. Castellani, President & CEO at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am very pleased to appear before the subcommittee to reflect the innovative biopharmaceutical's perspective on the proposed Transatlantic Trade and Investment Partnership.

Up to 80% of the medicines currently in development around the world are being researched and tested in the United States and the European Union. This figure is a testament to the fact that the United States and the European Union, as a general matter, provide the strongest global support for biopharmaceutical research and development. The continued, strength, however, of the innovative biopharmaceutical industry in both regions is far from guaranteed. On the contrary, the time and investment required to research and develop new drugs continues to increase and the global ecosystem to support innovation grows more hostile. As a result, PhRMA and its member companies strongly support the promise of a high-standard trade liberalizing agreement between the United States and the European Union (EU) that eliminates unnecessary non-tariff barriers between these regions and establishes a model for the United States and the EU to seek in all future bilateral, plurilateral, and multilateral trade agreements.

PhRMA represents America's leading biopharmaceutical companies. Our member companies pioneer new ways to save lives, cure disease, and promote longer, healthier, and more productive lives. In 2012, PhRMA's members alone invested almost \$50 billion in advanced research and development of new medicines to treat human diseases and conditions. Further, in 2011 the U.S. biopharmaceutical sector employed more than 810,000 workers, supported a total of 3.4 million

jobs across the country, and contributed \$789 billion in economic output when direct, indirect, and induced effects are considered.

PhRMA welcomes the expansion of the world's most dynamic trading relationship that already contributes to the economies and job creation on both sides of the Atlantic.

Negotiations between the U.S. and the EU to enhance the trade relationship between these regions should be comprehensive and ambitious, addressing not only regulatory compatibility initiatives, but also intellectual property protections, market access provisions, and customs and public procurement measures. PhRMA believes that further reduction of non-tariff barriers in both markets will spur future and critical innovation.

That said, there are a number of issues of considerable concern to the industry in the current European environment:

- Short-sighted cost containment measures – ostensibly proposed in response to the financial crisis, but too often implemented without predictable, transparent and consultative processes – have significantly impacted our member's businesses in Europe, with negative spill over as a result of parallel trade and international reference pricing. These measures raise serious concerns regarding the commitment in a number of EU Member States to adequately reward innovation.
- Another issue of concern to the industry is the EMA's current and proposed data disclosure policies. The biopharmaceutical industry is firmly committed to enhancing the public health through responsible reporting and publication of clinical research and safety information. However, disclosure of companies' non-public data submitted in clinical

and pre-clinical dossiers and patient-level data sets risks damaging public health and patient welfare. PhRMA and its members urge the U.S. government to engage with the EU in every available venue to ensure responsible data sharing that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research by adequately shielding confidential commercial information from inappropriate disclosure. The EMA's current and proposed data disclosure policies jeopardize these principles.

As a more general matter, PhRMA recommends that the biopharmaceutical market access commitments included in the Korean-U.S. Free Trade Agreement (KORUS) and the EU-Korea Free Trade Agreement form the basis for the market access commitments included in any U.S.-EU trade liberalizing agreement. Key principles, however, that should be built into an EU-U.S. pharmaceuticals chapter include:

- Recognizing the value biopharmaceuticals can play in reducing other more costly medical expenditures and improving the lives of patients (consistent with Article 5.1(b) of KORUS); and
- Respecting the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need.

Further, both the United States and the EU recognize that IP protections are the lifeblood of innovation. As a result, both, as a general matter, provide strong IP protections within the rubric of their respective systems and any agreement between the United States and the EU should not

dilute these protections. Particular areas, however, where PhRMA would encourage enhancements and greater alignment between the respective IP systems include:

- Strong regulatory data protection provisions. This should include 12 years of regulatory data protection for biologics as provided by U.S. law;
- Affirmation or harmonization of certain patent standards;
- Seeking patent term adjustments for patent office delays in the EU; and
- Ensuring that the EU Member States adopt effective patent enforcement system or systems that allow for early resolution of pharmaceutical patent disputes before an infringing product is launched on the market.

With several countries, such as India, pursuing industrial policies that invalidate IP protections, it is imperative that the U.S. and EU seek similar commitments to strong IP from their trading partners as part of their free trade agreements with other countries.

In addition, PhRMA has proposed a number of regulatory compatibility initiatives, per a joint submission with its European sister association last fall. These proposals seek:

- Greater coordination to reduce the regulatory burden for both sponsors and agencies;
- To increase collaboration under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
- To establish a procedure for developing scientific and other regulatory guidelines for specific therapeutic areas; and

- To ensure that national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary, harmonized international standards.

By addressing these key issues and promoting even greater regulatory cooperation between the U.S. Food and Drug Administration and the European Medicines Agency, PhRMA believes that the U.S. Government and the European Commission will help spur further biopharmaceutical innovation, which will lead to healthier patients and more dynamic economies.

In summary, the proposed agreement provides an important opportunity for the two sides to demonstrate international economic leadership and a steadfast commitment to free trade, as well as to establish minimum benchmark standards that the United States and the European Union should seek in all future bilateral, plurilateral, and multilateral trade agreements.

We thank you for the opportunity to provide these comments and look forward to being an active stakeholder throughout the negotiations.

Mr. TERRY. And, Mr. Dooley, thank you for being here once again. And you are now recognized for 5 minutes.

**STATEMENT OF THE HON. CALVIN M. DOOLEY**

Mr. DOOLEY. Thank you, Mr. Chairman. I want to thank all the members of the subcommittee for an opportunity to speak today.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. And the business of chemistry is a \$770-billion enterprise which provides about 788,000 high-paying jobs in this country. A lot of folks don't also realize that the American chemistry industry produces 15 percent of the world's chemicals, which represent—and we also provide about 12 percent of all U.S. exports.

ACC and its member companies are strong supporters of the Transatlantic Trade and Investment Partnership. Two-way trade in chemicals across the Atlantic totaled more than \$51 billion in 2012, and Europe remains one of the U.S. industry's largest markets.

The reduction and elimination of transatlantic tariffs and barriers to trade in chemicals would contribute to a significant expansion of U.S. chemical manufacturing and exports, allowing us to capitalize on our enhanced competitiveness of the U.S. chemical industry due to increased supplies of natural gas, primarily from shale formations.

Since 96 percent of all manufactured goods rely on the business of chemistry, this would provide a major boost to overall economic growth and job creation, enhance U.S. competitiveness, and expand consumer choice.

The purpose of pursuing closer regulatory cooperation between the U.S. and EU should be to explore opportunities for creating efficiencies within and between regulatory systems while maintaining high levels of protection for human health and the environment. The goal is not to undermine or weaken existing regulatory mandates, but rather to ensure that those mandates do not result in unnecessary barriers to trade.

The U.S. and the EU regulate chemicals in different ways. That is not going to change because of TTIP. In fact, recent congressional action affirms that the U.S. will continue to embrace a more risk-based approach to chemicals management than the more hazard-based approach embodied in the EU's REACH regulation.

Where TTIP can add value is in ensuring that these different regulatory systems operate as coherently as possible, promoting efficient and effective regulatory approaches, and exploring opportunities for cost reduction and burden-sharing.

Specific areas that might be addressed include efforts to promote the better sharing of sound science. The goal should be to minimize the potential for imposing additional regulatory barriers when revising or developing new regulations and to develop a common scientific basis for regulation. This could, in turn, promote enhanced data- and information-sharing, which would result in significant efficiencies for both government and industry, reducing the need for duplicative testing.

Consistent with the comments of Congresswoman Schakowsky, TTIP should also focus on ensuring greater transparency and transatlantic cooperative activity between regulators. Stakeholders

on both sides of the Atlantic are aware that regulator-to-regulator discussions are occurring, but information on when cooperative activity is taking place and what issues are being addressed is typically not made available to stakeholders in advance of those discussions. Stakeholder input and, where appropriate, participation in relevant cooperative activities would facilitate expert input and help enhance stakeholder confidence and support for the regulatory cooperation.

ACC also calls on U.S. negotiators to explore opportunities for promoting enhanced coherence in chemical prioritization and assessment. The development of common principles for prioritization and a process for comparing lists of chemicals that are defined as priority could lead to greater efficiencies, primarily by sharing the burden of review. Final risk management decisions would remain sovereign, but a joint approach in this area could promote greater certainty in chemical assessment process, significantly reduce costs for government and industry by avoiding duplication and unnecessary testing, and accelerate chemical reviews.

ACC strongly supports the negotiation of a comprehensive and ambitious TTIP. In our view, the chemical industry is well-placed to be a priority sector for enhanced regulatory cooperation under TTIP. For the chemical industry and for the broader U.S. economy, the TTIP has a potential to provide significant boosts to growth and job creation, which in turn would promote innovation and strengthen the international competitiveness of U.S. exporters.

Thank you.

Mr. TERRY. Thank you.

[The prepared statement of Mr. Dooley follows:]



**TESTIMONY OF CALVIN M. DOOLEY  
ON BEHALF OF THE AMERICAN CHEMISTRY COUNCIL  
BEFORE THE COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITTEE ON  
COMMERCE, MANUFACTURING AND TRADE**

July 24, 2013

Chairman Terry, ranking member Schakowsky, and distinguished Members of the Subcommittee, my name is Cal Dooley. I am President and CEO of the American Chemistry Council. Thank you for the opportunity to speak today.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The business of chemistry is a \$770 billion enterprise providing approximately 788,000 high-paying jobs in the United States. The American chemical industry produces 15 percent of the world's chemicals and represents 12 percent of all U.S. exports.

ACC represents chemical manufacturers of all sizes, from SMEs to large multinational corporations. Reducing or eliminating tariff and non-tariff barriers to trade with the EU would create new commercial growth and export expansion opportunities for U.S. SME manufacturers and large enterprises alike. A recent study by the Centre for Economic Policy Research estimates that an ambitious and comprehensive TTIP that addresses both tariff and non-tariff barriers could boost U.S. exports to the EU by an additional \$123 billion. In addition, a successful TTIP could potentially break the deadlock over the World Trade Organization Doha Development Round by serving as a template for addressing difficult trade issues. While the TTIP negotiations will not be easy, the potential benefits in terms of growth, productivity, and influencing international trade rules are substantial.

As one of the nation's largest export sectors, the U.S. chemical industry has long been a strong supporter of free and open, rules-based international trade. Europe is one of the largest markets for U.S. chemical manufacturers, with two-way trade totaling more than \$51 billion last year. The reduction or elimination of trans-Atlantic barriers to trade in chemicals would result in a significant expansion of U.S. chemical exports, capitalizing on the enhanced competitiveness of U.S. chemical manufacturers due to increased supplies of low-cost shale gas. Since over 96% of all manufactured goods rely on the business of chemistry, this would provide a major boost to overall economic growth and job creation, enhance U.S. competitiveness, and expand consumer choice.

Current tariff barriers on trans-Atlantic trade in chemicals are low, averaging around 3%. Due to the high volume of trade, however, the benefits of removing the remaining tariff barriers would be significant, resulting in savings of around \$1.5 billion per year, over a third of which would be intra-company trade. These savings would immediately reduce the costs of production for business, and the benefits would be reflected throughout the economy.

The potential savings from reducing – and where possible eliminating – regulatory barriers to trade are even greater. Enhanced regulatory cooperation has the potential to significantly reduce costs for governments and industry alike, while maintaining high levels of protection for human health and the environment. The goal of stronger U.S.-EU regulatory cooperation is not to weaken regulatory mandates, but rather to ensure that those mandates do not result in unnecessary barriers to trade. A more efficient and effective trans-Atlantic regulatory environment would provide a significant boost to innovation, growth and jobs, while ensuring that regulatory objectives are achieved.

Enhanced U.S.-EU regulatory cooperation should include the implementation of previous agreements and principles between the U.S. and EU for promoting regulatory coherence. Horizontal issues that might be addressed in the context of TTIP include assessing current areas of regulatory divergence and options for narrowing them; developing mechanisms to ensure that potential future areas of regulatory divergence are identified and addressed; determining whether

differing regulatory approaches are equivalent in meeting a similar regulatory objective; and promoting greater regulatory transparency, including in regulator-to-regulator discussions.

The U.S. and EU regulate chemicals in different ways. That is not going to change as a result of the TTIP. In fact, the evidence shows that risk-based approaches to chemicals management continue to attract strong bipartisan support in the U.S. Where the TTIP can add value is in ensuring that these differing regulatory systems operate as coherently as possible, promoting efficient and effective regulatory approaches and exploring opportunities for cost reductions and burden sharing. In our view, the chemical industry is well placed to be a priority sector for enhanced regulatory cooperation under TTIP.

Even though approaches to regulating chemicals in the U.S. and Europe differ, there are common elements and issues in their efficient and effective operation. These issues are fundamental to consideration of chemical regulatory cooperation under the TTIP, and include:

- Data and information on which regulatory decisions are based.
- Processes for identifying priority substances.
- Approaches for characterizing risks and hazards.
- Transparency in regulatory processes
- Rules to protect commercial and proprietary interests.

These are areas where the U.S. and EU can seek efficiencies within current regulatory structures, while maintaining high levels of protection for human health and the environment.

Enhanced U.S.-EU regulatory cooperation in the chemical sector should not only address actual and potential areas of regulatory divergence that impose barriers and increase costs of trans-Atlantic trade. ACC calls on negotiators to seek efficiencies within and between regulatory systems, and where appropriate, explore opportunities for burden sharing. The scope of this enhanced cooperation should be forward looking, and focused on addressing and mitigating the potential for creating new regulatory barriers. But it should also seek to identify areas where addressing existing regulatory barriers would reduce costs for industry and governments alike.



The overriding principle behind enhanced regulatory cooperation on chemicals is that both sides should agree to consult and to cooperate when developing new chemicals regulations. Even where regulatory approaches differ, opportunities should be pursued to minimize divergence in regulatory outcomes and reduce costs of compliance. Understanding the data used and process employed for science-based decision-making will be key in this regard.

Enhanced U.S.-EU regulatory cooperation on chemicals issues should focus attention on the following priority areas, which are of particular interest ACC and its member companies:

#### Enhanced Scientific Cooperation

A mechanism to promote stronger trans-Atlantic scientific cooperation and enhanced coordination on scientific assessments could help minimize the potential for imposing additional regulatory barriers when revising or developing new regulations. For example, discrepancies in chemical assessments (risk assessment versus hazard assessment) could impose barriers either directly or through secondary regulations, e.g. on cosmetics and food packaging. Enhanced scientific cooperation could include:

- Developing criteria for the reliability and quality of scientific data underpinning regulatory decisions;
- Providing opportunities for stakeholder input on emerging scientific issues; and,
- Considering the impact of new scientific developments on regulatory decisions.

An example of a current regulatory issue with potential for significant impact on trade and where enhanced scientific cooperation could help minimize the potential for regulatory divergence is the identification of endocrine disrupting chemicals of regulatory concern. At present it appears possible that approaches to identifying endocrine disrupting chemicals in the US and EU will differ significantly. It is critical that regulatory approaches in this area focus on screening and testing substances that may have endocrine disrupting properties in an effort to determine whether endocrine activity linked to these substances leads to adverse effects. Any approach that seeks to identify potential or suspected endocrine disrupting chemicals, without hazard characterization and clear scientific evidence of adverse effects, could precipitate



decisions to stop using these chemicals or products containing them, or could promote the switch to alternatives whose health effects may be less well understood.

A lack of regulatory compatibility with respect to endocrine disrupting chemicals could have a significant impact on trans-Atlantic trade, on agricultural as well as industrial goods. Regulatory compatibility is desirable not only with regard to criteria and methodology for reviewing substances of regulatory concern, but is also desirable when it comes to questions of thresholds. Should the EU, for example, proceed to regulate endocrine disruptors in a way that does not differentiate between products that contain significant quantities of a given substance and those that contain only an incidental amount, the cascading effect on a large number of industry sectors important to both the U.S. and EU would be enormous. The EU may well decide in the coming weeks not to include such a threshold, imposing major unintended consequences on a wide range of industries, markets and consumers on both sides of the Atlantic.

The potential divergence between regulatory approaches in the U.S. and EU highlights the need to assess the impact of chemical regulatory proposals on trans-Atlantic trade as part of overall regulatory impact analysis. In the context of TTIP, U.S. and EU regulators should explore the potential for minimizing regulatory divergence in this area, including developing a common understanding of criteria for reviewing substances of regulatory concern, testing and assessment methods, and a thorough investigation of whether adverse effects exist, and at what thresholds.

#### Transparency in Cooperative Activity

Greater transparency in trans-Atlantic cooperative activity between regulators could help enhance stakeholder confidence and support for regulatory cooperation. Industry on both sides of the Atlantic is aware that regulator-to-regulator discussions are occurring, but information on when cooperative activity is taking place, and what issues are being addressed, is typically not made available to stakeholders in advance of the discussions. Increased transparency in cooperative activity between regulators could include:



- Opportunities for stakeholder notice and comment on the proposed agenda for cooperation.
- Opportunities to suggest that particular issues will be addressed.
- Opportunity for stakeholder participation in relevant cooperative activities, where appropriate.
- For the chemical industry, stakeholder input might include consultation with experts in particular chemistries under review on both sides of the Atlantic. This approach would help ensure a common understanding of the technical and scientific information that exists, and could help expedite government assessment of chemicals.

#### Data and Information Sharing

ACC would like to see a potential US-EU trade agreement include a commitment to address apparent and potential barriers to information sharing on chemicals across the Atlantic, including regulatory barriers, cost considerations, and the protection of legitimate commercial information. Minimizing demand for new information should be a key area of focus for enhanced trans-Atlantic chemical regulatory cooperation, and this can be facilitated by better sharing of data and information. Enhanced data and information sharing would result in significant efficiencies for both governments and industry, including eliminating unnecessary or duplicative generation, testing and submission of data. The ability to share relevant information – both the data itself and information on the *interpretation* of that data – is likely to become even more critical in the future given the emergence of new assessment technologies. The chemical industry would support further efforts under the TTIP to review the potential barriers and mechanisms for facilitating trans-Atlantic data and information sharing on chemicals, including regulatory barriers.

#### Prioritization of Chemicals for Review and Evaluation

Prioritization of chemicals in commerce for further assessment enables governments and industry to focus attention and limited resources on the substances of highest concern. Enhanced



U.S.-EU cooperation in this area should include an agreement to establish and apply common principles for prioritization that are clear, specific, and transparent. These criteria should:

- Be science and risk-based, considering both the degree of hazard (hazard identification and characterization) and the extent of exposure potential (risk assessment).
- Be based on existing, available information.
- Have the flexibility to incorporate relevant scientific advances (e.g. understanding what emerging science and technology suggests for prioritization).
- Provide an opportunity for stakeholder review and comment at key points in the prioritization process, including the opportunity to provide additional, existing information in advance of final prioritization decisions
- Consider a chemical's uses and applications in the prioritization review process.

The chemical industry would support the development of an agreed process for comparing lists of chemicals prioritized for assessment in each jurisdiction. We would anticipate that the lists would contain a similar set of chemicals if the prioritization process in both jurisdictions takes account of the factors listed above, and could lead to greater efficiencies by sharing the burden of review. For example, a preliminary assessment by the American Chemistry Council indicates that there are at least 13 chemicals in common between USEPA's TSCA work plan<sup>1</sup> chemicals and the REACH list of Substances of Very High Concern (SVHC).

#### Coherence in Chemical Assessment

An important objective of regulatory cooperation should be to develop a common scientific basis for regulatory decisions. If both jurisdictions have confidence in their respective assessment procedures, there is the potential for additional efficiencies to be identified, and the burden associated with the assessment of priority chemicals to be shared between U.S. and EU regulators. A core objective should be to create certainty in the chemical assessment process on both sides of the Atlantic by understanding how common issues (such as integration of weight-

<sup>1</sup> Information on the EPA Office of Pollution Prevention and Toxics (OPPT) work plan chemicals – the Agency's current effort to identify, prioritize, and assess existing chemical risks – is available at <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>.



of-the-evidence approaches) are addressed. While final risk management decisions should remain sovereign decisions, a common understanding on assessment could significantly reduce costs for both governments and industry by avoiding duplication and unnecessary additional testing, which would accelerate chemical reviews. Achieving greater coherence in chemical assessment processes should be a priority in discussions on chemical regulatory cooperation under the TTIP.

#### **Conclusion**

ACC and its member companies strongly support the negotiation of a comprehensive, ambitious Trans-Atlantic Trade and Investment Partnership. For the chemical industry, and for the broader economy, it has the potential to provide a significant boost to growth and job creation, which in turn would promote innovation and strengthen the international competitiveness of U.S. exporters. The successful conclusion of negotiations on the TTIP would also send an important signal to the rest of the world at a time when multilateral approaches to trade liberalization have stalled.

Thank you again for inviting me here today. I look forward to your questions



Mr. TERRY. Now, Mr. Garfield, you are recognized for your 5 minutes.

#### **STATEMENT OF DEAN C. GARFIELD**

Mr. GARFIELD. Great.

Thank you, Chairman Terry, Ranking Member Schakowsky, members of this committee. On behalf of the world's most dynamic and innovative companies that make up the global tech sector, we thank you for the opportunity to talk to you about this issue today.

As well, we thank you for your work in general on trade. The hearing you held last month on India has already had a significant impact in pushing back on the preferred market access regime that they tried to put in place there. In fact, our hope for today's hearing is that it will have a similar salutary impact as we move forward on TTIP.

As you have noted, this agreement has the potentially precedent-setting impact, both economically and otherwise. And given the eloquence of the other colleagues who have been on this panel, rather than go through my entire written testimony, I thought I would simply share our three objectives for the potential partnership.

One, and foremost for you, I know, as well, is economic growth and job creation. In order to ensure that this agreement lives up to the forecast and that that forecast, in fact, becomes fact, it is important that we include aspects of the economy that are critical to economic growth.

The colleagues on the panel have highlighted a number of areas. I would also like to point to electronic goods in commerce. That e-commerce has the potential to be a significant force multiplier for the entire economy, both businesses large and small. So whether you are talking about AppleLink or an app developer or the Apple vendor in each of your communities, the potential impact is significant. And so we would suggest a focus there.

As well, we would suggest focusing on the policy issues that would impact e-commerce. A number of people on this panel have already spoken about the importance of cross-border data flow and the rules that need to be put in place to ensure that that occurs, and we think that should be a priority.

Our second objective for this agreement is to make sure that it is, in fact, a model for the rest of the world. A number of economies, in an effort to drive innovation and economic growth, have put in place forced localization requirements like those that we saw in India or have tried to fix things that are not broken—for example, creating new governance models for the Internet.

Both the European Union and the United States have acted as a bulwark against those sorts of pernicious policies. And TTIP has the potential to align us in a more significant way in pushing back against those sorts of problematic policies on a global basis.

Our third and final priority for this agreement, potential agreement, is something that the other folks on this panel have spoken of already, which is greater regulatory alignment where possible.

The reason we have almost as many mobile phones as people in the world and the reason we have almost 3 billion people accessing the Internet is because it is an open, interoperable platform that

is built on global consensus-based standards. That is a model that we think is apt for purposes of these discussions, as well.

We recognize that we are not going to be able to align and harmonize all regulation, but where we can, we should. It will reduce costs and will continue to improve lives, as we have seen with the Internet generally and the availability of mobile technologies.

Related to that, we think it is important, where it isn't possible to have alignment, that we have an alarm system so that there is greater transparency and certainty around where those disagreements are and the reasons for the disagreements.

And so we look forward, as the tech sector, in working with this committee and with Congress generally in making sure that TTIP is not only completed but it is completed in a way that advances both U.S., European, and world economic interests.

Thank you.

Mr. TERRY. Very well done. Thank you very much.

[The prepared statement of Mr. Garfield follows:]



## Information Technology Industry Council

### "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"

Testimony of  
**Dean C. Garfield**  
**President & CEO, Information Technology Industry Council (ITI)**

Before the  
**U.S. House of Representatives**  
**Committee on Energy and Commerce**  
**Subcommittee on Commerce, Manufacturing and Trade**

July 24, 2013  
2123 Rayburn House Office Building  
Washington, DC



**"The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"**

**Testimony of ITI's Dean C. Garfield**

**House Energy and Commerce**

**Subcommittee on Commerce, Manufacturing and Trade**

July 24, 2013

Chairman Terry, Ranking Member Schakowsky, members of the Subcommittee, thank you for the opportunity to testify today. I am Dean Garfield, president and CEO of the Information Technology Industry Council, or ITI, a Washington-based non-profit business association representing 52 of the most innovative technology companies in the world. We applaud the subcommittee's interest in the Transatlantic Trade and Investment Partnership, or T-TIP, and welcome the opportunity to appear before you today to share our views on this major endeavor.

ITI's member companies span the information and communications technology (ICT) industry: infrastructure, computer hardware, software, telecommunications, consumer electronics, and IT, e-commerce and Internet services. This technology is essential to every sector of our nation's economy, and enables individuals of every age and ability to improve their quality of life.

Among ITI's highest priorities are global policies that advance technology and innovation, promote open markets, rely on market-based solutions, protect intellectual property, and develop and advance the use of global, voluntary standards. Unfettered market access is critically important to our ability to sustain U.S. technology leadership here and abroad. Even though there is already substantial trade between Europe and the United States, the T-TIP negotiations present an important opportunity for the world's two major economies to address global trade issues of common concern. Accordingly, ITI is actively engaged in achieving a T-TIP that will advance competitiveness, growth, and job creation, especially in the area of digital trade; reduce and minimize regulatory burdens and barriers to trade; and establish transparent, predictable regulatory convergence. My testimony highlights a number of issues where progress needs to be made to achieve these goals.

**FOSTERING COMPETITIVENESS, GROWTH, AND JOBS THORUGH DIGITAL TRADE**

As the digital trade becomes an even more fundamental element of the global economy, provisions to support the development and growth of ICT services, cloud computing, and e-commerce are critical if both sides of the Atlantic are to fully realize our shared potential in terms of investment and new business and job creation.

Digital trade, investment, and business and job creation are coming from a number of sources, a few of which are important to highlight here, namely, ICT services and cloud computing.

**ICT Services**

The ICT sector provides the infrastructure and technology that enable cross-border delivery of services for a number of sectors, ranging from financial services, and express delivery and retail – just to name a few. Growth in transatlantic services trade will not only benefit ICT service companies, but will also benefit manufacturers of ICT infrastructure and platforms, which allow for the fast and efficient delivery of services. To maximize the economic potential of ICT services, providers should have the freedom to choose the most efficient, cost-effective mean to deliver the services,



e.g., through cross-border delivery or via a commercial presence. As these companies gain greater market access, U.S. high-tech companies will benefit by supporting their transatlantic operations.

#### **Cloud Computing**

By centralizing data storage and governance, clouds can actually provide better security at a lower cost than can traditional computing environments. Cloud environments can also provide differentiated levels of security, reflecting the fact that certain types of data warrant a higher level of protection. Fundamentally, the growth of cloud computing, and the cloud's value to future economic growth, will continue only if its development is guided by the same open, market-based approach that has long enabled the dynamic growth of the Internet and ICT generally.

To ensure transatlantic gains that advance ICT services, cloud computing and other similar aspects of digital commerce, the T-TIP should include the following:

- Strong, binding provisions to support the cross-border flow of data. Service suppliers across all industry sectors and their customers should be able to freely transfer, access, process, store, and manage information across borders, all of which are essential to meeting contractual obligations. Product developers and service suppliers rely on the free-flow of information, and the T-TIP should include workable mechanisms that allow for greater interoperability, thereby facilitating cross-border data flows.
- An explicit agreement assuring that ICT service providers will continue to be free to choose the methodology for delivering cross-border services, without country-specific, local data server, cross-border services or similar data requirements.
- Technology-neutral approaches to ensure that current services, including cloud computing, Web hosting, software as a service, audio visual services, and others, are all covered, and that commitments in computer and related services also cover emerging and evolving services as technology advances.
- Measures that embrace the promotion of interoperability and mutual recognition of privacy, data protection, and cybersecurity frameworks.
- Continued reliance on global ICT standards developed via standard-setting processes that are consensus-based, transparent, and industry-led, with participation open to interested parties.

Even if the United States and the European Commission (EC) reach agreement on the above, if the two markets are not aligned relative to policies and protections afforded to services and content, then the potential for expanding digital trade -- and the economic growth and job creation it stands to generate -- will remain unnecessarily constrained. Accordingly, it is essential that the T-TIP address three key, related policy areas:

#### **Intellectual Property**

The T-TIP should strive to sustain and enhance cooperation on the protection of intellectual property rights. It should provide effective protection and enforcement of intellectual property rights to create a climate in which innovators are encouraged to invest in the research, development, and commercialization of leading-edge technologies, and promote the dissemination of technologies and services. New and complementary approaches that enable the digital economy to function, balanced to include effective protection of intellectual property, should be encouraged, and should respect principles such as freedom of expression, fair process, and privacy.

#### **Trade Secrets Protection**



ITI urges both the United States and the EC to strive toward a uniform trade secrets protection regime. Through the T-TIP, the United States and the EC have the opportunity to create a global model for the protection of trade secrets and increase cooperation on theft by third countries.

ITI also urges the United States and the EC to develop model protections for trade secrets in addition to those provided via the World Trade Organization's (WTO) Technical Barriers to Trade Agreement (TBT) that are submitted to government authorities as a condition of market access (i.e., where the disclosure is linked to the importation and/or sale of goods). Our industry, like others, is concerned with the increasing number of overbroad testing or certification systems and other regulatory schemes being developed by foreign governments that require the disclosure of unnecessary proprietary information. The risk that the required sensitive information will leak to domestic competitors is compounded by the reality that many governments have inadequate procedures to protect such information and some of those governments are focused on increasing indigenous innovation.

Industry recognizes that in certain circumstances, some proprietary product information needs to be provided to governments, including ours, for legitimate health, safety, security and other reasons. In such cases, however, U.S. agencies have detailed procedures to protect confidential business information, which are enforceable against the officials that administer them. T-TIP could seek agreement from the EC and Member States to emulate the principles embedded in such procedures, and set a global standard for other governments to follow.

#### **Copyright Levies**

Collecting societies in a number of Member States of the European Union have been granted the right to charge levies on specific goods to provide compensation to the rights holders of certain copyrighted material that has been subject to private copying. These levies are an outdated method of compensating content rights holders in light of highly effective digital rights management tools. Moreover, copyright levies on digital goods undermine the objectives of the Information Technology Agreement to reduce costs of and expand trade in information technology products. The levies are a prime example of the type of tariffs or duties that should be eliminated through the T-TIP, especially given their negative impact on demand for ICT products that is so critical to increasing the productivity and innovation capability of the transatlantic economy.

#### **Movement of STEM Workers**

High-value innovation is increasingly collaborative and cross-border, involving multiple sites, corporate affiliates or other parties, and is especially important when it comes to fostering growth in the digital economy. U.S. and European workers with science, technology, engineering, and mathematics (STEM) degrees often are involved in transatlantic R&D projects that require regular in-person interaction with employees at other sites. Moreover, U.S. employers should be able to easily hire highly skilled workers from the European Union and vice-versa. Too often, however, visa applications take an unreasonable amount of time to process and these delays restrict important business activities. T-TIP provides an opportunity to modernize the rules guiding workforce mobility for employees with STEM degrees and their employers who are based in the United States and European Union. Simpler and more streamlined immigration policies for employees with STEM degrees will strengthen the U.S.-European relationship and enhance innovation and cooperation between U.S. and European companies.

Accordingly, for employees with STEM degrees, U.S. and EC negotiators should include in T-TIP commitments providing for the expansion of permissible business activities, a new treaty visa similar to the one created for Canada and Mexico



in the NAFTA agreement, streamlined procedures for intra-company transfers, better treatment for family members relocating with a worker, and an adjustment to the J-1 home residency requirement.

#### **REDUCING BURDENS TO TRADE THROUGH EXAMPLE**

##### **Forced Localization**

The trend towards forced localization policies is a serious and growing concern. More and more governments are pursuing “forced localization” policies designed to boost domestic manufacturing, high-tech and R&D capabilities, and service industries, often at the expense of foreign players. These policies include troubling provisions, including requirements on technology transfer, local sourcing in government and private sector procurements, sharing of software source code and other sensitive design elements, and flow of data. And they conflict with international norms, jeopardize future growth of global ICT and other industries, and threaten the advance of innovation and job creation tied to the global technology industry. The ability to develop new innovations through cost-effective global supply chains, and access and compete in global markets has been critical to the health of our industry.

The United States and Europe have been working together to combat forced localization policies. Mr. Chairman, last month, ITI testified before this Subcommittee on India’s planned forced localization policies on ICT products and services. Last week, the Prime Minister of India announced that these policies would be put on hold pending a more extensive review. This was an important, positive step – one that would not have been possible without the participation and encouragement of public and private entities within the European Union.

We believe the United States and Europe can build on that collaboration and promote sound regulatory approaches that can serve as an alternative model for building innovation and manufacturing capabilities. Specifically, the T-TIP commitments should clarify that market access for ICT goods and services shall not be conditioned on involuntary requirements to transfer technology, or invest in, develop, or use local R&D, intellectual property, ICT manufacturing or assembly capabilities.

##### **Internet Governance**

Free of encumbering government controls and regulations, the Internet continues to transform the world in ways that benefit all nations, regardless of economic status or geographical region. Internet usage continues to grow exponentially in most of the world. For example, studies indicate that, since 2000, Internet usage growth has exceeded 3,500 percent in Africa, and 1,300 percent in Latin America. Despite such incredible numbers, it is important to bear in mind that, as a technology and platform, the Internet is still in its infancy. It continues to evolve in unanticipated ways and produce benefits well beyond expectations.

It is widely acknowledged that the current approach to Internet governance has provided a stable, predictable environment that has helped to facilitate global innovation and investment. Yet, despite this success, we hear criticism from some corners about the unfairness and concentration of control in the current governance model. Variations on this inequity theme can be heard almost weekly at conferences and workshops sponsored by the International Telecommunication Union (ITU), a specialized agency of the United Nations.

The United States and Europe worked together to resist threats to Internet governance at last December’s ITU World Conference on Information Technology. While we achieved a degree of success, opponents of the current governance model are at work devising plans that would force the United States and our partners to either accept radical changes to Internet governance or leave the ITU altogether. There is simply no good economic justification, or otherwise, for



undermining the current Internet model, particularly for the sake of political expediency. The risks to innovation, job creation, and consumer freedom are far too high.

The T-TIP provides us with the opportunity for both parties to reiterate our commitment to an open, multi-stakeholder approach to Internet governance. In addition, both the United States and Europe should expand their efforts to communicate with and educate other ITU Member States about the benefits of a free and open Internet to businesses and citizens alike.

#### **Cybersecurity**

ITI commends the United States and Europe for undertaking the challenging task of developing policies and strategies for cybersecurity. The ICT sector has a direct stake in effective security management and best practices. In June 2012, ITI, DIGITALEUROPE, and the Japan Electronics & Information Technology Industries Association (JEITA) issued a "Global ICT Industry Statement: Recommended Government Approaches to Cybersecurity." In the document, industry expressed the view that, to be effective, efforts to enhance cybersecurity must:

- Leverage public-private partnerships and build upon existing initiatives and resource commitments;
- Reflect the borderless, interconnected, and global nature of today's cyber environment;
- Be able to adapt rapidly to emerging threats, technologies, and business models;
- Be based on effective risk management;
- Focus on raising public awareness; and
- More directly focus on bad actors and their threats.

The statement provides governments worldwide with a common foundation for policymaking in the area of cybersecurity. The recommendations present a cooperative approach between government and industry that meets security needs, including preserving interoperability, openness, and a global market, while permitting industry to innovate and compete. ITI will continue to urge the United States and Europe to promote the use of such approaches to governments globally.

We will urge the two governments to ensure the commitments ultimately obtained in T-TIP are consistent with the approaches set forth in these documents so as to ensure compatible policies across the Atlantic will promote security while also enabling innovation and trade. In particular, in the realm of government advocacy or promotion of the use of cybersecurity standards and best practices in the commercial sector, we will urge the two governments to commit to continue relying on globally accepted voluntary standards, best practices, and international assurance programs developed via standard-setting processes that are consensus-based, transparent, and industry-led, with participation open to interested parties.

This approach will improve security, because nationally focused efforts may not have the benefit of the best peer review processes traditionally found in global standards bodies; because proven and effective security measures must be deployed across the entire global digital infrastructure; and because the need to meet multiple, conflicting security requirements in multiple jurisdictions raises enterprises' costs, diverting valuable security resources. This approach also will: 1) improve interoperability of the digital infrastructure, because security practices and technologies can be better aligned across borders; 2) permit more private sector resources to be used for investment and innovation to address future security challenges; 3) increase international trade in cybersecurity products and services that can be



sold in multiple markets; and, 4) allow countries to comply with their international commitments, such as the WTO TBT Agreement.

Finally, in developing cybersecurity-related policies, ITI will urge the United States and Europe to avoid U.S.- and European-specific approaches to cybersecurity that fail to reflect cyberspace's borderless nature, and to also avoid static, "check-the-box" compliance regimes that would encourage some firms to invest only in meeting requirements that may well be outmoded before they can even be published.

#### **PROMOTING REGULATORY CONVERGENCE**

In the area of regulatory convergence, ITI is urging the United States and Europe to develop a framework that will focus on current regulatory burdens and, in particular, avoid unnecessary regulatory divergences in emerging sectors that are ripe for future growth and job opportunities, such as nanotechnologies. Alignment of regulations and standards-setting could significantly reduce costs, create conditions that make both markets attractive for new investment and startups, and compel other countries and regions of the world to engage in similar harmonization efforts to stay competitive.

Greater regulatory transparency is also particularly important. An "early warning system" on prospective or revised regulations would reduce uncertainty for business, while also providing industry with the opportunity to share essential, timely market and technical expertise with regulators and other stakeholders. We are also recommending conformity assessments that would ensure the greatest degree of compliance at the lowest level of government intervention, as justified by science-based risk assessment. Currently, Europe employs what is known as the "precautionary principle," which permits the imposition of rules and regulations based on assumptions or potential risks that may never arise. This approach forces manufacturers to waste resources that could be better utilized expanding R&D, hiring new workers and reducing costs to consumers. We urge the avoidance of redundant and/or unnecessary testing and certification requirements, as they can create delays and barriers to entry, and may prevent the uptake of new, innovative and more efficient technologies.

Finally, we recommend wider adoption of supplier's declaration of conformity in both markets, where companies can self-evaluate and report on compliance with standards and regulations. Experience has shown that self-declaration, coupled with effective post-market regimes (including surveillance and enforcement), offers a more flexible, trade-friendly, and cost-effective approach for meeting regulatory objectives.

#### **ICT Standardization**

During the past several years, ITI has invested considerable effort into advocating government acceptance of global, private sector-led, voluntary, consensus standards to advance ICT innovation and competition. The motivation was to encourage a broader view on what constitutes a global ICT standard and promote greater transparency and openness in the methodology employed for identifying relevant standards. ITI believes the T-TIP negotiations provide an excellent opportunity to develop a common approach on global standards and corresponding conformity assessment schemes in a manner that could serve as a model for other countries seeking to leverage ICT investments to enhance economic growth and job creation.

United States and European standards policies reflect a firm commitment to the WTO TBT Agreement, including an emphasis on the use of voluntary global standards. This common foundation should be further leveraged both bilaterally and globally when dealing with other countries of common concern. There are still, however, notable



differences between the two standards systems, which are built on a different view regarding the role of the public and private sectors.

In some cases, those differences present distinct challenges to American and European tech companies doing business in both markets. To eliminate potentially discriminatory practices and thereby ensure the broadest possible benefits of ICT innovation and trade via T-TIP, ITI recommends that the United States and EC develop a joint approach to ICT standardization that maximizes reliance on global, private sector-led voluntary consensus standards. The EC has already moved in this direction for public ICT procurements, but more progress can be made. T-TIP should also include agreement on a definition of what constitutes global standards-developing organizations, or SDOs, giving due deference to those whose standards are widely implemented globally rather than merely nationally or regionally. Both the United States and EC should recognize the important role of those global SDOs by defining appropriate preferences for global ICT standards over other types of standards.

By establishing mutual policies for advancing non-discrimination and transparency, the common approach would serve as a model to help both governments to better address many of the emerging practices of concern to the transatlantic ICT community, such as opaque standardization practices, inadequate participation rights and comment periods, and the creation of unique national technical specifications that deviate from global standards. A common transatlantic approach to standardization that adheres to the above criteria could serve as an effective tool to discourage certain standards-setting approaches in emerging markets that deviate significantly from relevant global standards and tend to favor domestic businesses.

#### **Regulatory Product Marks & Labeling**

ITI recommends that the United States and EC strive toward greater regulatory alignment on product marks and labeling for ICT products. Countries around the world are increasingly requiring regulatory marks and labels on ICT products, with more labels for energy and environmental requirements expected in the near future. Manufacturers are struggling to find the necessary space to accommodate these labels on devices that are manufactured for a global market. The problem is exacerbated for small products with limited surface areas for product marks and labels. As ICT products become overcrowded with marks and other information, customers are more likely to ignore what they perceive as clutter, and government surveillance for regulatory compliance is not well served.

Without a global body to govern or coordinate these national requirements, industry and regulators will have to work together to find a solution. ITI believes the United States and EC should take this opportunity to address the issue. There should be a joint regulatory effort to eliminate requirements for product marks and labels to display nonessential information. Manufacturers should be allowed greater flexibility to place information deemed essential on the product, in the product manual, on packaging, or on the manufacturer's website.

ITI is therefore urging in the T-TIP negotiations greater regulatory alignment between the United States and EC on ICT product marks and labeling, which will provide needed global leadership on this issue of importance to our industry.

#### **ICT Accessibility**

The global ICT response to the accessibility needs of people with disabilities and age-related limitations has been accelerating in the past decade. This activity has been spurred in large part by U.S. leadership and by industry support for the World Wide Web Consortium's Web Content Accessibility Guidelines. As a result, numerous technical advancements in hardware and software have created improvements in video, data display, sound, voice and touch technologies, resulting in improved access for individuals with accessibility needs.



Governments are paying greater attention to the issue of accessibility due to a variety of factors, including the increasing role of ICT in national economies, the rapid migration of government services and data to the Internet, and the expansion of entertainment and communication services via the Internet and wireless technologies. Both the United States and Europe are in the process of identifying and updating ICT accessibility technical criteria. ITI members have supported this effort, including the commitment of both governments to work together to align their respective requirements. A common approach on accessibility will help streamline transatlantic trade in accessible ICT solutions, and create greater incentives for business to invest in new innovation. It is equally important, however, that both governments align conformity assessment requirements.

When the United States adopted ICT accessibility standards for public procurements, federal experts evaluated various approaches to helping agencies identify products and services that conform to the new standards. Ultimately, they decided to adopt the supplier's declaration of conformity (SDoC) model, which allows manufacturers to evaluate and report conformance through the use of such tools as the Voluntary Product Accessibility Template® (VPAT®). Under this approach, the market for accessible ICT has thrived in the United States. Given the EC's long-standing support for SDoC, we believe that adoption of a common approach on conformity assessment based on SDoC principles will magnify the benefits of US-EC alignment on accessibility, while reducing roadblocks to new accessibility technologies.

In the T-TIP context, ITI is recommending that the two governments continue to work together to achieve a harmonized approach to ICT accessibility, including alignment on the timing of implementation of the forthcoming requirements. This will help expand consumer access to the latest technology while avoiding unnecessary costs due to redundant or contradictory administrative requirements. A common approach on ICT accessibility can also serve as a model for other nations that are looking to advance opportunities for citizens with disabilities.

#### **CONCLUSION**

Mr. Chairman, Members of the Subcommittee, the opportunities and challenges presented by the T-TIP negotiations are considerable and exciting. A successful outcome is by no means assured as there are some significant differences in how we run our two economies. Nevertheless, we remain optimistic that a deal can be achieved, and look forward to working with you and other Members of Congress on finding solutions for next-generation trade issues impacting the high-tech sector, many of which we feel can be advanced in the T-TIP negotiations.

Thank you for this opportunity to provide comments on the Transatlantic Trade and Investment Partnership. I will be happy to answer any questions you may have.

-30-

Mr. TERRY. Now, Ms. O'Halloran—I am sorry, Halloran. I have a good friend, O'Halloran, so I apologize. You are not Terry. But you are now recognized for 5 minutes. Thank you.

#### **STATEMENT OF JEAN M. HALLORAN**

Ms. HALLORAN. Thank you.

Thank you for inviting me to testify today, and I am pleased to be able to give you the consumer viewpoints on the trade negotiations.

I represent Consumers Union, the policy arm of Consumer Reports, which has 8 million subscribers to its print and Web editions. And I am also representing the views of the Transatlantic Consumer Dialogue, which includes all the major consumer organizations, some 60 groups, on both sides of the Atlantic.

Trade between the EU and U.S. already has many obvious benefits for consumers, increasing choices in products and services ranging from automobiles to banking to wines. However, consumer groups are extremely concerned about the avowed focus of this negotiation, which is regulatory and non-tariff barriers. We are concerned this may erode safety, threaten privacy, and even increase prices by extending patent protections and other means.

In citing the need for regulatory convergence and harmonization and mutual recognition, we think there are many hazards.

The EU and U.S. are both advanced, highly civilized societies which have high standards of consumer protections for its citizens, so what could be wrong with this? The answer is, unfortunately, a lot. Theoretically, harmonization, if it is to the highest standard of consumer protection, could bring great benefits. However, that is not the history of trade agreements, and it doesn't appear to be the goal of the U.S. negotiators nor of a number of my colleagues here.

Meanwhile, the scope of topics being tackled in this negotiation is breathtaking, including, potentially, auto safety, chemical safety, biotechnology, nanotechnology, pharmaceutical safety, patent protections, privacy on the Internet, banking regulations, food safety, medical device safety, and toy and consumer product safety. We find the potential for erosion of standards in these areas alarming.

Let's look at a few examples of why consumer groups are extremely concerned.

The concept of regulatory convergence implies some sort of movement to the middle where standards differ. In the area of toy safety, this committee and the U.S. Congress, with bipartisan support, addressed a sudden influx of hazardous toys, in most cases made in China, bypassing the CPSIA.

A key provision of that law requires toy companies to obtain independent third-party certification from an accredited laboratory that says that U.S. standards for the lead in the paint on the toys and other safety standards are being met. Europe does not require third-party certification for toys. How do we converge that?

The idea of mutual recognition is equally concerning here. Some might propose that we simply recognize that the self-certification behind the CE mark in Europe is comparable to our provision. We feel, however, that this could potentially open the door for toys made in China by European companies, exclusively designed for sale in the United States, which could be less safe than toys made

by U.S. companies and, therefore, subject to CPSIA. Consumers could be put at risk, and U.S. toy companies could be put at a disadvantage.

Let's take another example, in the food area. When mad cow disease was discovered in the U.K. A number of years ago, the U.K. And other European regulators continued to allow European beef products to be sold and shipped across borders. The U.S., prudently, did not. We shut our doors to European beef quickly.

We think the U.S. action was entirely correct and appropriate. The U.S. had a plentiful supply of beef here and did not need to take any risks with the European beef. But what if the EU and U.S. had a mutual recognition scheme in place at the time? The U.S. could have been forced to keep taking European beef for as long as Europeans deemed it safe enough to sell to Europeans.

I would like to quickly bring up a couple of other topics.

Investor-state dispute resolutions concern us greatly. They were originally developed in trade agreements to provide a means for U.S. corporations who invested in countries who had poor legal systems to obtain compensation if a government acted to, say, nationalize their oil wells. Such mechanisms are completely unnecessary, however, in the EU-U.S. context, where we both have well-developed court systems to deal with these kinds of difficulties.

Finally, a few words about secrecy in this discussion. A critical area of concern is the secrecy with which the Obama administration's appointed negotiators will be conducting this. We certainly understand, as do Members of Congress, that not every conversation needs to be conducted or can be conducted in public. But Congress makes pending legislation public at numerous stages. By contrast, drafts and texts in this negotiation are being classified as Top Secret, unavailable to public and stakeholders at this table as well as to Members of Congress. This has not always been the case, and we urge you to demand that USTR periodically make public the texts that they are drafting.

Thank you.

Mr. TERRY. Thank you.

[The prepared statement of Ms. Halloran follows:]

**SUMMARY OF TESTIMONY**

**Testimony of Jean M. Halloran**

**Senior Advisor for International Affairs, Consumers Union**

**U.S. House of Representatives, Committee on Energy and Commerce,**

**Subcommittee on Commerce, Manufacturing and Trade**

**"The U.S.-E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"**

**July 24, 2013**

In sum, Consumers Union, and consumer groups on both sides of the Atlantic, are deeply concerned that this agreement, focused on "regulatory convergence" and "mutual recognition," will lead to an erosion of consumer protection in the vast areas it is addressing. We are also deeply concerned that an agreement on investor-state dispute resolution will potentially create a new court system that could end run the one we currently rely upon. These concerns are intensified by the secrecy in which the two sides intend to conduct this negotiation, which means that the public and Congress itself will have no opportunities to point out or address serious problems.

We urge Congress and the Administration to establish "harmonization upward" to the highest levels of consumer protection as an avowed goal of this negotiation, to abandon any effort to establish an investor-state dispute resolution mechanism, and to insist on, at the very least, publication of draft negotiating text at regular intervals, so we call all see what is going on.

**Testimony of Jean M. Halloran**  
**Senior Advisor for International Affairs, Consumers Union**  
**U.S. House of Representatives, Committee on Energy and Commerce,**  
**Subcommittee on Commerce, Manufacturing and Trade**  
**“The U.S.-E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers”**

**July 24, 2013**

Thank you for inviting me to testify today and I am pleased to be able to give you the consumer viewpoint on the trade negotiations that have just begun between the European Union (EU) and the United States (US). I represent Consumers Union, the policy and advocacy arm of Consumer Reports, which has 8 million subscribers to its print and web editions. The views I am presenting are also those of the Transatlantic Consumer Dialogue (TACD) which includes all the major consumer organizations on both sides of the Atlantic (see [www.tacd.org](http://www.tacd.org)).

Trade between the EU and US already has many obvious benefits for consumers, increasing choices in products and services, ranging from automobiles to banking to wines. For example, a new trade agreement that reduced certain tariffs or harmonized the different regulations of each so that they were more protective of consumer health and safety would obviously be very beneficial.

**Harmonization, Regulatory Convergence and Mutual Recognition**

However, consumer groups are extremely concerned that the avowed focus of this negotiation, which is regulatory and other non-tariff barriers, and “behind the border” impediments to trade will not achieve this objective. There has been much discussion of

the need for regulatory convergence and harmonization, possibly by “mutual recognition” of standards. The EU and US are both advanced, highly civilized societies, which both have high consumer protections standards for their citizens, so one would think we could be on the right track.

The answer, unfortunately, is we are probably not. Theoretically, harmonization, if it is to the highest standard of consumer protection, could bring great benefits. However, this has not been the history of trade agreements, and it does not appear to be the goal of US or EU negotiators. The scope of topics being tackled in this negotiation is breathtaking, including potentially auto safety, chemical safety, biotechnology and nanotechnology safety and labeling, pharmaceutical safety and patent protections, privacy on the internet, banking regulations, food safety, medical device safety, and toy and consumer product safety. We find the potential for erosion of standards in these areas alarming.

Let’s look at a few examples of why consumer groups are extremely concerned. The concept of “regulatory convergence” implies some sort of movement to the middle where standards differ. In the area of toy safety, however, this Committee and the US Congress with bi-partisan support worked hard to pass the Consumer Product Safety Improvement Act (CPSIA), a law to address a sudden influx of hazardous toys – toys that, in most cases, were made in China. A key provision of the law requires children’s product manufacturers, such as toy companies, to obtain independent third party certification from an accredited laboratory that says US standards for the lead and other

safety standards were being met. Europe does not require third party certification for toys. How do we converge here?

The idea of “mutual recognition” is equally concerning here. Some might propose that we simply recognize the company self-certification behind the “CE” mark as comparable to our requirement for third party certification. We feel, however, that this could potentially open the door for toys made in China by European companies, for sale in the United States, to be less safe than toys made by US companies and therefore subject to the CPSIA provisions. Consumers could be put at risk and US toy companies could be forced to compete on an un-level playing field.

Let me take another example, from the food safety area. When mad cow disease was discovered in the UK a number of years ago, the UK and other European regulators struggled with what action to take, and continued to allow European beef products to be shipped and sold across borders, while slowly increasingly stringent restrictions were put in place on animal feed, the source of the problem. The US by contrast took prompt and definitive action to close its border to beef from the UK and other countries where the disease surfaced.

We think the US action was entirely correct and appropriate. The US had a plentiful supply of beef here in the US and did not need to take risks with European beef. But let's look for a minute at what would have happened if the EU and US had agreed to a scheme of mutual recognition on the safety of livestock products at that time. The US could have been forced to keep taking European meat for as long as Europeans deemed it safe enough to sell to Europeans.

To take a third example, the Congress struggled long and hard to pass Dodd-Frank, which contains vitally and profoundly important provisions to protect consumers, and the nation, from another financial industry melt down. Europe does not have similar legislation or protections. We see grave dangers to attempts to harmonize in this area, unless of course Europe is agreeing to all the protections the US is developing under Dodd-Frank.

Clearly harmonization can work if the two sides harmonize to the highest level of consumer protection in either the EU or US. We would, for example, support a negotiation in which the EU agreed to require nutritional labeling on packages with all the information required in the US, and the US agreed to require labeling where genetically engineered ingredients were present. We would also support NHTSA's adoption of the EU's child occupant protection standards, as the European tests and rates the fit of child safety seats in cars, as well the performance of child safety seats in car crashes. But we have seen little evidence that this is how the negotiation will proceed. "Regulatory convergence" in which one side's regulations are watered down, or "mutual recognition," in which each side is forced to accept products from the other side that potentially don't meet domestic standards, are not, in our view, acceptable or wise goals of a trade agreement.

#### **Investor State Dispute Resolution**

Investor state dispute resolution mechanisms were originally included to provide a means for US corporations who invested in countries that had poor legal systems to obtain compensation if a government acted, to say, nationalize their oil wells. Such

mechanisms are completely unnecessary in the EU-US context. Both societies have very well established court systems and abide by the rule of law.

An investor-state mechanism could allow a European funeral parlor company to bring a case in a special trade tribunal and demand compensation if, say, the state of Mississippi, or the Federal Trade Commission, enacted new standards for funeral parlors, which the European company did not meet and it was forced to close. Indeed something like this has already happened under NAFTA dispute resolution proceedings.

Investors should not be empowered to sue governments to enforce the agreement in secretive private tribunals, and to skirt the well-functioning domestic court systems and robust property rights protections in the United States and European Union. Experience elsewhere shows how powerful interests from tobacco companies to corporate polluters have used investor-state dispute resolution provisions to challenge and undermine consumer and environmental protections. Investors must not be empowered to sue governments directly for compensation before foreign investor tribunals over regulatory policy.

#### **Secrecy Versus Transparency**

One last critical concern of consumer organizations is the secrecy in which these negotiations will be conducted. We certainly understand, as you do as members of Congress, that not every conversation about policy can or needs to be held in public. But Congress makes public pending legislation—when it is introduced, marked up in committee, passes the House or Senate, and after conference. Our trade negotiators have no such obligations. Rather, all drafts and related documents will be classified as top secret. They have no plans to release negotiating texts at any point, until the entire

agreement is completed to their satisfaction, at which point it will be up to Congress and the public to take it or leave it.

It is not just consumers who suffer from being in the dark. You as members of Congress are also prohibited from seeing negotiating texts. This has not always been true in the past—the negotiating texts of the Doha Round and the Free Trade of the Americas agreement were periodically made public. The US global food standards agency, known as the Codex Alimentarius Commission, conducts all its work entirely in public.

Secrecy is not how our democracy normally functions. There is no reason why negotiating texts, especially where regulatory issues will be so involved, cannot be released after each negotiating session. Consumer groups have specifically requested that a Consumer Advisory Committee be established that can provide input on texts and policy in an open, non-classified manner.

We urge you to demand that USTR periodically make public the texts they are drafting.

#### **Conclusion**

In sum, Consumers Union, and consumer groups on both sides of the Atlantic, are deeply concerned that this agreement, focused on “regulatory convergence” and “mutual recognition,” will lead to an erosion of consumer protection in the vast areas it is addressing. We are also deeply concerned that an agreement on investor-state dispute resolution will potentially create a new court system that could end run the one we currently rely upon. These concerns are intensified by the secrecy in which the two sides intend to conduct this negotiation, which means that the public and Congress itself will have no opportunities to point out or address serious problems.

We urge Congress and the Administration to establish “harmonization upward” to the highest levels of consumer protection as an avowed goal of this negotiation, to abandon any effort to establish an investor-state dispute resolution mechanism, and to insist on, at the very least, publication of draft negotiating text at regular intervals, so we call all see what is going on.

Mr. TERRY. And, Mr. Muffett, you are now recognized for your 5 minutes.

#### STATEMENT OF CARROLL MUFFETT

Mr. MUFFETT. Thank you, Chairman Terry, Ranking Member Schakowsky, and members of the subcommittee, for the opportunity to appear before you today on a matter of profound importance for the people of the United States, Europe, and the world.

I am Carroll Muffett, president of the Center for International—

Mr. TERRY. Mr. Muffett, would you pull your microphone a little bit closer to you?

Mr. MUFFETT. I am Carroll Muffett, president of the Center for International Environmental Law, a nonprofit organization that uses the power of the law to protect the environment, promote human rights, and ensure that—ah, is that better?

Mr. TERRY. We will leave it to the IT guy.

Mr. GARFIELD. If you have a problem back there, I can help you.

Mr. TERRY. Thank you for being here, Mr. Garfield.

Mr. MUFFETT. For over 20 years, CIEL has worked with partners around the world to support a positive trade agenda, where increased market access does not undermine environmental protections or human rights.

I offer this testimony on behalf of CIEL, Friends of the Earth, and the Sierra Club. I have submitted a full statement for the record and would like to briefly summarize my testimony here.

The current system for regulation of chemicals in the United States is wholly inadequate to meet the challenge posed by the modern chemicals economy. The rate of cancer and other adverse effects continues to increase among Americans. The amounts of synthetic chemicals in our bodies have also increased and are among the highest in the world. Absent greater regulatory action, they will continue to increase.

This is an international public health problem that remains unsolved. Public health is one of the core responsibilities of a government to its citizens, and this responsibility is not being met with regard to chemicals.

The limited information on TTIP, particularly from the United States, makes assessments of its eventual impact inherently speculative. While TTIP could offer an opportunity to increase protections in the U.S. and the EU, experience with other trade agreements, industry submissions on TTIP, and the parties' express goal of reducing perceived regulatory barriers to trade make it far more likely that TTIP will hinder progress on chemical safety and potentially move us backward.

Of particular concern is the risk that TTIP will be used to weaken the stronger chemical standards that already exist in the EU and in some U.S. States, rather than to raise U.S. standards to achieve higher levels of protection.

To reduce this risk, TTIP must respect and protect the right of citizens in the United States and Europe, through their governments, to choose their own levels of environmental protection and to set the standards needed to achieve those levels.

TTIP must avoid measures likely to delay or dilute the creation of new rules for the protection of human health or the environment, including stronger chemicals laws. TTIP should not include provisions for mutual recognition for the chemical sector and other sensitive sectors that reduce domestic regulatory control in crucial public health and safety matters.

TTIP must not elevate the narrow interests of private corporations above the public good through provisions for investor-state dispute resolution. TTIP should not preempt or impede the rights of State and local governments or of governments outside the United States and EU to adopt new initiatives on toxic chemicals and other threats, including their rights to choose higher levels of protections for their citizens and to innovate new and better approaches to achieving that protection when the Federal Government is unwilling or unable to do so.

TTIP should not impede regulatory efforts to address emerging threats such as nanotechnologies, endocrine-disrupting chemicals, or hydraulic fracturing, which have profound implications for our health and our environment.

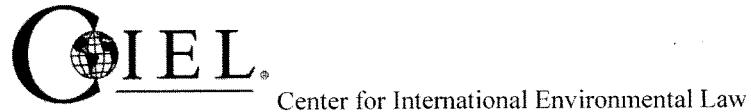
Finally, TTIP must be negotiated in an open, transparent, and participatory matter that safeguards the universal and fundamental public interest in the outcome of the negotiations. In recent years, the United States has conducted trade negotiations with a secrecy and a lack of transparency wholly inconsistent with basic principles of good governance in a constitutional democracy and inconsistent with the public's right to informed, meaningful participation in a public policy dialogue of profound national consequence on both sides of the Atlantic. Both parties should commit to broad public access to negotiating documents and positions to facilitate informed public debate regarding the negotiations and any resulting agreement.

To protect the environment, health, and safety of consumers, workers, and children around the world, what is needed is not free-trade agreements but better trade agreements—agreements that see public protection not as a competing goal but the highest goal and leverage the power of markets to serve the global good; agreements that enhance trade by strengthening and advancing environmental health and safety standards, rather than viewing them as irritants to be reduced and eliminated. We look forward to an open, transparent, and inclusive dialogue on whether and how such an agreement can be achieved.

Thank you again for the opportunity to testify.

Mr. TERRY. Thank you, Mr. Muffett.

[The prepared statement of Mr. Muffett follows:]



Center for International Environmental Law

STATEMENT OF  
CARROLL MUFFETT  
PRESIDENT AND CEO  
CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL)  
ON BEHALF OF CIEL, FRIENDS OF THE EARTH AND SIERRA CLUB

BEFORE  
THE U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUB-COMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

HEARING ON  
THE U.S. – E.U. FREE TRADE AGREEMENT: TIPPING OVER THE REGULATORY  
BARRIERS

JULY 24, 2013

1350 Connecticut Avenue N.W. Suite 1100 • Washington D.C. 20036-1739  
Phone: 202-785-8700 • Fax: 202-785-8701 • Email: [info@ciel.org](mailto:info@ciel.org) • Internet: <http://www.ciel.org>

15 rue des Savoises, 1205 Geneva, Switzerland  
Phone: 41-22-789-0500 • Fax: 41-22-789-0739 • Email: [geneva@ciel.org](mailto:geneva@ciel.org) • Internet: <http://www.ciel.org>

Thank you, Chairman Terry and Ranking Member Schakowsky for the opportunity to appear before this subcommittee today.

I am Carroll Muffett, President and CEO of the Center for International Environmental Law (CIEL), a nonprofit organization that uses the power of the law to protect the environment, promote human rights, and ensure a just and sustainable society. CIEL works closely with a broad range of stakeholders in the United States, Europe and around the world on a diverse range of issues in environmental law and policy, including climate change, toxic chemicals, natural resource conservation and extraction, international financial institutions, human rights, biodiversity and international trade. CIEL offers this testimony on its own behalf and on behalf of Friends of the Earth and the Sierra Club

#### **I. Summary of Key Messages**

I would like to begin by briefly summarizing the key messages of my testimony.

The current system for regulation of chemicals is wholly inadequate to meet the challenge posed by the modern chemicals economy. Cancer rates have increased. The amounts of chemicals in our bodies have increased. Absent greater regulatory action, they will continue to increase. This is a international public health problem that *remains unsolved*. Public health is one of the core responsibilities of a government to its citizens, and it is one that is currently not being adequately addressed with regard to chemicals. The scarcity of detailed information on TTIP, particularly from the United States, make any assessment of its eventual impact inherently speculative.

While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, experience with other trade agreements, together with the explicit intention of reducing regulatory barriers to

trade, make it far more likely that TTIP will hinder important public health and safety goals related to chemicals. To reduce this likelihood, TTIP:

- must ensure that both the EU and U.S. retain the right to determine their own levels of health protection from toxic chemicals, and develop measures to reduce exposure to hazardous chemicals as they see fit;
- should not include provisions for mutual recognition for the chemicals sector and other sensitive sectors;
- must not include provisions for investor-state dispute resolution;
- should not impede the rights of states and local governments, or of governments outside the United States and E.U., to adopt new initiatives on toxic chemicals and other environmental issues, including their right to choose higher levels of protection for their citizens;
- should not impede regulatory efforts to address emerging issues of concern, such as nanotechnologies, endocrine disrupting chemicals or hydraulic fracturing;
- must be negotiated in an open, transparent and participatory manner that safeguards the universal and fundamental public interest in the outcomes of the negotiations.

## **II. Introduction**

For over twenty years, CIEL has advocated for a positive trade agenda, where increased market access does not undermine environmental protections or human rights. Until 2011, CIEL served on the Trade and Environment Policy Advisory Committee (TEPAC), a Tier 2 Policy Advisory Committee. In addition, a senior attorney from CIEL served as the first public interest representative on a Tier 3 Technical Advisory Committee for the chemical and allied industries. CIEL has previously testified before the Committee on Ways and Means on trade matters and

has testified before this Subcommittee with regard to prioritizing chemicals for safety determination. In recent months, CIEL has published two major reports documenting the often positive relationship between stronger regulation and innovation in chemicals markets and identifying critical gaps in the global framework for chemical safety.

I have been invited to address the environmental implications of removing perceived regulatory barriers to trade between the United States and the European Union through the Transatlantic Trade and Investment Partnership (TTIP). My testimony will focus on the potential impact of the negotiations on regulations intended to protect people and the environment from toxic chemicals.

This testimony, and the conclusions and inferences drawn here, are necessarily preliminary in nature and, to some extent, speculative. This owes not only to the early stage of these negotiations, but to the consistent and regrettable practice of the United States government in limiting public access to information in all of its trade negotiations. In consequence, my conclusions here are drawn from the limited information that is publicly available, key pieces of which are months out of date or at high levels of generality. They draw heavily on materials released by the European Union on its own positions because comparable materials reflecting the initial positions of the United States have not been shared with the general public.

We have chosen the chemicals sector because of the significance of recent shifts in outdated chemical policies in the European Union (EU), and the potential benefits of implementing related laws in the EU on the health and environment of people around the world, including those in the U.S.

Both the UN Environment Program (UNEP) and Organisation for Economic Cooperation and Development (OECD) project that chemical production use and therefore disposal will continue to increase significantly over the next several decades. On both sides of the Atlantic, the public is concerned about the long-term effects of chemicals on health, including increasing incidence of asthma, autism, birth defects, infertility, Alzheimer's and Parkinson's diseases, and certain types of cancer. These problems are especially troubling in light of the growing evidence that industrial chemicals are increasingly present in our bodies and in the environment. In seventeen years, we have seen a 20 percent increase in the incidence of childhood cancer – an increase that cannot be explained by genetics or lifestyle choices.<sup>1</sup> Recent polls show over 70 percent of Americans, throughout the political spectrum support stronger rules for toxic chemicals.

Since the formation of the World Trade Organization (WTO) in 1995, U.S. and European officials have accelerated transatlantic efforts to develop and apply three significant trade promotion devices: harmonization, equivalence, and mutual recognition. Their goal has been to reduce what industry considers non-tariff (or technical) barriers to trade posed by regulatory requirements. The three trade promotion mechanisms are closely related but are not interchangeable. With respect to TTIP, chemical manufacturers, downstream users of chemicals and related trade associations call for the elimination of non-tariff barriers to trade through “enhanced regulatory coherence” or similar terminology.

As implied by the Final Report of the High Level Working Group on Jobs and Growth and explicitly recognized in the EU's position papers, the “[e]limination, reduction and prevention of

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<sup>1</sup> U.S. EPA, *America's Children and the Environment, Third Edition* (last accessed July 23, 2013), available at: [http://www.epa.gov/envirohealth/children/health/childhood\\_cancer.html](http://www.epa.gov/envirohealth/children/health/childhood_cancer.html) (citing data from National Cancer Institute, Surveillance, Epidemiology and End Results Program)

unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP.<sup>2</sup> Industry submissions reflect a similar expectation that TTIP will serve primarily as an opportunity reduce non-tariff barriers to trade. Provisions on harmonization, equivalence, mutual recognition and other provisions that may be included in TTIP could weaken standards for human health and the environment in both the EU and U.S., preempt state laws in the United States, restrain the continued development of REACH in the European Union, and influence the development of chemical laws outside the U.S. and EU, in particular the BRIICS countries (Brazil, Russia, India, Indonesia, China, South Africa). I will focus on five specific issues: (1) harmonization (2) mutual recognition; (3) investor state dispute settlement; (4) preemption of laws at the state-level in the United States and the national-level by EU member countries; and (5) influencing the development of laws outside the U.S. and EU .

### **III. Harmonization**

Harmonization takes two or more differing standards or procedures and converts them into a single, uniform standard. While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, the harmonization of regulatory standards to the “lowest-common denominator” has often been the result of recent U.S. trade agreements, decreasing the level of protection afforded to the public in favor of private interests.<sup>3</sup> Other agreements, such as the North American Free Trade Agreement (NAFTA), failed to harmonize standards between

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<sup>2</sup> *EU-US Transatlantic Trade and Investment Partnership: Trade Cross-cutting disciplines and Institutional provisions–Initial EU position paper*, EC (July 16, 2013) [hereinafter Trade Cross-cutting disciplines], available at [http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc\\_151622.pdf](http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151622.pdf).

<sup>3</sup> For example, although the U.S.-Korea Free Trade Agreement has provisions intended to prevent the two countries from easing environmental standards in order for firms on their territory to gain a competitive trade advantage, U.S. automakers will be considered in compliance with new South Korean fuel economy or greenhouse gas emissions standards if they meet a target level that is 19 % more lenient than the relevant target level provided in the regulation that would otherwise be applicable to that manufacturer, WILLIAM H. COOPER ET AL, CONG. RESEARCH SERV., RL34330, THE U.S.-SOUTH KOREA FREE TRADE AGREEMENT (KORUS FTA): PROVISIONS AND IMPLICATIONS (2013), available at <http://www.fas.org/sgp/crs/row/RL34330.pdf>.

Mexico, the U.S. and Canada, which has resulted in the transfer of dangerous and environmentally unsound industrial activity to Mexico.<sup>4</sup> This poses a serious threat to the environment, working families, and communities. It is therefore imperative not only that regulations are harmonized upward, but also that any convergence of regulations serves as a regulatory floor that allows governments the flexibility to develop more ambitious environmental and public interest policies in the future.

In the case of certain regulations in the EU and U.S., it is difficult to envision any degree of harmonization. Regulations for chemicals management offer one such example. EU and U.S. approaches diverge significantly, with the European Commission acknowledging in documents prepared for TTIP that "US requirements [for chemicals] are less strict" and that, in the view of the EU, "neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU."<sup>5</sup>

A fundamental difference between U.S. and EU approaches to chemicals management is how the safety of chemicals is assessed. For several decades, the EU had laws in place for industrial chemicals that were similar to the 1976 U.S. Toxic Substances Control Act (TSCA), employing a risk-based approach. However, since the adoption of REACH in 2006, the EU has taken hazard-based approach to industrial chemicals, a substantial but necessary step towards reducing the use of and exposure to hazardous chemicals.

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<sup>4</sup> For example, a disturbing trend involving the export of Spent Lead-Acid Batteries (SLABs) for recycling has developed over the last several years. While the U.S. battery recycling industry has increased safety standards and lowered emissions, developing countries, like Mexico, are not keeping pace. While the U.S. has strict regulations governing lead emissions and employee blood lead exposure, no similar comparable regulatory regime can be found in Mexico. The Blacksmith Institute estimates that more than 12 million people are adversely affected by lead contamination from improper processing of SLABs. Since NAFTA, an increasing number of SLABs are exported to Mexico from U.S. battery dealers and manufacturers. In 2012, 754 million pounds of used batteries were exported to Mexico, see SLAB WATCHDOG, <http://www.slabwatchdog.com/problem/slabs-2/> (last visited July 23, 2013).

<sup>5</sup> Note for the Attention of the Trade Policy Committee on the Transatlantic Trade and Investment Partnership, Annex 2--Initial Position Paper: Chemicals in TTIP, June 20, 2013, EC Trade Policy Committee (June 21, 2013) [hereinafter Chemicals in TTIP].

The EU's REACH Regulation for industrial chemicals is heralded as a necessary paradigm shift away from the dangerous presumption of safety that applied to over 60,000 chemicals in the United States and over 100,000 chemicals in the European Union in the 1970s – an assumption that has repeatedly been shown to be false. REACH clearly identifies hazardous properties that are not acceptable in society, generates information about these properties in chemicals produced over one ton per year, and encourages the substitution of hazardous chemicals with safer alternatives in a systematic way.

Under REACH, hazardous chemicals that are not acceptable include those that: are carcinogens, mutagens, or toxic to reproduction; exhibit a certain degree of persistence in the environment and the ability to accumulate in living organisms; or otherwise rise to an equivalent level of concern, such as endocrine or hormone disrupting chemicals. Categorized as substances of very high concern (SVHCs) under REACH, these chemicals are subject to certain requirements to protect people and the environment, and help downstream users of these chemicals transition to safer alternatives. According to the European Commission's mandated assessment of the impact of REACH on innovation, this hazard-based approach to listing of substances of very high concern in the candidate list is "*the driver for change at the present.*"<sup>6</sup> In other words, the hazard-based approach in REACH is driving innovation away from the status quo mix of hazardous chemicals on the market, and is not an impediment to innovation.

By contrast, the risk-based approach to chemicals management applied by the United States has not been significantly updated since TSCA was adopted more than 35 years ago, notwithstanding tremendous and fundamental changes in our understanding of chemical hazards over the ensuing

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<sup>6</sup> CENTRE FOR STRATEGY & EVALUATION SERVICES, FINAL REPORT, INTERIM EVALUATION: IMPACT OF THE REACH REGULATION ON THE INNOVATIVENESS OF THE EU CHEMICAL INDUSTRY xii (June 14, 2012) (emphasis added), [hereinafter REACH Innovation Report], available at [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf).

decades.<sup>7</sup> This risk-based approach requires projections for exposure level and other socio-economic considerations to be taken into account before chemicals are restricted. Although in theory this approach could enable a scientific approach to assessing the risk associated with a substance, the theory is not borne out in practice. It demands a complete risk assessment before any regulatory action is taken, requiring a reasonably complete set of data on hazard and exposure, as well as significant resources for its analysis from public authorities, rather than placing the burden of proving safety on the regulated industry. As one commentator observed, "The balancing of risks in the face of a very high hurdle of uncertainty under TSCA leaves EPA almost paralyzed to take action to regulate toxic substances."<sup>8</sup> Over 35 years of experience from the U.S. and around the world<sup>9</sup> has proven that this approach is unable to drive innovation away from hazardous chemicals and enable the entry of safer alternatives.

Most existing chemicals still lack toxicity data relevant to hazard assessment.<sup>10</sup> Regarding exposure, data also are lacking on production volume and use, which are critical for determining the potential for human and environmental exposure and for risk assessments and prioritization. Human bio-monitoring data exists for only a hundred or so of the tens of thousands of industrial chemicals and pesticides that are regularly used and released into the environment. Moreover,

<sup>7</sup> See, e.g., LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL34118, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 25 (2008) (noting that TSCA was adopted only four years after the first textbook on toxicology was published and observing that "TSCA reflects the concerns of the early days of toxicology, and the knowledge and methods of that first toxicology book."); *see id.* at 36 ("Even if one concludes that TSCA has performed successfully in the past, it may be reasonable to question the adequacy of a 1976 chemical law in the light of thirty years of scientific and technological advances."); Compare LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RS22673, CHEMICAL REGULATION IN THE EUROPEAN UNION: REGISTRATION, EVALUATION AND AUTHORIZATION OF CHEMICALS (2012).

<sup>8</sup> Robert B., Reform of the Toxic Substances Control Act: Achieving balance in the regulation of toxic substances, 6 ENVTL. LAW, 99, 119 (1999) (quoted in CRS Report RL34118, *supra* note 7).

<sup>9</sup> The EU abandoned this approach because it concluded that chemicals were not properly controlled; there was a general lack of knowledge about the properties and the uses of existing substances; and the risk assessment process was slow and resource-intensive, which did not allow the system to work efficiently and effectively, *see* THE ONLY PLANET GUIDE TO THE SECRETS OF CHEMICALS POLICY IN THE EU: REACH (2004).

<sup>10</sup> CRS Report RL34118, *supra* note 7, at 17.

with respect to new chemicals, roughly two-thirds of submissions for approval to manufacture the new chemical do not include test data on chemical properties, and almost 85% of submissions provide no data on health effects.

A fundamental problem with the risk-based approach is that it disregards that there will always be data gaps in the scientific part of the assessment and assumptions must be made. These assumptions, from the degree of exposure to the potential for a chemical to accumulate in living organisms, are often not accurate.

Nor would the proposed, but widely criticized, Chemical Safety Improvement Act close this gap between US and EU regulatory approaches in the absence of significant improvements. As the EU's initial position paper on Chemicals highlights, "the draft legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation."<sup>11</sup>

Recently, the European Union has emerged as a global leader in acknowledging and beginning to address urgent issues in chemicals management, such as endocrine disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. Endocrine or hormone disruption is an intrinsic hazard of certain chemicals, linked to a myriad of adverse effects that have been on the rise over the past several decades. As there is no safe level of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that need to be phased out globally. Nanomaterials have unique physical and chemical properties that make them distinct from traditional substances. They are increasingly used in a wide-range of products, but assessment methods are still not attuned to the properties of nanomaterials and precaution is warranted. Mixture toxicity recognizes that we are exposed to

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<sup>11</sup> Chemicals in TTIP, *supra* note 5.

hundreds of hazardous chemicals daily. Adverse effects have been observed by mixtures of chemicals at levels where the individual chemical is not expected to result in any adverse effects, i.e. the additive, synergistic or ‘cocktail’ effect of chemical mixtures.

Submissions by the chemical industry highlight these as “current regulatory issues with potential for significant impact on trade.”<sup>12</sup> Regulations for these issue areas are still in development and generally not yet in place. The European Commission notes that “where neither side has regulations in place, the making of common – or at any rate coherent – technical regulations may be considered by the Parties.” TTIP should seek to address market access issues and to facilitate the resolution of differences without prejudice to the right of the parties to adopt and enforce measures necessary to pursue legitimate public policy goals such as public health, safety and protection of the environment. Initial documents and position papers by the European Commission show varying emphasis to this important flexibility, with greater commitment in some subject areas (SPS and financial regulation) than in the case of technical or non-tariff barriers to trade.<sup>13</sup>

For the past 30 years the OECD has been working to harmonize chemical safety tools and policies across Asia, Europe and North America. Considerable steps and savings for governments and industry have been realized under this process, in which 30 OECD members and several developing countries are participating. Although experts have legitimate criticisms of OECD activities on chemicals, given the rapid expansion of the chemical industry outside the U.S. and EU, such as Asia and Latin America, harmonization discussions should take place in broader multilateral fora, not in the narrow confines of bi-lateral discussions.

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<sup>12</sup> AMERICAN CHEMISTRY COUNCIL, ACC SUBMISSION TO USTR, May 10 2013.

<sup>13</sup> Compare, e.g., EC position papers on SPS (strong language) and TBT (weak chapters of TTIP).

One of five regulatory components of TTIP is the creation of a framework for future regulatory cooperation, including an institutional basis. Position papers by the European Commission suggest the creation of sectoral regulatory cooperation working groups chaired by the competent regulatory authorities, which would in turn report to a regulatory cooperation council or committee. The proposals outline substantial bi-lateral consultation provisions.<sup>14</sup> In addition, position papers also point to the increased use of voluntary instruments to achieve regulatory objectives.<sup>15</sup> Together, these elements have the significant potential to delay or dilute the creation of adequate rules to protect human health or the environment.

Given both the substantial differences in approaches between the EU and U.S. and experience with efforts to reform TSCA in the United States, the likelihood of harmonization, ‘scientific cooperation,’ or ‘regulatory coherence,’ resulting in a “highest-common denominator” outcome to chemicals management is very unlikely. EU trade negotiators state that they have no intention of lowering EU standards for protecting people and the environment from chemicals under TTIP, and rightfully so. The U.S. should use TTIP as an opportunity to better protect Americans from toxic chemicals, not private interests from the cost of regulations designed to protect people and the environment. At the very least, TTIP should ensure that both the EU and U.S. retain the right to determine their own levels of health protection from toxic chemicals, and develop measures to reduce exposure to hazardous chemicals as they see fit.

#### **IV. Mutual Recognition**

A second trade promoting measure is mutual recognition. The EU and the United States have been developing mutual recognition as a trade policy tool over the course of the last decade as

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<sup>14</sup> *Trade Cross-cutting disciplines*, *supra* note 2.

<sup>15</sup> EU-US Transatlantic Trade and Investment Partnership: Technical Barriers to Trade, EC (July 2013) [hereinafter TBT position paper], available at [http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc\\_151627.pdf](http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf).

part of their international trade liberalization efforts. Mutual recognition is an agreement between countries to recognize and accept the results of assessments performed by assessment bodies of countries that are parties to the agreement. While the purported objective of mutual recognition measures is to reduce perceived regulatory barriers to trade, they also have considerable potential to reduce existing levels of national health, safety, and environmental protection.

Supporters of mutual recognition provisions expect them to result in reduced costs and increased market access for industry, as well as freeing up scarce regulatory resources. Consumers are supposed to see these cost savings passed on to them in addition to seeing a wider variety of safer goods appearing earlier in the marketplace. However, it remains to be seen whether these benefits actually do accrue to consumers.

The potential drawbacks of mutual recognition provisions include the following: (1) the transfer of regulatory authority and duties from national regulatory agencies to foreign entities who may operate under different conflict of interest standards and rules of transparency and liability; (2) the privatization of public functions; (3) a loss of domestic regulatory control in crucial public health and safety matters; (4) reduced levels of public participation in regulatory decision making; (5) increased opportunities for regulatory evasion by industry; and (6) reductions in the levels of health, safety, and environmental protection.<sup>16</sup>

The European Commission notes that the “1998 Mutual Recognition Agreement has been successful only in two [of six] areas: telecommunications, and electromagnetic compatibility.”<sup>17</sup>

The European Commission states that it is not proposed to consider extending the 1998 Mutual

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<sup>16</sup> TRANS ATLANTIC CONSUMER DIALOGUE, TACD BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (March 2001), available at [http://tacd.org/index2.php?option=com\\_docman&task=doc\\_view&gid=102&Itemid=](http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=).

<sup>17</sup> TBT Position Paper, *supra* note 15.

Recognition Agreement “in its present form” to new areas, which does not entirely foreclose the possibility of extending it to other areas.<sup>18</sup>

The potential dangers of mutual recognition provisions are well illustrated by their possible application to the chemical regulation. Laws are developing and being implemented in the EU to minimize the use of hazardous substances and encourage their safe substitution. The 2001 ‘White Paper’ by the European Commission estimated that around 1,400 Substances of Very High Concern will be banned in Europe unless an authorisation of a specific use is granted when REACH was implemented. Although slower than expected, progress towards this ambitious but necessary goal is being made. Today, 144 substances are categorized as being eligible for the Authorization procedure and listed under the Candidate List. 22 substances are already scheduled to be phased-out except for certain authorized uses, as early as August of 2014. In addition, another 24 substances are undergoing or are proposed to be subject to REACH’s Restrictions process, including the use of bisphenol A or BPA in receipts and other uses of thermal paper.

By contrast, TSCA has only regulated the use of only *six* existing industrial chemicals under TSCA since 1976, from a universe of over 60,000 existing chemicals. U.S. EPA has been unable to use its authority under TSCA to restrict the use of certain chemicals, including numerous chemicals that 179 countries have agreed to phase-out under a global treaty that restricts the use of some of the world’s most dangerous industrial chemicals and pesticides.

The regulation of chemicals in cosmetics offers another illuminating example of how little overlap there is between chemicals restricted from certain uses in the EU versus the U.S. The

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<sup>18</sup> *Id.*

EU Cosmetics Directive (76/768/EEC) was revised in January 2003 to ban 1,328 chemicals from cosmetics; the U.S. FDA has banned or restricted only eleven.<sup>19</sup> More recent improvements in the EU include the explicit authorization of colorants, preservatives and UV-filters, including those that are nanomaterials. In addition to giving the Commission the power to require a full safety assessment of nanomaterials used in cosmetics when there is a reason for concern, nanomaterials must be specifically identified in the list of ingredients in cosmetics with the word 'nano' in brackets following the name of the substance.

Some have commented that thirteen chemicals overlap between the EU's candidate list and the U.S. EPA's work plan on existing chemicals and implied that this points to the possibility of convergence around prioritization of hazardous chemicals for regulatory action. It is important to bear in mind, however, that these thirteen substances are drawn from a much larger list of 144 Substances of Very High Concern listed today on the candidate list and 83 chemicals included in EPA's workplan, and possibly over 1,400 in the coming years.<sup>20</sup> In reality, however, EPA's work plans have not produced legally-binding obligations on any chemical included, and thus the number of chemicals that overlap would be far fewer. The chemical industry is lobbying to weaken the candidate list to "better accommodate business needs."<sup>21</sup>

Mutual recognition in the chemical sector and other sensitive sectors involving public health, safety or the environment is wholly inappropriate. For chemicals, mutual recognition provisions would essentially erase the measures for chemicals that are restricted in only one jurisdiction. Procter and Gamble states that mutual recognition would "allow[] for the

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<sup>19</sup> Campaign for Safe Cosmetics, *European Laws*, CAMPAIGN FOR SAFE COSMETICS, <http://safercosmetics.org/article.php?id=346%20&E> (last visited July 21, 2013),

<sup>20</sup> TSCA Work Plan Chemicals, EPA, <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html> (last visited July 23, 2013).

<sup>21</sup> BUSINESS EUROPE, EU LEGISLATIVE BURDENS ON SMEs (Dec. 20, 2012), available at <http://www.businesseurope.eu/content/default.asp?PageID=568&DocID=31123>.

production, sale and use of chemicals that are lawful in one continent to also be lawful in the other.”<sup>22</sup>

Many chemicals are or will be subject to be significant restrictions in the European Union, but are not subject to similar legally binding measures in the United States. These include: certain phthalates, for uses beyond toys and children’s products such as plastics, medical devices and cosmetics, which are linked to reproductive disorders, including genital malformations and decreased sperm levels; hexabromocyclododecane (HBCD), which 179 countries have agreed to phase-out under the Stockholm Convention on Persistent Organic Pollutants, because of its ability diffuse around the world, accumulate in living organisms and evidence of serious adverse effects in animals; and 1,4 dioxane, classified by some entities as a known carcinogen, and prohibited in personal care products. These and other future protective measures are at risk of delay or even elimination with mutual recognition.

Such provisions would require the EU and U.S. to both decide that a chemical warrants restriction in order to protect people in one or both jurisdictions. The continued population of the Candidate List could be delayed, to the benefit of chemical manufacturers with a vested interest retaining the status quo mix of chemicals on the market. The EU has expressed its intention to identify and assess no less than 500 substances of very high concern for substitution by 2020.<sup>23</sup> Such provisions could subject European citizens to the inability of U.S. regulators to take meaningful steps towards chemical safety under a deeply flawed TSCA. Nor are the risks and complexities of mutual recognition limited to the chemicals sector. Rather, mutual recognition measures

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<sup>22</sup> Procter and Gamble, submission to European Commission

<sup>23</sup> Under the EU’s “roadmap,” the EU has signaled its intention, by 2020, to assess and include as a Substance of Very High Concern, all substances known to be carcinogenic, mutagenic, or toxic to reproduction, as well as those that are “persistent, bio-accumulative and toxic” (PBTs), endocrine (hormone) disrupting compounds (EDCs), and sensitizers.

threaten to impair effective regulation across a broad range of sensitive sectors, from chemicals to pharmaceuticals to cars. For example, the EU's initial position paper on Motor Vehicles in TTIP explicitly proposes that:

"[I]n order to facilitate trade and the recognition of the substantial technical requirements, EU type-approval authorities would be required to test US vehicles destined for the EU market against US regulations using US testing methods, while US bodies would, in their market surveillance activities, test EU vehicles against EU/UNECE regulations and their testing methods."<sup>24</sup>

This would effectively require vehicle testing authorities in each party to maintain and operate two parallel systems for vehicle testing, depending upon the origin of the vehicle.

Mutual recognition provisions are only ever appropriate if they: (1) enhance the well-being of consumers; (2) are not applied in sensitive sectors involving public health, safety, or the environment; (3) are negotiated in open and accountable fora; and (4) are negotiated between countries having equally strong consumer safeguards, including mechanisms for public participation in domestic regulatory decision making and corporate liability structures.<sup>25</sup> These necessary elements are not met in the chemicals sector. Therefore, mutual recognition provisions should not be included for the chemicals sector and other sensitive sectors.

#### **V. Investor-State Dispute Settlement**

Investor-state dispute settlement would allow foreign corporations to bypass domestic courts and sue governments in private tribunals over laws and policies that the corporations allege reduce

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<sup>24</sup> NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE ON THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP, ANNEX I--INITIAL POSITION PAPER: MOTOR VEHICLES IN TTIP, EC TRADE POLICY COMMITTEE (June 21, 2013).

<sup>25</sup> TACD BRIEFING PAPER, *supra* note 17.

their expected future profits. The inclusion of such extreme provisions in prior trade and investment deals has enabled powerful interests, from tobacco companies to corporate polluters, to use investor-state dispute resolution to challenge and undermine consumer, public health and environmental protections. Investor-state tribunals have ordered taxpayers to compensate foreign corporations for the domestic, non-discriminatory enforcement of such protections.

Investment provisions in existing free trade agreements, including the North American Free Trade Agreement (NAFTA), have facilitated a proliferation of legal challenges to bans on toxic chemicals, mining regulations, energy regulations, and more.<sup>26</sup> These rules have been replicated in various U.S. free trade agreements (FTAs), including the Central American, Peru and Oman FTAs, and the recently passed deals with Korea, Panama and Colombia. The inclusion of very broad investor protections, such as a guarantee of “fair and equitable treatment,” could open the door to investment cases when governments put in place new or amend existing laws and policies designed to protect the public interest.

Over US \$365 million in compensation has already been paid out to foreign investors in a series of investor-state cases under NAFTA-style deals.<sup>27</sup> This includes attacks on health and safety measures, natural resource policies, environmental protection, and more. Of the over US \$13.1 billion in the 16 pending claims under NAFTA-style deals, all relate to public health, environmental, energy, land use and transportation policies – not traditional trade issues.<sup>28</sup>

Cases in recent years have demonstrated that companies are both willing and able to locate or relocate their foreign operations for the express purpose of choosing the most investor-friendly

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<sup>26</sup> *Table of foreign investor-state cases and claims under NAFTA and other U.S. trade deals: March 2013*, PUBLIC CITIZEN, <http://www.citizen.org/documents/investor-state-chart1.pdf> (last visited Apr.11, 2013).

<sup>27</sup> *Investor-State Attacks on the Public Interest*, PUBLIC CITIZEN, <http://www.citizen.org/Page.aspx?pid=5329> (last visited July 23, 2013).

<sup>28</sup> *Id.*

forum for potential trade disputes, regardless of whether they have a legitimate business nexus with the countries involved. More troublingly, tribunals in investor state disputes have proven willing to accept such "treaty shopping" as legitimate, provided it takes place before the formal initiation of a dispute. For example, in a case brought under the U.S.-Central American Free Trade Agreement (CAFTA), a Canadian mining corporation, operating in El Salvador through a subsidiary registered in the Cayman islands, sought recourse to U.S. investor protections under CAFTA by the simple expedient of deregistering its Cayman Islands subsidiary and re-registering the enterprise in Reno, Nevada. While the company's CAFTA claim was ultimately rejected on the ground that the company had abused the process by relocating to a CAFTA country during an active dispute, the panel opined that the issue was primarily one of timing: had the company registered in a CAFTA country prior to the onset of the dispute, even for the express purpose of getting recourse to the investor protections, it might have been accorded those protections under the agreement.<sup>29</sup> Not surprisingly, law firms and consulting firms have developed a thriving industry in advising corporations how to restructure to take strategic advantage of such "treaty shopping" opportunities.<sup>30</sup>

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<sup>29</sup> *Pacific Rim Cayman, LLC. v. Republic of El Salvador*, ICSID Case No. ARB/09/12, Decision on the Respondent's Jurisdictional Objections, June 1, 2012. § 2.41.-2.52 See also *Mobil Corporation and others v. Bolivarian Republic of Venezuela*, ICSID Case No. ARB/07/27, Decision on Jurisdiction, 10 June 2010, § 204 ("As stated by the Claimants, the aim of the restructuring of their investments in Venezuela through a Dutch holding was to protect those investments against breaches of their rights by the Venezuelan authorities by gaining access to ICSID arbitration through the BIT. The Tribunal considers that this was a perfectly legitimate goal as far as it concerned future disputes.").

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*See, e.g.*, Calvin Chan, *Structuring Oil and Gas Investments to Take Advantage of Substantive Rights under Investment Treaties*, Skadden, Arps, Slate, Meagher & Flom (October 27, 2011), available at [http://www.oilandgasasiapacific.com/\\_assets/\\_slides/Calvin%20Chan%20Oil%20and%20Gas%20Investments.pdf](http://www.oilandgasasiapacific.com/_assets/_slides/Calvin%20Chan%20Oil%20and%20Gas%20Investments.pdf); Baker & McKenzie, *Opportunities in Structuring and Re-structuring Investments and Business Relationships*. Presentation at Latin America 2010: Proactive Strategies for Doing Business in Today's Changing Landscape. (Miami, March 17, 2010), available at [http://www.bakermckenzie.com/files/Uploads/Documents/\\_Locations/Latin%20America/pn\\_latax2010\\_01\\_opportunitiesstructuringinvestmentsbusinessrelationships\\_mar10.pdf](http://www.bakermckenzie.com/files/Uploads/Documents/_Locations/Latin%20America/pn_latax2010_01_opportunitiesstructuringinvestmentsbusinessrelationships_mar10.pdf).

The risk of such treaty shopping is compounded by the growing number of companies and individuals claiming, and receiving, investor protections on grounds that bear little resemblance to direct investment in a country. In a case still pending under NAFTA, for example, Mexican truck drivers have argued that they are entitled to investor protections under NAFTA's Chapter 11 because certification fees they pay to the Federal Highway Traffic Safety Administration qualify them as investors.<sup>31</sup>

To date, the United States has entered into more than fifty agreements according some form of investor protection. The EU member countries have concluded more than 1,200 such agreements. Notwithstanding the demonstrated risks of specious litigation, treaty shopping and attenuated and costly claims of investor protection under these existing agreements, both parties have declared an objective to go beyond any previous agreement to afford even greater levels of investor protection under TTIP. The extensive and troubling record of abuse under the existing system should raise grave concerns regarding that objective.

After Philip Morris' challenge to measures designed to protect citizens' health, Australia decided to discontinue investor-state dispute settlement mechanisms. The government's official position states: "Nor will the Government support provisions that would constrain the ability of Australian governments to make laws on social, environmental and economic matters in circumstances where those laws do not discriminate between domestic and foreign businesses."<sup>32</sup>

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CANACAR v United States of America - Notice of Arbitration - NAFTA - 02 April 2009.

<sup>32</sup> AUSTRALIAN GOVERNMENT, DEPT. OF FOREIGN AFFAIRS AND TRADE, GOVERNMENT TRADE POLICY STATEMENT (April 2011), available at <http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html#investor-state>.

A potential agreement between the United States and EU must not include investor-state dispute resolution. If concluded, TTIP could be enforced through ordinary courts of the U.S. and EU. Because U.S. and EU property rights laws and courts are robust, there is no pretext for granting foreign investors superior rights to domestic firms or subjecting our judicial systems to tribunals empowered to put the American public in a lose-lose situation. The inclusion of such provisions would have a chilling effect on the future development of regulations for public health, safety and the environment in the EU and U.S.

To avoid such overreaching procedural and substantive investor privileges, greater than those afforded to domestic firms in either the United States or the EU, any deal must exclude investor-state dispute resolution.<sup>33</sup>

#### **VI. Preemption**

Closely related to the question of harmonization and mutual recognition is the divergence of approaches to health, safety and environmental protection at various levels of governance at the sub-national or sub-regional level in the U.S. and EU respectively.

In the United States, over 30 states have enacted different measures to protect people and the environment from toxic industrial chemicals, due to the inability of the U.S. federal system to fill this role. California, Maine and Washington State are a few of States that have emerged as leaders in enacting measures to reduce exposure to toxic chemicals in products, food, water and the environment. Several submissions received in response to the various public consultations on the TTIP report on EU exporters' difficulties with accessing and understanding the rules they

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<sup>33</sup> Letter to President Barack Obama, President José Manuel Barroso, and President Herman Van Rompuy from consumer and public interest organizations in the U.S. and EU, dated July 8, 2013, available at: <http://www.citizen.org/documents/public-citizen-letter-to-obama-alerting-to-tafta-concerns.pdf>

have to comply with to gain access to the US market, in particular where multiple layers of regulation.<sup>34</sup>

According to initial position papers, the “EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered.”<sup>35</sup> This expectation is set forth clearly and repeatedly as a central EU objective for the negotiated outcomes under TTIP. EU documents set forth a further position that the EU should be notified and consulted on any significant regulations at the sub-federal level that may affect trade, and that any such regulations should be held to a standard that avoids unnecessary interference with transatlantic trade. A range of state-level initiatives on toxic chemicals and other environmental issues could be preempted by various provisions of TTIP, which could also have a chilling effect on their future development. Indeed, a significant factor in this chilling effect could arise simply from the extensive and costly additional burdens such consulting obligations would impose on policymakers and regulatory authorities at the state and local level. In addition, provisions such as investor state dispute resolution could preempt sub-federal or sub-regional laws that are more protective of health, safety and the environment.

Regarding divergent approaches in the EU, the US Trade Representative and industry has complained about Member States interpreting provisions of REACH in ways that would lead to improved consumer protection. Efforts are also ongoing in EU Member States to take precautionary approaches to health, safety and environmental protection, for example in the creation of registers for manufactured nanomaterials and moratoria on the use of hydraulic

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<sup>34</sup> TBT POSITION PAPER, *supra* note 15.  
<sup>35</sup> *Id.*

fracturing for shale gas extraction or ‘fracking.’ For example, a French initiative is in force for a mandatory register for nanomaterials that covers the entire supply chain is being imitated and expanded by the Danish, Belgian and Italian governments. In terms of moratoria on fracking, France, Germany, Spain, Bulgaria, Romania, and the Czech Republic, have placed moratoria on the use of this technology as a precautionary measure. These and similar efforts taking place at the state level here in the U.S. or at national level in the EU are at risk of being preempted by possible provisions of TTIP.

Of considerable concern in ongoing efforts to fix TSCA here in the U.S. is the inclusion of state preemption provisions in the Chemical Safety Improvement Act (S. 1009), the latest Senate proposal for reform, recently introduced by Senator Vitter and the late Senator Lautenberg. Likewise, provisions for investor state dispute settlement and other trade promotion measures, such as harmonization and mutual recognition, can also result in the preemption of laws for public health, environmental protection and safety at the state level in the U.S. and national level in the EU.

#### **VII. Influencing the development of laws outside the U.S. and EU**

Beyond its potential chilling effect on future regulatory advances in the United States and the EU, , a US.-EU trade agreement could have chilling effects on the development of regulations far outside these two economic superpowers, shaping and potentially slowing progress on environmental, health and safety standards in Eastern Europe, Asia and beyond.

The chemical industry has not hidden its displeasure with REACH from government officials in the U.S. or EU, and continues to complain about its costs, burdens and complexity. During the

Bush Administration, a U.S. Commerce Department paper recorded that “[i]ndustry . . . would like the [U.S. Government] to work to educate [other countries] so that they can join the United States in raising concerns.”<sup>36</sup> In March 2002, Secretary of State Colin Powell sent a cable directing U.S. diplomatic posts to “raise the EU chemicals policy with relevant government officials” and to object to the REACH proposal as “a costly, burdensome, and complex regulatory system.”<sup>37</sup>

In addition to contesting REACH in the EU, the U.S. government and industry has been working to prevent the expansion of REACH-like policies outside the EU, especially where countries propose to go beyond what REACH currently requires. Despite these efforts, elements of the EU’s REACH legislation continue to be adopted by countries outside the EU. These countries include countries with significant levels of chemical manufacturing and chemical use, such as China, Japan, Australia, Korea, Turkey, Taiwan, Vietnam, and Malaysia. In addition, India and Indonesia are each drafting national legislation that includes elements of REACH. It is worth noting that over the next two decades, worldwide chemical production is projected to double from 2010 to 2030, with 71 percent of this new production expected outside the OECD, especially among the so-called BRIICS countries.<sup>38</sup> Many of these countries are among those drafting and adopting chemical legislation similar to REACH.

But, in the case of Korea’s version of REACH, K-REACH, while intensive lobbying efforts did not prevent the adoption of a REACH-like system, they did result changes to the legislation that

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<sup>36</sup> *The Chemical Industry, The Bush Administration, and European Efforts to Regulate Chemicals*, House Committee on Government Reform, report prepared for Rep. Henry Waxman (2004), available at: <http://oversight-archive.waxman.house.gov/story.asp?ID=427>

<sup>37</sup> *Id.*

<sup>38</sup> ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, OECD ENVIRONMENTAL OUTLOOK TO 2050: THE CONSEQUENCES OF INACTION (2012).

would otherwise have afforded greater protection than REACH itself. Provisions of the U.S.-Korea FTA were used to seek revisions to the proposed Korean law, such as an increase in the *de minimis* production volume exclusion from 0.5 tonnes to 1.0 tonnes, a potential impediment to accessing information about speciality chemicals, such as manufactured nanomaterials, that may be manufactured in commercially significant volumes while still falling below these tonnage requirements.

Regardless of the adoption and ongoing implementation of REACH in the EU, the chemical industry is viewing TTIP as an opportunity to establish a global standard for chemicals regulation at the national or regional level by decreasing regulatory divergence between two of the three major chemical countries or regions of the chemical industry. Procter and Gamble states that “[a]n ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries’ regulatory systems, in particular of BRICs countries.”<sup>39</sup> To the extent that TTIP results in stronger levels of protection in the U.S. for human health, safety and the environment, and does not delay the implementation of REACH, this could be a positive development. Anything less, however, would have a chilling effect on the development of chemical regulations outside the EU that impose measures more stringent than the EU or U.S.

### **VIII. Conclusion**

To conclude, we would first like to offer some comments on the process moving forward. Since NAFTA, the United States has conducted its trade negotiations with other countries and regions in a manner that does not satisfy the requirements of transparency in a constitutional

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<sup>39</sup> Proctor & Gamble submission to COM.

democracy, despite the profound implications of these negotiations for public health, well-being and the environment. To date, negotiations between the United States and the EU have followed a similar path. Although the EU's public disclosure of its initial negotiation positions has been a small but positive step in the right direction, the EU's recent release of a letter describing its confidentiality practices for the negotiations raises serious questions as to whether even the current, limited levels of transparency will continue as the negotiations progress.

The secrecy and opacity observed in other trade negotiations, including the negotiations for the Trans Pacific Partnership, are inconsistent with basic principles of good governance and with the public's right to informed, meaningful participation in what amounts to a public policy dialogue of profound national consequence on both sides of the Atlantic. Negotiations between the United States and the EU should demonstrate a clear commitment to public participation and should be conducted in an open, transparent and participatory manner. Specifically, the United States and the EU should commit to broad public access to negotiating documents and positions, to facilitate informed public debate regarding the negotiations and any resulting agreement.

In their communications with the public, both the United States and the E.U. have communicated an interest in defining a “positive” trade agenda—one in which increased trade mutually supports environmental protection and social development, and does not come at the expense of environment or labor rights. The EU outlines a number of goals that might be achieved in such an agenda, and explicitly acknowledges as a fundamental element of sustainability the need to recognize “each party’s right to define and regulate its own domestic levels of environmental and labor protection at the level deemed necessary.”<sup>40</sup> Language on effective domestic

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<sup>40</sup> *Trade and Sustainable Development: initial EU position paper*, EC (2013), available at [http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc\\_151626.pdf](http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151626.pdf).

implementation of internationally agreed environmental principles, suggests a view that convergence must result in a regulatory floor that bolsters consumer interests, not a regulatory ceiling that constrains them. Disincentives for trade in illegal products, and incentives for those that are truly sustainable, also show promise for building a positive trade agenda.

However, other provisions point to a high-level of emphasis on evaluating the potential impacts of environmental and labor provisions on trade. End of the day cost-saving to consumers from trade agreements that lower consumer and worker safeguards are modest at best, while the cost of inaction on health, safety, labor and environmental concerns borne by the public-at-large are staggering at present, and grow with each passing day.<sup>41</sup> Even using consistently over-estimated costs of regulation and benefits of deregulation or harmonization,<sup>42</sup> these estimates do not come anywhere close to the cost of inaction on public health, safety, labor and environmental issues that are at risk from a trade agreement that puts trade ahead of the public interest.

Thank you, again, for the opportunity to testify on this critical issue. CIEL and our partners look forward to working with US lawmakers and officials in an open, transparent and participatory manner, as they explore whether an agreement is possible that increases trade while being mutually supportive environmental protection and social development, and does not come at the expense of environment or labor rights.

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<sup>41</sup> See e.g. Public Citizen, *TAFTA's Trade Benefit: a Candy Bar in Eyes on Trade* (blog) (July 11, 2013), available at <http://citizen.typepad.com/eyesontrade/2013/07/taftas-trade-benefit-a-candy-bar.html> (quoting a study that finds that "the trade-related benefits we should expect from TAFTA amount to...an extra three cents per person per day...starting in 2029"). Compare to, UN Environment Program, Cost of Inaction (2012) (costs of certain hazardous chemicals with data estimated at hundreds of millions to tens of billions of dollars annually to people and governments); and Nicholas Stern, *Stern Review on the Economics of Climate Change* (2006) (calculating that the level of inaction in 2006 on climate change will be equivalent to losing at least 5% of global gross domestic product (GDP) each year, now and forever. When including a wider range of risks and impacts, GDP losses could increase to 20% or more, also indefinitely).

<sup>42</sup> See e.g. The International Chemical Secretariat, *Cry Wolf: Predicted Costs by Industry in the Face of New Regulations* (2004), available at [http://www.chemsec.org/images/stories/news\\_publications/Cry\\_wolf\\_report\\_040422.pdf](http://www.chemsec.org/images/stories/news_publications/Cry_wolf_report_040422.pdf)

Mr. TERRY. Now, at this time, we will all ask the questions. So my first question—I recognize myself for 5 minutes of questions.

Mr. Blunt, Mr. Castellani, Dooley, and Garfield, I will ask you this question. You set out your goals for each one of your industries. Now, it seems like the easiest approach here would simply be, who has the most restrictive, and we will harmonize to that level. Is that an appropriate strategy for the USTR?

Mr. Blunt, you can start.

Mr. BLUNT. We would argue that, since both economies have very sophisticated regulatory regimes today with very similar environmental and safety outcomes, that the real goal should be mutual recognition of vehicles built to either economy's standards, so that vehicles built to the EU standard would be acceptable for sale in the U.S. and vice versa.

Mr. TERRY. So you would disagree with just harmonize to the most restrictive standards?

Mr. BLUNT. We think you should look at the results of the standards that exist today and that the results would demonstrate that you have very high levels of environmental and safety performance in both economies and that you should just recognize that you are achieving the same thing through the two regulatory processes.

Mr. TERRY. All right.

Mr. Castellani?

Mr. CASTELLANI. Mr. Chairman, in our industry, as you know, both the EU and the U.S. have very strict and very important regulatory regimes. What we are suggesting in this agreement is we take the best of the both but give the opportunity, from the patient perspective, to have harmonization that makes it more efficient for, for example, our FDA and the EMA.

In our industry, we have very high standards on both sides of the Atlantic, obviously, for our manufacturing practices and for our clinical trial practices. We think if we could harmonize to that high standard, we could free up FDA resources and EMA resources to focus on countries that present more of a risk and manufacturing practices that present more of a risk for patients.

So it is not a simple "yes" or "no." It is taking the best, from a patient perspective, and applying it equally on both sides of the Atlantic.

Mr. TERRY. OK.

Mr. Dooley? And you may want to add some context for Mr. Muffett's comment.

Mr. DOOLEY. Yes, I would say that, no, we have no interest in a harmonization to the most restrictive standard.

And, you know, our companies, whether they are manufacturing and introducing chemicals and products in the United States or the EU or anyplace in the world, their first commitment is that they are safe for their intended use.

But I would also just give a couple examples. You know, you can look at what we would assess as a non-science-based approach in the EU to the evaluation of the safety of GMO products in agriculture. It is not just an accident that BASF and Syngenta, both European-based companies, have moved all of their bio-ag research and development to North Carolina, and it is a direct response to the regulatory impact.

On the issue of REACH, BASF, one of the largest chemical companies in the world, are now assessing that the regulatory costs to their company to comply with REACH is going to amount to about \$650 million or \$700 million. You know, we don't think that that is contributing to safer outcomes and safer products, because they are marketing the same products in the EU as they are in the U.S. But they are facing an additional cost of operation, which is siphoning dollars away from innovation.

What we are suggesting, though, that a lot of that research and assessment and data that is being developed by BASF, what they are spending some of that \$650 million on, is that there are opportunities for the sharing of that data between the U.S. and the EU that can achieve greater efficiencies for industry as well as for government.

Mr. TERRY. Mr. Garfield?

Mr. GARFIELD. The answer is also "no" for us, but nor are we advocating for the adoption of the least restrictive either. I think that dichotomy is a false one.

What we are encouraging is that we use greater, more objective standards that are science-based and, as well, that we look at the impact and also avoid redundancy. So oftentimes we, in fact, do have very similar standards, where you couldn't point to any great distinction, but we have redundancies anyway.

Mr. TERRY. All right. Very good.

I will yield back my 15 seconds and recognize the gentlelady from Illinois, Jan Schakowsky.

Ms. SCHAKOWSKY. Thank you very much, Mr. Chairman.

Mr. Castellani, in your testimony, you talked about, quote, "issues of considerable concern to the industry," unquote, and among them you mentioned, quote, "shortsighted cost-containment measures," talking about the European environment.

And, to me, it is a little ironic. You also said something about "too often implemented without predictable, transparent, and consultative processes," which we are talking about, too, as a shortcoming, I think, of these trade negotiations, that it is not very transparent.

But I wanted you to tell me, yes or no, is PhRMA opposed to the following cost-containment measures:

One, Medicaid drug rebates, the current Medicaid drug rebates. Yes or no?

Mr. CASTELLANI. We are opposed.

Ms. SCHAKOWSKY. You are opposed.

The 340B program, which would allow reduced costs for certain safety net providers?

Mr. CASTELLANI. We favor the 340B program.

Ms. SCHAKOWSKY. Favor.

A ban on pay-for-delay that would prohibit drug companies from paying to keep generics off the market?

Mr. CASTELLANI. We oppose that.

Ms. SCHAKOWSKY. State law limits on pharmaceutical company payments to doctors?

Mr. CASTELLANI. We oppose that.

Ms. SCHAKOWSKY. Medicare negotiation for prescription drugs?

Mr. CASTELLANI. We already have Medicare negotiations.

Ms. SCHAKOWSKY. OK, but allowing Medicare to fully negotiate, as the VA does, for lower drug prices?

Mr. CASTELLANI. Oh, the negotiations that occur now occur through the insurance companies that provide the drug benefit.

Ms. SCHAKOWSKY. Right. But Medicare, itself, negotiating?

Mr. CASTELLANI. No. We think the current system works fine.

Ms. SCHAKOWSKY. VA negotiations currently?

Mr. CASTELLANI. The current system is fine.

Ms. SCHAKOWSKY. Negotiating authority for Federal Employees Health Benefits Program?

Mr. CASTELLANI. Well, again, the insurers do have that authority.

Ms. SCHAKOWSKY. OK. And you wouldn't oppose that or want to change that in any way?

Mr. CASTELLANI. That is how prices are determined by insurance companies.

Ms. SCHAKOWSKY. OK. And formularies?

Mr. CASTELLANI. That is how formularies are determined by insurance companies.

Ms. SCHAKOWSKY. OK.

The elimination of existing cost-containment measures and the restriction on possible future ones that we see could be coming up increases cost to States, taxpayers, and consumers. And, at the very least, I think all of these cost-containment changes that could possibly be in this agreement should be discussed publicly rather than just behind closed doors.

Turning to another issue, auto safety. And, Ms. Halloran, I wanted to ask you and Governor Blunt if you wanted to comment.

In meetings regarding this hearing, companies pointed to the auto industry as one space where they believe there can be substantial progress made toward their goal of regulatory harmonization.

So, in your testimony, you mentioned child occupant protection standards. I have long supported efforts to strengthen U.S. requirements for car seats and boosters. It is only recently that the U.S. has added a child-sized crash dummy to its testing, which is the size of the typical 10-year-old, as well as a standard crash test for rear occupants.

Can you describe the difference between the U.S. and EU standard for car seats and why you think the EU standard is safer?

Ms. HALLORAN. I think it might be best if I get back to you on that.

The EU does have a number of standards which are better than ours, we think, and ones which we would advocate for NHTSA to adopt. And this is a clear area where it would be good to harmonize up.

But I think I should get back to you on the specifics after I talk to my colleagues.

Ms. SCHAKOWSKY. OK.

And let me ask you, Governor Blunt. I mean, there are many efforts right now where consumer groups are looking at those ways in which European standards are higher.

My understanding of what you are saying is neither one should have to change and that each should be accepted in each country. Is that—that is your goal?

Mr. BLUNT. That is our goal, though if a new need emerged, we are not stating that we are opposed to new regulations in either economy if there is a new safety need that needs to be addressed. But our goal would be to recognize that today you achieve essentially the same environmental and safety outcomes and have mutual recognition of those standards.

Ms. SCHAKOWSKY. OK.

And with just a few seconds, I would love to meet with you about the regulation that would require rear visibility through cameras, which has been held up at the National Highway Transportation Safety Board. That would prevent two children, on average, a week being killed by back-overs. And if we could at some point meet about that, I would appreciate it.

Mr. BLUNT. Look forward to it.

Ms. SCHAKOWSKY. Thank you.

I yield back.

Mr. TERRY. Thank you.

And I now recognize Mr. Lance for 5 minutes.

Mr. LANCE. Thank you, Mr. Chairman.

To Mr. Castellani, the rapid deterioration of Indian intellectual property protections are direct evidence that India's industrial policies are designed to take American and European innovation for its own domestic industries, the industries affected by India's actions cover a broad range of innovative industries here and in Europe, including high tech, telecom, green technology, and your industry as well.

In light of this threat, how can we use this trade agreement to set global standards that value strong IP protections?

Mr. CASTELLANI. Thank you, Mr. Lance.

As I said in my testimony, we view and I think across industry we all had agreed that we view this as an opportunity to set a standard that should be applied around the world. In our industry, the ability to reward and protect innovation is key to the ability to meet patient needs, and particularly to develop medicines where none exist right now. We think the high standards that the Europeans have and the high standards the United States have present an opportunity to demonstrate to the rest of the world that you can have both the innovation that is necessary to serve patients and the affordability of medicines at the same time. And you can't have one without the other.

I would quote what the vice president said in India this morning, where he said a young Indian physician who is a researcher is motivated by his or her ability to discover and to continue that discovery process because they can be rewarded and encouraged because of the protection of what they develop. And we think that should be the standard around the world.

Mr. LANCE. Thank you. Isn't it true that many of the innovations that occur in your industry occur based upon research and development here in the United States?

Mr. CASTELLANI. About 65 percent of all of the research that is done in biopharmaceuticals is done in the United States. It, as I

said, represents—the National Science Foundation has told us that we do 20 percent of all the industry-funded research and development in the United States. It is also about 20 percent of our revenues, which I think is the highest of any sector in the economy. So it is absolutely vital to the United States and the United States as a leader.

Mr. LANCE. We will be having a major discussion on tax policy in this country out of Ways and Means, not E&C, but of course, we want as much research and development as possible. And I think the 20-percent figure is extraordinary in relationship to what it is across other sectors.

Now, as I understand it, the cost of generic drugs is higher in developing parts of the world than perhaps many realize; is that accurate?

Mr. CASTELLANI. Generics are higher in price across the board in Europe than they are in the United States, yes.

Mr. LANCE. Thank you. Would others on the panel like to comment on intellectual property matters as they relate to your fine industries?

Congressman Dooley, it is a pleasure to meet you, sir.

Mr. DOOLEY. I would just say we are very much aligned and consistent with the policy that Mr. Castellani said. We are one of the leading innovation manufacturing sectors in the United States; about 20 percent of all patents are issued to our industry. So protection of that intellectual property is a high priority.

Mr. LANCE. And do you see challenges in that regard in other parts of the world for your industry?

Mr. DOOLEY. There are challenges, you know, throughout the world. I would say with the EU, that is not where we are facing the greatest challenges.

Mr. LANCE. I am not suggesting the EU.

Mr. DOOLEY. Significant concerns—

Mr. LANCE. This is a model for other parts of the world.

Mr. Garfield.

Mr. GARFIELD. Yes. I would add two things. One is, we do see challenges in other parts of the world, particularly around tech transfers as a part of a requirement for participating in a market. That was one of the challenges that we faced in that India that we are now seeing a bit of a reprieve on, but there is still a lot of work to be done there.

The second is as we think about IP, I would ask that we also think about trade secrets, which there is a great opportunity for greater harmonization between here and Europe and for it be to a model for the rest of the world.

Mr. LANCE. Thank you.

Ms. Halloran.

Mr. HALLORAN. I think everyone needs to just think for a moment, though, about the recent Supreme Court decision in the Myriad case, where they decided that a breast cancer gene could not be patented. This is an example of how patenting may be going too far in a number of cases and getting in the way of actual innovation and unnecessarily raising healthcare costs for consumers.

Mr. LANCE. Thank you. My time has expired.

Thank you, Mr. Chairman.

Mr. TERRY. At this time, I recognize the emeritus of the entire Congress, Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman. I thank you for your courtesy, and I commend you for holding this important hearing. I am delighted to see the subcommittee is exercising its long neglected jurisdiction over matters related to international trade.

At the April 10 hearing of this subcommittee about domestic automobile manufacturing sectors, I tried to establish that some form of regulatory harmonization or mutual recognition of standards with the European Union would allow U.S. automakers and others to be more globally competitive. While it is arguable that regulatory harmonization or mutual recognition of standards would be helpful to industry, I also want to make sure that the health and safety of American consumers does not result from either.

Now, to Messrs. Blunt, Castellani, Dooley, and Garfield, all of you posit in your written testimony that a U.S.-EU free-trade agreement should include some form of regulatory harmonization or mutual recognitions of standards. I am asking that you and the other panelists submit to us a brief definition of these terms and how this would benefit the United States.

Now, again, to Messrs. Blunt, Castellani, Dooley, and Garfield, this is a yes or no question. Do each of you believe that the regulatory harmonization or mutual recognition of standards will not result in any diminution of the health or safety of American consumers? Yes or no.

Mr. BLUNT. Yes.

Mr. CASTELLANI. Yes.

Mr. DOOLEY. Yes.

Mr. GARFIELD. Our experience is yes.

Mr. DINGELL. All right. Now, to Ms. Halloran and Mr. Muffett, do you agree with your fellow witnesses responses? Yes or no.

Mr. HALLORAN. Absolutely not.

Mr. DINGELL. Sir?

Mr. MUFFETT. No.

Mr. DINGELL. Now, I would like to hear what our witnesses have to say about regulatory transparency as it relates to transatlantic regulatory harmonization or mutual recognition in standards. As we all know, the Administrative Procedure Act provides for substantial stakeholder input in the U.S. regulatory process. And essentially, that is a manifestation of the requirements of the constitution.

Now, to all witnesses, yes or no: Do you believe that the regulatory harmonization or mutual recognition of standards between the U.S. and the European Union would afford Americans the same level of stakeholder input in the regulatory process as they currently enjoy under the Administrative Procedure Act? Yes or no?

Mr. BLUNT. No.

Mr. DINGELL. Mr. Castellani?

Mr. CASTELLANI. I am not sure I can answer for both sides of the Atlantic.

Mr. DINGELL. Well, if you want to submit the answer later, that would be acceptable.

Mr. CASTELLANI. I would be happy to do that, but I think generally, yes, it should be the objective.

Mr. DOOLEY. I will submit a written answer.

Mr. DINGELL. Next witness.

Mr. GARFIELD. I hate to fall prey to peer pressure, but I will submit as well. I would say that it is something that we should insist upon in view of it about very important.

Mr. DINGELL. I am down to a minute, 38 seconds.

Ma'am, if you please.

Mr. HALLORAN. No.

Mr. MUFFETT. Most emphatically no.

Mr. DINGELL. Now, to all witnesses, do you believe that regulatory harmonization or mutual recognition of standards would make it more difficult in general for the United States and the European Union to promulgate new regulations in the future? Yes or no. Starting on your—at this end of the table.

Mr. BLUNT. No.

Mr. CASTELLANI. No.

Mr. DOOLEY. No.

Mr. GARFIELD. No, as well.

Mr. HALLORAN. Definitely yes.

Mr. MUFFETT. Yes.

Mr. DINGELL. Now, to all witnesses, similar, do you believe that regulatory harmonization or mutual recognition of standards would constrain the ability of the United States and the European Union to promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens? In other words, do you believe that regulatory harmonization or mutual recognition of standards would diminish the regulatory sovereignty, so to speak, of the United States and the European Union? Yes or no.

Mr. BLUNT. No.

Mr. CASTELLANI. No, sir.

Mr. DOOLEY. No.

Mr. GARFIELD. No.

Mr. HALLORAN. Yes.

Mr. MUFFETT. Yes.

Mr. DINGELL. OK. Now, again to all witnesses, I would like that you would submit additional comments on these matters for the record.

Now I would like to indicate my displeasure with the manner in which the TransPacific Partnership has been negotiated. Congress and the public have had far too little access to details in the draft agreement. I believe that a lot of sunshine is warranted.

Now, to all witnesses, would you support legislation that improves the transparency in trade agreement negotiations, particularly by granting improved access by all stakeholders to negotiating texts on future trade agreements? Yes or no.

Mr. BLUNT. Yes.

Mr. CASTELLANI. With all due respect, Mr. Chairman, I think you have to ask the negotiators; that is really the government's business.

Mr. DINGELL. Mr. Dooley.

Mr. DOOLEY. I concur with Mr. Castellani.

Mr. GARFIELD. I do as well. I think the negotiators should be the ones who determines it.

Mr. DINGELL. Ma'am.

Mr. GARFIELD. And it will be different in each instance.

Mr. DINGELL. Ma'am.

Mr. HALLORAN. I concur with auto representative, yes.

Mr. DINGELL. And.

Mr. MUFFETT. I will support it and march through the streets for it.

Mr. DINGELL. Now, one question—I know that I am exceeding my time, and I thank you for your courtesy to me, Mr. Chairman.

On a more parochial matter, do you, each of you, support or oppose the inclusion of currency manipulation disciplines in future U.S. trade agreements? Yes or no, with starting this end of the table.

Mr. BLUNT. Yes. Absolutely.

Mr. CASTELLANI. It is not an issue on which we have taken a position.

Mr. DOOLEY. It would vary with respective countries.

Mr. DINGELL. Sir.

Mr. GARFIELD. We don't have a position on that issue.

Mr. DINGELL. Ma'am.

Ms. HALLORAN. No position.

Mr. MUFFETT. No position.

Mr. DINGELL. Mr. Chairman, you have been extraordinarily courteous to me. I thank you and yield back the balance of my time.

Mr. TERRY. Thank you.

At this time, recognize the gentleman from the great state of Texas, Mr. Olson.

Mr. OLSON. I thank the chair. And want to thank our witnesses for coming here this morning. This is a very timely hearing. Given that just down the road the first round of negotiations of the Transatlantic Trade and Investment Partnership, or TTIP, were completed. Now, trade relationship with the EU is very significant, accounting for 40 percent of global output and nearly \$1 trillion in trade.

Of course, foreign trade gives me a chance to brag about my home State of Texas. The largest petrochemical complex in the world lines the 50-mile-long Port of Houston. The Port of Houston is the largest foreign tonnage port in America. Last week, the Department of Commerce's International Trade Administration announced that the greater Houston area is the top market for exports, with \$110.3 billion in merchandise exports in 2012, \$110.3 billion. And TTIP gives Houston a chance to get even bigger. Only one of the top five countries that Houston exports to are in the EU. That is The Netherlands. Recent study by the Paramount Group found that Texas could add \$17 billion if tariffs on the barriers with the EU were eliminated. More foreign trade means more American jobs and a more safe and secure world.

My former boss, United States Senator Phil Gramm, summed it up best when he said that American democracy and American free enterprise have given more hope and more freedom to more people than all the wars in history combined.

Against that backdrop, my first question is for you, Mr. Dooley. Your testimony and in public, you stated that the American Chemical Industry is poised to capitalize on enhanced competitiveness

due to increased supply from shale formations all across our country. As you know, most of the shale gas is being produced in Texas. The Barnett Shale played the first up there by Dallas-Fort Worth, Eagle Ford Shale played south of San Antonio, towards Laredo. Happening all over our country. Could you please go into detail about how the FTA and TTIP in particular could positively affect the petrochemical industry? Because, again, as I have told you in the past, sir, in the last 4 years, I have noticed a difference. Before chemical guys were talking about going to overseas. Now they are talking about coming back to America, keeping those jobs here. A lot of it is because of cheap energy. Details about that for petrochemicals.

Mr. DOOLEY. There has been a dramatic shift in the international competitiveness of the U.S. chemical industry in just the last 5 years. We have gone from in that period of time from one of the highest cost producers of chemicals globally to now the lowest cost producer of chemicals globally. There is one reason for that, and that is the increased supplies of natural gas, which for the chemical industry, we use natural gas, not only as an energy source but as also a feedstock. It is like flour is to bakery, natural gas is to the chemical industry. So when we see this dramatic increase in supplies which is resulting in more competitively priced natural gas, that gives us a significant competitive advantage internationally.

We keep a running total of new investments. We have now, looking by the year 2020, we will have 72 billion in new capital investments and chemical manufacturing in the United States. And important to note is over 50 percent of that is from direct foreign investment, companies located outside the U.S. We are in-shoring investment into the United States, which is a dramatic shift from over 10 years ago. And there has probably never been a point in time when you are seeing a dramatic—such a divergence in energy policies between the EU and the United States. In the United States, we are seeing the prospects of having domestic energy security, we see a commitment to develop our fossil fuel sources, primarily natural gas.

And if you look at the EU, they are putting policies in place that are banning fracking, that are moving away from nuclear energy. Their energy costs and feedstock costs are projected to go up significantly over the next decade, ours are going to stay flat. So when we also capitalize on the opportunity to reduce tariff barriers and regulatory barriers, that gives us the opportunity to further capitalize on this competitive advantage, and that's why the U.S. chemical has a vested interest in seeing progress on a TTIP being finalized.

Mr. OLSON. I told you I have seen a dramatic shift in the chemical industry in the last 5 years. They were talking about not growing business here in America, not building new chemical plants, moving overseas. Now that has changed. Coming back home or staying here. That is a great problem to have or solution to have.

One final question, in your testimony, you talked about the greater regulatory transparency. What are you concerned about? Is the process breaking down, and should we be concerned going forward with TTIP?

Mr. DOOLEY. Well, what we are referring to here is there is an opportunity—and we're not—contrary to what was implied by an earlier question, we are not for regulatory harmonization or standardization between the U.S. and the EU. But we do think that there are opportunities for cooperation where we can through the U.S. and EU through TTIP identify, you know, scientific assessment protocols. You know, we ought to be developing the best way to identify what are the scientific studies and the way that you are preparing data that can provide information on a risk of a particular chemical. You might have different standards of risks that EU would take versus the U.S. And that should—we should respect that. But you are going to have industry as well as government investing significant dollars to develop this data. And we ought to be providing ways to share that. And there ought to be transparency in terms of how those studies are being identified and developed that would help inform the—you know, whether the U.S. or in the EU.

So that is where we think that there is a lot of savings in terms of this regulatory cooperation as well as transparency to build a trust in confidence in the respective approaches to the safety of chemicals in coppers.

Mr. OLSON. Thank you, sir.

I've got all my time. I want to take this interpretation, the chairman loves Texas.

But thank you, sir. Appreciate it.

Mr. TERRY. Chair recognizes the gentleman from California, Mr. McNerney, for 5 minutes.

Mr. MCNERNEY. I thank the chairman for holding this important hearing.

My first question goes to Mr. Muffett. You indicated that, in your opinion, U.S. chemical regulatory regime was not adequate in its current form. And I was wondering if you could, and a yes or no answer: Could our chemical regulatory regime benefit from harmonization with the EU? Could we benefit in our form? Yes or no.

Mr. MUFFETT. No.

Mr. MCNERNEY. No?

Mr. MUFFETT. It doesn't admit of a yes or no answer. If we were to harmonize up to the EU standard, yes, we could benefit.

Mr. MCNERNEY. So there is a potential for benefit. But my followup question is this: How could secrecy in the TTIP negotiations influence the outcome of the harmonized chemical regulatory regime and the need for sound science in general?

Mr. MUFFETT. Your preceding question is a case in point of the risk. The U.S. system for addressing chemical risks is far weaker than the European system. In efforts to harmonize, in efforts to find some places for regulatory convergence, the tendency will be to push toward the middle. And without the public there to participate, to engage, to defend the public's interest in strongest possible regulations, that movement towards the middle is the biggest risk.

Mr. MCNERNEY. Ms. Halloran, I do appreciate your concerns with regards to the trade negotiations. As harmonization and regulatory convergence are discussed, how can we ensure the maintenance of U.S. consumer protections?

Ms. HALLORAN. The first step has obviously got to be to have a more public process for this. The extent of the entire thing is just enormous. And then they have to set goals, I believe, that I think are in direct conflict, for example, with those of the auto industry, which says there should be no increases. I think the proper approach has to be to try to go for the best level, the highest level of consumer protection, which may be the EU standard in one case and maybe the U.S. in another. And convergence towards the middle won't get us there.

Mr. MCNERNEY. Thank you for that answer.

Mr. Dooley, thank you for coming here today. I understand the potential benefits of the enhanced EU-U.S. cooperation when it comes to regulations within the chemical industry clearly. Can you suggest how to uphold the highest standards when sharing scientific assessments and test results that may differ between our two locations?

Mr. DOOLEY. I'm not sure I understood the question.

Mr. MCNERNEY. Sure. Can you suggest how to uphold the standards that will protect consumers when we are talking about scientific assessments and test results that may differ between our two regimes?

Mr. DOOLEY. I think that, it is clear that whether you are producing a chemical in the United States or the EU, and our companies are multinational, is that, the first commitment has to be to the certainty of the safety of the product for its intended use. We would contend that the REACH program has that similar objective that is differing outcomes. But those outcomes are not markedly different than what is being determined and assessed through the U.S. EPA's review of the safety of chemicals in commerce. I think it is also notable that we see in the Senate today, or in the last few months, a bipartisan bill was introduced that is supported by industry, ACC, as well as the Environmental Defense Fund, that develops a reform and modernization of TSCA that is taking a more risk-based approach than what the EU under the REACH program. But there is a collective understanding that that will result in the EPA having authority to make a determination on the safety of chemicals in commerce that will be every bit as accurate and as effective as the REACH program, but at a far less cost. And that is what we are looking for. How do you have the most efficient and effective program of assessing the safety of chemicals for industry as well as the regulators, whether it is in the U.S. or the EU. And that is where we have differences and where we don't want to harmonize to the EU's REACH program.

Mr. MCNERNEY. Good answer there.

Mr. Castellani, simple question. You folks thought IP—and I have IP myself, so I appreciate that. What location, do members of your industry prefer IP to reside, in the United States, in Europe, or in third countries?

Mr. CASTELLANI. It needs to be—it needs to reside where it is developed. And the nature of our industry is such that because of the unique both existence of the scientific ecosystem here in the United States, because of the strong intellectual property protection that U.S. Provides, because of the transparent and rigorous regulatory system that we have, and because of our valuation system for

medicines, the preponderance of it lies here in the United States. It needs to reside where it is developed, but it needs all four of those elements to be able to be developed.

Mr. MCNERNEY. All right. Thank you.

I yield back.

Mr. TERRY. Thank you, Mr. McNerney.

Now the chair recognizes for 5 minutes the vice chairman of the full committee, gentlelady from Tennessee.

Mrs. BLACKBURN. Thank you, Mr. Chairman. And I want to thank each of you for taking your time to be here today.

Chairman Terry has done a great job in putting the focus on how we bring jobs back to the U.S. And some of you, we have had the opportunity to visit with previously, and I have tremendous respect for the way each of you have looked at intellectual property and the protection thereof.

Mr. Blunt, I know you have engineers who are seeking to protect their IP that are very concerned with reverse engineering. Mr. Dooley, I know the same thing happens with some of your members. So I want to just stay with that for just a minute, with the IP issues.

Mr. Garfield, we had someone from your organization at a hearing recently here. We talked about India and the PMA. And that is something that I understand now that India is going to review that policy. And we are pleased with that. So we know that it could be reinstated. So I want you to just discuss for a moment, as you look at this, as you are learning lessons from what has happened with India and the PMA, as we look at protecting IP and looking at some of these transfer rights, if you will, that are there through the Internet, and you spoke a little about that global platform, talk to me about what we could do here in Congress, from a policy point of view, that would help us to forestall, if you will, things like the situation in India with the PMA. And then what would be helpful for the administration to do, for USTR to do, and kind of where we stand. Take it from there.

Mr. GARFIELD. It is a great question. Thank you for it. I will start, and I am sure some of my colleagues on the panel will jump in.

I began the testimony by thanking the committee for its vigilance and oversight as it relates to India. But India is—and we are pleased that we are seeing some reprieve, at least temporarily, on India. But India is not alone. In a number of markets that are looking to engender innovation and economic growth, I believe the way to do that is to have—is to take other countries' intellectual property or other companies' intellectual property or force the transfer of IP as a requirement for being in that market.

The lesson learned from India, I think, is largely one of having high standards, which we do in the United States, certainly can be approved. But we do. Two, remaining vigilant in oversight and our resistance to succumbing to countries who suggest that we should compromise on those intellectual property rights. And then the third that I would point to, and it is still early days yet to fully assess, and we still have work to do with India, but the alignment of the messaging and consistency of the messaging between Congress and the administration was such that it was clear and has

been clear to India that there was no space between the private sector, Congress, and the administration, which I think served us exceptionally well. This TTIP has the potential to do that on a much broader basis. And it is something that we are strongly supportive of.

Mrs. BLACKBURN. Mr. Dooley, I saw you——

Mr. DOOLEY. I am not familiar with the—the India, you know, reference that you made there. But I would just put it in the context of TTIP and make an argument for why we are not for, in some instances, regulatory harmonization. In the United States, we currently bring three times the number of new chemicals and innovations to the marketplace as they do in the EU. That is in large part because of the regulatory structure that is in place and the cost of compliance and whether or not you have an environment that is conducive to that. So that is where we have some concerns about whether or not it is in our interest to go down that path, which we concluded it is not. But there is an opportunity to ensure that there is a sharing of data and information that results in cost savings to industry as well as to the regulators and the agencies and the United States and the EU. And that is where we think that there is significant benefit through a TTIP in terms of trying to find ways in which we can share that information, which also has to be done in a way that it protects intellectual property rights. In the sharing of that information. And how do you control that, which all has to be part of the negotiations that are taking place.

Mrs. BLACKBURN. OK. Mr. Castellani, did you have anything to add?

Mr. CASTELLANI. Yes, ma'am. I think that one of the things that you have to focus on is, I am not aware of any economy that has been able to develop sustained economic growth over a long period of time by stealing intellectual property. One of the reasons why the United States is as strong economically as it is in also the EU is that we have the infrastructure to develop the intellectual property here. And that benefits not only the customers for it, in our case, patients, but also obviously the economy where it is developed. So the challenge with India is that the actions that they have taken, at least in our sector, just to usurp and therefore confiscate property that was developed with substantial investment in other parts of the world, in the United States and in Europe, has turned out so that it doesn't help their economy in the long run and it certainly doesn't help their patients because they are precluding the Indian patient from the most innovative medicine in the world. So thank you.

Mr. TERRY. Chair would now recognize gentlelady from Virgin Islands for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

And welcome to the panel. A growing body of scientific evidence demonstrates that many chronic illnesses on the rise in the industrialized world are linked to exposure to toxic chemicals, including many cancers, learning disabilities, asthma, Alzheimer's, and Parkinson's disease, as well as fertility problems. The most comprehensive review to date of environmental factors that may increase the risk of breast cancer found that 216 chemicals are associated with

the disease, including 73 that have been present in consumer products or food.

I would like to ask Mr. Muffett a series of questions. And so in light of the alarming health risks posed by some toxic chemicals, I can assume that you prefer the EU hazard-based approach to the U.S. risk-based approach?

Mr. MUFFETT. That is correct.

Mrs. CHRISTENSEN. And do you find that TSCA limits the ability to control some of those risks? Is TSCA not strong enough?

Mr. MUFFETT. I think it is clear there is a broad, there is a broad consensus or at least the overwhelming weight of perspectives on TSCA is that it is not strong enough to respond to those risks. It is important to recognize that TSCA was adopted in 1976, just 4 years after the very first book on toxicology, the very first textbook on toxicology was published. And TSCA was based on that very early, early understanding of toxicological risks and toxicological science. Our understanding has changed dramatically, profoundly over the ensuing 35 years, and TSCA hasn't changed with it. And this is one of the fundamental differences between TSCA and REACH, is that REACH is targeted to responding to the world as we increasingly understand it, rather than the world as we understood it in 1976.

Mrs. CHRISTENSEN. And, you know, I have heard Congressman Dooley's position and—which is on behalf of the council, really not in favor of trying to harmonize any more towards the REACH areas. But there are some chemical manufacturers and downstream users of chemicals that have called for the expansion of REACH-like systems around the world to help level the global playing field. Can you share your point of view of why some of the companies or the council might oppose the REACH-like initiatives in the U.S., especially since some of those companies are arguing for harmonization?

Mr. DOOLEY. Absolutely. Because we think there is a better and more effective way to assess the safety of chemicals in commerce. I agree with Mr. Muffett that we need to modernize and reform TSCA, and that is exactly what has led to a bipartisan introduction of a TSCA reform bill, the Chemical Safety Improvement Act in the Senate. It is the first time continues TSCA was introduced in 1976 that there has been broad bipartisan support for the legislation to reform TSCA, which takes a risk-based approach, which gives EPA more authority in terms of requiring information and data from the industry. It is legislation that has the support of unions and the machinists, the ironworkers, sheet metal workers, as well as the transportation union, as a support of Environmental Defense Fund, a number of other NGOs, and has the broad support of the industry, large members, small members, throughout the value chain. And it is a risk-based approach that is viewed as being equally effective in the assessment of safety and chemicals as REACH but is done in a much more efficient and effective manner.

Mrs. CHRISTENSEN. Mr. Muffett, I was really directing the question to you on that issue. With regard to the new legislation that is being proposed, do you find that that would satisfy your idea of where we ought to go with the regulation of chemicals?

I can see I'm not going to get my next question in.

Mr. MUFFETT. Thank you for the question.

The Chemical Safety Improvement Act, in our view, is not adequate without substantial amendments. And I think it is important to recognize that the EU in its position papers on chemical safety in the context of TTIP has acknowledged the same thing. So the bipartisan bill that was referred to is not sufficient, even from the EU's perspective, to bring the U.S. to the same level of protection that the EU is achieving.

Mrs. CHRISTENSEN. I think my time is up.

Thank you, Mr. Chairman.

Mr. TERRY. Thank you.

Chair now recognizes Mr. Long for 5 minutes.

Mr. LONG. Thank you, Mr. Chairman.

And thank you all for your testimony.

Here today—and, Mr. Castellani, I will start with you, if you don't mind. As you noted in your testimony, the U.S. and the EU already provide the strongest global support for pharmaceutical research and development. Pharmaceutical tariffs between the U.S. and the EU are zero under the WTO pharmaceutical agreement. And you obviously support a high standard, ambitious agreement. But what exactly do your members' companies hope to gain from such an agreement?

Mr. CASTELLANI. As I mentioned in my testimony, from a regulatory standpoint, we are starting, as you said, from a very, very hard standard. It is absolutely essential to our industry. And we are not asking that those standards be reduced. But, rather, there is in our process of discovery a rather expensive part of the process; cost us about a billion and a half dollars to develop one medicine, takes about 10 years. Half of that cost, for example, is in clinical trials. It is very important that clinical trials adhere to the highest standards to both protect the patients and ensure a valuable outcome.

We have clinical trial standards and inspection process in the United States to make sure that occurs and they have them in Europe. We believe those could be harmonized so that those inspectors could be freed up to cover other areas of the world where you perhaps don't have as high of standards. Same is true in our manufacturing practices. Both very high. And it seems to us that there is a better use of time and a better use of resources than to have an AMA inspector come into one of our facilities followed by a FDA inspector, both having the same standards. So it is an opportunity to make our processes more efficient and an opportunity for the government agencies to be able to focus where there is higher risk.

Mr. LONG. Did I understand earlier in your testimony that 80 percent of R&D, research and development, is done between the U.S. and EU?

Mr. CASTELLANI. Yes, that is correct.

Mr. LONG. And then you had a figure in there later in your questioning; I think it was 65 percent.

Mr. CASTELLANI. Sixty-five percent—

Mr. LONG. U.S. 65 of the overall—

Mr. CASTELLANI. U.S. is 65 percent; Europe is about 15 percent.

Mr. LONG. OK. That was my question.

I have another question for you. How do the European Medicine Agency's current and proposed data disclosure policies present potential problems regarding the protection of a patient privacy and shielding confidential commercial information?

Mr. CASTELLANI. Thank you. The AMA has proposed some very extensive transparency requirements on our conduct of clinical trials that cause concern in one of the three areas, potentially two of the three areas that are essential for the trials to continue and the investment to continue.

Here is no disagreement that we must protect patient-specific data. It absolutely has to be so that people who participate in clinical trials do not run the risk of having their participation and their medical records being released.

Secondly, we have to make sure that the clinical trial data as it is released is consistent with the regulatory process so that we are not creating two different standards, one at the regulatory agency and one within academic discussion.

Third, where we have the biggest concern with the EMA's proposal is EMA is proposing to release what is called commercially confidential information, that is, the intellectual property into the whole environment. And, therefore, the companies who have invested the billions of dollars to develop it will lose that exclusivity because it will just go into the world and anybody can copy it.

So our concern is that we protect patients; we enhance the transparency of the clinical trial process; we protect the regulatory process; but we also protect the ability the continue to invest.

Mr. LONG. OK. Thank you.

And the next question goes to a gentleman that I would like to thank, Governor Blunt, number one, for your service to our country in the Navy, and your service in our area, my neck of the woods, as a State rep and a Secretary of State and then Governor. So thank you for all of the above.

And a question for you. If mutual recognition of a regulation is achieved, is it your expectation that an automaker could then sell a vehicle built in either recognized standard or sell—to either recognized standard—would they be able to sell that in either market then with no further?

Mr. BLUNT. Yes. That is our aspirational goal.

Mr. LONG. I feel like with Chairman Dingell with a yes or no answer. You said yes.

Mr. BLUNT. We believe that that would increase trade and lower cost and create jobs and obviously improve the international competitiveness of the industry in the United States and Europe and also afford lots more choices for consumers in both markets. They would see a more rapid option of the newest and latest technology.

Mr. LONG. Thank you.

And, for the record, I would note that in your 5-minute opening, you had 5 seconds remaining, and I have 1, so I got closer than you did.

Mr. TERRY. At this time, recognize the gentleman from Maryland for 5 minutes.

Mr. SARBANES. Thank you, Mr. Chairman.

Ms. Halloran, do you think there is any chance that we can achieve mutual recognition or harmonization between your side of the table and this side of the table any time soon?

You don't have to answer.

I wanted to ask you about the—this whole transparency issue in terms of the negotiations. How does it compare to other negotiations? Is this one particularly opaque, would you say, in comparison? Or is it about standard? And so forth.

Ms. HALLORAN. Negotiations like this with respect to always so secret. The Doha round, the drafts were periodically published. The Free Trade of the Americas agreement, draft texts were periodically published. Bob Zoellick, the former U.S. trade representative, just recently said in a speech that he doesn't know quite why things have gotten so closed down. And so it's—especially in a negotiation like this, which is on regulation, which is of such broad interest and importance to so many sectors, I think there has got to be a higher level of openness.

Mr. SARBANES. Do you have any theories, either you or Mr. Muffett, about what is going on?

Mr. HALLORAN. Well, I think if you are a negotiator at USTR, it is obviously a much easier job if you are just talking to your European counterparts and you don't have to show anything to anybody until 2 years from now and you can hand it out on a take-it-or-leave-it basis. And I think they have actually said that they really don't want to be burdened by the public feedback. And you can sort of understand their position. But it is something that in a democracy, I mean, you as Congressmen are—deal with the burden of public feedback all the time, and it is sort of how we should work, I think, in a democracy.

Mr. SARBANES. What is the perspective on this on the European side, this issue of the transparency of it?

Mr. HALLORAN. They are also in favor of the—behind-closed-doors approach. Ironically, because they have to share everything with all of their member states, their control over their positions and so forth is not very tight. So we have been finding out the most about what is going on from European League documents which seem to be leaked very regularly, and they also don't have the stringent penalties we do under the Espionage Act for disclosures. But, on the other hand, Europe has much less of a history. They don't have an Administrative Procedures Act, they have much less of a history of public discussion and input than we do. So they are amenable to the idea of doing it behind closed door, but I think they could also be amenable to more disclosure.

Mr. SARBANES. Arguably, we have got a higher standard to meet based on our history in terms of this transparency, it sounds like.

I wanted to ask you, all of the answers to Mr. Dingell's questions were predictable, except there was one question where I was surprised that the industry folks, at the answer there, and that was this notion that if you had harmonization for example or mutual recognition, it would not affect the ability to establish new standards in response to things that might happen, which to me seems—that is very hard for me to understand why you would not acknowledge that that would tie your hands certainly a little bit when you

want to find new standards. And I wonder, either Mr. Muffett or Ms. Halloran, if you could speak to that issue.

Mr. MUFFETT. I think the clearest example of how a TTIP agreement and these expectations of harmonization would affect the ability to develop new standards lies with the ability of the States to innovate and develop new standards. One of the things that the EU has identified as a major objective for it coming out of TTIP is harmonization to Federal levels, and that includes sub-national standards coming up to a relatively similar level so you don't have wide divergences between what is going on at the Federal level in the United States and what is going on at the State level.

Unfortunately, in the U.S., it is at the State level where all the innovations in chemicals regulation and chemical policy have been going on. If States are required to undertake additional consultations and defend their decision-making processes not only to U.S. industry and the U.S. public but to the European industry and European public through these processes, the additional burdens on regulators, particularly local and State regulators, will be profound. And that itself will I think impede the development of new protections.

Mr. SARBANES. So if you are a good federalist, that might cause you some concern.

I am going to yield back.

Mr. TERRY. Thank you, Mr. Sarbanes.

At this time, recognize gentleman from Florida for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

I appreciate it and thank the panel for their testimony. Most of my questions were already asked, but I do have a question for Governor Blunt.

The United States and Europe differ quite a bit with regards to safety and vehicle emissions requirements. Has your association or members been in discussions with NHTSA or the EPA about these issues with regard to TTIP?

Mr. BLUNT. Thus far, most of our discussions have been through the U.S. Trade Representative's Office, but we have presented our proposal to representatives of all of those—of agencies.

Mr. BILIRAKIS. Have they been receptive to your industry?

Mr. BLUNT. I think they understand if we are going to maximize the benefits of TTIP, some convergence is necessary. We understand that we have set a high goal, both industry and the United States and Europe for the negotiations. But we are certainly willing to work with them as we evaluate data and methodologies that would allow us to come to what we think is the natural conclusion that both sets of regulatory standards achieve the same environmental and safety outcomes.

Mr. BILIRAKIS. Very good.

Thank you, Mr. Chairman. I yield back.

Mr. TERRY. All right. Well, that concludes all of the questions.

I have a little bit of business to do before we adjourn.

And I want to put nine statements into the record. Number one, American Apparel and Footwear Association; the Alliance of Automobile Manufacturers statement; Global Automakers statement; Handmade Toy Alliance statement; Marketing Research Association statement; Society of Chemical Manufacturers and Affiliates

statement; Tech America statement; Toy Industry Association statement; and the Biotechnology Industry Association statement. There all being nine. And these have all been shared with the minority.

[The information appears at the conclusion of the hearing.]

Mr. TERRY. Now without any objections, they will be in the record.

Now yield for the same to Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you.

Let me just say that while I don't agree with a number of those statements that are going in for the record, we did approve them and agree to their submission.

In addition, we would like to add the statement of the Coalition for Sensible Safeguards; the Transatlantic Consumer Dialogue; and the Maine State Representative Sharon Anglin Treat in a relevant testimony that she gave on a trade agreement.

Mr. TERRY. I am sure I have the same thoughts on those, that we probably don't necessarily agree. But all statements should be in the record. So, therefore, those are also in.

Hearing no objections.

[The information appears at the conclusion of the hearing.]

Mr. TERRY. I want to thank all of you.

If there is one thing I think we can take away from this hearing today is that TTIP is not going to be easy. All of your statements have been good and insightful. And I thank you for being here.

So, at this time, we are adjourned.

[Whereupon, at 11:37 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

#### PREPARED STATEMENT OF HON. FRED UPTON

Earlier this month, the United States and the European Union held the first round of negotiations on what we all hope is the first step toward achieving an historic trade agreement: the Transatlantic Trade and Investment Partnership. This has the potential to be the most comprehensive bilateral agreement ever developed, addressing non-tariff impediments in ways never previously attempted.

We have a long and valuable relationship with our European allies. These ties have created great cooperation on many fronts and led to a flourishing trade relationship. Together we account for almost half of world GDP and world trade. And as investment partners, there is no greater bilateral relationship than between the U.S. and the EU: we are the largest single recipient of EU foreign direct investment and we are the largest source of foreign investment in the EU.

The benefits of this trade partnership cannot be overstated: additional jobs, income, and economic growth on an annual basis going forward—something both sides desperately need. U.S. job creators like the Big Three automakers in Michigan have the potential to make significant gains. And Congress doesn't have to appropriate a penny to reap the potential rewards.

We are all hopeful of achieving the most ambitious trade agreement possible. The sheer size of our bilateral trade and investment with the EU means that any significant progress to cut regulatory costs and bureaucracy, reduce market access barriers, and eliminate tariffs will translate into positive economic growth for both sides of the agreement.

To achieve our shared goal, we need to work together. Both sides agree we have different, but mature regulatory regimes, which, in most cases, attain equivalent outcomes. Unfortunately, the outright elimination of regulations is a lot more difficult than eliminating tariffs; however, we can and should reduce the costs of these dual regulations.

In our federalist system, different (even incompatible) state regulations exist yet we do not allow them to impede interstate commerce. For example, states can and do regulate auto safety inspections for vehicles registered in their state in different

ways and under different timelines, but it would be counterproductive if states were able to block residents of other states from traveling across state borders unless they complied with the exact standards of the visiting state. We wouldn't stand for it. So if we allow recognition of different state standards, there is no reason we can't find a way to similarly work with the EU to harmonize or recognize each other's standards to avoid duplicative and costly regulations designed to achieve the same goals.

We have a distinguished panel of witnesses today who can elaborate on the real costs of trade barriers.

They also know how reducing those costs will benefit more than just the individual companies and industries. It will provide all of our citizens with a more prosperous future. It is our job to ensure they are not denied that opportunity.

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footwear association

**we wear our mission<sup>®</sup>**

**Statement for the Record**

by the

**American Apparel & Footwear Association (AAFA)**

**Regarding**

**The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers**

**United States House of Representatives Energy & Commerce Committee  
Subcommittee on Commerce, Manufacturing, and Trade**

**Wednesday, July 24, 2013**

Thank you for this opportunity to provide a statement for the record regarding regulatory barriers in consideration of the U.S. – E.U. Free Trade Agreement. This agreement holds immense potential to grow the U.S. apparel and footwear industry, create U.S. jobs, and support the U.S. economy.

The American Apparel & Footwear Association (AAFA) is the national trade association representing apparel, footwear, and other sewn products companies, and their suppliers, which compete in the global market. Our membership consists of about 425 American companies that represent one of the largest consumer segments in the United States. The apparel and footwear industry overall represents \$350 billion in annual domestic sales and sustains more than four million American jobs. Our members are present throughout Europe, where they employ millions of Europeans and sell billions of dollars' worth of clothes, shoes, and other fashion products.

Our industry is on the frontlines of globalization. AAFA members produce, market, and sell apparel and footwear in virtually every country around the world. With all the benefits that come with being a global industry also come the extreme challenges created by regulatory differences. AAFA has been a strong supporter of efforts between the United States and European Union to establish a comprehensive, liberalizing, free trade agreement to eliminate market barriers and reduce costs. By fostering greater regulatory coherence between the United States and European economies, the United States and the European Union can set a strong example for future trade agreements and help strengthen our collaborative positions as leaders in the global economy. Below are several illustrative examples of regulatory differences which hinder economic growth for the apparel and footwear industries in both the European Union and the United States as negotiations gain momentum, we envision providing more detailed input on these and other matters that would be addressed in such talks.

1601 North Kent Street  
Suite 1200  
Arlington, VA 22209

(703) 524-1864  
(800) 520-2262  
(703) 522-6741 fax  
[www.weare.org](http://www.weare.org)

**Product Safety - Phthalate Testing for Children's Pajamas**



The United States Consumer Product Safety Commission (CPSC) staff has declared that Children's Pajamas are considered to be a childcare article under the Consumer Product Safety Improvement Act (CPSIA) phthalate requirements.<sup>1</sup> The practical result of these decisions is sleepwear (and presumably related garments including loungewear) is subject to testing and certification requirements for certain phthalates. The phthalate ban in the CPSIA is ultimately based on a nearly identical ban enacted in the European Union. Using virtually identical terms, the European Union has issued guidance on childcare articles, explaining it does not consider sleepwear to facilitate sleep. The EU guidance states, "The main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Pyjamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive."<sup>2</sup>

The context of the childcare phthalate ban is also critical to understanding why it is inappropriate to include pajamas in the definition of childcare articles. In the text of both bans, The United States Congress and the European Commission define childcare articles as those intended by the manufacturer to "facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething."<sup>3</sup> The concept of facilitating sleep in this context involves articles children suck in order to fall asleep, such as a pacifier. The common denominator of these actions is mouthing articles which might contain one of the banned phthalates. Clearly, sleepwear, by any examination, is not an article intended to be associated with mouthing.

While there is no evidence proving children's pajamas pose a phthalate hazard, these United States determinations pose a huge burden on sleepwear manufacturers, brands, and retailers in the United States and have also encouraged European Union manufacturers to refrain from selling their products in the United States.

When considering other testing requirements and rules which apply to childrenswear it is also important to note that the United States considers childrenswear to be clothes meant for children 12 years of age and under, while the European Union considers childrenswear to be clothes meant for children age 14 and under.

#### **Conformity Assessment and Testing Harmonization**

AAFA strongly believes in the need for international testing harmonization. In relation to product safety, when the goal is the same, the method to establish that goal should also be the same. When testing for compliance under a certain regulation, duplicative testing is both burdensome and counterproductive as it does not provide any greater assurance of compliance. As a result the United States and European Union should work to remove unnecessary and duplicative testing by expanding acceptance of conformity assessment bodies and moving toward a single international standard test method. On such method of harmonization would be to develop a harmonized certificate of conformity that would allow for a product to be certified compliant in both the United States and the European Union.

#### **Labeling Collaboration**

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<sup>1</sup> <http://www.cpsc.gov/library/foia/advisory/321.pdf>

<sup>2</sup> [http://ec.europa.eu/enterprise/sectors/toys/files/qd008\\_en.pdf](http://ec.europa.eu/enterprise/sectors/toys/files/qd008_en.pdf)

<sup>3</sup> <http://www.cpsc.gov/cpsia.pdf>

In 2010, the European Union, United States, and several other countries developed a Textile, Apparel, Footwear, and Travel goods (TAFT) labeling proposal as part of the ongoing Doha Round of global trade negotiations under the auspices of the World Trade Organization (WTO). This is a development that is ripe for early harvest in efforts by the United States and the European Union to forge regulatory coherence.

Labeling requirements for apparel, footwear, and travel goods vary widely between the United States and the European Union and make it difficult for manufacturers to create one product for both markets. We would like to see a harmonization of labeling requirements such as:

- Country of origin – the United States requires country of origin labeling while the European Union does not
- Care symbols – the United States allows only the use of ASTM symbols for care labeling while the European Union uses international ISO/Ginitex symbols (The United States Federal Trade Commission recently proposed changes to their care labeling requirements which will allow for the use of 2005 ISO symbols in the United States. This is a great step, but still just a proposed change)
- Footwear labeling – the United States does not require parts of footwear to be labeled while the European Union does.

It should be noted that while working on methods to harmonize labeling efforts between the United States and European Union there needs to be further progress in harmonizing labeling requirements within the European Union itself. Certain components of textile and footwear labels are required to be in a language of the country in which the product is being sold in absence of a general labeling requirement for the entirety of the European Union.

#### **Develop a Regulatory Cooperation Committee**

In order to improve and expedite the review of current areas of harmonization as well as increase collaboration and prevent future discrepancies, the United States and European Union should develop a Committee of regulators and stakeholders that will:

- Work with regulatory agencies, government bodies, and standard setting organizations.
- Engage in any regulatory development to ensure alignment before regulations are passed and not after the fact.
- Communicate with stakeholder industries both for the purpose of solicitation of comments as well as education of implementation.'
- Track the progress of regulatory cooperation and set goals for future alignment.

The formation of this committee is critical as we approach new initiatives on both sides of the ocean, such as REACH expansion, Conflict Minerals, Federal Trade Commission Green Guidelines, and Eco Labeling.

#### **Focus on Internal Harmonization**

We strongly urge the United States and European Union to not lose sight of internal harmonization as they move toward international harmonization. While collaborative national harmonization is a crucial and necessary task it is very important not to let the effectiveness be diminished by an increase in internal regulations. A focus on preemption must be key in an attempt to keep from having 28 different sub-national regulations in Europe or 50 different state regulations in the United States cause even greater confusion and chaos in regulatory compliance.

**Conclusion**

Discrepancies in regulations are burdensome not only to the regulated community, but on the regulators themselves. AAFA applauds both sides for striving to relieve the unnecessary burdens on industry and remove the confusion that is involved with conflicting regulatory requirements. While this is not the first time the European Union and U.S. have attempted to address these challenges, it is crucial that we continue to collaborate to remove these trade barriers to benefit all parties involved.

Thank you for your time and consideration in this matter. Please do not hesitate to contact AAFA at [mdavignon@wewear.org](mailto:mdavignon@wewear.org) or 703-797-9038 if we can be of any help to you.



July 24, 2013

The Honorable Lee Terry  
 The Honorable Jan Schakowsky  
 Subcommittee on Commerce, Manufacturing, and Trade  
 Committee on Energy and Commerce  
 U.S. House of Representatives  
 Washington, DC 20515

Re: The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers

Dear Chairman Terry and Ranking Member Schakowsky:

The Alliance of Automobile Manufacturers (Alliance) and its twelve member companies welcome the Subcommittee's thoughtful examination of regulatory barriers in the proposed U.S.-EU free trade agreement. The Alliance is the leading advocacy group for the auto industry, and represents 77% of annual new car and light-truck sales in the United States.

Automakers are encouraged by the recent launch of formal negotiations for a comprehensive Transatlantic Trade and Investment Partnership (TTIP). This is an unprecedented opportunity to more closely integrate our two economies on either side of the Atlantic and as a result, generate significant economic benefits in the United States and European Union. As the negotiation process moves forward, we wish to express our support for the mutual recognition of existing automotive technical standards and the creation of a joint process for harmonization of common future automotive regulations.

Auto manufacturing is a driving force in both the U.S. and EU economies. According to the International Organization of Motor Vehicle Manufacturers (OICA), the U.S. and the EU together account for 32% of global auto production and 35% of global auto sales. In 2012, the United States exported nearly \$8 billion worth of passenger vehicles to the EU and nearly \$5 billion in automotive parts.<sup>1</sup> During the same period, the U.S. imported approximately \$32 billion in passenger vehicles from the EU and more than \$12 billion in auto parts.<sup>2</sup> Therefore, as these trade negotiations continue, it is essential to ensure that regulatory costs do not inhibit the critical role the auto industry serves in our transatlantic economies.

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<sup>1</sup> United States Department of Commerce and United States International Trade Commission  
<sup>2</sup> Ibid.

Inconsistent or duplicative regulations can often act as non-tariff barriers (NTBs) to trade and increase the costs of doing business. Both the U.S. and EU have highly advanced automotive safety and engineering standards and regulatory certification procedures that have been independently created and implemented. Therefore, certifying U.S. vehicles for sale in the EU and vice-versa requires additional testing and modifications.

It is important to stress that regulatory convergence need not compromise vehicle safety or environmental performance. In many cases, the regulatory differences between the two governments do not appreciably enhance safety or environmental performance, but they do impose additional and unnecessary costs on manufacturers that are often passed on to consumers. According to a study conducted by ECORYs and commissioned by the European Commission, current auto NTBs are equivalent to an ad valorem tariff of approximately 26%.<sup>3</sup> Reducing the regulatory burden will stimulate positive economic growth in the U.S. and the EU and allow both to remain leaders in the vast global market.

The United States and European Union are presented with a unique opportunity. Rarely has there been such unified support within government and the business community for a broad and ambitious transatlantic trade agreement. Such an agreement, with effective regulatory convergence as a critical component, between two vast economic markets would bring economic growth, competitiveness, and, most importantly, job creation. Furthermore, the trade agreement could promote international cooperation and encourage other nations and regions to adopt U.S.-EU harmonized regulations, creating additional economic benefits for the United States and European Union.

The Alliance appreciates the opportunity to offer the Subcommittee our views on the proposed Transatlantic Trade and Investment Partnership, and we respectfully ask that they be included in the hearing record. We remain committed to engaging constructively throughout the negotiating process to ensure a successful TTIP with increased regulatory convergence is ultimately achieved.

Sincerely,

Mitch Bainwol  
President & CEO  
Alliance of Automobile Manufacturers

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<sup>3</sup> ECORYs Nederland BV, "Non-Tariff Measures in EU-US Trade and Investment: An Economic Analysis", p. 48.  
12/11/2009



Audi • BMW • Ford • Honda • Hyundai • Isuzu • KIA • Maserati  
Mercedes-Benz • Nissan • Peugeot • Subaru • Suzuki • Toyota

July 23, 2013

Chairman Lee Terry  
Committee on Energy and Commerce  
Subcommittee on Commerce, Manufacturing,  
and Trade  
2125 Rayburn House Office Building  
Washington, DC 20515

Ranking Member Jan Schakowsky  
Committee on Energy and Commerce  
Subcommittee on Commerce,  
Manufacturing, and Trade  
2322A Rayburn House Office Building  
Washington, DC 20515

Re: Statement for the Record

Dear Chairman Terry and Ranking Member Schakowsky:

The Association of Global Automakers respectfully submits this statement for the record in connection with the Subcommittee's hearing on July 24, 2013 entitled "The U.S.-EU Free Trade Agreement: Tipping Over the Regulatory Barriers."

The Association of Global Automakers represents international motor vehicle manufacturers, original equipment suppliers and other automotive-related trade associations. These companies have invested \$46 billion in U.S. based production facilities, directly employ more than 90,000 Americans, and sell 43 percent of all new vehicles purchased annually in the United States. Our members operate more than 260 production, design, R&D, sales, finance and other facilities across the United States.<sup>1</sup>

As a general matter, Global Automakers supports the expansion of international trade and endorses negotiations toward that objective, including the proposed Transatlantic Trade and Investment Partnership (TTIP) negotiations. We agree with Former Acting United States Trade Representative Demetrios Marantis that, "An ambitious, comprehensive, and high-standard TTIP can generate new business and employment by significantly expanding trade and investment opportunities in the United States and the EU."<sup>2</sup> As detailed below, we believe the TTIP can promote economic growth, increase jobs, and enhance the global competitiveness of U.S. and European producers – both in general and within the automotive sector in particular – through regulatory convergence, mutual recognition, the elimination of tariffs, and other facilitation measures. In 2012, U.S.-EU trade in motor vehicles and auto parts totaled approximately \$57 billion, accounting for 9 percent of total bilateral trade of \$646

<sup>1</sup>For more information on Global Automakers, visit [www.globalautomakers.org](http://www.globalautomakers.org).

<sup>2</sup> March 20, 2013, letter from Acting U.S. Trade Representative, Demetrios Marantis, to U.S. House of Representatives Speaker, John Boehner, found here: <http://www.ustr.gov/sites/default/files/03202013%20TTIP%20Notification%20Letter.PDF>.

billion.<sup>3</sup> Given the significance of this sector in bilateral trade, provisions that expand automotive trade are fundamental to delivering the potential benefits of a TTIP. Global Automakers believes the measures outlined below will help meet this objective.

***The TTIP should eliminate tariffs on automotive products***

Tariffs on passenger vehicle imports are 2.5 percent in the U.S. and 10 percent in the EU. Tariffs on trucks and buses range from 2 percent to 25 percent in the U.S. and from 16 percent to 22 percent in the EU. The elimination of these tariffs would facilitate bilateral trade and enhance the competitiveness of U.S. and European-made products. Global Automakers therefore supports the immediate elimination of tariffs on motor vehicles and auto parts.

***The TTIP should provide regulatory convergence for the automotive sector***

The United States and EU maintain significantly different regulatory regimes for the automotive sector, not only with respect to safety and emissions requirements, but also for testing, certification, reporting and recordkeeping. Complying with both regulatory regimes is quite costly for automotive producers. Regulatory convergence through the TTIP would simplify global sourcing, production and sales, and would significantly reduce costs and redundancies for automotive manufacturers.

Global Automakers strongly believes the TTIP should create a process to harmonize, to the extent possible, U.S. and EU regulations in the automotive sector. This would comport with one of the key TTIP objectives identified by the Obama Administration of “reducing costs associated with unnecessary regulatory differences and facilitating trade.”<sup>4</sup> While we recognize the U.S. and the EU have sovereign interests that must be respected, we believe the TTIP should establish that, as a general principle, regulatory policy should be grounded in a scientific approach and promulgated in a transparent manner, through a process that includes outreach to, and input from, private stakeholders.

Global Automakers recommends the following tripartite approach to achieve regulatory convergence:

- *Part 1:* During the TTIP negotiations, mutually recognize existing U.S. and EU requirements in the following high priority areas:

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<sup>3</sup> Automotive trade data from U.S. Department of Commerce, U.S. International Trade Commission and Eurostat, as cited in “U.S.-EU Automotive Regulatory Convergence: Joint U.S.-EU Industry Presentation, U.S.-EU High Level Regulatory Cooperation Stakeholders Forum,” April 10-11, 2013, by the European Automobile Manufacturers’ Association and the American Automotive Policy Council; total U.S.-EU 2012 trade from “Foreign Trade – U.S. Trade with European Union,” [www.census.gov/foreign-trade/balance](http://www.census.gov/foreign-trade/balance).

<sup>4</sup> USTR TTIP notification letter to Congress, March 20, 2013.

- Child restraint systems (FMVSS 213/225/UN ECE Reg. 14,16, 44);
  - Fuel system integrity (FMVSS 301/ UN ECE Reg. 34, 94, 95);
  - Heavy duty vehicles emissions (EPA 2010/Euro VI/GTR 4);
  - Light duty vehicle emissions (EPA Tier 2/3 / Euro 5 and 6);
  - Occupant crash protection (FMVSS 208/UN ECE Reg. 94);
  - Occupant protection for interior impacts (FMVSS 201/UN ECE Reg. 21);
  - Side impact protection (FMVSS 214/UN ECE Reg. 95)
  - Tire pressure monitoring systems (FMVSS 138/UN ECE Reg. 64) ; and
  - Bumper Standard (FMVSS 581/UN ECE Reg.42).
- *Part 2:* Given the ambitious schedule for negotiating the TTIP, Global Automakers recognizes it may not be possible to complete the mutual recognition process for all existing automotive regulations during the course of the negotiations. To address any remaining regulatory issues, negotiators should lock in a clear and transparent process to continue work on convergence, even after the negotiations have concluded. To do so, the TTIP should create a standing forum for consultations and should, at a minimum, require regular consultations between U.S. and EU officials. As part of this ongoing process, there should be active outreach to U.S. and EU automotive producers to ensure their input.
  - *Part 3:* The TTIP should include a provision whereby the Parties mutually recognize each other's testing, certification, reporting and recordkeeping requirements for the automotive sector. In other words, if a company meets the relevant standards in one Party, it should be deemed to meet the standards in the other, allowing its products to be sold in both markets and establishing it as compliant.

***The TTIP should utilize existing structures for global harmonization of future regulations***

The automotive industry is highly globalized, with production and supply chains reaching across the globe and sales in virtually every market. To ensure the continuing competitiveness and compatibility of U.S. and European producers, it is essential that future regulations be channeled through global bodies such as the United Nations' Working Party 29 (WP.29). Given the complexities of the global supply chain and marketplaces, the need for global technical regulations, rather than national or regional ones, is likely to continue growing.

Global Automakers believes the TTIP should include a provision requiring the TTIP Parties to notify each other of any significant automotive regulations under consideration and to jointly evaluate whether such regulations should more appropriately be addressed in the global context. Now is a particularly propitious time to embrace such a provision, because the automotive industry is

transitioning to next generation technologies, and future models will increasingly incorporate advanced technologies. The TTIP can help pave the way towards global technical regulations, to the benefit of U.S. and European producers.

***The TTIP rules of origin should allow multiple methodologies for automotive products***

As noted previously, all automotive producers have global supply chains. U.S. manufacturers generally import thousands of products and source them from many countries. While similar with regard to global supply chains, each company has its own sourcing and production patterns and, even within each company, the sourcing mix differs by product line.

Therefore, to maximize the opportunity for U.S.-made motor vehicles and auto parts to benefit from the TTIP, the agreement must establish flexible rules of origin. Specifically, the TTIP rules of origin should allow multiple methodologies for determining qualifying content for automotive products - for example, as is currently allowed under the Dominican Republic-Central American-(CAFTA-DR) and Korea-United States (KORUS) free trade agreements. Under these FTAs, a manufacturer may elect to use one of three methodologies: net cost (which aggregates manufacturing costs), build up (which considers the value of originating merchandise as a percentage of the adjusted value of the product), or build down (in which the value of non-originating components is subtracted from the adjusted value of the product).

These methodologies provide automotive producers with important options, allowing each manufacturer to determine the approach that best fits its systems and procedures. This enhanced flexibility significantly expands opportunities for U.S. producers by recognizing global supply chain complexities and each company's unique operational structure. For these reasons, Global Automakers believes these three methodologies, at a minimum, should be incorporated into the TTIP.

***The TTIP should facilitate mutual recognition of trusted trader status, with attendant benefits***

In the post-9/11 world, supply chain security programs have proliferated. Members of Global Automakers and many other companies dedicate considerable resources to supply chain security and to compliance with the specific programs promulgated by the U.S. and EU (Customs-Trade Partnership Against Terrorism (C-TPAT) and Authorized Economic Operator (AEO) programs, respectively). While the U.S. and the EU currently have a mutual recognition agreement with respect to their supply chain security programs, implementation of that agreement relies on the efforts of the respective customs administrations; the agreement is not self-executing. Therefore, Global Automakers strongly supports the position of the American Association of Exporters and Importers (AAEI) that "companies who invest corporate resources in supply chain security programs are immediately granted 'mutual recognition'

(i.e., are recognized and receive the benefits of ‘trusted trade’ status) by other signatories.”<sup>5</sup> The immediate recognition of trusted trader status, and the concomitant extension of trusted trader benefits, offers an important, tangible facilitation benefit for the many U.S. companies (including Global Automakers’ members) that have demonstrated their strong commitment to supply chain security.

***The TTIP should embrace state-of-the-art customs processes***

Global Automakers believes the TTIP should include customs and facilitation provisions that mirror those in recent U.S. free trade agreements, such as KORUS. In particular, negotiators should ensure the customs chapter:

- Encourages a process of modernization of customs practices throughout the EU.
- Requires automated processes.
- Encourages use of a single window.
- Protects business confidential information.

***The agreement should allow self-certification of TTIP status***

To maximize the benefits of the TTIP, the process for claiming preferential status under the agreement should be as streamlined as possible. In particular, Global Automakers believes the TTIP should allow traders to self-certify that their products meet the agreement’s rules of origin. Self-certified preferential claims should be appropriately documented, and be subject to verification and audit, under provisions similar to those in recent U.S. FTAs such as KORUS and CAFTA-DR.

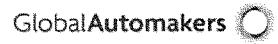
**Conclusion**

Global Automakers believes the policies outlined in this statement would enhance the competitiveness of U.S. and EU based automakers, reduce costs, and increase trade. We also believe a harmonized regulatory structure and reduced tariffs between the economies of the U.S. and EU will benefit consumers on both continents while reinforcing the stringent vehicle emission and safety standards that currently exist and that may be contemplated in the future.

We appreciate the opportunity to bring these views to the attention of the Commerce, Manufacturing, and Trade Subcommittee.

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<sup>5</sup> See March 19, 2013, AAEI letter to Office of Management and Budget regarding the U.S.-EU High Level Regulatory Cooperation Forum – Stakeholder Session.



Respectfully submitted,

A handwritten signature in black ink that reads "Michael J. Stanton".

Michael J. Stanton  
President and CEO

CC: Members of the Subcommittee on Commerce, Manufacturing, and Trade



July 22, 2013

To: The Honorable Lee Terry  
 Chairman, Subcommittee on Commerce, Manufacturing, and Trade  
 2266 Rayburn House Office Building  
 Washington, D.C. 20515

Re: July 24 2013 hearing titled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"

### **Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.**

#### **Introduction**

The Handmade Toy Alliance (HTA) was formed in response to the Consumer Product Safety Improvement Act (CPSIA) passed in August of 2008 by the U.S. Congress. We are an alliance of nearly 800 independent specialty toy stores, small batch toy makers and children's product manufacturers from across the United States and Europe who want to preserve access to unique handmade and small batch toys, clothes, and all manner of children's goods. The HTA seeks to:

- lend a voice to specialty toy stores, small batch toy makers and children's product manufacturers;
- assist in raising awareness of the issues that directly impact HTA members;
- provide HTA members access to their larger scale peers;
- support and promote HTA members.

The U.S. Consumer Product Safety Improvement Act drastically changed the landscape for producing and retailing specialty toys and children's products in the United States. Business is hampered by an arduous journey through a morass of regulations. Plentiful options of unique specialty products for filling store shelves withered away. Similarly, producers of small batch children's products in Europe saw their markets shrink and opportunities for expansion to the U.S. evaporate.

At the same time, there is a growing group of consumers who prefer durable toys that cater to a child's imagination and creative ability. Rather than entertain, small batch specialty toys encourage exploration, stimulate creativity and problem solving, promote playing together with others and allow growing confident at the child's own pace.

Specialty small batch toys reach consumers at several thousand independently owned toy stores all across America and Europe. Generally, the inventory for these stores comes from three sources;

1. toys from the E.U. produced in small quantities by second tier companies,
2. domestically manufactured toys produced in small quantities by second tier companies,
3. and to a lesser extent – toys produced in larger quantities in the US, Europe and the Far East.

The CPSIA has negatively affected two of the three supply sources for specialty retailers. The primary cause of the supply chain disruption for these types of toys is similar but differing safety regulations in the U.S.



### ***Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.***

and the European Union, (E.U.) As a result, many specialty toy stores have been forced to close or alter and rescale their businesses<sup>1</sup>.

Independently owned specialty toy stores are economically viable because they differentiate themselves from mass market retailers selling children's products mass produced in the Far East. Providing unique and distinctive children's products affords them opportunity as well as a reason to exist. Without this distinction there is no practical way to compete with mass market retailers, no business opportunity, and no reason to exist.

The Handmade Toy Alliance (HTA) represents these specialty retail stores and they comprise 25% of our membership. We also represent the domestic small batch producers and those who import and produce European small batch items.

#### **The E.U. Predicament**

Certainly there are small batch toy manufacturers all over the world, but by-and-large, those large enough to consider international markets are concentrated in the European Union. These second tier companies often produce toys by hand within Europe and not in completely automated factories. They employ workers from their communities and are important in their local economies. Typical yearly revenue for a second tier manufacturer ranges from €3 million to €30 million.

The countries that make up the E.U. already have stringent toy regulations in place as does the U.S.

**European Union – EN-71 European Toy Safety Standard and the recent Directive 2009/48/EC.**

**United States – CPSIA and ASTM F963-11 Toy Safety Standard**

These toy safety standards share some commonality, but because the standards are not identical, small batch manufacturers in Europe and the U.S. are forced to perform multiple additional tests in Consumer Product Safety Commission (CPSC) approved labs. The economic burden of additional tests required by the dissimilarities makes it extremely difficult to economically bring these products to market in the U.S. or the E.U. Many small batch toy suppliers from the E.U. have been forced to cease exports to the U.S. or limit the number of products they export<sup>2</sup>. It is not that the products these companies produce are not safe, but that the economics of compliance with two differing safety standards is unaffordable. The CPSIA and EN-71 place a trade barrier between European small batch manufacturers and U.S. specialty retailers and to a lesser extent also between U.S. small batch manufacturers and European specialty retailers.

Typical testing costs for compliance and certification to EN-71, the European Union toy safety standard, range from \$1,000 to \$3,000 per product. The additional costs for third party testing for certification to the CPSIA and ASTM F963 range from \$750 to \$2,500. When manufacturing batch quantities that are typically less than 500, the amortization of these costs results in price increases that cannot be borne by the manufacturer, the importer, nor the consumer. It's an easy to understand equation:

$$\text{Additional cost to manufacture each product} = \text{additional batch testing cost} / \text{batch size}.$$

Large multinational companies producing toys have found ways to comply with both U.S. and E.U. regulations without significant economic burden through special rulings like firewalled labs and batch sizes that are well past 10,000 units, even into the hundreds of thousands. These companies also have the legal staff and infrastructure to navigate the myriad of regulations that apply. Second tier companies have none of these possibilities available to them.

Yet these small batch toys and these countries have not been the source of unsafe products. The safety record of small batch toys produced in Europe and the U.S. is exemplary. The Consumer Product Safety

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<sup>1</sup> See listings - Partial List of Retail Businesses Altered or Closed Due to CPSIA - in the Appendix

<sup>2</sup> See listings - Partial List of Businesses within E.U. Limiting or Ceasing Export to the USA - in the Appendix

**Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.**



Commission's recall data show no recall activity from small batch manufacturers in these jurisdictions in 2011 and 2012. In the past four years, out of 155 recalls for toys, only 2 have been from the European Union and neither of those from a small batch manufacturer. We must go all the way back to 1999 to find a recall from a small batch manufacturer in the E.U.

It is clear that both U.S. and E.U. toy safety standards work to provide excellent protection for consumers in both regions. The HTA supports a process of mutual recognition of toy safety standards by each jurisdiction to restore free and unencumbered trade of these products.

**The H.R.2715 Attempt at U.S. Recognition of EN-71**

For three years, the Handmade Toy Alliance worked on Capitol Hill for a legislative fix for these unintended consequences caused by the CPSIA. We wrote letters, worked on language, testified before Congress, attended hearings and markups, visited Senators and Representatives, all to have our collective voice heard. There was wide agreement within Congress that relief should be provided for businesses represented by the HTA. This culminated in the passing of H.R.2715 in August of 2011 that has provisions that are a direct outgrowth of our work.

Specifically, attempts at legislative relief for the international small batch supply chain appear in two sections of the Consumer Product Safety Act (CPSA) as amended by H.R.2715.

- First, section 14(d)(3)(A)(v) under REDUCING THIRD PARTY TESTING BURDENS,  
 "... (A) ASSESSMENT.—Not later than 60 days after the date of enactment of this paragraph, the Commission shall seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation. The request for public comment shall include the following:  
 "...  
 "(v) The extent to which evidence of conformity with other national or international governmental standards may provide assurance of conformity to consumer product safety rules, bans, standards, or regulations applicable under this Act.  
 ..."
- and second, 14(d)(4)(A)(iii) under SPECIAL RULES FOR SMALL BATCH MANUFACTURERS.  
 "...(A) SPECIAL CONSIDERATION; EXEMPTION.—  
 "...  
 (iii) CERTIFICATION.—In lieu of or as part of any alternative testing requirements provided under clause (i), the Commission may allow certification of a product to an applicable consumer product safety rule, ban, standard, or regulation, or portion thereof, based on documentation that the product complies with another national or international governmental standard or safety requirement that the Commission determines is the same or more stringent than the consumer product safety rule, ban, standard, or regulation, or portion thereof. Any such certification shall only be allowed to the extent of the equivalency with a consumer product safety rule, ban, standard, or regulation and not to any other part of the consumer product safety rule, ban, standard, or regulation.  
 ..."
- (E) DEFINITIONS.— For purposes of this paragraph—  
 (i) the term 'covered product' means a consumer product manufactured by a small batch manufacturer where no more than 7,500 units of the same product were manufactured in the previous calendar year; and  
 (ii) the term 'small batch manufacturer' means a manufacturer that had no more than \$1,000,000 in total gross revenue from sales of all consumer products in the previous calendar year. The dollar amount contained in this paragraph shall be adjusted annually by the percentage increase in the Consumer Price Index for all urban consumers published by the Department of Labor."

The driving force behind this language was the lobbying effort of the HTA for the restoration of small batch supply across the Atlantic. It was a first attempt at mutual recognition, from the U.S. towards the E.U. toy safety directive.

*Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.*

The CPSC has already requested comments as required under the clause 14(d)(3)(A)(v) REDUCING THIRD PARTY TESTING BURDENS and CPSC staff has prepared a document titled "*Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products*", dated August 29<sup>th</sup>, 2012. This document includes the following language:

*"Staff recommends that the Commission consider creating, maintaining, and recognizing a list of equivalent tests in international standards, conformity to which would be indicative of conformity to the corresponding test in a CPSC-administered children's product safety rule.*

*While no other international standard is identical to a CPSC-administered children's product safety rule, there are many tests within certain other international standards that are the same, or that are more stringent than, their equivalent test within the CPSC-administered children's product safety rule. For example, the toy abuse tests in the European standard EN71, part 1, and the International Standard ISO 8124-1 are the same, or more stringent than, their corresponding tests in ASTM F963-11. Recognizing other international standards, or tests within a standard, as equivalent to a CPSC rule, could allow children's product certifiers to avoid repeating some third party tests for the same product and directly avoid additional testing costs, while assuring compliance to the applicable children's product safety rules. This scheme could be used for certification, material change, and periodic testing purposes. Harmonized or equivalent tests would be required to be conducted by a CPSC-accepted testing laboratory. Thus, a project to consider establishing equivalency between tests in our regulations and comparable international standards must also consider how third party conformity assessment bodies will be accredited to perform tests to such standards.*

*It is possible that an effective implementation of this recommendation could result in a significant reduction in third party testing costs that might be realized by many manufacturers."*

Subsequently, the CPSC Commissioners voted to move forward on this issue, but then chose not to fund the effort during the 2013 budget year. It does show that the staff of the CPSC sees significant cost reduction benefit in recognition or harmonization with the E.U. safety standard. This in turn provides opportunity for restoration of small batch toy commerce across the Atlantic.

The subsection (iii) of SPECIAL RULES FOR SMALL BATCH MANUFACTURERS indicates that the CPSC may accept compliance with an international standard as an alternative test when it is determined to be "the same or more stringent" than what is required by the CPSA. The intent being that if a small batch product is already undergoing third party tests to ensure safety and if those tests prove to be adequate, then that small batch product should be allowed entry to the specialty toy market in the U.S.

This small batch rule includes the definition of the size of the manufacturer as one that has revenue of less than \$1 million yearly and produces no more than 7,500 units of the same product in the period of one year. The definition serves to limit the size of a company that can benefit from the small batch rule. Unfortunately the definition excludes second tier small batch manufacturers within the U.S. and those in the E.U. through the revenue cap. This definition of a small batch manufacturer actually only encompasses the smallest of businesses and home-based crafters rather than the manufacturer that actually produces product in small batches.

The CPSC has also interpreted the law so that in cases where a combination of a foreign manufacturer and a domestic importer bring product to the U.S. that the rule applies to both. This interpretation renders any hope that legislative relief might be applicable for a small importer useless as a means for breaking the small batch children's product trade barrier between the U.S. and E.U. For instance, it was previously common for a small importer to bring products from a few European second tier manufacturers to the U.S. and to distribute those products to specialty retail.

***Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.***



**The Birthing of H.R.2715**

It is instructive to see the progression of the language chosen to provide relief for European and U.S. small batch producers on the legislative side. The working bill preceding H.R.2715 was H.R.1939, also known as ECADA. That bill included no language referencing international toy standards. Full markup of that bill was cancelled the morning of June 2<sup>nd</sup>, 2011, but Congressman Pitts was prepared, with bipartisan support, to offer an amendment to H.R.1939 that allowed for the use of an international toy safety standard for compliance. It included language that read "substantially equivalent or more stringent."<sup>3</sup> This amendment never had opportunity to be offered.

Then on August 1<sup>st</sup>, 2011, the confluence of three forces caused movement of a different CPSIA fix – H.R.2715.

1. The retroactive 100 ppm lead limit approved by the CPSC two weeks earlier,
2. The need to increase the U.S. debt ceiling to avoid a default a day later,
3. and Congress' desire to start August recess.

H.R.2715 was created, passed through the House under suspension of rules and then through the Senate by unanimous consent because the collision of these circumstances created a necessity to move quickly without the usual due process. So it is even remarkable that the Pitts amendment, which was never offered, was split into two and included in H.R.2715 as detailed above. This indicates congress does have a desire to remove the trade barrier.

Unfortunately, the degree of equivalency for toy safety standards was tightened to be "same" rather than "substantially equivalent." It is one step short of recognition of E.U. toy safety standards.

**Routes for Relief**

We are left to sort out the details and what possibilities are available for relief from this predicament.

Under current legislation, this boils down to the following possibilities:

1. Have the CPSC recognize European Union toy safety standards as an adequate alternate test for certification of product – as a "reasonable method" for a small batch manufacturer – and increase the financial cap for definition of a small batch manufacturer to a level that allows actual second tier small batch product to navigate the trade barrier.

This requires legislative action to change the revenue cap for the definition of a small batch manufacturer to include 2<sup>nd</sup> tier manufacturers in Europe. Alternatively, a method for allowing a U.S. based importer to be subject to the revenue cap once for each foreign company it imports provides a starting point towards a permanent solution.

2. Provide relief through CPSA section 14(d)(3)(A)(v) under REDUCING THIRD PARTY TESTING BURDENS. This is outside the small batch provisions of H.R.2715 and provides a route for relief in a broader context. This includes actively seeking mutual recognition of toy safety standards between the U.S. and the E.U.

The CPSC must be pressured to act on this issue to provide tangible results rather than issuing hollow edicts that go nowhere. The legislation allows for this to occur, but there is presently no willingness within the leadership of the Commission to make the commitment to actually reduce the regulatory burden in this way.

**Conclusion**

Independently owned specialty toy stores help to ensure diversity and enhance consumer choice in the children's product marketplace, both in the U.S and the E.U. Toys sold by these retailers encourage and

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<sup>3</sup> See text of Amendment to be Offered to H.R.1939 in the Appendix

*Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.*



stimulate a child's imagination and provide alternatives to mass produced toys that simply entertain. Since August of 2008 when the CPSIA was signed into law, the number of specialty toy stores in America has been decreasing, and safe small batch products from the E.U. have gradually left the U.S. market.

Requiring these second tier manufacturers who already comply and test to rigorous standards, to do it all over again, and absorb the costs, just to enter the market is a functional trade barrier and causes economic hardship for retailers, importers, and second tier manufacturers and does nothing to improve safety. The end result is: fewer specialty toy shops, less jobs, limited choice for consumers in the U.S., and a shrinking market for small batch producers in the U.S. and the E.U.

To this point, efforts by the U.S. Congress and the CPSC to solve this problem and remove the trade barrier have been ineffective and half-hearted.

We urge the House Subcommittee on Commerce, Manufacturing, and Trade to consider and work actively for mutual recognition of U.S. and E.U. toy safety standards, the most rigorous and comprehensive toy safety standards in the world.

Respectfully,

Randall Hertzler,  
Vice President of Handmade Toy Alliance Board of Directors – [www.handmadetoyalliance.org](http://www.handmadetoyalliance.org)  
President euroSource LLC – [www.eurosourcellc.com](http://www.eurosourcellc.com)

Jolie Fay – President, Board of Directors  
Erika Hickey – Secretary, Board of Directors  
Mary Newell – Treasurer, Board of Directors  
  
Lynn Persson – Board of Directors  
Adam Frost – Board of Directors  
Stephanie Stewart – Board of Directors



## **Appendix**

### **Partial List of Retail Businesses Altered or Closed Due to CPSIA (Compiled 2009 – 2011)**

A Cooler Planet – Chicago, IL	Mahar Dry Goods – Santa Monica, CA
A Kid's Dream – Conway, AK	Moon Fly Kids – Las Vegas, NV
Attic Toys – Naples, FL	Nova Naturals – Williston, VT
Baby and Beyond – Albany, CA	Obabybaby – Berkley, CA
Baby and Kids Company – Danville, CA	OOP! – Providence, RI
Baby Sprout Naturals – Fair Oaks, CA	Oopsie Dazie – South Jordan, UT
Bellies N Babies – Oakland, CA	Phebe Phillips, Inc. – Dallas, TX
Black Bear Boutique – Portland, OR	Red Rock Toys – Sedona, AZ
Creative Hands – Eugene, OR	Storyblox – New Vienna, OH
Curly Q Cuties – Texas	Sullivan Toy Co. – Jenks, OK
Due Maternity – San Francisco, CA	The Green Goober – Minneapolis, MN
Eleven 11 Kids – Santa Rosa, CA	The Kids Closet - Rochester, IL
Essence of Nonsense – St. Paul, MN	The Learning Tree – Chicago, IL
euroSource LLC – Lancaster, PA	The Lucky Pebble – Kailua, HI
Fish River Crafts – Fort Kent, ME	The Perfect Circle – Bremerton, WA
Gem Valley Toys – Jenks, OK	The Wiggle Room – Slidell, LA
Hailina's Closet – Ellensburg, WA	Toy Magic – Bethlehem, PA
Honeysuckle Dreams – Rockville, MD	Toys From The Heart – Royersford, PA
Kidbean – Asheville, NC	Urban Kids Play – Seattle, WA
Kungfubambini.com – Portland, OR	Waddle and Swaddle – Berkley, CA
LaLaNaturals.com – Bellingham, WA	Whimsical Walney, Inc. – Santa Clara, CA
Lora's Closet – Berkley, CA	Wonderment – Minneapolis, MN
Magical Moon Toys – Logan, UT	Wooden You Know – Maplewood, NJ

### **Partial List of Businesses within EU Limiting or Ceasing Export to the USA due to the CPSIA**

#### **(Compiled 2009 – 2011)**

Bartl GmbH dba Wooden Ideas – German	Joal – Spain
Brio – Sweden	Kathe Kruse – Germany
Castorland – Poland	Kinderkram – Germany
Detox – Czech Republic	Margarete Ostheimer – Germany
Eichorn – Germany	Saling – Germany
Finkbeiner – Germany	Selecta Spielzeug – Germany
Gollnest & Kiesel KG (GOKI) – Germany	Siku – Germany
HABA – Germany	Simba – Germany
Helga Kreft – Germany	Woodland Magic Imports – France
Hess – Germany	

**Amendment to be Offered to H.R.1939**

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 1939  
OFFERED BY MR. PITTS**

Page 15, line 2, strike "testing" and insert "bases or".

Page 16, after line 4, insert the following:

1                "(C) ALTERNATIVE BASES.—The alter-  
2                native bases or procedures for certification for  
3                any product described in subparagraph (A)(iii)  
4                may include evidence that the product conforms  
5                with a standard or safety requirement, includ-  
6                ing an international standard or requirement,  
7                that the Commission determines is substantially  
8                equivalent or more stringent than the applicable  
9                consumer product safety rule.".





### **Supplemental Materials**

European Manufacturer Letters

**Andrea-Kathrin Christenson**, Managing Director, KK Produktions - und Vertriebs GmbH (Käthe Kruse),  
Donauwörth, Germany

**Matthias Menzel**, Managing Director, Selecta Spielzeug AG, Edling, Germany

**Manfred Käfer**, Managing Director, Käfer & Partner GmbH - Glückskäfer Kinderwelt, Reutlingen,  
Germany

**Detlef Schülingkamp**, Sales Manager, Büngern-Technik - fagus Holzspielwaren, Borken, Germany

**Sven Grimm**, Managing Owner, Grimm's GmbH, Hochdorf, Germany



*Käthe Kruse*

KK Produktions - und Vertriebs GmbH  
Alte Augsburgerstr. 9  
86609 Donauwörth  
Deutschland

May 24<sup>th</sup>, 2011

Käthe Kruse - a company founded 100 years ago has been known for making handmade dolls and baby toys around the world. Our Vision is to offer handmade toys to babies and children that are made with the love and care to detail as every mother would love to make them. Tradition in the making means for us to carry safety, trust, lifestyle and values into the future.

Our toys are tested according to the current regulations from the EU – EN 71 respectively. The EU has stringent toy regulations in place and thus already means a significant economic burden for a small company. The additional testing required by the regulations in the USA makes it extremely difficult to economically bring these products produced in small quantities to the market in the USA. This has already resulted in limiting the export of toys to the USA even though the products are safe.

Käthe Kruse toys encourage children's imagination, fantasy and creativity. We put all our love and experience into the elaborate making of our dolls and toys. Käthe Kruse offers over 1000 SKUs, of which many are only produced in small batches as low as 200 pieces.

Käthe Kruse toys is one of the manufacturers providing these kind of toys necessary to the independent specialty retailer. Ever since August 2008 we have seen this group of retailers struggle to find the appropriate toys, as many of the foreign toy makers have been forced to cease exports due to the mentioned reasons.

We therefore suggest accepting the current regulations from the EU, and thus allow companies that make handmade toys in small quantities to export to the USA. It will result in diversity for both consumers and retailers.

In case of any further questions we are happy to support more details.

Sincerely yours,  
Andrea Christenson  
Owner and Managing Director

**Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.**



Selecta Spielzeug AG  
Rommerstraße 1  
83533 Erding

Telefon (0 80 71) 10 06-0  
Telefax (0 80 71) 10 06-40

MenzelM@selecta.ag  
<http://www.selecta-spielzeug.de>

Handmade Toy Alliance

Ihre Zeichen/Ihr Nachtrag von

Unsere Zeichen/Unsere Nachricht von

Durchsetzt

Datum

Vorstand Matthias Menzel

+49 (0) 80 71-10 06-78

25.05.2011

**CPSCIA and possible changes**

Dear Members of the Handmade Toy Alliance,

We really appreciate your efforts to give us as a small manufacturer from Europe a voice in the discussion around CPSCIA.

We were selling our toys, around 200 different items for babys and children between 0 and 5 year for more than 10 years into the US. Each individual item was sold with a total year quantity of around maximum 2.000 units per item (a lot of items with less than 500 units per year) in the US. Our total export volume with specialty toy stores was around 250.000 \$ - since the CPSCIA we stopped our export to the US market.

We are very sorry with the retail stores, who are losing that business, especially because there is no obvious safety issue with our decision involved.

Our toys fulfill the European safety standards, which are sufficient enough to ensure child's safety but they are different in several testing methods and therefore using different maximum allowed levels for example for lead.

As our toys are voluntarily tested from an European accredited laboratory in Germany (there is no law in Europe which forces third party testing) according to the European safety standards, we cannot also effort to spend testing cost for another third party, which is allowed to do CPSCIA.

Also due to our small batch production, which is done in our own plant here in Germany, we cannot track the production date for each single component produced to be used in our toys. So the necessary marking of products with the production date is impossible. We are not a mass market producer, who produces and exports within one container thousands of toys of one production batch.

The cost for testing for us is now around 50.000 Euro for testing according to the EN 71, and we would have to spend another 30.000 Euro for the US-regulation testing – and we cannot afford that. So any change, which allows us to export our products with third party testing according to the European EN71, done by a test lab who is accredited within Europe, and we would be back on your market.

We wish you all the best and success for your way.

Best regards,

Selecta Spielzeug AG

Matthias Menzel  
Vorstand  
Managing Director

Vorstand: Matthias Menzel; Aufsichtsrat: Prof. Dr. Wolfgang Buchholz (Vorsitzender)  
Registergericht: Traunstein HRB 13063

***Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.***

 Glückskäfer

25 May 2011

To whom it may concern:

The heirloom quality toys from Glückskäfer have been carefully designed and manufactured for use by children for generations since its founding over 60 years ago. The toys purchased from Glückskäfer will support a child as it grows through the developmental stages. They are found in classrooms and playrooms throughout the world, many have been awarded the coveted German "Spiel Gut" (Good Toy) award.

Our dedication to the highest quality goes beyond design and manufacturing to safety and the use of the finest materials sourced in Europe and other reliable sources. Our materials and production procedures meet or exceed the European safety and quality standard for baby and child products. All items are VRIF tested and certified.

Because of the special high range character of our toys we produce SKU's in batches of 50 to 1,000 pieces. Such conditions of manufacturing will make any type of third party testing prohibitive and impossible.

Over the past years the demand in the US market for our products has greatly increased. There is a new understanding from the consumers that there are alternatives to mass produced disposable toys just designed to make extended and fast financial profits instead of focusing on giving children maximum value for their healthy holistic development.

If the CPSIA continues unamended the consequences for children will be that these specialized toys with high playing value will disappear from the US market, with all consequences for the individual growth and impacts on the further development of our civilization.

The European Union has also recently tightened their regulations in terms of banned toxins and production line oversight, traceability that easily meets or exceeds the CPSIA standards.

If you have any further questions we would be happy to answer them.

Sincerely yours,

KÄFER & PARTNER GMBH

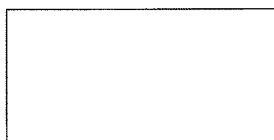
Manfred Käfer 

Käfer & Partner GmbH  
Glückskäfer Spielwaren  
Camillostrasse 10  
D-8053 Regensburg

Glückskäfer Spielwaren  
Camillostrasse 10  
D-8053 Regensburg  
Telefon: +49 911 54714476

***Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.***

Amerikanische Werkstatt für Menschen  
mit Behinderungen gemäß § 142 SGB IX



25.05.2011



SPIELZEUG AUS HOLZ · WOODEN TOYS · JOUETS EN BOIS

fagus has produced the highest quality of wooden trucks and cars by hand for 30 years. The company is founded on basis that only the highest quality of materials, workmanship and quality control are to be used in making children's toys: we believe passionately that children should play with the best!

Our wood is certified German forested wood, all of our parts are independently certified and all vehicles for the past 20 years have been tested to EU EN71 by the independent Testing Company TÜV Nord. Since this is not a certified CPSC testing facility (of which they are only very few in Germany) we would have to undertake a retesting to CPSIA standards which would be completely impossibly financially for us and would make it impossible to serve the US Market. We produce 57 SKU's in batches of less than 1000 per piece

We have over the past years found a demand in the US market for our toys, as parents turn from mass produced to handmade and high quality. They have confidence in the high standards demanded by law in Europe and the natural materials used to build our trucks and cars.

We urge you to consider the EN71 as an alternate and complementary standard. This will ensure that consumers continue to have access to a wide variety of special toys and not just those of the mass produced variety.

Warmest regards

**Büngern Technik**

Mr. Detlef Schülingkamp  
Sales manager



 **Träger:** Charité-Borchardt e.V.  
Poststraße 44–46 · 46399 Bocholt · Tel.: 02871/25139  
Fax: 02871/251323 · info@charita-bocholt.de · www.charita-bocholt.de  
Vereinregister: VR 2226 · Amtsgericht: Coesfeld

*Regulatory Trade Barriers for Small Businesses in the U.S. and the E.U.*

To whom it may concern

2<sup>nd</sup> of May, 2011

**CPSIA requirement for small batch manufacturer**

Dear Sirs,

Grimm's is a small wooden toy manufacturer based in Germany. All our products are manufactured in Germany in small batches. We have 500 different SKUs and each one of them does not exceed 5,000 pieces manufactured and sold per annum.

All products are tested to EN 71 and our quality is constantly controlled throughout production to make sure, we do fulfil those requirements not only during certification, but throughout whole product life cycle.

It takes an enormous amount of time and money to comply with the European EN 71 regulation.

The CPSIA standards are a lot like the EN 71 requirements, which we already do fulfil. All the components we use are tested and certified to EN 71 and CPSIA standards.

But even though they, we are asked to test all our products again to CPSIA standards.

For a small wooden toy manufacturer like us, it is very hard to spend time and money for this double effort.

I am afraid, that if the CPSIA requirements stay as they are right now and if there will be no relief or simplification for small batch manufacturers like us, we need to consider whether we can still afford to sell our products in the US.

This really would be a shame and I am convinced that hundred and thousand US fans of our products would be totally disappointed and they would loose a source for good, creative toys made from sustainable resources.

Actually the CPSIA requirements, as they are today, do exactly the opposite of what the original intend was. They drive the small businesses, which always were able to control quality, because everything was local, out of business. Where on the other hand, bigger companies, who started those quality issues by importing from poor quality manufacturers in Asia, they can afford to have all this expensive testing done and they stay in business.

I ask everyone involved in this, for the future of good and valuable toys for American children, to reconsider and change the CPSIA requirements for smaller businesses.

Sincerely,

Grimm's GmbH  
Spiel und Holz Design  
[www.grimms.eu](http://www.grimms.eu)

Ostring 1  
73269 Hochdorf  
Germany

Phone: +49-7153-61034-0  
Fax: +49-7153-61034-10  
[info@grimms.eu](mailto:info@grimms.eu)

Handelsregister Stuttgart, HRB 720693  
Managing owner: Sven Grimm  
UStID No. DE 146428416



July 23, 2013

**Hon. Lee Terry (R-NE-02)**  
**Chairman**  
**Commerce, Manufacturing & Trade**  
**Subcommittee**

**Hon. Jan Schakowsky (D-IL-09)**  
**Ranking Member**  
**Commerce, Manufacturing & Trade**  
**Subcommittee**

**Re: Tomorrow's hearing on EU-US Free Trade Agreement**

Dear Chairman Terry and Ranking Member Schakowsky,

On behalf of the Marketing Research Association (MRA), I write in hopes that you will take the opportunity of your Subcommittee hearing on July 24 regarding the Transatlantic Trade and Investment Partnership (TTIP) to consider the issues of data privacy and cross-border data trade between the US and European Union (EU). This is urgent given reports that European officials, including European Commission Vice President Viviane Reding, have threatened the standing of the US-EU Safe Harbor.<sup>1</sup>

MRA, a non-profit national membership association, represents the survey, opinion and marketing research profession<sup>2</sup> and strives to improve research participation and quality. We are keenly focused on data privacy, since personal data is essential to the research process and our ability to deliver insights to our clients.

The 1998 European Commission's Directive on Data Protection ("Data Directive") prohibits the transfer of "personal data" to non-EU nations that do not meet the European "adequacy" standard for privacy protection. The EU Data Directive places significant restrictions on the collection, use and disclosure of personal data that prove taxing for many researchers. Despite some complaints that the US, unlike the EU, lacks an organized and comprehensive federal privacy law, EU privacy law is not perfectly organized either, fragmented across its member states, with each implementing the Data Directive differently.

Intentionally or not, the EU wields the Data Directive and its "adequacy" standard as an anti-competitive trade measure, discriminating against US companies in digital trade because they do not deem the US to have "adequate" data privacy protections. Fortunately, in addition to adopting binding corporate rules, US companies can self-certify to the US Department of Commerce that they comply with the seven principles of the US-EU Safe Harbor<sup>3</sup> and at least have some mechanism for data

<sup>1</sup> "EU questions decade-old US data agreement." By Nikolaj Nielsen. EUObserver.com, July 22, 2013. <http://euobserver.com/justice/120919>

<sup>2</sup> The research profession is a multi-billion dollar worldwide industry, comprised of pollsters and government, public opinion, academic and goods and services researchers, whose members range from large multinational corporations and small businesses to academic institutes, non-profit organizations and government agencies.

<sup>3</sup> Notice, Choice, Onward Transfer (to Third Parties), Access, Security, Data Integrity and Enforcement. <http://export.gov/safeharbor/eu/index.asp>

transfer. While it is a self-certification, the Federal Trade Commission (FTC) enforces compliance with the Safe Harbor under its Section 5 authority to prosecute deceptive practices (not living up to one's public claims).

As the EU tries to rewrite their Data Directive, it is essential that we maintain the Safe Harbor – our primary protection for the conduct of digital commerce and research.

Of course, defending our interests is good, but advancing our interests is better. Comprehensive data privacy proposals have been advanced for the last few years by the FTC, the White House, and Members of Congress. All of them hope to better emulate the EU privacy regime in hopes that the US will be deemed “adequate” in its privacy protections by the EU.

While MRA supports some form of baseline consumer data privacy law, the expansive measures envisioned by some parties go far beyond the baseline – with questionable promise of success. “Harmonization” of US law to an EU standard may not make the most sense economically. As outlined by several large technology companies’ chief privacy officers at an Internet Association panel discussion on March 5, innovative data businesses generally develop and grow in the US, not in Europe, and our approach to data privacy may be a key factor in our competitive advantage.<sup>4</sup>

More importantly, over the course of many public and private engagements in the last year, Members of the European Parliament and European Commission have indicated that none of the comprehensive proposals offered so far in the US would, if enacted, win the US the coveted “adequacy” designation by the EU. It is possible that nothing short of a complete substitution of EU law for US law would satisfy EU authorities.

MRA asks that you consider the importance of “harmonization” of the US and EU privacy regimes as a part of this hearing, but not in the traditional way that the term is used. There may be great value to both sides of the Atlantic in bringing our privacy approaches closer together. However, the concept of harmonization should focus more on modeling EU law after the strong enforcement mechanisms and self-regulation of the US.

We look forward to the Subcommittee’s hearing tomorrow and hope you will address the importance of maintaining the US-EU Safe Harbor and the potential for harmonizing EU data privacy law to a more entrepreneurial approach.

Sincerely,

Howard Fienberg, PLC  
Director of Government Affairs  
Marketing Research Association (MRA)

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<sup>4</sup>“Corporate privacy officers discuss global compliance, trans-Atlantic competition, a comprehensive privacy law, and the US-EU Safe Harbor.” March 7, 2013.  
<http://www.marketingresearch.org/news/2013/03/07/corporate-privacy-officers-discuss-global-compliance-trans-atlantic-competition-a-co>



July 24, 2013

The Honorable Lee Terry  
 Chairman, Energy and Commerce Committee  
 Subcommittee on Commerce, Manufacturing and Trade  
 US House of Representatives  
 2125 Rayburn House Office Building  
 Washington, DC 20515

The Honorable Jan Schakowsky  
 Ranking Member, Energy and Commerce Committee  
 Subcommittee on Commerce, Manufacturing and Trade  
 US House of Representatives  
 2125 Rayburn House Office Building  
 Washington, DC 20515

Dear Chairman Terry and Ranking Member Schakowsky,

The Society of Chemical Manufacturers and Affiliates (SOCMA) respectfully submits this letter for the record regarding the hearing on the US-EU Free Trade Agreement: Tipping Over the Regulatory Barriers. We appreciate the Subcommittee hosting a hearing on this issue, which is of great interest and importance to our membership.

SOCMA supports a comprehensive Transatlantic Trade and Investment Partnership (TTIP) with the European Union. The transatlantic economic relationship is already the world's largest, accounting for one third of total goods and services trade and nearly half of global economic output. Transatlantic trade and investment currently supports 13 million jobs on both sides of the Atlantic. Europe is the top export market for US chemical manufacturers, comprising 20.2% of exports valued at \$53 billion in 2012. In 2011 \$600 million was paid in tariffs; eliminating tariffs alone would have a significant impact.

With such large trade flows between these economies, eliminating tariff and non-tariff barriers would benefit both economies and SOCMA's members. Through greater cooperation we hope to see efficiencies for business and government regulators and a reduction in the cost of doing business at a time when resources are scarce in public and private sectors.

Today the US and EU take divergent approaches to regulating chemicals. As a result, unfortunate trade barriers have been created and disadvantaged US chemical



manufacturers, especially small and mid-sized US companies. However, there are opportunities for greater regulatory cooperation in the future.

SOCMA fundamentally supports approaches to regulating chemicals that are based on sound science and risk. Such approaches factor the hazard, or intrinsic characteristics, of a chemical with the potential for exposure. In contrast, approaches based more on the precautionary principle would be detrimental to our industry and not achieve the shared goals of the US and EU on facilitating trans-Atlantic trade and enhancing protection of human health and the environment.

Additionally, regulations should not be disproportionately burdensome to small US manufacturers. The impact of trade barriers like REACH is not limited to US manufacturers; it also affects the accessibility of chemicals and innovative products in the EU market.

SOCMA supports the basic goal of regulatory compatibility between the US and EU with the understanding that there may be areas where this is more appropriate than others. The following recommendations outline opportunities for greater regulatory cooperation:

#### **Data Sharing between US and EU agencies**

- Permissible use of data that has been generated for regulatory purposes and information sharing, provided that confidential business information (CBI) is adequately protected. The US Environmental Protection Agency (EPA) and the European Chemicals Agency (ECHA) should establish a formal data sharing agreement, given the breadth of information being submitted under REACH and likewise for the US to share domestically conducted work.
- However, it should not hold up the development of an efficient mechanism for sharing non-CBI data. Also, data could be shared in an aggregated manner to improve modeling accuracy (i.e. hazard, risk), reduce testing costs, and improve regulatory outcomes. Model development based upon improved data must be more transparent and involve user input. This will ultimately lead to reduced administrative and testing efforts.

#### **Increased transparency in the evaluation process**

- Increased transparency of chemical information and evaluation processes with the understanding that protection of CBI is critical to promoting innovation and the vitality of our members' businesses. Since the EPA and European Chemicals Agency (ECHA) do not have comparable practices, this is an area that will need to be further explored.



- Companies should also have access to regulators to ask questions and aid in their compliance efforts.
- Currently our members have seen their chemicals nominated for inclusion on SVHC lists based on old and erroneous data, which has resulted in the filing of law suits. Ideally, there would be a way to appeal to the agency prior to this escalation so that the SVHC listing can be reevaluated based on current data. A more formal mechanism to submit updated data to allow agencies to make regulatory decisions on the best available science might be a solution, in addition to a mechanism to appeal when agencies do not.
- Globally Harmonized System of Classification and Labeling of Chemicals (GHS) classifications set in sound science.

**Continued regulatory dialogue with goal to minimize differences between systems**

- EPA, ECHA, and any other appropriate agencies should have a regular dialogue to be aware of each other's rules, minimize differences when possible, and harmonize regulations on emerging issues and new regulations in areas where relevant.
- Where relevant agencies should seek mutual recognition of standards.
- Additionally, the US and EU should seek to align different approaches to change management of active pharmaceutical ingredient (API) manufacture & control, agreeing on annual reportable changes as a first step.
- Additionally, any future coordination on regulations should be transparent and allow for input from US and EU stakeholders.

**Streamlined work between agencies**

- Work can be streamlined by prioritizing chemicals in commerce in a rigorous risk-based and transparent fashion, reducing or eliminating duplicative standards and protocols by using uniform definitions and guidelines, such as OECD definitions and test guidelines, and ISO standards, and consideration of work, where it exists, in international organizations like APEC or the OECD.
- Agencies can share cost-benefit-risk assessment methods.
- For finished drug products and active pharmaceutical ingredients (APIs), the US and EU could sign a mutual recognition agreement on inspections. This would eliminate duplicate inspections of the same site using the same standard and be an immediate saving in inspection resources in EU and US. Importantly, this would permit redeployment of saved resources to inspect sites in 3<sup>rd</sup> countries. Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) is also an option.
- The US and EU could also recognize the equivalence of their GMP standards for APIs. The process has already begun; ideally Step 1 will be complete by July 2013.



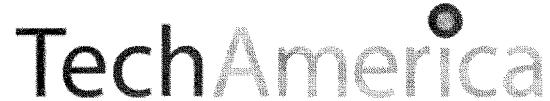
- 
- SOCMA supports harmonization of the Pharmacopoeia. This would eliminate unnecessary, costly, multiple testing of raw materials & products. EU-US harmonised monographs will revitalise the goal of a global standard for all pharmacopoeia

We look forward to working with you and other members of the House, as well as the other stakeholders towards a successful conclusion of this agreement.

Kind regards,

A handwritten signature in black ink, appearing to read "WE Allmond".

William E. Allmond, IV  
Vice President, Government and Public Relations  
Society of Chemical Manufacturers and Affiliates (SOCMA)



Prepared Statement  
for the Record of

TechAmerica

Before the

**U.S. House of Representatives Energy & Commerce Committee  
Subcommittee on Commerce, Manufacturing & Trade**

Hearing on

**The U.S. – EU Free Trade Agreement: Tipping Over the Regulatory Barriers**

Wednesday, July 24, 2013  
2123 Rayburn House Office Building  
9:45 AM EST

For Questions or Further Information:  
Shawn Osborne  
President & Chief Executive Officer  
TechAmerica  
[shawn.k.osborne@techamerica.org](mailto:shawn.k.osborne@techamerica.org)

TechAmerica Statement Before  
 The U.S. House Committee on Energy & Commerce  
 July 24, 2013  
**2 | Page**

Chairman Terry, Ranking Member Schakowsky and distinguished Members of the Subcommittee, thank you for convening this important hearing and for the opportunity to provide a statement on the Transatlantic Trade and Investment Partnership (TTIP).

TechAmerica represents over 550 premiere global technology companies of all sizes – headquartered both in the U.S. and European Union (EU) – that are engaged in a wide spectrum of the information and communications technology (ICT) sector. TechAmerica and its member companies strongly welcome the launch of the TTIP negotiations and share the goal of concluding a high-standard agreement which could produce up to 1 million new American and European jobs and increase U.S. exports by 8%.

The technology industry directly supports 5.95 million jobs in the U.S. and over 2.4 million jobs in the EU. According to the National Science Foundation, between 1998 and 2010 total export volume for high-tech goods between the U.S. and the EU increased by 5-7% annually, and according to the U.S. Trade Representative (USTR), in 2012, the U.S. exported over \$31 billion in computer and electronic goods to the EU. Among the top five exporters of computer and electronic goods to the EU were California (\$6.9 bn), Texas (\$4.5 bn), Massachusetts (\$1.7 bn), New York (\$1.7 bn) and Illinois (\$1.3 bn), respectively. Considering the already robust economic relationship the two allies have, we believe that there is even more potential to achieve economic growth through the TTIP negotiations. For example, the TTIP could increase GDP for both the EU & U.S. by 3%, and potentially increase global GDP by almost \$128 billion.

We believe that the opportunities provided by these negotiations have the potential to not only shape the trading relationship between the U.S. and the EU, but also establish a 21st century model for future trade agreements. Therefore, negotiations should be pursued in ways that encourage innovation and creativity, reduce regulatory barriers, with the recognition that differing approaches to these issues can achieve compatible outcomes.

My statement today highlights the technology sector's four key priorities (below) to ensure the TTIP becomes a 21<sup>st</sup> century trade agreement that drives innovation in both economies and throughout the world.

#### **TechAmerica's Four Key Priorities**

1. Cross-Border Data Flows
2. Digital Goods and Services
3. Privacy
4. Cybersecurity

##### **1. Cross-Border Data Flows**

We believe the number one priority for the negotiations should be to preserve the ability to allow cross-border data flows between the EU and the U.S., which is a universal issue that impacts every industry that uses the internet to market and sell their services and/or goods through websites, e-mail, social media, mobile devices, cloud services and online money transfer services. In fact, through the utilization of cross-border data flows, cloud computing has increased efficiency and productivity of businesses, and supported

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research and development across the globe. According to a study, U.S. exports of cloud computing services in 2010 were estimated to be worth \$1.5 billion with projections indicating a 600% increase by 2015.

Since 1998, the EU - U.S. Safe Harbor Agreement has successfully bridged the different regulatory approaches the two allies have on privacy matters and the movement of data. However, we think that there is still more work to be done. We believe the TTIP should further promote the ability to transfer data across borders with strong and binding provisions, prohibit server and data localization requirements, and make commitments on the transatlantic transfer of data on a "negative list" basis while establishing an interoperable system with the EU's Binding Corporate Rules and the Asia-Pacific Economic Cooperation's (APEC) Cross-Border Privacy Rules (CBPR) rules. We also recommend the expeditious allocation of all available spectrum using impartial, market-based mechanisms on service-flexible, technology-neutral terms.

The TTIP is an unprecedented opportunity to build on the achievements of 1998 and set the next level example on how governments across the globe can foster cross-border data flows, while promoting free market policies and protecting legitimate privacy and security concerns.

## 2. Digital Goods and Services

The U.S. and the EU are the world's largest exporters of digital goods and services, accounting over 70% of global services trade. Considering the new technologies such as cloud computing, mobile application development and big data analytics, we believe that there are incredible new opportunities to provide new technologies to consumers across the globe, and particularly to small businesses and entrepreneurs. For example, small businesses can use internet enabled platforms and services to boost productivity and efficiency, while expanding their reach to new markets around the world. Studies have also shown that businesses that use the internet grow faster than companies that are not online.

As new technologies rely more on cloud resources, new opportunities will surface to build faster and more reliable ICT infrastructure to keep with soaring demand; therefore, supporting hardware suppliers. However, we believe the TTIP must ensure that governments promote consumers' ability to access and distribute information and run applications and services of their choice regardless of their origin. The TTIP should also include non-discriminatory access to respective markets to avoid any requirements that force ICT service providers to use local infrastructure, or establish local presence as a condition of supplying services. Lastly, the allocation of spectrum for commercial purposes should be carried out in an objective, timely, transparent and non-discriminatory manner, with the aim of fostering competition and innovation.

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### 3. Privacy

New analytical solutions are revolutionizing the way we process data, giving us the opportunity to drive greater benefit in the areas of medicine, science, education, healthcare, government and cybersecurity. Unfortunately, divergent legal and regulatory obligations surfacing across the globe could endanger the ability to provide consistent protections to consumers. Therefore, we believe that the mandatory government collection/processing of data and its use should not be conflated with private sector collection of data and should not endanger the promise of the TTIP negotiations. Both parties should also work to preserve the U.S.-EU Safe Harbor Framework and expand the ability to obtain safe harbor protections. Lastly, the TTIP should avoid any specific technology or technological specifications to conduct transatlantic trade.

### 4. Cybersecurity

Just as cross-border data flows, digital goods and services, and privacy, cybersecurity should be viewed through a global lens, considering the cross-border nature of cyber threats and the interdependent nature of cyberspace. To ensure protections from the treats of cyberspace, there must be continued coordination on various cybersecurity policies across the globe to ensure the security of the Global Digital Infrastructure (GDI). Therefore, in order to further cooperation and collaboration with the EU and its 28 member countries, we suggest that the TTIP:

- includes guiding principles and best practices regarding security requirements and their impact on market access issues.
- aims to strengthen public-private partnerships and avoid any EU-or-U.S. specific approaches to cybersecurity that fail to reflect cyberspace's borderless nature.
- leverages market forces to drive greater adoption of security standards and best practices
- leverages existing and strengthen public-private partnerships.
- strengthen interoperability between the U.S. and EU
- focuses on education, awareness and workforce training which are critical to improving cybersecurity posture.
- strengthens coordination within the EU-U.S. Cybersecurity Working Group

Through the negotiations, the U.S. and EU should build upon existing rights and obligations to develop trade disciplines that further foster transatlantic trade in digital information, products and services across sectors. This includes establishing a framework that fosters the sale of digital goods and services and allows for flexibility on cross-border data flows, privacy and continuing cooperative work on cybersecurity matters.

We appreciate the opportunity to provide a statement, and we are readily available to work with the both of you, your colleagues and the Energy & Commerce Committee staff, on these important issues as the TTIP negotiations move forward.



**Toy Industry Association Statement for the Record: "U.S. – EU Free Trade Agreement: Tipping Over the Regulatory Barriers"**

**House Energy and Commerce Committee  
Subcommittee on Commerce, Manufacturing and Trade  
July 23, 2013**

The Toy Industry Association (TIA) is generally supportive of efforts to pursue a comprehensive U.S.-EU transatlantic trade and investment partnership (TTIP). The U.S. and EU already have the world's largest commercial relationship. Increasing trade, investment and cooperation between the two markets will strengthen the relationship between the U.S. and the EU, enhance both economies and create jobs on both sides of the Atlantic. Moreover, a bilateral agreement that reduces trade barriers and fosters greater regulatory coherence would set a strong example for future trade agreements and help cement the U.S. and EU positions as leaders in the global economy.

As background, TIA has a membership of more than 600 businesses – from toy manufacturers, retailers and importers to inventors, designers and testing labs – all involved in creating and bringing safe toys and games to children. Our members account for 85% of the \$22 billion U.S. toy market. The U.S. toy industry supports an estimated 533,177 jobs (FTE) generating \$25.8 billion in wages for U.S. workers, with a total annual economic impact in the U.S. of nearly \$81 billion.

Thank you for the opportunity to submit a statement for the record on TTIP and regulatory cooperation. The regulatory cooperation objectives highlighted in the Final Report of the High Level Working Group on Jobs and Growth could have a significant impact on the U.S. and EU toy industries. Our specific comments on regulatory cooperation are below.

**Regulatory Cooperation**

The toy industry in both the U.S. and EU has espoused the goal of greater regulatory cooperation for a number of years. Our experience, however, has shown that there are very significant political and other barriers to this very worthwhile goal. These challenges notwithstanding, we believe the process of seeking greater regulatory cooperation has the potential to yield positive results for the EU and U.S. economies, which are the largest toy markets in the world.

While toys are regulated differently in the U.S. and EU markets, both regulatory systems provide strong and effective consumer protection. Another way to state this is that toys are safe in both markets, but the regulatory approaches to achieving this end differ between the two markets. Given the differences in regulatory approach, in order to sell in both markets, companies often have to make design and/or manufacturing changes to meet both sets of requirements and must at a minimum perform redundant testing in order to demonstrate compliance to both sets of requirements. These costs to the toy industry add up to an estimated US\$3 billion annually – unnecessary and redundant costs of demonstrating compliance – and costs ultimately shared by consumers – without improving the safety of toys. As a result of our ongoing work to promote greater standards alignment, there already exists significant congruence between many of the over 100 separate tests and design specifications in the ASTM F963 and EN 71 toy safety standards. In fact, we estimate that standards are currently about 80% “aligned.”

Achieving the current level of alignment has taken a tremendous amount of time and effort from all involved. In fact, within the 80% of those standards that are “aligned,” only a small handful (about 10% of the EU and US physical and mechanical standards) are word-for-word identical. The other standards that are “aligned,” though not identical, are fundamentally the same or functionally equivalent. In these situations, companies often still have to test to both standards to demonstrate compliance with ASTM F963 and to secure a presumption of conformity to the TSD by testing the identical parts to EN71.

Significant barriers to further alignment, namely politics and differences in regulatory approach, remain on both sides of the Atlantic. Our experience has also shown that politics and differences in regulatory philosophy are the root causes of differences in toy safety standards. Therefore, approaching regulatory cooperation as strictly a technical alignment effort will result in marginal benefits – especially considering the short time frame set to complete negotiations. While we recognize that addressing the political barriers to alignment will also be challenging, with support and commitment from senior officials and regulators on both sides of the Atlantic, we are optimistic that the TTIP negotiations may result in meaningful progress.<sup>1</sup>

The toy industry is not alone in pursuing and recognizing the benefits of greater regulatory cooperation. The European Commission’s Directorate General for Enterprise

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<sup>1</sup>As an example of politics resulting in a difference in U.S. and EU standards, the Consumer Product Safety Improvement Act (CPSIA) of 2008 set a U.S. *total* lead content standard of 100 parts per million (ppm). However, prior to this, the EU toy safety standard had a 90 parts per million (ppm) soluble lead content standard. While the soluble approach is preferable because it more closely correlates with exposure and risk, there is no evidence that either limit is more protective than the other; in fact, products typically meet both standards, but the misalignment results in additional (and totally unnecessary) testing and compliance costs. This example also highlights the need for political support of greater regulatory cooperation as the U.S. would likely not be able to align nor recognize the EU standard without Congressional assent.

and Industry (DG ENTR) and the U.S. Consumer Product Safety Commission (CPSC) signed a Recognition of Mutual Interest (RMI) Agreement last year with the purpose to, “memorialize DG ENTR’s and the CPSC’s common understanding of the benefits of continuing and enhancing our cooperation on toy safety issues.” The RMI further states, “Both sides are confident that pursuing such initiatives will ensure that the safety of toys sold on the EU and U.S. markets will be further enhanced.” In fact, DG Enterprise and CPSC note that regulatory cooperation in the toy industry can inspire greater regulatory cooperation in other industries like electrical appliances and fireworks.

TIA views regulatory cooperation as two separate exercises: addressing current regulatory divergences and promoting greater alignment for future regulations.

#### General Principles

Any regulatory outcomes in the TTIP must adhere to sound principles of science, risk assessment and cost-benefit analysis. As mentioned above, regulatory differences are often politically motivated and these measures add burden to companies without introducing a significant difference in the level of safety. TIA believes this to be a flawed approach. Decisions should be based on sound science, rather than children’s safety being used for political purposes.

Some decision-makers and EU Member States have recently proposed unscientific restrictions in an effort to be seen by citizens as “stricter” than their counterparts, thereby creating a “solution” that does not necessarily fit the situation. Industry is committed to meeting safety requirements, but such rules must be based on sound scientific evidence and risk assessments.

We regret that this approach has resulted in regulatory divergences where standards were once harmonized. As an example, projectiles requirements had to be changed in EN 71-1 some years ago, following a request from one EU national authority. Similarly, hemispheric toy requirements in EN 71-1 were also changed following requests from EU member states; Neither change had any valid scientific rationale, and as a result standards in both areas are no longer aligned with those in the US or elsewhere. In both of these cases, the changes were motivated by a desire to address problems not demonstrated to actually exist.<sup>2</sup>

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<sup>2</sup> In July 2013, the chemical requirements of the Toy Safety Directive (TSD) go into effect once again moving the U.S. and EU toy safety standards further away from alignment. In 2011, ASTM F963 was updated to bring the U.S. standard’s eight heavy metal limits into alignment with the EU toy safety standard. Unfortunately, the European Commission updated the Toy Safety Directive, effective 2013, making the current heavy metal requirements unnecessarily divergent from the currently aligned limits. The differing limits on the already regulated chemicals do not make the toys safer. CPSC noted in a status report, “Review of Metals in the Toy Safety Standard, ASTM F963” in March, 2012, “that the existing intake limits in ASTM F 963-07 and EN 71-3 are sufficiently protective of children who use toys that conform to the current standard.” Additionally, the TSD added new requirements for 11 additional heavy metals – including metals like aluminum that have been determined safe for use in more sensitive applications such as food contact, like aluminum foil.

Additionally, we caution that the benefits of regulatory cooperation between the U.S. and the EU will be significantly lessened if EU national or sub-national, or U.S. state, local, and/or city governments enact different regulations that address the same risk of harm addressed by EU or U.S. Federal standards.

#### **Addressing Current Regulatory Divergences**

Addressing current regulatory divergences will be significantly more challenging than promoting greater future regulatory cooperation. This is because both sides' standards have been set through long-established procedures and each party has significant investment in their own process. However, since differences in methodology are due largely to political considerations, not technical or scientific ones, these differences do not result in differences in the safety of the regulated toy. As current regulatory divergences do not alter the underlying safety of the product, **when addressing regulatory cooperation between existing standards, it is important to focus on the regulatory outcomes (ensuring toy safety) and not the specific approaches of the regulations themselves.**

Experience has shown that achieving full regulatory alignment will be extremely difficult and may have some drawbacks (as discussed below) that may result in additional costs to businesses without benefiting consumer safety. Therefore, instead we ask that regulators pursue **mutual recognition**. This would mean that each jurisdiction would agree to accept suitable demonstration of conformance to the other's standards as presumptive evidence of an adequate level of safety and acceptability for importation and sale.

Seeking mutual recognition depends on the understanding, acknowledgment and acceptance of the fact that regulators on both sides of the Atlantic set **effective** toy safety standards based on a unified objective (to ensure that toys are safe) and consumers in **both** markets enjoy a high level of regulatory protection. **When one recognizes this, it naturally follows then that toys that are compliant with either the U.S. or the EU toy safety standard are safe – regardless of where the toy is sold.** Therefore, mutual recognition would not result in any reduction in toy safety.

Mutual recognition is ultimately a better and more realistic alternative than full regulatory alignment, at least for toys. Mutual recognition would not undermine either side's regulatory sovereignty nor should it mandate that one adopt the other's regulatory approach. Moreover, regulatory alignment could result in significant costs to businesses especially if regulators decide to simply adopt the most onerous standard regardless of effectiveness, or the risk of hazard. However, the most stringent standard is not necessarily a better or more protective standard, and is not necessarily one based on any underlying science. Frequently, standards that are stricter than their international counterparts are promulgated due to political influence or the (often

unstated) desire to erect technical barriers to trade, and not predicated by science or risk factors.<sup>3</sup>

#### **Establishing a Framework that Promotes Greater Regulatory Cooperation for Future Regulations and Emerging Hazards**

A significant deliverable that the TTIP can produce for EU-U.S. trade is to promote greater regulatory alignment for new standards and emerging issues. We believe this area is the most promising as there are already frameworks that exist that can be used as a basis for future regulatory cooperation between the U.S. and the EU.

As mentioned above, the U.S. and the EU have different processes for setting regulations which have resulted in differences in the regulations themselves. While the goal of regulatory cooperation is to limit these divergences and differences, this agreement does not need to rework current regulatory processes or undermine either the U.S.'s or EU's regulatory sovereignty. A mutual recognition agreement should respect both the U.S. and EU governments' respective standard setting and regulatory powers. Promoting greater alignment for future standards should simply build on past and ongoing alignment efforts by adding a formal, "international regulatory alignment" mandate in addition to domestic priorities of protecting the health safety and welfare of consumers. We envision such a framework as mandating alignment with an existing standard (or recognizing compliance with that standard) in the other counterpart market unless it can be demonstrated by evidence that it is inadequate to address the hazard concerned or is not evidence-based.

To a certain extent, ASTM International already engages in trans-Atlantic and international regulatory alignment. ASTM F15.22 (the Subcommittee on Toy Safety that is responsible for ASTM F963) regularly considers, as part of its standard operating process, opportunities to align with EN-71 and other international standards. The Subcommittee then proposes revisions to ASTM F963 to align the standard with its international counterparts where valid and possible. Additionally, as emerging issues are identified (something at which the ASTM Subcommittee has become particularly adept, given the nimbleness of the ASTM process and the access to CPSC data), the Subcommittee readily shares new standards and supporting information with its counterparts in CEN and ISO.

CEN also engages in international regulatory alignment (though not specific to ASTM F963) through the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement), which creates a framework for regulatory cooperation between ISO

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<sup>3</sup> As an example, U.S. Consumer Product Safety Commission (CPSC) commissioned extensive academic study of anthropometry and strength characteristics of children and these data have been used to set various U.S. standards including the U.S. tension test at 15lbf. In contrast, the EU requirement of 90N (20.2lbf) is an historical artifact, incorporated from a predecessor standard with no valid underlying rationale, and requiring additional testing above that required for the U.S. market.

and CEN. The principles within the Vienna Agreement should be broadened to include other international standards development organizations, such as ASTM International. In addition, other preexisting international regulatory alignment efforts must be subject to the above presumptive mandate.

Whenever a standard setting body begins to consider a new regulation, it is important that its international standard setting counterpart is not only alerted but is continuously updated throughout the process. An ‘open’ standards process should allow active participation and input. Should the standards setting body diverge from a preexisting regulation, it should demonstrate a compelling need for divergence from that requirement, and demonstrate convincingly that the costs of that divergence do not outweigh the manifest benefits of alignment. The standard setting body must also consider whether the divergent regulation achieves the same regulatory outcome as the preexisting standard. If both standards adequately protect human health and safety, then the respective regulatory bodies should grant “mutual recognition” of regulations.

Finally, in order to implement, promote and enforce regulatory cooperation, an agreement should create a committee consisting of stakeholders from standard setting bodies on both sides of the Atlantic to mediate any disagreements. Enforcement of a regulatory cooperation agreement will be an important element as an agreement will not be useful if these bodies do not observe their obligation to follow its international alignment mandate.

### **Conclusion**

Toy Industry Association is supportive of overall efforts to facilitate trade between the United States and the European Union. Mutual recognition could address most of the divergences in regulations that unnecessarily burden companies who sell to both markets while reinforcing consumer confidence that toys compliant with either standard can be trusted as safe for children. Moreover, establishing a strong regulatory cooperation agreement will assure a joint U.S.-EU leadership role in international regulations, provide a basis for future trade agreements and help provide a benchmark for third country standards development efforts.

**Some economic facts on the toy markets in the EU and the US:**

EU	US
<ul style="list-style-type: none"> <li>■ Significant differences in average price of toys in each country</li> <li>■ Estimated 1.4 billion units sold each year (2009)</li> <li>■ 73% of sales in France, Germany, Italy, Spain and UK (2010)</li> <li>■ US\$21 billion in toy sales (2012)</li> <li>■ EU Toy Industry provides 220,000 EU jobs</li> <li>■ 25% of the global toy market (2010)</li> <li>■ 5000 companies (2012)</li> <li>■ 99% of producers are SMEs (2012)</li> </ul>	<ul style="list-style-type: none"> <li>■ Average price of a toy is under US\$8.00</li> <li>■ Estimated 3 billion units sold each year (2012)</li> <li>■ US\$22 billion in toy sales (2011)</li> <li>■ US Toy Industry provides 500,000+ US jobs</li> <li>■ Total annual economic impact of US\$81 billion</li> <li>■ 27% of the global toy market (2011)</li> <li>■ 80%+ of producers are SMEs (2011)</li> </ul>

**Leading regulatory agencies in charge of toy safety:**

EU	US
<ul style="list-style-type: none"> <li>■ European Commission, DG Enterprise, Unit C/1 Internal Market and its International Dimension (lead within the Commission)</li> <li>■ National and regional Governments (implementation, market surveillance) <ul style="list-style-type: none"> <li>• CEN/CENELEC (standards)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ Consumer Product Safety Commission (CPSC)</li> <li>■ Food and Drug Administration (FDA)</li> <li>■ Federal Trade Commission (FTC)</li> <li>■ Customs and Border Protection (CBP)</li> <li>■ ASTM International (standards)</li> </ul>

### Main legislation on toy safety

EU	US
<ul style="list-style-type: none"> <li>Toy safety Directive 2009/48</li> <li>Other relevant legislation includes:           <ul style="list-style-type: none"> <li>General product safety directive 2001/95</li> <li>Regulation 765/2008 on requirements for accreditation and market surveillance</li> <li>Decision 768/2008 on the marketing of products</li> <li>Regulation 1907/2006 REACH (Registration, Evaluation and Authorisation of Chemicals)</li> <li>Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)</li> <li>Directive 2011/65 RoHS (Restriction on the use of certain Hazardous Substances in electric and electronic products)</li> <li>Directive 2012/19 WEEE (Waste Electrical and Electronic Equipment)</li> <li>Regulation 1223/2009 on Cosmetics</li> <li>Directive 2008/98 on waste</li> <li>Directive 94/62 on packaging and packaging waste</li> <li>Directive 87/357 concerning products which, appearing to be other than they are, endanger the health or safety of consumers</li> <li>Regulation 1935/2004 on materials and articles intended to come into contact with food</li> <li>Regulation 10/2011 on Food contact plastic materials and articles</li> <li>Directive 1999/5 Radio- and tele-terminal equipment (R&amp;TTE)</li> <li>Directive 2004/108 Electromagnetic Compatibility (EMC)</li> <li>Directive 2006/66 Batteries</li> <li>Directive 2006/95 Low voltage</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Consumer Product Safety Improvement Act</li> <li>Federal Hazardous Substances Act</li> <li>Flammable Fabrics Act</li> <li>Child Safety Protection Act</li> <li>Consumer Product Safety Act</li> <li>Food, Drug and Cosmetic Act</li> <li>Fair Packaging and Labeling Act</li> <li>Country of Origin Marking</li> </ul> <p>Various State Requirements (Stuffed toy labeling, California Proposition 65, Illinois LPPA, Washington CSPA, Maine KSPA, etc.)</p>

Plus a number of national restrictions applying only in some Member States.	
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### Standards on toy safety

EU	US
<ul style="list-style-type: none"> <li>■ EN71-1 Mechanical and physical properties</li> <li>■ EN71-2 Flammability</li> <li>■ EN71-3 Migration of certain elements</li> <li>■ EN71-4 Chemical experimental sets</li> <li>■ EN71-5 Chemical toys</li> <li>■ EN71-7 Finger paints</li> <li>■ EN71-8 Activity toys</li> <li>■ EN71-9 to 11 Organic chemical compounds</li> <li>■ EN71-12 N-Nitrosamines and N-Nitrosatable substances*</li> <li>■ EN71-13 Olfactory board games, cosmetic kits and gustative games*</li> <li>■ EN71-14 Trampolines*</li> <li>■ EN62115 Electric toys</li> </ul> <p style="text-align: center;"><small>* under development</small></p>	<ul style="list-style-type: none"> <li>■ ASTM F963 series under ASTM International</li> </ul>

**A concrete example**

Below is an example of the rules with which a simple plastic toy is required to comply for both EU and US markets. All these requirements aim to ensure children's safety. However, due to legislative differences, however, these requirements oblige industry to carry out duplicative tests in order to comply with safety requirements which convey the same goal.

EU	US
 <ul style="list-style-type: none"> <li>EN71-1 Mechanical and Physical Properties</li> <li>EN71-2 Flammability Requirements</li> <li>EN71-3 Migration of Certain Elements</li> <li>Total Cadmium Content, REACH Annex XVII</li> <li>Total Phthalate Content, REACH Annex XVII</li> <li>Total Benzene Content, REACH Annex XVII</li> </ul>	<ul style="list-style-type: none"> <li>ASTM F963 / 16 CFR 1500 Physical and Mechanical Requirements</li> <li>16 CFR 1500 Flammability Requirements</li> <li>ASTM F963 Soluble Migrated Elements Requirements</li> <li>Total Lead Content, Consumer Product Safety Improvement Act of 2008</li> <li>Total Phthalate Content, Consumer Product Safety Improvement Act of 2008</li> </ul>



James C. Greenwood  
President & CEO

**Committee on Energy & Commerce Subcommittee on Commerce, Manufacturing, and Trade Hearing "The U.S. - E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"**

**July 24, 2013**

**Comments Submitted by:**

**Biotechnology Industry Organization (BIO)**

**Introduction**

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit its perspective on non-tariff measures affecting the industry that should be addressed in the negotiation of a Transatlantic Trade and Investment Partnership (TTIP) agreement. BIO applauds the U.S. and EU governments for their courage and ambition in launching an initiative that holds tremendous promise for the long-term competitiveness of the Transatlantic economy, and which can contribute specifically to shared U.S. and EU leadership with regard to innovative technologies.

BIO represents more than 1,100 companies, academic centers and research institutions involved in the research and development of innovative biotechnology products and services. Our members are primarily small- and medium-sized enterprises working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment. Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of hundreds of thousands of jobs in the United States and Europe, and millions more through indirect employment.

To fully appreciate the biotechnology perspective on TTIP, it is necessary to understand the nature of the biotechnology enterprise and the elements that enable biotechnology innovation. Biotechnology research and development is capital intensive. It is generally acknowledged that it takes more than a decade and costs on average \$1.2 billion to bring a biotechnology therapy to market<sup>1</sup>. The history of the industry is replete with anecdotes of

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<sup>1</sup> Grabowski, Henry. "Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition" *Nature* 7 June 2008 Pg. 482



meticulous, lengthy and expensive experiments that have failed. It is estimated that only one in 10,000 experimental compounds make it to market as successful medicines<sup>2</sup>.

Yet because of its tremendous potential, the U.S. and most major European economies have invested significant capital resources in this industry. As such, U.S.- and EU-based innovators boast a tremendous number of scientific discoveries, many of which have the potential to yield the next cure for cancer, Alzheimer's, diabetes or other diseases. A concerted effort through the TTIP to unleash the potential of biotechnology in the Transatlantic economy and beyond will go a long way to bringing innovative products to consumers, create jobs, and improve economic prospects on both sides of the Atlantic.

The TTIP represents an important opportunity to advance progress in these areas. BIO has submitted detailed public comments to the U.S. Trade Representative, outlining its chief objectives for the agreement. Aside from the vital area of intellectual property rights, these objectives all fall broadly within the category of non-tariff barriers to trade, and fall into three categories: 1) regulatory issues connected to the approval of new medicines; 2) transparency and accountability of governmental systems to reimburse and price medicines, and 3) the regulatory process for agricultural biotechnology products.

#### *I) The Regulatory Process for Approval of New Medicines*

##### *General Perspective*

The prospect of significantly deeper regulatory cooperation and convergence related to bio-pharmaceuticals represents one of the most promising aspects of the TTIP. Such convergence will enhance Transatlantic innovative leadership in a sector that benefits the well-being of people in the U.S., the EU, and around the world. BIO requests that USTR pursue a distinct and targeted set of sectoral outcomes on bio-pharmaceuticals as part of the TTIP negotiations on regulatory convergence and cooperation.

Objectives with especially promising prospects for advancing innovation include:

- **Mutual Recognition of Inspection Findings:** The FDA and EMA have pursued pilot programs on coordination of inspections to assess compliance with Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). The agencies have a confidentiality agreement governing this cooperation. Based on this progress, TTIP should aim to produce agreement for mutual recognition of FDA and EMA GMP and GCP inspections. Under such an arrangement, regulatory authorities could

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<sup>2</sup> Ernst & Young report, Beyond Borders 2009f



also work to identify systematically high-risk sites and to coordinate inspection schedules.

- **Parallel Scientific Advice Mechanisms:** TTIP should aim to build on an existing FDA and EMA program to provide parallel scientific advice in order to remove remaining limitations on use of this program. Specifically, the EMA and FDA should amend the current program policy to expand its applicability to all medicines, and grant sponsors the right to receive parallel scientific advice upon request.
- **Parallel Evaluation on Quality by Design (QbD) Applications:** TTIP should aim to achieve formal adoption of current “pilot” efforts between FDA and EMA to conduct parallel assessment of QbD applications. This will enable parallel evaluation of relevant development and manufacturing quality components submitted to both agencies.
- **Data Field Requirements for Clinical Trial Disclosure:** FDA and EMA could establish a harmonized list of clinical trial result data fields and agree on which of these data fields may be disclosed to the public.
- **Collaboration in Developing Therapeutic Area Guidelines:** FDA and EMA should establish a procedure for collaboration in developing scientific and other regulatory guidelines for specific therapeutic areas, in order to eliminate unnecessarily divergent requirements that are burdensome for innovators and delay the delivery of new treatments to market.
- **Verification of Falsified Medicines:** A TTIP bio-pharmaceutical work program could develop common national/regional coding systems for purposes of supply chain monitoring in connection with the control of falsified medicines. Work would focus on use of common standards for unique identifiers, developed using non-proprietary, harmonized international standards.

A number of additional components of regulatory cooperation can be built upon ongoing FDA-EMA collaboration under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). These include:

- **Pediatric Medicines:** The FDA and EMA should work within the ICH framework to reduce divergences and achieve greater regulatory convergence in the scope, content, and timing of submission of pediatric investigation plans (PIP), so that companies are required to prepare only a single plan for submission in both territories. Such convergence could promote increased research efficiencies and result in more rapid completion of pediatric trials.
- **Safety Reporting Requirements:** Existing disparities between EU and U.S. safety reporting requirements should be targeted for intensified convergence work within the ICH. Specifically, the agencies should add an ICH “cluster” on pharmacovigilance issues to their existing slate of ICH priorities.



- **Duplicative Testing Requirements:** Existing ICH documents describe considerations for accepting foreign clinical trial data to support approval of the tested medicine in the EU or U.S. In practice, however, regulators from countries other than the U.S. and EU may require unnecessarily onerous bridging studies before a sponsor may gain approval of a medicine based on foreign test results. Additional work within the ICH could be useful in reducing the requirements of these bridging studies. FDA and EMA should also provide harmonized advice on the design of multi-regional clinical trials to support approval in both regions.
- **Benefit-Risk Assessment:** EMA and FDA should develop a harmonized structural framework and methodology for benefit-risk assessment, while retaining authority to make different risk-benefit judgments under their individual approval processes.
- **Submissions Requiring Manufacturing Changes:** EMA and FDA have similar requirements for submissions regarding manufacturing changes, but the details of these requirements can diverge. The agencies should work together to develop a harmonized approach to post-approval variation submissions for manufacturing changes.

Establishment of a “Working Group on Biopharmaceuticals” to oversee implementation of all aspects of regulatory cooperation foreseen under provisions of the TTIP.

*Non-Disclosure of Data – An Issue Requiring Priority Attention*

In addition to the regulatory objectives outlined above, BIO requests USTR to address, as a matter of priority, the need to ensure the non-disclosure of all personal data and other confidential commercial information (CCI) submitted to the EMA in connection with the marketing approval process. BIO is deeply concerned about recent indications by the EMA that it may disclose such information, including patient-level data, if requested by a third party, and its proposal to disclose such information proactively. This is inconsistent with the treatment of such information by the U.S. FDA, which appropriately applies a presumption that new drug applications and, indeed, marketing applications for all regulated products constitute confidential information that are generally not considered available for public release.

**2) Market Access for Bio-Pharmaceuticals**

*General Perspective*

Both the United States and the EU have recognized, in past free trade agreements, the particular challenges confronting market access for pharmaceuticals and medical devices. The product-specific chapters negotiated in respective U.S. and EU FTAs with Korea, for example, address the circumstances surrounding regulatory determinations on pricing and reimbursement of drugs and devices. The FTA chapters sought to surround these



determinations with rules and disciplines that ensure procedural fairness, transparency, non-discrimination, and improved patient access to innovative medical products.

The experience of BIO members in the EU market has reinforced that addressing these issues in the TTIP will be critical to advancing meaningful improvements in market access for our industry's bio-pharmaceutical products. BIO recognizes the significant fiscal challenges faced by all governments, and stands ready to be a productive partner in finding solutions.

A bio-pharmaceutical market access component of the TTIP should address the following major issues. Implementation of these provisions should be overseen on an ongoing basis by a specialized committee or working group.

#### A. General Provisions/Principles

- Recognize the economic and social value of promoting the development of, and facilitating access to, pharmaceutical products and medical devices for U.S. and EU citizens;
- Ensure sound incentives that promote near-term access to pharmaceutical products and medical devices and foster an innovative environment capable of sustaining research and development investment and advancing medical science;
- Recognize that bio-pharmaceuticals have a role in reducing the need for other more costly medical expenditures and improving the lives of patients;
- Respect the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need;
- Recognize the value of ethical interactions between bio-pharmaceutical representatives and health care professionals; and
- Agree that any reimbursement controls/determinations should apply only to products dispensed and reimbursed in that Party.
- Identify specific international organizations/workstreams to foster further cooperation among the Parties to improve patient access to safe and effective medicines.

#### B. Access to Innovation

Beyond the general principles reflected above, the TTIP should reflect a common understanding that innovative medicines should be priced and reimbursed at levels that appropriately reward and recognize their value. The agreement should:

- Provide that during the patent term or term of regulatory exclusivity of a bio-pharmaceutical product, the government price for that product should be based on the value of that product and never be set by reference to prices for generic products. Stipulate that, in the framework of pricing and reimbursement decisions, the parties



should not reassess the elements on which the market authorization for a product is based, which can include the quality, safety, efficacy or bioequivalence of the medicinal product based on specific national regulatory policies.

- Clarify that the negative impacts – to patient access and innovation – of a government entity establishing prices for bio-pharmaceuticals under patents or regulatory exclusivity mechanisms based on prices of the same product in other countries, are significantly exacerbated if the reference countries are dissimilar in terms of their socio-economic level, populations, disease burdens and health care systems. Government prices for patented bio-pharmaceuticals or bio-pharmaceuticals covered by regulatory mechanisms should be prohibited from being set by reference to prices for the same product in countries in economic or political crisis (for example, countries receiving aid from the International Monetary Fund or countries identified by the U.S. State Department as terrorist or unstable states); and
- Provide that a manufacturer should be permitted to apply for an increased amount of reimbursement and/or government price based on evidence of the safety and efficacy of its patented bio-pharmaceutical or bio-pharmaceutical protected by regulatory exclusivity mechanisms.
- Emphasize that a manufacturer should be permitted to apply for reimbursement for additional medical indications based solely on evidence of safety and efficacy.

### C. Transparency

A transparent, timely and predictable pricing and reimbursement process that provides applicants with meaningful due process is essential to ensure patient access to innovative medicines. USTR should pursue the following provisions within the TTIP:

- Clarify that all provisions in a TTIP bio-pharmaceutical chapter apply to laws, regulations, procedures, administrative rulings, and implementing guidelines concerning all aspects of the pricing and reimbursement process, including, but not limited to, health technology assessments or other medical assessments of the clinical effectiveness of a pharmaceutical, demand-side measures and “clawback” mechanisms.
- Clarify that the obligation to address substantive comments in writing and explain any substantive revisions made to proposed regulations should be completed before the proposed regulations are adopted.
- Include an obligation to ensure that all applications are processed within a reasonable, specified period, clarifying EU Member States should be subject to all applicable provisions associated with the timelines mandated in the EU Transparency Directive.
- Include language providing that if an application is inadequate or insufficient, the relevant authority must notify the applicant of what additional information is required to resume the application review process in a timely manner.



- Clarify that the relevant regulatory authority should not request any additional information which is not explicitly required under national legislation or administrative guidelines to complete the decision-making process.
- Detail the requirements for providing an applicant with a pricing and/or reimbursement decision (including a negative decision), including that the decision must specify the basis for the determination, with specific reference to objective and verifiable criteria.
- Require that the final reimbursement notice should advise the applicant of its rights and the relevant timelines for seeking an independent review of the reimbursement decision.
- Require each Party to ensure access for stakeholders with legitimate commercial interests to full information about each Party's pricing and reimbursement systems and processes, including to a positive list of products covered, if any, published at least annually, and a negative list, if any published at least every six months.
- Require that confidential information contained in agreements signed between private sector actors (e.g., bio-pharmaceutical companies) and government entities that were entered into with the explicit understanding that the details included in those agreements will be kept confidential.

**D. Dissemination of Information to Patients and Health Care Professionals**

The TTIP should include language permitting manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites, predicated on such information being truthful, not misleading and balanced.

**E. Other Barriers to Market Access/Patient Access**

Reflecting on the experience of BIO member companies in the EU market for bio-pharmaceutical products, BIO requests USTR to supplement the foregoing provisions, which are largely based on provisions found in previous U.S. and EU trade agreements, with the following provisions intended to address additional, practical impediments to EU market access:

- Requirement to respect the payment terms established by U.S. law/the EU's Late Payments Directive, respectively.
- Requirement that any "clawback" or rebate tax levied in response to an economic crisis should not disproportionately burden pharmaceutical manufacturers temporarily holding an exclusive position (i.e., any tax should be borne by the entire supply chain), and should be subject to a transparent, annual review process that affords those subject to the tax the opportunity to comment on whether it remains necessary



to continue the tax. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

### **3) The Regulatory Process for Agricultural Biotechnology**

Comments in this section build upon previous submissions from both BIO and its partner EuropaBio. We encourage the U.S. and the EU to find a long-term solution to normalize trade in products derived through agricultural biotechnology. BIO believes that this can be accomplished within the existing legal and regulatory framework. Doing so would be to the mutual benefit to consumers, farmers and the economies of the United States and the European Union.

Agricultural biotechnology is an important tool that is being embraced globally to help address challenges such as food and energy security, environmental sustainability, and changing climactic conditions. With that promise in mind, it is critical that the US and EU take full advantage of the TTIP to forge a new trading relationship that can keep pace with the rapid adoption of agricultural biotechnology globally.

Most significantly, the TTIP should result in increased predictability and implementation of existing EU laws and regulations consistent with legislated timelines, and should also seek to incorporate internationally recognized approaches to risk assessment. The TTIP should provide for a mechanism to reduce risk of trade disruption resulting from gaps between the approval in the U.S. and EU. The TTIP should also establish improved dialogue and greater accountability at the ministerial and technical levels to address both existing trade issues, as well as promote cooperation as innovation in agriculture continues to evolve.

The comments which BIO submitted to USTR provide more detail on specific objectives it is seeking with respect to the EU's regulatory process.



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

**May 10, 2013**

**Re: Coalition for Sensible Safeguards' Comment Concerning Proposed Transatlantic Trade and Investment Agreement, Docket No. USTR-2013-0019, posted 04/01/2013**

This comment letter is submitted on behalf of the Coalition for Sensible Safeguards (CSS) in response to the USTR's request for comments on the proposed Transatlantic Trade and Investment Partnership (TTIP) and the High Level Working Group's recommendation to negotiate "non-tariff barriers" and "behind the border obstacles."<sup>i</sup> CSS is an alliance of over 150 consumer, small business, labor, scientific, research, good government, faith, community, health, environmental, and public interest groups, joined in the belief that our country's system of regulatory safeguards provides a stable framework that secures our quality of life and paves the way for a sound economy that benefits us all. As you conduct your negotiations we hope you will consider:

**The High Level Working Group's outline for negotiations call for the elimination of "non-tariff barriers" and "behind the border obstacles" will diminish the ability of the United States to continue to meet legitimate regulatory objectives.** This language shares a familiar deregulatory tone with the Transatlantic Business Council's calls for the elimination of "trade irritants" and "regulatory convergence."<sup>ii</sup> This language is code for sweeping deregulation and binding rules that prevent governments from developing domestic standards and safeguards.

**The framework's guidance to "resolve concerns and reduce burdens arising from existing regulations through equivalence" and reduce costs through harmonization should not result in uniform, one-size-fits-all standards that will strip down current protections serving the interests of American families.** If across-the-board standards are adopted they should not harmonize down to embrace the lowest cost effective standards. They should instead harmonize upward, ensuring broadly shared prosperity across borders that will help us compete on the right things – the emerging, innovative industries of the future that will lead on clean manufacturing, safer chemicals, clean energy solutions and more -- and permit parties to adopt more stringent standards. Regulatory ceilings that buoy corporate influence and

hamstring the US' ability to democratically devise and enforce common-sense domestic safeguards are unacceptable. Additionally, negotiators should reject calls for subjecting regulations to a trade-impact assessment. Regulators are already overburdened with business-impact assessments, and such a requirement would fundamentally distort regulatory policy, requiring regulators to subordinate their mission of protecting the public to commercial trade interests.

**Negotiations with the potential to drastically affect domestic regulatory policy must be transparent and open to the public.** Far too often, corporations enjoy disproportional access to high-level negotiators and their materials. If the negotiators intend to act with the public's best interests at heart, then they ought to quickly provide full public access to the details of the negotiations and suggestions from states and actors. Moreover, ample time should be given for interested public parties to review said materials, so that they may make worthwhile contributions. The single most important transparency imperative is to make negotiating texts available to the public as they are tabled.

In sum, the Coalition for Sensible Safeguards is troubled at the prospects of surrendering regulatory safeguards in the name of trade efficiency. As these negotiations proceed, decisions ought to be brokered in the light of day, and corporate interests should not override the public interest. Effective standards and safeguards provide health, safety and financial security for American families; and are a key component of a strong economy. More than that, standards and safeguards are at the very core of our American way of life and should not be sacrificed.

Sincerely,

Katherine McFate, President and CEO, OMB Watch  
Co-chair, Coalition for Sensible Safeguards

Robert Weissman, President, Public Citizen  
Co-chair, Coalition for Sensible Safeguards

<sup>1</sup> "Final Report," High Level Working Group on Jobs and Growth, Feb. 11, 2013. Available at: [http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc\\_150519.pdf](http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf)

<sup>ii</sup> "The Transatlantic Economic Partnership: Overview and Assessment," Directorate General for Trade of the European Commission, Oct. 2000, at 5. Available at: [http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc\\_111712.pdf](http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111712.pdf)

July 8, 2013

Dear President Barack Obama, President José Manuel Barroso, and President Herman Van Rompuy:

The United States and the European Union are set to begin negotiations of a "trade" and investment agreement, a proposed Transatlantic Trade and Investment Partnership (TTIP), also referred to as a Transatlantic Free Trade Agreement (TAFTA). **We the undersigned organizations from Europe and the United States wish to register our early concern based on the information about the coming negotiations and state our opposition to the use of behind-closed-door trade negotiations to change and lower public interest measures for the sake of commercial interests.**

As both parties have noted, because tariffs in the United States and European Union are already low, the proposed agreement would focus in particular on "regulatory issues and non-tariff trade barriers." We are concerned that the process leading to the launch of TAFTA negotiations has been dominated by transatlantic business interests, which appear intent on undermining the strongest public interest safeguards on either side of the Atlantic with which their products and operations must now conform. Their agenda is to use these negotiations as a means to pursue deregulation efforts that have been unsuccessful to date. Industry representatives, organized since 1995 as the Transatlantic Business Dialogue, recently renamed the Transatlantic Business Council, have pushed for "harmonization" of divergent standards, free passage of goods and authority to operate services under "mutual recognition" terms and elimination of what they call "trade irritants" and we consider some of our most important consumer and environmental safeguards.

A transatlantic agreement that is little more than a vehicle to facilitate deregulation would not only threaten to weaken critical consumer and environmental safeguards, but also conflict with the democratic principle that those living with the results of regulatory standards – residents of our countries – must be able to set those standards through the democratic process, even when doing so results in divergent standards that businesses may find inconvenient.

**Thus, we are highly skeptical that an agreement focused on regulatory "harmonization" will serve consumer interests, workers' rights, the environment, and other areas of public interest.** Rather, it could lead to lower standards and regulatory ceilings instead of floors. A "free trade" deal must not limit the United States or the EU (or its member states) from adopting and enforcing standards that provide higher levels of consumer, worker, and environmental protection.

**We denounce the particularly opaque and exclusive nature of recent trade negotiations and insist that negotiating texts be released to the public.** Given a prospective agreement would impact on a broad array of public interest policies, the process must be open to the public. The U.S. and EU governments must commit to make negotiating texts and country submissions for TAFTA publicly available. Stakeholder groups, including those not granted the preferential access of official trade advisory committees, must be able to review the proposed text if they are to give meaningful input on the critical policy decisions at issue. Consultations with diverse stakeholders should occur early on and throughout the process. The disproportionate consultation with business and industry groups in prior agreements negotiated by the U.S. and EU has resulted in a narrow array of input and outcomes which has benefited industry over communities and the environment.

**In addition, we wish to highlight just some of the consumer, environmental, and worker interests, which we will be watching closely and for which we will be demanding accountability, given the potential scope of the proposed agreement:**

**No Investor-State Dispute Resolution:** A potential agreement between the United States and EU must not include investor-state dispute resolution. Particularly given that U.S. and EU property rights laws and courts are robust, there is no pretext for granting foreign investors superior rights to domestic firms or subjecting our judicial systems to tribunals empowered to raid our Treasuries. The inclusion of such extreme provisions in prior trade and investment deals has enabled powerful interests, from tobacco companies to corporate polluters, to use investor-state dispute resolution to challenge and undermine consumer, public health and environmental protections. Investor-state tribunals have ordered taxpayers to compensate foreign corporations with billions of dollars for the domestic, non-discriminatory enforcement of such protections. To avoid such overreaching procedural and substantive investor privileges, greater than those afforded to domestic firms in either the United States or the EU, any deal must exclude investor-state dispute resolution.

**Safe Food:** Trading partners must be free to establish facially non-discriminatory food safety, nutrition and labeling standards that are stronger than any harmonized norm set in an agreement and that meet the objective of consumer protection and environmental and ethical considerations. Each nation must be allowed to set such standards based on consumer demands and priorities alone, even in the face of scientific uncertainty. Food safety and inspection standards must be established at the highest level to ensure consumer protection, and should include plans for a transatlantic rapid alert notification system and a phase out of the non-therapeutic use of antibiotics in animals.

**Financial Stability:** Any harmonized standards must set a floor of strong financial regulation, based on the most robust U.S. and EU reregulation efforts, to reflect the lessons of the deregulation-fueled financial crisis of 2007-2009, and must ensure the freedom of the trading partners to establish and enforce more robust regulations. The United States and EU must be free without exception to establish limits on the size of financial institutions; establish strong regulations on mergers and acquisitions; insist on separation of commercial banking, investment banking, and insurance functions; ban or restrict the offering of risky financial services or products; establish fees and taxes for financial institutions and financial transactions; adopt reserve requirements above international standards; impose performance standards and investment obligations; cap fees and interest rates, and enact capital controls.

**Access to Affordable Medicines and Innovation on the Internet:** Consumers' access to affordable medicines and their ability to innovate on and use the Internet must not be restricted. The United States and EU should ensure that consumers will maintain their ability to use the Internet freely and not be subjected to increased healthcare costs for the sake of pharmaceutical corporations' narrow business interests. This prospective agreement should exclude all intellectual property provisions, including, among others, those relating to patents, copyright, trademarks and data protection.

**Climate Security:** Any agreement must provide policy space for signatory countries to respond to the emerging climate crisis and facilitate a transition to more sustainable consumption and production patterns. To advance sustainability and avert catastrophic climate change, trading partners must have the policy space to adopt tax policies, mandatory performance standards, carbon and pollution regulations, schemes for self-generation or "feed-in" electricity tariffs, procurement policy that gives preference to renewable energy and green products, renewable energy standards, or other policies without being subject to challenge under the agreement.

**Safe Drugs, Medical Devices, and Chemicals:** Trading partners must be free to establish high safety and efficacy standards that drugs, devices, and chemicals must meet before being afforded market approval or market access. The United States and the EU must be free to institute the testing regimes they deem appropriate.

**Effective Regulation of Emerging Technologies:** Trading partners must be afforded discretion to regulate products of emerging technologies, such as nano- and bio-technologies. Flexibility must be preserved to enact new facially non-discriminatory regulations to meet the objectives of consumer protection and environmental or ethical protections in the face of evolving technologies.

Given the breadth of consumer, worker, and environmental implications of such an extensive potential agreement between the United States and the EU, this letter does not represent an exhaustive list of our concerns. We will be monitoring the negotiations closely and will defend our rights against behind-closed-door decision-making at the service of corporate interests. We will also continue our efforts to develop and promote alternative approaches to global challenges of climate change, environmental deterioration, unemployment, increasing inequality and food insecurity that are based on democratic accountability and cooperation instead of economic competition and "trade" liberalization.

Sincerely,

U.S. and EU  
Transatlantic Consumer Dialogue (TACD)

U.S.  
Coalition for Sensible Safeguards  
Open The Government  
Citizens Trade Campaign

**U.S. (continued)**

Healthcare for America Now  
 International Brotherhood of Teamsters  
 American Federation of State, County and Municipal Employees (AFSCME)  
 National Family Farm Coalition  
 Family Farm Defenders  
 Presbyterian Church (USA)  
 US Public Interest Research Group (PIRG)  
 Consumer Federation of American (CFA)  
 Public Citizen  
 Liberty Coalition  
 Public Knowledge  
 Center for Food Safety  
 Center for Digital Democracy  
 American Medical Student Association  
 Friends of the Earth, U.S.  
 Center for Effective Government  
 Alliance for a Just Society  
 New Rules for Global Finance Coalition  
 Global Exchange  
 National Association of Consumer Advocates  
 Institute for Policy Studies - Global Economy Project  
 Food & Water Watch  
 Center for Policy Analysis on Trade and Health  
 Institute for Agriculture and Trade Policy  
 Farmworker Association of Florida  
 Fair World Project  
 Just Foreign Policy  
 Health GAP  
 International Center For Technology Assessment  
 Knowledge Ecology International  
 Columban Center for Advocacy and Outreach  
 The Second Chance Foundation

**Europe**

BEUC – The European Consumer Organisation  
 Food & Water Europe  
 Friends of the Earth Europe (FoEE)  
 Corporate Europe Observatory  
 Transnational Institute  
 Fair Trade Advocacy Office  
 11.11.11, Belgium  
 Transport & Environment (T&E), Belgium  
 ATTAC Vlaanderen, Belgium  
 Africa Contact, Denmark  
 Association internationale de techniciens, experts et chercheurs – AITEC, France  
 ATTAC France  
 ATTAC Finland  
 PowerShift - Verein fuer eine oekologisch-solidarische Energie- & Weltwirtschaft e.V., Germany  
 World Economy, Ecology & Development, Germany  
 ATTAC Hungary  
 Fairwatch, Italy  
 Both ENDS, Netherlands  
 Platform Duurzame en Solidaire Economie, Netherlands  
 Platform Aarde Boer Consument, Netherlands  
 Women's International League for Peace and Freedom (WILPF), Netherlands  
 Trade Justice Movement (TJM), UK  
 PoHG - The Politics of Health Group, UK  
 National Health Service Consultants' Association, UK  
 Keep Our National Health Service Public (KONP), UK  
 No2EU-Yes to Democracy, UK  
 GeneWatch UK  
 Campaign against Euro-federalism (CAEF), UK  
 National Health Action Party (NHAP), UK

**CHICAGO ROUND TRANS-PACIFIC PARTNERSHIP AGREEMENT  
STAKEHOLDER PRESENTATION - SEPTEMBER 10, 2011**

**PHARMACEUTICAL REIMBURSEMENT RESTRICTIONS AND PUBLIC HEALTH, ANALYSIS OF  
U.S. AND OTHER TPP COUNTRY PRACTICES: *The impact of pricing provisions on U.S.  
Medicaid and other health access programs***

Rep. Sharon Anglin Treat<sup>1</sup>

Assuring access to affordable health care is one of the highest priorities of policymakers and nongovernmental organizations at both the federal level in the United States and at the state and local levels. Indeed, it is one of the central challenges of our time. Certainly it is one of my highest concerns- as a state legislator who walks door to door on a regular basis talking with the people of my district in rural central Maine, as a board member of an NGO that is dedicated to finding solutions to poverty and improving the lives of low income people, and as the director of an organization of state legislators working together to reduce prescription drug costs.

Thus the potential impact of trade policies on affordability and availability is a key concern, one that health advocates and policymakers in states across the U.S. are starting to voice publicly in forums such as this and with trade negotiators and our members of Congress. In particular, how trade agreements affect pricing of pharmaceuticals and the availability of generics has been of great interest.

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<sup>1</sup> Sharon Anglin Treat is a current Maine State Representative and has served 19 years in the Maine Legislature in both the House and Senate. She is a former Maine Senate Majority Leader and has chaired numerous committees including Health & Human Services and Insurance & Financial Services, where she is currently the lead minority member. From 2006-2011, Rep. Treat was a member of Maine's Citizen Trade Policy Commission, which has submitted testimony and written to USTR concerning health care and trade policies, and since 2004 she has directed the National Legislative Association on Prescription Drug Prices, a nonprofit organization of legislators working to reduce prescription drug costs and promote access to medicines. Rep. Treat served from 2009-2011 on the Executive Committee of the National Conference of State Legislatures and is a member of the executive committee of State Legislators for National Health Reform. She is a member of the U.S. Intergovernmental Policy Advisory Committee (IGPAC). These comments represent the author's views and not necessarily the views of all the organizations she is affiliated with.

Policymakers at the state level have concerns about the inclusion of pharmaceutical provisions in the TPPA if those provisions are similar to or go beyond the Korea-US FTA (KORUS) and Australia pharmaceutical annexes. Our overall concern is that if similar provisions are adopted in the TPPA, they could be used to restrict current and future drug reimbursement and pricing options and result in increased costs of health care and reduced access to medicines at a time when those costs are already excessive and many people in the U.S. lack access to care.

The Maine Citizen Trade Policy Commission has adopted a policy statement in support of access to medicines, has written to our Congressional delegation objecting to pricing provisions of past FTAs, and has testified concerning the Special 301 Report. The Maine Legislature in 2011 enacted a Joint Resolution calling for greater transparency and consultation with states in the trade negotiation process.<sup>2</sup>

*We have concerns about both procedural and substantive provisions in KORUS and US-Australia FTAs that we understand may be a starting point for TPPA discussions.*

**Procedural and transparency provisions.** It is important that these provisions balance procedural fairness and transparency, a goal embraced by state leaders, with practical considerations. In other words, trade agreements should not impose unnecessary red tape or procedural hurdles on U.S. states or the federal government that interfere with the effective administration of Medicaid and other health programs, delay the addition of generic versions of drugs to PDLs or the timely removal of drugs with emerging efficacy and safety concerns, or provide grounds for overturning legitimate evidence-based reimbursement decisions.

At least 40 states negotiate prices based on an open formulary known as a preferred drug list (PDL). They compare evidence on the safety, efficacy, and cost-effectiveness of new drugs to existing drugs in the same therapeutic class, not unlike private insurance companies or foreign governments. States revise evidence based PDLs on a regular basis and at times, on short notice, to take advantage of market changes and the availability of new generic drugs, or to respond to new evidence of contraindications or clinical studies that require prompt reassessment of efficacy. Washington State has the most comprehensive such program which extends beyond pharmaceuticals; it has developed its own Health Technology Assessment Program, which contracts for scientific, evidence-based reports about the safety and efficacy of certain medical products including medical devices. This process informs reimbursement and coverage decisions for programs including Medicaid.<sup>3</sup>

It is also important that procedural so-called “transparency” trade provisions not become a mechanism to inject pharmaceutical industry influence and conflicts of interest into what is now

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<sup>2</sup> Maine Legislature's 2011 Joint Resolution on Trade:  
[http://www.mainelegislature.org/legis/bills/bills\\_125th/billpdfs/JR115201.pdf](http://www.mainelegislature.org/legis/bills/bills_125th/billpdfs/JR115201.pdf)  
 Letters and testimony of the Maine Citizen Trade Policy Commission (MCTPC):  
<http://www.maine.gov/legis/opla/citpoltradedocs.htm>  
 MCTPC 2009 assessment of trade impacts on Maine: <http://www.maine.gov/legis/opla/citpolassessments.htm>  
 2010 CTPC policy statement on trade: <http://www.maine.gov/legis/opla/citpol.htm>

<sup>3</sup> For more about the Washington State program: <http://www.hca.wa.gov/>

an evidence based process. For example, KORUS Article 5.3.5(f) would “make all reimbursement decision-making bodies open to all stakeholders, including innovative and generic companies,” inserting major conflicts of interest into the reimbursement and PDL decision by *requiring* that the very manufacturers that directly benefit from reimbursement and pricing decisions make those decisions. This violates the law in many U.S. states, as well as best practices for evidence based decision-making.

**Substantive pricing provisions.** Language in KORUS about “appropriately valuing” drugs, or requiring a premium for “innovative” products, or - as suggested by the pharmaceutical industry in public statements - possible new TPPA text requiring linkage of reimbursement and pricing decisions to in-country market prices, all raise red flags. Such language is designed to keep drug prices high, and the United States already has some of the highest pharmaceutical prices in the world.

State and federal Medicaid pricing and reimbursement models are changing as a result of the Affordable Care Act. Federal officials are moving for the first time to establish a national reference price list for Medicaid instead of the state-by-state negotiated rebate system currently in place. Such a national reference price system would be very similar to the systems in place in other countries including TPPA parties. Thus any FTA language restricting such pricing mechanisms would appear to directly challenge the new U.S. Medicaid drug pricing system.

While the current state-by-state reimbursement system has its flaws, it has nonetheless resulted in substantially reducing the cost of prescription drugs for 58 million Americans. For example, the prices paid by the State of Maine for prescription drugs in its Medicaid program average around 50% of the “Average Wholesale Price” as a result of the federal Medicaid rebate, additional discounts through the state’s supplemental rebate program, group purchasing with other states, and a tiered PDL. During a decade when brand-name drug prices and spending has increased annually in the double digits, Maine has been able to keep its drug spend relatively flat. Maine’s approach to drug pricing is consistent with the approach taken in the majority of states in the U.S.

**Is the KORUS Medicaid carve-out effective?** Since Medicaid is a joint federal-state program (funded by both the federal and state governments; administered by states according to federal guidelines) it was unclear whether the terms of the Australia FTA would apply to Medicaid. State leaders sought a binding clarification from USTR that Medicaid could not be affected by these provisions, but no such clarification was received.

Subsequently, during the negotiation of the KORUS FTA, state leaders lobbied – successfully – for a specific carve out of Medicaid in the text of the agreement. The pharmaceutical provisions apply to negotiations conducted by the “central” government, and a footnote to Article 5.8 reads: “*For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.*”

As state leaders have become better educated about the overlap between trade policy and state government programs, they now understand the potential reach of TPPA and other FTAs into the complex web of state-federal partnerships, a web which is particularly complicated and

extensive in health care. State leaders now recognize that FTA pharmaceutical pricing and transparency provisions could be applied to core state health policies outside of Medicaid, such that a Medicaid carve out will not adequately protect these programs.

For example, **Medicare Part B** sets statutorily-defined prices for pharmaceuticals used in medically necessary services for Medicare beneficiaries (disabled and older persons). **Section 340B of the Federal Public Health Act** requires drug companies to provide statutorily-defined discounts on covered outpatient drugs purchased by federally-funded clinics and other safety net providers as a condition of having their drugs covered by Medicaid – at prices that are substantially lower than Medicaid. *Neither of these programs is part of "Medicaid".*

As Vermont Governor Shumlin pointed out in his June 1, 2011 letter to US Trade Representative Ron Kirk,<sup>4</sup> 340B programs include all of his state's federally qualified health centers and Fletcher Allen Health Care, Vermont's largest teaching hospital. In addition, Vermont has begun a new 340B pilot project with Rutland Regional Hospital to provide broader 340B access through local pharmacies.

*Vermont is not alone in its extensive use of the 340B program, a program that is a central level of government health care program also operated by the states, and which is NOT part of Medicaid.* An increasing number of states are turning to the program to expand access to affordable health care, and new partnership opportunities with private-sector pharmacies were authorized in the Affordable Care Act, which will likely expand the reach, and state reliance on 340B, even more. Some examples of expanded 340B programs in the states include:

- **Vermont H. 792** (enacted 2010): Supporting state collaboration with community health centers, critical access hospitals and sole community hospitals to care for individuals with disabilities, mental health needs and substance abuse issues, and supporting 340B participation for newly eligible hospitals.
- **Connecticut H.B. 5545** (enacted 2010): Requiring community health centers participating in state general assistance program to enroll in 340B and provide pharmacy services via in-house or contract pharmacies.
- **Kansas S.B. 572** (enacted 2010): Subsidizing the cost of pharmaceuticals purchased by community health centers through 340B and dispensed to low income patients using sliding scales.
- **Utah's Medicaid** program has a sole source contract with a 340B hospital for providing factor products and case management services to hemophilia population statewide; the parties are exploring expansion of program to other disease groups.
- **Pennsylvania's** Medicaid managed care organization has contracted with a community health center to manage a high-cost chronically ill enrollee population and to provide pharmacy services at lower prices.

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<sup>4</sup> Vermont Governor Peter Shumlin wrote on June 1, 2011 to U.S. Trade Representative Kirk and President Obama to oppose the inclusion of a pharmaceutical or healthcare annex in the TPPA. The letter is posted here: <http://freepdfhosting.com/6ee2e21e4c.pdf>. Letters and resolutions concerning prior TPAs have been written by officials or commissions in states including California, Vermont, Maine, Washington State, Connecticut, Arizona, West Virginia, Massachusetts, Alaska, Hawaii, and New Hampshire. Some of these letters and resolutions are posted here: <http://www.wcl.american.edu/pjip/go/trade-statedocs>.

- **340B and correctional populations:** In 2001, the Texas Legislature passed Senate Bill 347 to implement a program to access 340B pricing for prisoner medications, translating into significant savings of 30 to 35 percent over previous prices. **Virginia** has also used 340B to obtain medicine for correctional institutions, as have county jails, such as Dade County's in **Florida** and San Bernardino County's in **California**.

The largest individual cost drivers for a state Medicaid program include such populations or disease states as mental health patients, transplant recipients, hemophiliacs, People Living With HIV/AIDS, or other categories of patients with expensive and chronic disease states. The 340B Program is relied on by many states to provide these expensive pharmaceuticals to these high-risk populations.

**AIDS drug assistance programs (ADAPs) are just one example of the reliance by states on 340B.** ADAPs are critical in providing HIV/AIDS treatment to low-income, uninsured, or underinsured patients within the United States and its territories. ADAPs are eligible to participate in the 340B program as either a direct purchaser of discounted drugs or by receiving rebates from manufacturers (similar to Medicaid drug rebate program). Direct purchase ADAPs receive better pricing – about 15-20 percent better – than rebate model ADAPs. With new opportunities to contract with multiple contract pharmacies (authorized by the Affordable Care Act in 2010), direct purchase ADAPs can have the same large pharmacy networks as rebate model ADAPs and create new state savings.

**Trade-driven pharmaceutical price increases would devastate state health care and Medicaid budgets and further delay or eliminate treatment for millions of Americans.** Most U.S. states have been facing budget cuts in successive budgets since at least 2008, resulting from revenue shortfalls caused by the ongoing worldwide recession – cuts that have hit health care funding especially hard. This year, many states have ended or cut back prescription drug assistance programs and Medicaid eligibility.

As an example, even with the availability of PDL-based rebates and federal matching funds, the 2011 budget proposed by Maine Governor Paul LePage would have eliminated the state's MaineRx discount drug program, eliminated the state-funded Drugs for the Elderly Program, dropped Medicaid eligibility for childless adults, and reduced or eliminated the Medicare Savings Program assisting 40,000 seniors and some disabled Mainers with prescription drug payments. Through cost-shifting copayment increases and additional fees, most of these cuts were postponed, but are likely to be proposed again in 2012.

Nationwide, the number of patients sitting on AIDS Drug Assistance Programs (ADAP) waiting lists, denied the life-saving treatment they need, have risen dramatically over the past two years. In January 2010, 361 individuals were on ADAP waitlists; that number grew to 7,873 across eleven states as of May 5, 2011 (a 2100% increase over less than sixteen months). Recent data published by the National Alliance of State and Territorial AIDS Directors reports that as of August 11, 2011, there were 9,217 individuals on ADAP waiting lists in 12 states, representing a 20% increase over a four month period. These states include Alabama, Arkansas, Florida, Georgia, Idaho, Louisiana, Montana, North Carolina, Ohio, South Carolina, Utah, and Virginia.

In addition to these waiting lists, six states, including Arkansas, Illinois, North Dakota, Ohio, South Carolina, and Utah have limited eligibility - some by more than 50% - as a cost-containment measure. Seventeen states and the territory of Puerto Rico reported instituting other cost containment strategies including, among others: reduced formularies, capped enrollment, monthly or annual expenditure caps, disenrolling clients not accessing ADAP for 90-days, discontinuing reimbursement of laboratory assays, instituting client cost sharing, and restricting eligibility criteria. Other states are considering adopting waiting list of additional cost-shifting measures.

*In sum, should negotiators include language similar to the KORUS pharmaceutical pricing and transparency provisions in the TPPA, even with the Medicaid carve-out, those provisions could cripple our ability to provide access to pharmaceuticals and medical devices to low income and middle class Americans and populations with special health needs. That the TPPA is a multi-country treaty is of particular concern because the policies and disciplines it adopts will be enforceable by such a wide range and large number of trading partners.*

**While one approach is to expand the scope of the KORUS Medicaid carve-out in future TPAs, a better response would be to reconsider inclusion of the problematic provisions in the first place.** Even if the KORUS footnote language is redrafted to carve out more than Medicaid, we question the value of including such provisions in reciprocal trade agreements where key provisions supposedly do not apply to most of the existing and planned U.S. and state pharmaceutical and medical device reimbursement programs. It seems unlikely that such a one-sided agreement, which imposes tough restrictions on other countries but not our own, will remain unchallenged and not vulnerable to future interpretations that may be inconsistent with current U.S. intent.

Moreover, the very existence of these provisions inevitably will add to pressure from the pharmaceutical and medical device industry – which is already great – to replace current U.S. pricing and reimbursement provisions that are protected by specific carve outs, with programs that are not so protected.<sup>5</sup> There is a likelihood that new programs will have to conform to pricing and procedural disciplines in TPPA and other TPAs, leading to ever-higher health care costs and reduced access to health care, especially for low-income residents of our states.

As discussed above, U.S. Federal government agencies and state governments essentially use the same policy tools as foreign governments for public medicine purchasing and reimbursement, and they pay similar prices. We believe it to be inadvisable to use trade agreements and pressures to push pharmaceutical and medical device pricing policies abroad that we do not follow here at home.

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<sup>5</sup> Trade agreements may simply be an alternative method for the pharmaceutical industry to suppress pricing policies it has unsuccessfully challenged in the US courts. In the early 2000s, the industry launched three separate lawsuits against state programs in Maine, Michigan and Florida, claiming federal Medicaid laws prevented the use of PDLs in their programs. However, the plaintiffs lost all three cases, with federal courts, including the U.S. Supreme Court, upholding states' rights to negotiate prices through evidence based PDLs. Soon after, the industry urged trade officials to seek restrictions on evidence based drug pricing abroad, and the Australia-US FTA was the first bilateral trade deal to include a section directly addressing the pricing of pharmaceuticals [Annex 2(c)].

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
 COMMITTEE ON ENERGY AND COMMERCE  
 2125 RAYBURN HOUSE OFFICE BUILDING  
 WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
 Minority (202) 225-3641

April 9, 2014

The Honorable Matt Blunt  
 President  
 American Automotive Policy Council  
 1401 H Street, N.W., Suite 780  
 Washington, D.C. 20005

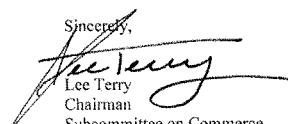
Dear Governor Blunt,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Wednesday, July 24, 2013 at 9:45 a.m. in 2123 Rayburn House Office Building, at the Subcommittee on Commerce, Manufacturing, and Trade hearing entitled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, April 23, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at [Kirby.Howard@mail.house.gov](mailto:Kirby.Howard@mail.house.gov) and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
 Lee Terry  
 Chairman  
 Subcommittee on Commerce,  
 Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
 Attachment



**Answers by Governor Matt Blunt,  
President of the American Automotive Policy Council**

To

**Questions for the Record**

**U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE**

On

**"The U.S. – E.U. Free Trade Agreement: Tripping Over the Regulatory Barriers"**

**July 24, 2013**

**The Honorable Lee Terry**

**1. You testified that your approach is guided by “strong and sustained political support at the highest levels of government, and the relevant regulatory authorities.” Does that mean our respective governments are already in agreement that there should be regulatory cooperation?**

A. We are of the view that for the Transatlantic Trade and Investment Partnership (TTIP) to reach its fullest potential we must have strong stainable political support at the highest levels of governments and the relevant regulatory authorities. Fortunately, there has been, from the beginning, strong support at the highest levels for regulatory cooperation in the TTIP.

On June 17, 2013, President Obama and European Commission President Barroso announced that "*The United States and the European Union will be launching negotiations on a Transatlantic Trade Investment Agreement.*"<sup>11</sup> As part of that announcement, the White House released a factsheet on TTIP that stated, that "*In particular, TTIP will aim to...significantly reduce the cost of differences in regulations and standards by promoting greater compatibility, transparency, and cooperation, while maintaining our high levels of health, safety, and environmental protections.*"<sup>11</sup>

We wholeheartedly agree and believe that what is critically important now is that this support continues throughout the TTIP negotiations.

**2. You testified that “past efforts to harmonize auto standards were ineffective and slow.” What was the fatal flaw in those past efforts and why does T-TIP hold more promise?**

- A. The last major effort to address the divergence in the U.S. and EU auto regulatory standards/systems took place in the mid-1990s. It was led by a coalition of U.S. and EU companies and associations under the auspices of the Transatlantic Business Dialogue (TABD). The effort made important progress in identifying the issues and obstacles, as well as the objectives and benefits.

However, the approach used at the time to narrow the differences in U.S. and EU regulations was unsuccessful, since the U.S. regulatory agencies were only willing to assess auto standards on a one-by-one “functional equivalence” basis, with a focus on the technical differences instead of looking to the results, or the performance and outcomes of the standard. Since there will always be differences when comparing one technical standard to another, this approach was unsuccessful. The only outcome from this effort was the establishment in 1998 of the Global Technical Regulation (GTR) development process in the United Nations WP.29. This process provides a process for all the major global automotive manufacturing nations to become involved in the GTR development process, but is institutionally incapable of developing GTRs at a useful rate. Since 1998, only 14 GTRs have been established, with only 10 of those relevant to passenger cars, and most are minor- e.g., door locks. With dozens and dozens of auto safety and emission standards, we will never overcome the regulatory divergence.

TTIP is different in three major respects. One, unlike in the mid-1990s, TTIP efforts to address regulatory barriers has support at the highest levels of government, which if sustained will ensure that *there will be a reduction “...in the cost of differences in regulations and standards by promoting greater compatibility, transparency, and cooperation, while maintaining our high levels of health, safety, and environmental protections.”*<sup>111</sup> Two, the transatlantic aligned industry is making a strong case for the need for progress, and has commissioned a study to be done by joint U.S. and EU academic institutions to provide an independent third-party analysis of the real-world performance of the two sets of standards and determine with the available data their equivalence. Three, there is an appreciation by the U.S. economic agencies of the major jobs and growth benefits of a more harmonized U.S. EU auto regulatory approach, and a recognition by the regulatory agencies that they need to pay attention to the U.S. and EU leadership’s goals (above), and the economic benefits.

**3. According to a study commissioned by the European Commission and conducted by the research and consultancy company ECORYS, current non-tariff barriers on automobiles are the equivalent of a value-added tariff of approximately 26 percent. Approximately how much of this “tariff” can be eliminated by regulatory convergence?**

- A. The ECORYS study commissioned by the European Commission cited in your question, says “*Regulatory divergence creating [Non-Tariff Measures] NTMs can be considered to be the main barrier to achieving a truly transatlantic car market... that the trade cost*

*associated with these NTMs is equivalent to a tariff of 26.8%...<sup>iv</sup>* We generally concur with the assessment, and note that even if the regulatory convergence effort only addressed half the regulatory divergence U.S. auto exports to Europe face, the benefits of that will exceed the benefit achieved by the elimination of the EU's 10% import tariff on U.S. passenger and light truck vehicle exports.

**The Honorable Jan Schakowsky**

**1. With regard to the proposed trade agreement between the United States and the European Union, please briefly submit your definition of “regulatory harmonization” and “mutual recognition.”**

- A. There is not a universally accepted definition of “Regulatory Harmonization” for the automotive sector. Regulatory harmonization is most frequently pursued on a case-by-case basis, and can result in a range of outcomes- from an identical or virtually identical regulation or requirement, to a narrowing (large to small) of the differences between existing regulations or requirements – e.g. common test procedures and equipment. Although having identical automotive requirements worldwide would be ideal, because of historical differences in regulatory development, this is rare and an unlikely outcome. Harmonization can also mean eliminating unnecessary differences and bringing regulations closer together. In this way, where possible and practical, a single vehicle specification can be built to satisfy all requirements.

Currently, automotive regulatory harmonization is best exemplified by the work being done to establish “Global Technical Regulations (GTRs)” under the World Forum for Harmonization of Vehicle Regulations in the United Nations Working Party 29. GTRs are formed based on the existing pool of regulations, and sometimes in areas not previously regulated. GTR development has been slow. So far, only a handful of GTRs (14) have been established since 1998, when the GTR process was first initiated.

- A. Mutual recognition is a more straight-forward concept. There are U.S. and EU auto regulations, or sets of auto regulations, that cover the same equipment or performance and have the same/similar safety and environmental outcomes, but, by virtue of being developed by two different regulatory bodies, differ in some technical respects. By using mutual recognition, the U.S. could officially recognize an EU regulation to satisfy its certification requirements, that had the same /similar performance or outcome (or vice versa), without requiring any changes to the U.S. and EU regulations. In other words, the governments would accept the other government’s regulation as sufficient as meeting its same/similar requirements.

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<sup>i</sup> FACT SHEET: *Transatlantic Trade and Investment Partnership (T-TIP)*, THE WHITE HOUSE, OFFICE OF THE PRESS SECRETARY, (Jun. 17, 2013), <http://www.whitehouse.gov/the-press-office/2013/06/17/fact-sheet-transatlantic-trade-and-investment-partnership-t-tip>.

<sup>ii</sup> *Id.*

<sup>iii</sup> *Id.*

<sup>iv</sup> *Impact Assessment Report on the Future of EU-US Trade Relations, authorising the Opening of Negotiations on a Comprehensive Trade and Investment Agreement, called the Transatlantic Trade and Investment Partnership.*

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*between the European Union and the United States of America*, EUROPEAN COMMISSION, (March 12, 2013), p.43, [http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc\\_150759.pdf](http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150759.pdf).

**Governor Matt Blunt, President of the American Automotive Policy Council****Responses to Additional Questions Asked**

House Committee on Energy and Commerce, Subcommittee on Commerce, Manufacturing and Trade's Hearing on "The U.S. – E.U. Free Trade Agreement: Tipping over the Regulatory Barriers."

July 24, 2013

The Honorable John Dingell:

**Q: (To Messrs. Blunt, Castellani, Dooley, and Garfield)** All of you posit in your written testimony that a U.S.-EU free trade agreement should include some form of regulatory harmonization or mutual recognition of standards. Would you each please briefly define those terms for the record? And how this would benefit the United States?

**A: Brief definition of regulatory convergence/harmonization being proposed:**

With regard to existing regulations, American Automotive Policy Council (AAPC) is proposing that mutual recognition should be presumed unless it is demonstrated that a regulation is deficient from a safety or environmental outcome perspective based on a data driven analysis. Mutual recognition would imply that vehicles in compliance with either the U.S. or EU safety or environmental regulations are considered to offer the same level of safety and environmental performance in both markets. An on-going commitment by all parties to work cooperatively to identify and resolve any obstacles to the practical implementation of the regulatory convergence effort will be essential.

With regard to new regulations, (when it is determined that one is needed (e.g. electric vehicles)), AAPC and ACEA recommend that the U.S. and EU implement a joint auto regulatory harmonization process that promotes and facilitates the development and adoption of common future new regulations. This approach will strengthen the U.S. and EU roles as worldwide auto standards setters, providing momentum for global auto regulatory convergence.

**How would it be beneficial to the United States?**

Eliminating tariffs and achieving greater regulatory convergence of current and future standards through the TTIP will increase trade, lower costs, create jobs, and improve the international competitiveness of the industry, strengthening the automotive industry and its economic contribution in both economies, while respecting U.S. and EU sovereignty and without sacrificing vehicle safety and environmental performance.

According to the EU Impact Assessment Reports,<sup>1</sup> current auto non-tariff barriers (NTBs) are equivalent to an ad valorem tariff of approximately 26%.<sup>2</sup> The elimination of tariffs and 10% of

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<sup>1</sup> Commission Staff Working Document (2013): "Impact Assessment Report on the Future of EU-U.S. trade Relations". (Hereinafter "Impact Assessment") and See

existing U.S. and EU NTBs would increase EU vehicle and parts exports to the U.S. by 71% and increase U.S. vehicle and parts exports to the EU by 207% during the period 2017-2027.<sup>3</sup> The elimination of tariffs and 25% of existing U.S. and EU NTBs would increase EU vehicle and parts exports to the U.S. by 149% and increase U.S. vehicle and parts exports to the EU by 347% during the period 2017-2027.<sup>4</sup> In fact, the increase in U.S.-EU auto trade associated with the elimination of tariffs and non-tariff barriers accounts for more than 1/3 of total estimated increase in bilateral trade flows associated with a successful TTIP negotiation.<sup>5</sup> Thus, to achieve an ambitious TTIP outcome that benefits the auto industry, as well as the U.S. and EU economies as a whole, the trade agreement must include meaningful regulatory convergence.

**Q:** (*To All Witnesses*) Do you believe that regulatory harmonization or mutual recognition of standards between the U.S. and European Union would afford Americans the same level of stakeholder input in the regulatory process as they currently enjoy under the Administrative Procedure Act? Yes or no.

**A:** Yes. The same transparencies afforded under the APA would continue to exist. In fact, regulatory harmonization or mutual recognition will encourage greater stakeholder engagement and cooperation.

**Q:** (*To All Witnesses*) Do you believe that regulatory harmonization or mutual recognition of standards would make it more difficult in general for the United States and European Union to promulgate new regulations in the future? Yes or no.

**A:** No. Including the regulatory harmonization or mutual recognition provisions proposed by AAPC and ACEA in the TTIP will simply encourage greater US-EU regulatory cooperation in order to achieve greater efficiencies, without sacrificing vehicle safety or environmental performance.

**Q:** (*To All Witnesses*) Similarly, do you believe that regulatory harmonization or mutual recognition of standards would constrain the ability of the United States and European Union to promulgate regulations it deems uniquely appropriate for specific threats to the health and safety of their respective citizens? In other words, do you believe regulatory harmonization or mutual recognition of standards would diminish the regulatory sovereignty, so to speak, of the United States and European Union, respectively? Yes or no.

**A:** No. The auto industry's regulatory harmonization or mutual recognition proposal respects U.S. sovereignty, without sacrificing vehicle safety or environmental performance.

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<sup>2</sup> See *Impact Assessment*, p. 43; *Reducing Barriers*, p. 20 and Table 2.

<sup>3</sup> See *Impact Assessment*, p. 43; *Reducing Barriers*, pp. 68-69 and Tables 31-32.

<sup>4</sup> See *Impact Assessment*, p. 43.; *Reducing Barriers*, pp. 68-69. Tables 31-32.

<sup>5</sup> See *Reducing Barriers*, pp. 68-69. Tables 31-32.

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

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**Congress of the United States**  
**House of Representatives**  
 COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
 WASHINGTON, DC 20515-6115

Majority (202) 225-2927

Minority (202) 225-3641

April 9, 2014

Mr. John J. Castellani  
 President and CEO  
 PhRMA  
 950 F Street, N.W., Suite 300  
 Washington, D.C. 20004

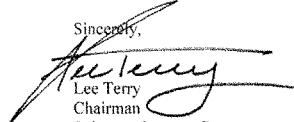
Dear Mr. Castellani,

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
 Lee Terry  
 Chairman  
 Subcommittee on Commerce,  
 Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
 Attachment

John J. Castellani  
President & CEO  
PhRMA

April 23, 2014

Additional Questions for the Record

**The Honorable Lee Terry**

1. The European Medicines Agency (EMA) recently began disclosing the clinical study reports of pharmaceutical marketing dossiers. This is a reversal of many years in which the EMA protected such detailed regulatory submissions. Please describe the issues faced by your industry as a result of the EMA's new data disclosure policy. Please also describe whether and how this practice is different than the recent actions of the Indian government.

**A: The EMA's current and proposed policies on the release of confidential regulatory submissions fail to take account of the highly confidential and valuable nature of the data in the marketing authorization dossier and the significant harm that would be suffered by marketing authorization holders if this information were released to competitors. Rather than being in the public interest, this policy could undermine incentives for innovative research into new medicines, to the detriment of public health. The EMA's proposed policy of last year addresses neither the consequences in other countries of the public availability of this information nor the potential use of the data in regulatory submissions even in the EU. For example, in neither its current nor proposed policies has the EMA explained how it would prevent disclosed confidential regulatory documents from being copied and used by competitors to gain approval in countries such as China. The policy is also inconsistent with the EU's obligations under international treaties. Finally, consideration should be given to possible alternatives to disclosure that could achieve the EMA's policy aims without undermining the incentives for innovative research. In conclusion, we believe that this is a topic that USTR should continue to address in the context of the T-TIP discussions with the European Commission.**

2. The rapid deterioration of Indian intellectual property protections are direct evidence that India's industrial policies are designed to take American and European innovation for their own domestic industries. The industries affected by India's actions cover a broad range of innovative industries in America and Europe, including high-tech, telecom, green technology, and biopharmaceuticals. In light of this threat, how can we use the T-TIP trade agreement to set global standards that value strong IP protections?

**A: The United States and the EU are well-positioned to identify best practices and achieve ambitious goals, especially with robust IP regimes on both sides. We share a long-standing commitment to and appreciation of IP protections and enforcement as fundamental to an innovative and dynamic marketplace. T-TIP presents a critical opportunity to set norms not only for future formal agreements with other trading partners, but generally for sustainable and rules-based global trade in the 21<sup>st</sup> century. Indeed, T-TIP must be a standard-setting agreement that places a high value on IP as the lifeblood of innovation. Achieving such an outcome will further highlight India as an outlier in the global market with its deteriorating IP regime and short-sighted policies that deter investment and**

undermine not only economic growth, but – most importantly – patient access to the state-of-the-art medicines our member companies develop and manufacture.

3. What would you like to see in a U.S.–EU trade agreement regarding market access for pharmaceuticals? Why is market access an issue for pharmaceuticals?

**A:** Biopharmaceuticals face unique market access challenges including cost containment measures and non-tariff barriers to patient access. To promote development of innovative medicines and thereby ensure patient access to medicines, it is critical that an ambitious T-TIP agreement include principles on pricing and reimbursement policies for innovative medicines that appropriately recognize and reward their value to patients and society. Such policies should be complemented by regulations governed by transparent and verifiable rules founded on science-based decision making and supportive of due process.

Both the U.S. and the EU have included specific pharmaceutical (and medical device) chapters in recent FTAs addressing these challenges. These FTAs have recognized that there should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies both in the development and specific implementation of all relevant laws, regulations, and procedures. Furthermore, applicants seeking pricing and reimbursement of their products should be provided the right of appeal to an independent objective court or administrative body. To this end, the U.S. and EU should reiterate the commitments already made in their respective trade agreements with Korea and build on those provisions to further eliminate barriers to patient access to innovative medicines.

4. You urged that T-TIP negotiations include addressing regulatory compatibility. What should that look like?

**A:** In October 2012, PhRMA and its European sister association (the European Federation of Pharmaceutical Industries and Associations or EFPIA) jointly submitted to the Office of the U.S. Trade Representative, the Office of Information and Regulatory Affairs and the EC Commission (Directorate Generals for Trade, and Enterprise and Industry) a comprehensive set of proposals to promote regulatory compatibility between the United States and the European Union. Generally speaking, the submission outlines a number of proposals to promote greater coordination between the United States and Europe to reduce the regulatory burden for sponsors and agencies and ensure patient safety, such as mutual recognition of inspection findings, enhanced use of parallel scientific advice, and parallel evaluation of quality by design (QbD) applications. The submission also outlines a set of proposals for increased collaboration under the auspices of the International Conference on Harmonization (ICH) to secure greater regulatory compatibility, such as reform of requirements for pediatric drug development, benefit-risk assessment, and safety reporting requirements, among several additional proposals. A copy of the written submission, which includes specific details of these proposals, is attached for the record.

5. One of the key principles you identified for inclusion in any agreement is “respecting the right of physicians and other healthcare providers to prescribe the appropriate medicines for their patients based on clinical need.” Can you please explain the importance of this principle and why its inclusion is necessary?

**A:** Certain EU members have imposed or considered measures that seek to override a physician’s clinical determination as to the appropriate treatment regimen for their patients, including rules mandating that a prescriptions issued by a physician list only the international non-proprietary name (INN), i.e., the generic name for the product, and that pharmacists fill prescriptions for branded products with a generic version if a generic is available (referred to as “automatic generic substitution”). Such measures disregard a physician’s clinical knowledge and experience regarding the most appropriate treatment for his or her patients and inappropriately assume that all generics are identical to branded product. While, by definition, a generic drug should be bioequivalent to the branded product – i.e., both products should be highly similar in terms of their active pharmaceutical ingredient – the maximum concentration of the active ingredient in the blood may vary and there may be other differences that impact a patient’s response to a generic medicine, such as the additional ingredients referred to as excipients. Although these additives are expected to be inert some may impact how a drug is absorbed, impacting bioavailability, i.e., the amount of drug that could potentially be absorbed into the bloodstream. In addition, the excipients contained in a generic version may unfavorably interact with other medications that the patient is taking, or be ones to which the patient has an adverse reaction. Furthermore, if the patient has become accustomed to taking a certain medicine, replacing that medicine with a generic version that may be a different color, shape and size and differs in terms of its dosage instructions and packaging may inadvertently contribute to patient confusion and negatively impact patient adherence to their treatment regimen.

Industry fully supports robust off-patent markets that result in safe and quality assured drug supply for patients in an environment that maximizes marketplace competition, respects intellectual property, and where savings are placed back into the healthcare system to benefit patients by using savings to expand access and to create headroom to support country-specific pharmaceutical innovation goals. This can and should be achieved, however, without overriding the physician’s determination as to what is in the best medical interest of his or her patients.

**The Honorable Jan Schakowsky**

1. With regard to the proposed trade agreement between the United States and the European Union, please briefly submit your definition of “regulatory harmonization” and “mutual recognition.”

**A:** Generally speaking, PhRMA considers “regulatory harmonization” as a relative term that can reflect somewhat different meanings depending on the context. For example, regulatory harmonization can take place at different levels, that is, it can occur with

technical requirements, among procedures and processes, and with laws and regulations. In some cases, it may mean that the standards or requirements are essentially the same or identical. In other instances, it can be more of a common framework for regulation that takes into consideration the existence of different political, economic, and health realities between and among countries. In any case, the goal of regulatory harmonization is to bring regulatory systems more in line with each other - all the while maintaining the high standards that government, industry and patients appropriately demand from their regulators - to enhance efficiency of drug development, reduce redundant testing, optimize deployment of limited regulatory agency resources, and encourage expedited patient access to new, innovative, life-saving medicines.

"Mutual recognition" often relies on an underlying understanding or assessment that two or more regulatory systems are "equivalent." In this instance, equivalency is meant to illustrate that while the regulatory systems might have some differences, it is expected that they produce the same outcomes. Such an assessment should be established through objective means and documented. For example, a mutual recognition agreement between two agencies as it relates to Good Manufacturing Practices (GMP) would allow each agency to recognize the GMP inspection findings of the other agency (or agencies) party to the agreement because it has been determined that even though the underlying regulatory requirements may be different, the findings of an inspection would be the same without regard to the party who conducted the inspection. Such agreements may eliminate unnecessary and duplicative inspections, allowing regulators to better focus their resources on inspecting facilities that have not been inspected and thus pose a greater risk to patient safety.

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

April 9, 2014

The Honorable Cal Dooley  
President and CEO  
American Chemistry Council  
700 Second Street, N.E.  
Washington, D.C. 20002

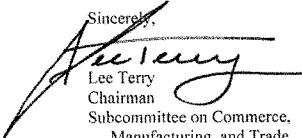
Dear Congressman Dooley,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Wednesday, July 24, 2013 at 9:45 a.m. in 2123 Rayburn House Office Building, at the Subcommittee on Commerce, Manufacturing, and Trade hearing entitled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, April 23, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at [Kirby.Howard@mail.house.gov](mailto:Kirby.Howard@mail.house.gov) and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
 Lee Terry  
Chairman  
Subcommittee on Commerce,  
Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
Attachment

Additional Questions for the RecordThe Honorable Lee Terry

1. You testified that reducing non-tariff barriers can result in greater savings than eliminating tariffs. Can you please explain?
2. Why do you believe the chemical industry is “well placed to be a priority sector for enhanced regulatory cooperation under TTIP” – when our respective regulatory approaches in this arena are so different?
3. In your testimony you recognized that our respective approaches are different – risk assessment in the U.S. versus hazard assessment in the EU. What would enhanced scientific cooperation look like? Why would such cooperation make a difference and how would it reduce inefficiencies if we employ different standards?
4. One of the areas on which you testified that you would like to see agreement is the “protection of legitimate commercial information.” Is this information not subject to confidential treatment already?
5. Your testimony suggested that many of the regulatory redundancies your industry experiences are in having to provide duplicative testing and other data. Why is reproducing this data problematic?
6. Both you and Mr. Muffett discussed endocrine disrupting chemicals in your written testimony. As I understand it, drinking orange juice and being normally exposed to sunlight both have an effect on the endocrine system, yet neither is considered a problem because the effect is not adverse on the endocrine system. Could you please explain the importance of pursuing endocrine disrupting chemicals that actually cause adverse impacts, and the need to prioritize them based upon validated screening and testing?

The Honorable Jan Schakowsky

1. With regard to the proposed trade agreement between the United States and the European Union, please briefly submit your definition of “regulatory harmonization” and “mutual recognition.”

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
 COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
 WASHINGTON, DC 20515-6115

Majority (202) 225-2927

Minority (202) 225-3841

April 9, 2014

Mr. Dean Garfield  
 President and CEO  
 Information Technology Industry Council  
 1101 K Street, N.W., Suite 610  
 Washington, D.C. 20005

Dear Mr. Garfield,

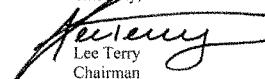
Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Wednesday, July 24, 2013 at 9:45 a.m. in 2123 Rayburn House Office Building, at the Subcommittee on Commerce, Manufacturing, and Trade hearing entitled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers."

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Lee Terry  
 Chairman  
 Subcommittee on Commerce,  
 Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
 Attachment

Additional Questions for the RecordThe Honorable Lee Terry

1. In your testimony, you stated that a U.S. – EU agreement should include “measures that embrace the promotion of interoperability and mutual recognition of privacy, data protection, and cybersecurity frameworks.” Would this be similar to the U.S. - EU Safe Harbor Framework? Why are such measures important, and how important are they on your list of priorities?
2. You recommended that any agreement include effective protection of intellectual property. Is the current system in either the U.S. or the EU ineffective? If so, how?
3. You urged the U.S. and EU to “strive toward a uniform trade secrets protection regime.” How do our approaches differ and why does such divergence matter?
4. Your testimony addressed “collecting societies” in the EU Member States and urged that the copyright levies they collect “are a prime example of the type of tariffs or duties that should be eliminated through T-TIP.” Do your private sector counterparts in the EU agree?
5. You suggested we develop an “early warning system” for prospective or revised regulations. How do you envision this would work? Is there an example in another industry or other countries that could provide a basis for such a system?
6. You expressed concern with an increasing number of overbroad testing or certification systems that also require disclosure of unnecessary information. Are the testing and certification regimes being erected as non-tariff barriers? Are the disclosure requirements in the certification regimes a method of obtaining proprietary information? If yes to either question, how can the U.S. address these issues in the context of T-TIP?

The Honorable Jan Schakowsky

1. With regard to the proposed trade agreement between the United States and the European Union, please briefly submit your definition of “regulatory harmonization” and “mutual recognition.”

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

April 9, 2014

Ms. Jean Halloran  
U.S. Liaison, Transatlantic Consumer Dialogue Secretariat  
Senior Adviser, International Affairs,  
to the President of Consumer Reports  
101 Truman Avenue  
Yonkers, NY 10703-1057

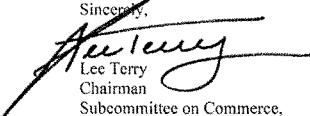
Dear Ms. Halloran,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Wednesday, July 24, 2013 at 9:45 a.m. in 2123 Rayburn House Office Building, at the Subcommittee on Commerce, Manufacturing, and Trade hearing entitled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers."

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To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, April 23, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at [Kirby.Howard@mail.house.gov](mailto:Kirby.Howard@mail.house.gov) and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
 Lee Terry  
Chairman  
Subcommittee on Commerce,  
Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
Attachment

Additional Questions for the RecordThe Honorable Jan Schakowsky

1. At the Subcommittee hearing on July 24, 2013, I expressed my interest in learning more about how child occupant standards in the United States and the European Union compare to each other.
  - a. Please describe the differences between U.S. and E.U. child occupant protection standards. Please also indicate which is considered safer, and why.
  - b. Are there other areas in which regulatory policy for auto safety differs notably between the United States and the European Union? If so, please provide examples. For each example, which policy is considered safer, and why?
2. Please discuss the concept of "mutual recognition" as it relates to the proposed U.S.-E.U. trade agreement, known as the Transatlantic Trade and Investment Partnership (TTIP). Do you have any concerns with efforts to achieve mutual recognition of U.S. and E.U. safety standards, such as those that pertain to motor vehicles, toys, or food?
3. Several witnesses at the Subcommittee hearing on July 24, 2013, discussed their desire to have the proposed U.S.-E.U. trade agreement serve as the default standard for all future trade agreements. If you were to assume for a moment that this agreement were in place, do you have any thoughts on how it would affect the ability of other nations, such as the BRICS countries, to address concerns unique to their locale?
4. In written testimony submitted for the Subcommittee hearing on July 24, 2013, you mentioned the idea of a Consumer Advisory Committee, which consumer advocates have proposed as a group that could review TTIP negotiating texts and provide input on policy from the consumer perspective. Do you believe the establishment of this type of entity would benefit consumers, and if so, why?
5. During the Subcommittee hearing on July 24, 2013, you were asked about several topics relating to the proposed trade agreement between the United States and European Union. If you would like to elaborate on your comments regarding any of the following topics, please do so:
  - The impact of regulatory harmonization or the mutual recognition of standards on the health or safety of American consumers.
  - The level of stakeholder input Americans are likely to have in regulatory harmonization or the mutual recognition of standards, compared to the level of input they are currently afforded for domestic laws and regulations.
  - Whether regulatory harmonization or the mutual recognition of standards would make it more difficult, in general, for the United States and the European Union to promulgate new regulations in the future – including on emerging threats to health or safety.

- Whether regulatory harmonization or the mutual recognition of standards would diminish the regulatory sovereignty of the United States and the European Union, *i.e.*, constrain the ability of the two entities to promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens.
  - The level of transparency in ongoing U.S.-E.U. trade negotiations, particularly compared to previous trade negotiations in which either entity was involved.
6. We have heard that in certain circumstances, foreign investment can have the unintended effect of providing advantages to foreign investors over domestic investors. An example of this advantage is the right of foreign corporations to bypass domestic state and federal courts and proceed to a form of international arbitration known as investor-state dispute settlement (or ISDS). ISDS mechanisms allow foreign companies to challenge U.S. laws that they claim unduly interfere not just with past or present operations but also with the expected future profits from their initial investment.
- a. Please elaborate on these investor state dispute settlement mechanisms and the effect they already have had on the United States. What is the impact of the inclusion of an ISDS mechanism in a trade deal?
  - b. Both the U.S. and the E.U. have highly developed, well-functioning judicial systems. Why do some companies and industries want ISDS to be included in TTIP? Should consumers?

FRED UPTON, MICHIGAN  
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA  
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2827  
Minority (202) 225-3641

April 29, 2014

Mr. Carroll Muffett  
President and CEO  
Center for International Environmental Law  
1350 Connecticut Avenue N.W., Suite 1100  
Washington, D.C. 20036

Dear Mr. Muffett,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on Wednesday, July 24, 2013 at 9:45 a.m. in 2123 Rayburn House Office Building, at the Subcommittee on Commerce, Manufacturing, and Trade hearing entitled "The U.S. – E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers."

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To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, May 6, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at [Kirby.Howard@mail.house.gov](mailto:Kirby.Howard@mail.house.gov) and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Lee Terry  
Chairman  
Subcommittee on Commerce,  
Manufacturing, and Trade

cc: Jan Schakowsky, Ranking Member, Subcommittee on Commerce, Manufacturing, and Trade  
Attachment



STATEMENT OF  
CARROLL MUFFETT, PRESIDENT AND CEO  
CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL)

IN RESPONSE TO ADDITIONAL QUESTIONS FOR THE RECORD  
THE U.S. – E.U. FREE TRADE AGREEMENT: TIPPING OVER THE REGULATORY  
BARRIERS

Submitted to

THE U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUB-COMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

MAY 6, 2014

1350 Connecticut Avenue N.W. Suite 1100 • Washington D.C. 20036-1739  
Phone: 202-785-8700 • Fax: 202-785-8701 • Email: [info@ciel.org](mailto:info@ciel.org) • Internet: <http://www.ciel.org>

15 rue des Savoises, 1205 Geneva, Switzerland  
Phone: 41-22-789-0500 • Fax: 41-22-789-0739 • Email: [geneva@ciel.org](mailto:geneva@ciel.org) • Internet: <http://www.ciel.org>  
Additional Questions for the Record

**The Honorable Jan Schakowsky**

1. At the Subcommittee hearing on July 24, 2013, witnesses discussed various issues related to company data that is shared with regulatory agencies. What is the importance of this data to public health and consumer safety? Do you have any thoughts on proposals to implement more stringent standards on data protection and confidential business information through the Transatlantic Trade and Investment Partnership (TTIP) negotiations?

Industry proposals to implement more stringent standards on data protection and confidential business information through the Transatlantic Trade and Investment Partnership (TTIP) negotiations would limit access to data and information, adversely affecting efforts to improve public health, consumer safety and the environment.

In the case of hazardous chemicals, inventors need access to information about chemical hazards and exposures to develop safer solutions. Consumers and downstream users need access to information about chemicals in products to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. And regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives.

Of particular concern to businesses is the need to protect confidential business information (CBI), including data. Industry's abuse of CBI privileges under U.S. laws designed to protect public health and the environment is well documented.<sup>1</sup> This abuse represents a serious barrier to the identification of hazardous chemicals and the development and entry of safer alternatives. Recent experiences show that the inability to access information can impede the development and adoption of safer alternatives. Incomplete information on potential alternatives enables "regrettable substitution," i.e. the transition from one hazardous chemical to a different hazardous chemical, instead of safer alternatives.<sup>2</sup>

While respecting the desire to protect legitimate CBI as a means of encouraging businesses to continue to innovate, policy makers around the world have long recognized the potential for the disclosure of information to promote additional innovation. Patents are based on this principle.

Recent changes to European laws that increase access to information on substances of very high concern are "the driver[s] for change at the present,"<sup>3</sup> according to a 2012 review of the impact of these stronger laws on innovation. For information to accelerate and steer innovation in a safer direction—and ensure the integrity, efficiency, effectiveness, and accountability of governments, institutions, and industry—health and safety information must be generated and access must be provided to that information.

Although U.S. laws for toxic chemicals and pesticides already recognize that health and safety information should never be CBI, they still have farther to go in properly balancing these interests. Despite limits to the type of information that may be claimed as CBI, regulators do not always require justification of claims of confidentiality or re-justification of claims after a period of time. Ingredients of pesticide formulations are not publicly disclosed, preventing the development of safer alternatives, despite the potential for over 99 percent of the chemical to be

an “inactive”—but not necessarily inert—ingredient. A further problem is the practice of allowing the identity of chemicals that are the subject of health and safety studies to be masked as CBI, impeding the identification of chemicals of concern. Unlike patents, which generally expire after twenty years, CBI can be kept confidential in perpetuity. The health and environmental risks of this approach are compounded when important information is inappropriately claimed to be CBI.

U.S. regulators have been taking steps to limit this abuse, and to afford protection only for legitimate CBI, raising concerns among the trans-Atlantic chemical industry.<sup>4</sup> But, despite their best efforts, proposals by regulators were delayed in ORIA review for years, and then abandoned. In the EU, court rulings to ensure consistency with obligations under the Aarhus Convention regarding access to information have been unjustly criticized by industry attorneys with blanket assertions of “threatening CBI protection.”<sup>5</sup>

Proposals under TTIP by the European Chemical Industry Association (Cefic) react to these innovation-friendly developments, which would increase access to information about the potential risks of chemicals and products on the market today. Cefic’s proposals would further limit the access of regulators, consumers and potential competitors producing safer alternatives to information relevant to determining the health and safety of chemicals to which workers and the public may be exposed, and the potential advantages of alternatives. Under current law, U.S. regulators have the power to compel the production of information by the chemical industry that is submitted to regulatory authorities abroad. ACC and Cefic propose to curtail this power by requiring that CBI that includes original study data--and thus goes beyond the “robust” summaries that industry prepares regarding the methods and conclusions of its own experiments--be shared only with the permission of the “owner” of the regulatory data.<sup>6</sup> Under EU law, chemical manufacturers produce these “robust” study summaries themselves with limited accountability and oversight, whereas under US law full study reports are required and robust study summaries are generally viewed as insufficient.<sup>7</sup>

TTIP is not necessary for U.S. regulators to access health and safety information regarding chemicals, and would in fact, as proposed, limit access to necessary information for U.S. regulators, progressive businesses, and consumers. Thus, industry proposals adversely affect ongoing efforts to improve public health, empower consumers and business, and protect the environment through enabling innovation in safer alternatives to hazardous chemicals.

2. **The primary federal law regulating chemical safety in the United States, the Toxic Substances Control Act (TSCA), differs greatly from its European counterpart (known as REACH) in that it takes a largely risk-based approach rather than the hazard-based approach employed by REACH.** At the Subcommittee hearing on July 24, 2013, you commented that TSCA, which was passed more than 36 years ago, is not strong enough to respond to the alarming health risks that we now know certain chemicals pose. You also expressed concerns with one current Senate proposal to update TSCA, known as the Chemical Safety Improvement Act, and stated that this bill is not sufficient to bring the U.S. to the same level of protection that the E.U. is achieving. Others argued that the ultimate outcomes that result from consideration of chemicals’ safety under REACH and TSCA are not markedly different from each other, and that, in some cases, current federal policies toward chemicals should not be adjusted through the

**TTIP process to better match their corresponding E.U. policies.**

**a. Did you have any concerns resulting from this discussion that you would like to share with the Subcommittee?**

In our testimony before the Subcommittee, CIEL cautioned that TTIP would provide a vehicle by which the chemicals industry could manipulate the pace and direction of chemicals regulation on both sides of the Atlantic. A [subsequent analysis of industry proposals for TTIP](#) prepared by CIEL and ClientEarth, a not-for-profit legal organization based in the European Union,<sup>8</sup> demonstrates that our concerns were warranted.

While the U.S. Toxic Substances Control Act (TSCA) was a pioneering step in chemicals legislation when it was adopted in 1976, the Act has not been meaningfully updated in nearly four decades. At the same time, two forces have served to build a widening gap between the United States and international best practice on chemicals management. First, and significantly, significant gaps and design flaws in TSCA, which have been exploited relentlessly and successfully by industry for decades, have left many of its original intentions largely unrealized. Consequently, TSCA--and chemicals management at the federal level in the United States--have failed to evolve with the rapidly changing science--and public preferences--in this field. Second, and simultaneously, the European Union itself has adopted a series of reforms in its own chemicals laws that have transformed the EU from a follower to a global leader in chemicals management. As a result, chemical safety standards in the United States are now far below those of the European Union. Ironically, it is this gap, precipitated and exploited by the industry itself, which lies at the root of the alleged "trade barriers" posed by European chemicals standards.

As your question rightly observes, a fundamental difference between the two systems lies in the divergent approaches to addressing chemical threats. Under U.S. chemical laws, the United States employs a risk-based approach to chemical regulation, which requires projections for exposure level and other socio-economic considerations to be taken into account before chemicals are restricted. This approach has failed the public for decades, by allowing toxic chemicals to remain on the market despite overwhelming evidence of risk to human health or the environment, and providing no incentive for the development and adoption of safer chemicals outside of public pressure. The EU's hazard-based approach for certain chemicals enables a systematic transition away from carcinogens, mutagens and other chemicals of concern toward intrinsically safer chemicals.

Put simply, the United States' own regulatory inertia in the face of evolving scientific understanding of chemical hazards for human health and the environment, and in the face of declining willingness to accept those risks on the part of consumers in large parts of the world, has created a regulatory chasm between this country and the European Union, which has moved more aggressively to respond to both changing science and changing consumer preferences. Industry and trade agencies have responded by invoking "trade" as an argument to oppose further development of EU laws, notwithstanding the clearly expressed and scientifically justified preferences of the European public.

In light of this wide and growing gap, only a deep structural reform of US chemicals legislation could create a sound basis for regulatory cooperation between the United States and Europe. Notwithstanding calls by chemical industry groups for closer regulatory cooperation, neither the profoundly mis-named Chemical Safety Improvement Act nor subsequent bills championed by industry in Congress have come close to the reforms needed to close or even significantly narrow that gap.<sup>9</sup>

Recently, for example, 72 environmental, health and safety organizations, including CIEL, submitted a joint letter to Representative John Shimkus, Chairman of the House Subcommittee on Environment and Economy, analyzing the newly-released discussion draft of the Chemicals in Commerce Act.<sup>10</sup> The concerns expressed with that draft demonstrate the distance still to go in U.S. chemicals reform. Under the draft Chemicals in Commerce Act:

- The existing federal program is weakened in several areas, including oversight of new chemicals, confidential business information, and the ability to restrict unsafe chemicals in consumer products.
- EPA will remain unable to impose needed restrictions on unsafe chemicals. While the new draft clarifies the role of cost benefit analysis in the regulation of existing chemicals compared to the earlier draft, the legal burden for EPA to take action is effectively the same as the unworkable current law.
- The required assessments fall short of the mainstream recommendations made by the American Academy of Pediatrics and the National Academy of Science, among others, which call for aggregating the chemical exposures to vulnerable populations like pregnant women, developing children or workers and ensuring they are protected.
- The precise meaning of “significant risk” in the draft is unclear.
- The “low priority” category still creates the possibility that many chemicals will be treated as safe --- and proliferate in new products and applications--- though they have not been subjected to a thorough safety review.
- The preemption remains sweeping, thereby curtailing functioning state programs in exchange for a federal program that will continue to be dysfunctional.<sup>11</sup>

U.S. EPA agreed with this analysis in many respects during recent testimony before the House Subcommittee on Environment and Energy, noting “that the revised draft of [the] House Toxic Substances Control Act (TSCA) reform bill does not align with the EPA’s stated principles for TSCA reform...and weakens existing law.”<sup>12</sup>

In the absence of needed reforms, and as discussed more fully below, proposals for regulatory harmonization and mutual recognition under TTIP offer little prospect of improving chemicals management--or the health and safety of workers, consumers and families--on either side of the Atlantic.

- b. I understand estimates vary as to what it costs chemical manufacturers to comply with REACH. What is your interpretation of these estimates, and what do you believe explains REACH compliance cost levels during the first few years it has been in effect?**

Industry consistently over-states the expected costs of environmental regulations. For example, environmental laws to protect human health and the environment from vehicle emissions, acid rain, ozone depletion, airborne toxic substances all resulted in far lower compliance costs than originally estimated.<sup>13</sup> These and other examples of inflated estimates demonstrate that industry projections of regulatory compliance costs are not reliable predictors of actual costs and, accordingly, should be viewed with substantial skepticism absent external validation.<sup>14</sup>

The projected costs of the EU's REACH regulation are no exception. Regarding the impact to jobs, industry estimates for the impact of REACH projected the loss of over 3 million jobs in France and Germany.<sup>15</sup> GDP was projected to decline by 4.7 and 6.4 percent for France and Germany, respectively.<sup>16</sup> Notwithstanding such doomsday predictions, the evidence to date tells a much different story about the economic impact of REACH.

Since the adoption of REACH, Germany and France have increased GDP ever year except 2009, due to the global recession.<sup>17</sup> According to the European Commission's analysis, during the period of developing debating, adopting and implementing REACH, "the EU chemical industry grew slightly higher than the average rate for all manufacturing sectors, and has largely recovered from the [economic] crisis of 2008."<sup>18</sup> Since the adoption of REACH, the "EU chemicals industry remains the world's largest exporter and its turnover has increased in absolute terms."<sup>19</sup> A commissioned study of the impact of REACH on innovation conclude that as a result of the regulation "it is envisaged that over time the number and quality ... of skilled human resources to industry will increase and be supportive of innovative activity."<sup>20</sup> And following the enactment of REACH, the European chemical industry continues to generate a positive trade balance and is particularly well-performing in high margin sectors of specialty chemicals.<sup>21</sup>

Nor is REACH likely to impose unbearable costs on domestic industry in the United States. Compliance costs for the U.S. chemical industry with REACH represent a modest 1% of the value of exports to the EU, and 0.0000035 of annual turnover.<sup>22</sup> Chemical industry executives acknowledge that the primary factors affecting the location of the chemical industry are proximity to feedstocks and manufacturing activity, not regulation.<sup>23</sup>

- c. How do you believe differing U.S. and E.U. regimes for chemical safety affect innovation in chemical manufacturing industries? Is there a particularly strong connection between stringent chemical safety standards and how many new chemicals come to market?**

CIEL examined trends in chemicals regulation and patent filings to evaluate the impact of stronger rules for hazardous chemicals on the innovation of new chemicals products. Looking at examples from within the United States and abroad, our study *Driving Innovation*<sup>24</sup> found that

stricter regulation of hazardous chemicals can not only drive innovation, but also create a safer marketplace. As overwhelming evidence continues to grow about the financial costs of inaction on the hazardous cocktail of substances to which Americans are exposed daily, the need to direct our effort on innovation toward safer chemicals is particularly pressing.

While certain chemical manufacturers publicly insist that “there is no evidence that stricter chemical laws promote innovation,”<sup>25</sup> our study found clear evidence that the prospect of stricter rules on toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stricter rules to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new rules to protect people and wildlife from certain phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Thus, notwithstanding that the EU and its Member States led the global community in taking action on these phthalates, the impacts on innovation were positive.

Innovation hinges on the adoption of inventions into the market. In the case of chemicals, 15,000 new chemicals are registered daily, with little evidence these figures have been negatively affected by regulation.<sup>26</sup> In our view, the key question is not the number of new chemicals that enter the market, but rather the growth of safer chemicals on the market today. The future of the U.S. chemical industry is not in bulk chemical manufacturing but rather in the development and adoption of safer alternatives.

Our case studies highlight how stricter rules for hazardous chemicals can accelerate this process, not only sparking the invention of new chemicals, but—critically—enabling safer chemicals to overcome currently existing barriers to entry. Barriers exist that often prevent the adoption of safer alternatives, such as economies of scale, the externalization of costs, and the lack of information about chemicals and products on the market today. In some cases these are new chemicals, but they may also be previously known chemicals. Overcoming the market inertia imposed by entrenched toxic chemicals typically requires the exercise of governmental regulatory authority. Stronger laws for toxic chemicals help to overcome this inertia, creating incentives that help to pull safer inventions into the market, and turn invention into innovation.

**3. Several witnesses at the Subcommittee hearing on July 24, 2013, discussed their desire to have the proposed U.S.-E.U. trade agreement serve as the default standard for all future trade agreements. If you were to assume for a moment that this agreement were in place, do you have any thoughts on how it would affect the ability of other nations, such as the BRICS countries, to address concerns unique to their locale?**

The European Commission has stated that TTIP will not only set standards for the US and the EU, but will lay the foundation of normative expectations for all actors in the global economy.<sup>27</sup> If the EU-US trade agreement results in weaker levels of protection in the areas of human health, safety and the environmental regulation, which it is likely to do as currently envisioned, TTIP will likely have chilling effects on the development of stronger public interest regulations in

other regions as well, including the BRICS countries.

Businesses and industry associations have expressed an explicit interest in using TTIP as a regulatory template in other regions. For example, Procter and Gamble has stated that “[a]n ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries’ regulatory systems, in particular of BRIC[S] countries.”<sup>28</sup> Recent industry proposals clearly demonstrate that the chemical industry views TTIP as an opportunity to establish a global standard for chemicals regulation at the national or regional level by decreasing regulatory divergence between two of the most important players in global chemical markets.

Chemical manufacturing is expected to double between 2010 and 2030, with over 71% of this expansion expected to occur outside of the OECD and amongst the BRICS countries.<sup>29</sup> The U.S. has already been working to prevent REACH-like chemical regulation in areas outside of the EU that are engaged in significant chemical production, such as China, Japan, Australia, Korea, Turkey, Taiwan, Vietnam, and Malaysia. For example, in the development of K-REACH, Korea’s version of EU REACH, the US government lobbied to seek revisions to draft proposals, such as an increase in the *de minimis* production volume exclusion from 0.5 tonnes to 1.0 tonnes.<sup>30</sup> This revision poses a potential impediment to accessing information about specialty chemicals, such as manufactured nanomaterials, that may be manufactured in commercially significant volumes while still falling below the minimum tonnage requirements, therefore affording less protection than the original provision. As other free trade agreements are concluded by the U.S., EU and/or the BRICS countries, there is a significant risk of creating a complex and onerous web of consultation processes for environmental, health, and safety standards, which would likely hinder the elevation of standards in the BRICS and elsewhere.

In addition, TTIP, together with Canadian and trans-Pacific trade and investment agreements could increase pressure for BRICS to adopt regulatory and legal standards that do not reflect their domestic needs and circumstances. For example, to address the need for access to life-saving medicines, the BRICS countries have advocated for flexibilities in intellectual property laws to help fight cancer and HIV in developing countries. Just as troublingly, trade rules have proven a significant barrier to efforts by developed and developing countries alike to spur the growth and deployment of healthy domestic renewable energy industries. By slowing progress to address the threat of climate change, these barriers present a risk not only to the environment within these countries, but to the global environment as a whole.

**4. Fuel efficiency standards in the United States and the European Union differ greatly from each other. Do you have any thoughts on these divergent standards, and on how various stakeholders have proposed trade negotiators treat them under TTIP?**

Fully addressing the differences between the US and EU for fuel efficiency standards and potential implications of TTIP would require additional research that we are unable to complete at this time. We would be happy to submit a response at a later point in time if requested.

5. During the Subcommittee hearing on July 24, 2013, you were asked about several topics relating to the proposed trade agreement between the United States and European Union. If you would like to elaborate on your comments regarding any of the following topics, please do so:

- The impact of regulatory harmonization or the mutual recognition of standards on the health or safety of American consumers.

Regulatory harmonization or the mutual recognition of standards would weaken or lower stronger standards for the health or safety of American consumers in those instances where they exist, and delay the development of stronger standards on both sides of the Atlantic. Although EU trade negotiators state that they have no intention of lowering EU standards for protecting people and the environment from chemicals under TTIP, the European Union's negotiation mandate states that the elimination of regulatory obstacles that may restrict the potential profits of transnational corporations operating in EU and US markets is a top priority for TTIP.<sup>31</sup> Tools for regulatory cooperation like harmonization and mutual recognition could be used to remove or reduce public health, environmental, labor, consumer, and other public-interest regulations including toxic chemical regulation and food safety rules.<sup>32</sup>

As noted in CIEL's testimony to the Subcommittee last July, and discussed more fully in response to question #2 above, it is difficult to envision any degree of harmonization with respect to certain environmental, health and safety standards due to a wide divergence in regulatory approaches and regulatory outcomes. The European Commission acknowledged in documents prepared for TTIP that "US requirements [for chemicals] are less strict" and that, in the view of the EU, "neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU."<sup>33</sup> Given both the substantial differences in approaches between the EU and U.S. and the fact that recent bills to reform TSCA in the United States bear no resemblance to EU laws, the likelihood of harmonization or mutual recognition between the U.S. and EU resulting in a "highest-common denominator" outcome to chemicals management is very unlikely, if not impossible.<sup>34</sup>

Nonetheless, proposals by the pesticide and industrial chemical sectors continue to advocate for harmonization or mutual recognition, both through targeted proposals to either U.S. or EU approaches deemed more favorable to industry, or via a permanent, overarching framework for trans-Atlantic regulatory cooperation.<sup>35</sup>

The Center for International Environmental Law and the European NGO Client Earth analyzed these industry proposals, and their potential impact on chemical safety in the United States and Europe, in the report *Toxic Partnership: A Critique of the ACC-CEFIC Proposal on Transatlantic Chemical Cooperation*. We found that the chemical industry's proposals for harmonization and mutual recognition would undermine more protective policies by the EU for workers, communities, consumers and wildlife, as well as necessary policies to compel the production of health and safety information for tens of thousands of chemicals on the market today.

For example, proposals by ACC and Cefic would undo the centrepiece of modern EU policies for industrial chemicals: to require basic health and safety data for over 30,000 of the most widely used industrial chemicals in order for these substances to retain market access, i.e. the principle of “no data, no market.”<sup>36</sup> U.S. law does not require any information be generated by the chemical industry in order to gain or retain market access. In addition, the chemical industry’s proposals for cooperation around priority chemicals for risk assessment by regulators on both sides would drastically reduce the number of chemicals to be assessed for potential public health and environmental concerns, and thus potentially subject to approval for certain uses of chemicals with intrinsic hazards.<sup>37</sup> Regarding pesticides, joint proposals by industry call for the EU to jettison precautionary policies that prohibit the use of pesticides that are carcinogens, endocrine (hormone) disruptors, and have other adverse intrinsic properties, and to raise minimum residue levels for certain chemicals on agricultural products.<sup>38</sup> These and other proposals by industry would place the public at greater risk by lowering relatively strong EU standards for toxic chemicals.

The industry groups disingenuously assert that they “are not proposing any changes to current regulations under TTIP.” While the TTIP proposals might not change the letter of existing chemical safety rules in the United States and the European Union, they would severely affect the implementation of those rules. Implementation is the key for any legislation, whether it is at the state, national or international level. The EU’s REACH regulation is many years away from being fully implemented. The final data call for health and safety information under REACH for tens of thousands of chemicals is not until 2018, and nearly 70% of previously submitted dossiers examined by the European Chemicals Agency (only about 5 % of the total number) are not in compliance. It could be said that US TSCA has never been implemented as intended for over 60,000 existing industrial chemicals over the past 38 years.

In addition, proposals to create an overarching institutional framework to minimize regulatory divergence between the U.S. and EU could freeze progress in protecting the health and safety of American consumers. Leaked position papers of the European Commission reveal an intention to alter lawmaking processes in the United States, subjecting both the states and federal government to new and additional obligations throughout legislative and regulatory processes<sup>39</sup>

Specifically, the EU has proposed the establishment of an overarching “Regulatory Cooperation Council (RCC)” to oversee the development and implementation of the vast majority of laws that protect public health, consumers, workers, the integrity of our banks, and the environment in both the EU and US. The U.S. Trade Representative is also calling for an institutional framework with similar objectives. As proposed, the RCC would hold regulatory dialogs between counterparts across the Atlantic throughout the lawmaking processes; create new and additional opportunities for industry to influence decisions under the guise of “transparency;” and carry out trade impact assessments for essentially every significant regulatory or legislative proposal. Without the added burden of trade impact assessments, onerous cost-benefit analyses have frozen the implementation of key provisions of the primary US law for toxic chemicals by regulators. These and other procedures proposed would fundamentally alter—and delay—the development and implementation of new and existing legislation in the EU and US. As discussed more fully below, TTIP would pose a particular barrier to regulations addressing new and emerging toxic hazards, including the hazards posed by endocrine (hormone) disrupting

chemicals and nanomaterials. Just as importantly, the processes envisioned for regulatory cooperation under TTIP would pose a particularly heavy burden on regulators at the state level in the United States and the individual member level in the European Union, where most regulatory innovations begin.

Thus, because of the widely divergent levels of protection in the EU and US, and different approaches to chemicals, harmonization and mutual recognition through either targeted changes to EU and US laws or the creation of an overarching institutional framework for regulatory cooperation would result in lower standards for the health and safety of American consumers.

- **The level of stakeholder input Americans are likely to have in regulatory harmonization or the mutual recognition of standards, compared to the level of input they are currently afforded for domestic laws and regulations.**

The ongoing and severe lack of transparency in the TTIP negotiations, discussed more fully below, makes it impossible to fully assess the level of input Americans would be afforded to regulatory harmonization and mutual recognition processes that result from those negotiations. Nonetheless, the limited evidence that has been released—or, more often, leaked—from the negotiations strongly indicates that ordinary Americans will have far lower levels of input in the harmonization and cooperation processes established by TTIP than they are currently afforded for domestic laws and regulations.

In the absence of publicly disclosed information from our own government regarding the nature of TTIP's evolving regulatory cooperation framework, we must look to other sources of information for insight into the likely impacts of TTIP on public participation.<sup>40</sup>

The most detailed of these sources, introduced above, is the EU's proposal of an overarching institutional framework, the "Regulatory Cooperation Council", to "... monitor the implementation of commitments made and consider new priorities for regulatory cooperation." As proposed, this body would have no accountability to the broader public at the sub-national, national and regional levels. This body would consist of the heads of the most important EU and US regulatory agencies and would monitor the implementation and development of legislation and regulation by the U.S. Federal Government and states. While the proposal explicitly envisions opportunities for input from transnational business groups in the policy-making process, neither the broader public nor civil society groups reflecting broader societal interests are afforded the same access, giving industry undue influence throughout the regulatory process.

EU proposals also outline substantial bi-lateral consultation requirements. Based on the EU position paper, both legislators and regulators in the US would have to undergo onerous consultations with trans-Atlantic counterparts, including time-consuming and unreliable trade-impact (cost-benefit) analyses.<sup>41</sup> Specifically, the EU has proposed that US legislators and/or regulators: (1) respond to EU proposals and comments; (2) provide periodic reviews of upcoming legislation; (3) maintain continuous dialogue with regulators across the Atlantic throughout the rulemaking process; and (4) fully disclose and explain all impact assessment/cost-benefit analyses to the EU Commission. This final point also risks the potential prioritization of

trade liberalization at the expense of environmental and social goals through cost-benefit analysis (i.e. impact assessments).

EU position papers indicate that proposals from stakeholders would be considered, but no further elaboration on the level of public participation or transparency is provided. Significantly, these requirements would apply not only to Congress and national regulators, but also to legislators and regulators at the state level, where international consultation requirements could pose an even heavier burden on comparatively smaller regulatory resources.

In addition, position papers point to the increased use of voluntary instruments to achieve regulatory objectives.<sup>42</sup> Together, these elements have the significant potential to delay or dilute rules needed to protect human health or the environment, with little to no public input.

- **Whether regulatory harmonization or the mutual recognition of standards would make it more difficult, in general, for the United States and the European Union to promulgate new regulations in the future – including on emerging threats to health or safety.**

Yes, regulatory harmonization and mutual recognition would make it far more difficult for the US and the EU to promulgate new regulations in the future, especially in response to emerging science regarding threats to health or safety.

In the 1970s and 80s, the US was the global leader in chemical safety, leading global effort to minimize the use of ozone-depleting substances, polychlorinated biphenyls (PCBs), and other chemicals of concern, with the EU following the U.S. lead. However, over the past few decades, the role of global leadership has shifted to European countries on a myriad of issues, including bisphenol A (BPA), phthalates, toxic flame-retardants, and numerous other chemicals of concern, with states in the U.S. and occasionally the federal government following European leadership.

Such regulatory divergence is how we have made progress on most environmental issues, with one jurisdiction going beyond the status quo, often to increase public protections through stronger regulations — resulting in divergent standards. Yet, it is in this critical regulatory arena that TTIP poses the most significant risks.

The example of endocrine disrupting chemicals is instructive. Nearly 800 chemicals are known, or suspected, to be capable of interfering with the normal function of our hormone systems which are crucial in laying the foundation for a healthy adult life. In 2012, the United States, European Union, over a hundred other countries—and industry—recognized hormone disrupting chemicals as being a global threat due to clear linkages with increased rates of a myriad of diseases which cannot be explained by genetics or lifestyle choices alone.

Member States have advocated for the EU to be a global leader in acknowledging scientific evidence of emerging threats in chemicals management, such as endocrine disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. However, the U.S. Trade

Representative and various industry groups have lobbied extensively against the promulgation of new regulations and criteria to address these emerging and known threats to health and safety.<sup>43</sup>

The longstanding and deep opposition that US diplomats have shown for pragmatic chemical policies by the EU has not been secret. An alliance of US Government officials and the chemical industry lobbied against these EU policies from 2002 until 2013, and continues today with debate over TTIP. A recent joint EU-US chemical industry proposal claims that emerging scientific issues present the EU and US with opportunities to align regulations and prevent divergence prior to their enactment. However, adding another regulatory consultation and co-ordination layer would delay that progress within the EU whilst alignment of regulation was considered. Indeed, CIEL's analysis of the chemical industry's proposal indicates that increasing such delays is an implicit objective of industry in seeking increased regulatory cooperation.<sup>44</sup>

Significantly, TTIP would pose a barrier to addressing emerging threats not only in Europe, but here in the United States as well. Just as U.S. industry and trade agencies have demonstrated strong opposition to REACH, European industry and trade agencies have expressed strong concerns with the more than 30 states that have enacted state-level measures to protect people and the environment from toxic industrial chemicals, due to the inability of the U.S. federal system to fill this role. Much of what is proposed under TTIP by the EU is an attempt to further limit the ability of states to regulate to address the concerns of their constituents. In doing so, TTIP would threaten progress by California, Maine, Washington and other states that have emerged as leaders in enacting measures to reduce exposure to toxic chemicals in products, food, water and the environment.

To reduce the likelihood that TTIP will hinder important public health and safety goals related to chemicals, TTIP must ensure that both the EU and U.S. retain the right to determine their own levels of protection for people, wildlife and the environment, and to develop measures to reduce exposure to hazardous chemicals and nanomaterials as they deem appropriate.

- Whether regulatory harmonization or the mutual recognition of standards would diminish the regulatory sovereignty of the United States and the European Union, *i.e.*, constrain the ability of the two entities to promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens.

Yes, regulatory harmonization or the mutual recognition of standards would diminish the regulatory sovereignty of both the United States and the European Union, both at the highest levels of government and, critically, at the subnational and subregional levels where regulatory innovations most often originate. Negotiators have stated that TTIP would not affect the right of the U.S. and the EU to regulate; however, TTIP would affect the ability of these Parties, including states and Member States, to exercise this right.

The proposed institutional framework for regulatory cooperation would be composed of representatives from both Parties, and cover "any planned and existing regulatory measures of general application" and "extend to regulations by US States and EU Member States." It would have the unstated power to constrain the ability of either Party to exercise its right to

promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens. Some of the key elements of this implicit power include:

- The use of “harmonization, recognition of equivalence, or mutual recognition” as tools for regulatory “cooperation” (see answers in questions 2 and 5 for additional details regarding their negative effects on regulatory sovereignty);
- The use of “cost-benefit” and “trade impact” analyses for proposed regulatory or legislative initiatives, with a special focus on international trade impacts, to be published with the proposed final measure;
- A requirement for “regulatory dialogues,” with trans-Atlantic governments;
- The creation of a trans-Atlantic scientific body to guide regulatory decision making ; and

The right of “stakeholders” to table “substantive joint submissions” for this body to consider. These types of provisions are designed to weaken or delay the development and implementation laws that specifically address priorities of either U.S. or EU citizens that might not be reflected across the Atlantic. For example, the recent decision to abandon the EU’s Fuel Quality Directive, which sought to curb the use of dirty energy sources and encourage renewable, was abandoned due to U.S. government and industry interference over the potential trade-related impacts.<sup>45</sup> An institutional framework would create a permanent avenue for foreign interference with the development and implementation of laws and policies sought by the public in the U.S. or EU to reflect their own values, judgments, circumstances and policy choices.

- **The level of transparency in ongoing U.S.-E.U. trade negotiations, particularly compared to previous trade negotiations in which either entity was involved.**

The level of transparency in ongoing U.S. and EU trade negotiations remains abysmal, has not improved relative to past agreement to any meaningful degree, and is wholly inappropriate given the focus of negotiations on U.S. and EU regulations and lawmaking processes. CIEL has addressed the systematic challenges to public participation imposed by the current U.S. Trade Advisory System in a statement made by Daniel Magraw before the U.S. House of Representatives Committee on Ways and Means Subcommittee on Trade on July 31, 2009.<sup>46</sup> Recognizing that these challenges have remained unresolved since we delivered that testimony, we attach it hereto and incorporate it herein by reference.

Because trade and investment between the EU and the US are already highly integrated, the main focus of TTIP will be to achieve regulatory convergence by removing non-tariff barriers to trade. Eighty percent of TTIP’s expected benefits will come from addressing present and future barriers to trade. Thus, TTIP has much less to do with traditional trade issues such as tariffs, than with U.S. and EU regulations and standards that affect every single aspect of citizens’ daily lives – from the quality of the food we eat to the safety of chemicals we use, the energy we consume, or the impact of financial services on each of us. This makes the need for transparency and public participation correspondingly greater, requiring at least the same level of transparency afforded to domestic lawmaking processes.

The creation of new stakeholder advisory groups for the negotiations by both the EU and U.S. – do not address this need. Members of the group will have limited access to the negotiating texts under strict confidentiality rules, with no access for nearly all civil society groups and citizens, as well as most policy-makers. Indeed, the creation of the new U.S. committee may actually result in a further erosion of the status quo.

The newly established Public Interest Trade Advisory Committee (PITAC) will be separated from the existing Industry Trade Advisory Committee process as are the current “tier two” committees for labor and environmental groups.<sup>47</sup> As a function of this separation, members of the Committee will be unable to attend meetings of any of the ITACs, unlike the ITAC members. The creation of a new segregated committee for the public interest does not address the problems and consequences of the wildly skewed composition of the current US Trade Committee System, which is overwhelmingly dominated by corporate and industry interests. According to a recent Washington Post article, representatives of industry and trade associations make up a total of 85% of the composition of trade committees.<sup>48</sup> In CIEL’s own analysis, out of roughly 600 committee members, fewer than 90 members across all committees that represent State governments, local governments, standardization organizations, academics, research institutions, think tanks, labor unions, and nonprofits of all kinds. The remainder (approximately 85%) represent individual corporations, industry associations, or trade advocacy groups.

Ironically, USTR’s decision, supposedly aimed at “providing a cross-cutting platform for input in the negotiations,” would serve to further marginalize civil society organizations by placing them in a single group that cannot provide adequate representation for the diversity of issues that concern multiple sectors of civil society. The scope and breadth of issues facing the committee will likely result in the dilution of the committee’s position with regards to specific issues, which will limit the committee’s efficacy.

ITAC members have insisted on segregating public interest viewpoints from their committees because “when they were in attendance, it made life very difficult.”<sup>49</sup> For more than a decade, industry has argued that ITACs should be limited to industry membership and reflect only industry voices. The idea behind segregating public interest groups originated from a 2010 meeting to review the membership of the ITACs and to determine whether to expand membership beyond industry representation--a proposition the ITAC members have unanimously rejected.<sup>50</sup>

The emphasis on segregation makes clear USTR’s vision of the advisory system as a vehicle for sector-specific advocacy rather than a forum for a balanced, multi-sectoral discourse regarding policy objectives. Just as the inclusion of a single public interest representative on a committee comprising dozens of industry members cannot be said to fulfill FACA’s requirement that advisory committees be “fairly balanced,” the creation of a single segregated committee comprised of public interest representatives cannot counter the input from 16 industry trade advisory committees and a separate suite of agriculture advisory committees in the creation of a balanced US trade policy.

Segregating the committee would continue to shield the ITACs from any public interest oversight of communications between ITACs and negotiators.<sup>51</sup> Although the PITAC will

have access to negotiating texts, it will not be privy to the informal oral advice that often guides negotiation, rendering the process more reactive than interactive.<sup>52</sup> Public interest representatives should be able to participate fully on every level, and balance is necessary in each committee. The PITAC does not address these critical needs.

The skewed nature of representation in the trade advisory system has concrete implications for public participation in the TTIP negotiations. At the start of the fourth round of TTIP negotiations, CIEL and ClientEarth issued a detailed critique of a document submitted to TTIP negotiators by the two main chemical industry lobbies, the American Chemistry Council (ACC) and the European Chemical Industry Council (Cefic). The industry document contained specific proposals and wording to affect the pace and direction of chemicals regulation through TTIP.<sup>53</sup>

The document, which as of this writing remains publicly available only on CIEL's and ClientEarth's websites, was leaked after the third round of negotiations in December 2013. This industry submission illustrates the significant disparities between public and industry access to trade negotiations--and to the negotiators themselves.

While the industry associations assert that their proposals and positions have always been available on their website, the facts suggest otherwise. ACC and Cefic posted their joint proposal in October of 2012, before new bills to reform US law were introduced, and ACC published a further position paper in May 2013. While these positions were indeed released publicly, the document leaked in December 2013 went well beyond these publicly released positions. Those public statements, for example, did not include:

- Draft legal text for discussion by negotiators (and convenient verbatim adoption);
- Mutual recognition of notifications (under US TSCA) and registration (under EU REACH) – which would undermine the “no-data, no-market” principle of REACH;
- Procedural (bureaucratic) mechanisms, such as the establishment of a “Chemical Sector Joint Cooperation Committee and a “Transatlantic Scientific Advisory Committee (TSAC)” for required consultation on emerging issues or areas of concern prior to the enactment of any regulations; or
- Reliance on a yet to be concluded UN Harmonized List of Classifications.

ACC and Cefic allege that this draft language for TTIP was developed following a request from negotiators. If so, the question arises: In whose interests are US and EU governments negotiating? In order to develop their draft language, ACC and Cefic must have had prior knowledge of the EU position paper on Regulatory Cooperation, which was only disclosed to the public immediately prior to the December negotiating round.<sup>54</sup> That disclosure came not from the governments themselves, but from the European organization, Corporate Europe Observatory (CEO), which released a leaked copy.<sup>55</sup> The public never had access to this document before it was leaked.

These disparities will be further exacerbated if Congress abnegates its own constitutionally mandated role in regulating foreign commerce by conceding to the President's request for Fast Track negotiating authority.

Proposals advanced by industry and entertained by negotiators would lower standards and remove safeguards across the board. Government proposals, which only surfaced through leaked documents, would create onerous processes in order for either Party, including states and Member States, to exercise their right to regulate to protect people, the environment, our financial systems, and other important public interests.

Because proposals under TTIP would affect domestic regulations, standards and safeguards on each side, as well as the processes from which they arise, citizens have the right to know what is being proposed and negotiated. The standard legislative and regulatory processes of the U.S. allow for public scrutiny of nearly every step of policy-making as well as full involvement of elected representatives. Given their far-reaching effects on fundamental public policy choices, these negotiations should adhere to similar standards of openness. The process should also allow for public accountability of the U.S. Trade Representative, European Commission, and other negotiators for the positions that they take.

Without full transparency, there can be no accountability, or meaningful engagement of policymakers, civil society groups, and the public in a process that could fundamentally change the ability of our local, state and federal governments to exercise their right to regulate. Basic transparency requirements include making the following available for the public at the earliest possible stage and at regular intervals:

- The text of the negotiating mandates;
- Initial position papers tabled by the U.S. and EU;
- Additional papers submitted by the U.S. or EU in the course of the negotiations that detail or explain positions on topics, and that are being used in the course of the negotiations with the other party; and
- Draft and final versions of individual chapters as well as the whole agreement at all steps of preparation and evolution (and at least before closing the negotiations and initialing so that lawmakers and the public can still assess the outcome and make comments and recommendations).

If the U.S. and EU are serious about openness and engagement of the public in TTIP, communications between the negotiators and other regulatory agencies, institutional bodies, states and Member States, as well as third parties (including companies, lobbyists, and industry associations) should be made available.

As CIEL observed during our earlier testimony, the secrecy and opacity observed in other trade negotiations, including the negotiations for the Trans Pacific Partnership, are inconsistent with basic principles of good governance and with the public's right to informed, meaningful participation in what amounts to a public policy dialogue of profound national consequence on both sides of the Atlantic. Negotiations between the United States and the EU should demonstrate a clear commitment to public participation and should be conducted in an open, transparent and participatory manner.

6. We have heard that in certain circumstances, foreign investment can have the unintended effect of providing advantages to foreign investors over domestic investors. An example of this advantage is the right of foreign corporations to bypass domestic state and federal courts and proceed to a form of international arbitration known as investor-state dispute settlement (or ISDS). ISDS mechanisms allow foreign companies to challenge U.S. laws that they claim unduly interfere not just with past or present operations but also with the expected future profits from their initial investment.
- a. Please elaborate on these investor state dispute settlement mechanisms and the effect they already have had on the United States. What is the impact of the inclusion of an ISDS mechanism in a trade deal?

On February 28 2014, the Center for International Environmental Law (CIEL) joined 42 other American and international civil society and public interest organizations, as well as members of academia, in a letter to United States Trade Representative Michael Froman, calling for public consultation to review the costs and benefits regarding Investor State Dispute Settlement provisions in free trade agreements, particularly with regards to the TTIP negotiations.<sup>56</sup>

First, the inclusion of ISDS provisions under TTIP would dramatically increase risk of ISDS suits against the U.S. According to the United Nations Conference on Trade and Development (UNCTAD), U.S. and European companies account for 75% of all investor-state disputes known globally.<sup>57</sup> This fact is not surprising when one considers that, in addition to being the world's largest economies, the U.S. and E.U. member countries have negotiated approximately 3000 multilateral, regional and bilateral investment treaties containing investor protection provisions.

The number of investor-state cases worldwide has increased exponentially in recent years.<sup>58</sup> ISDS provisions have enabled businesses to claim more than \$430 million in compensation, with \$38 billion sought under fifteen pending claims for public interest and environmental laws and policies.<sup>59</sup> Cases against the U.S. include laws to protect people from the emission of a neurotoxin additive in gasoline (Methanex), and to require the restoration of mines (Glamis Gold). Other examples of ISDS claims for public health and environmental laws and policies include suits against: (1) Germany for U.S.\$ 3.7 billion following a democratic decision to phase out nuclear energy;<sup>60</sup> and (2) Canada for CAN\$ 250 million for lost profits by a Canadian company due to a moratorium on hydraulic fracturing (fracking) for shale gas.<sup>61</sup> Numerous legal and policy experts have voiced concerns over investment tribunals hearing such disputes, as they are unlikely to adequately take into account human rights, labor rights, and environmental or other public interest concerns.<sup>62</sup>

While USTR asserts that the United States has never technically "lost" an ISDS case,<sup>63</sup> this conveniently overlooks settlements with investors and the growing trend of companies restructuring (and in some cases relocating) their operations to sue as protected investors under particular regimes. Indeed, global legal and consulting firms have developed a robust cottage industry in advising multinationals on how to structure their operations to make strategic use of these protections. With 75,000 companies already cross-registered in both the United States and the EU, the financial exposure from future investor claims and litigation response costs could increase dramatically if ISDS are included under TTIP.<sup>64</sup>

That recourse to these mechanisms would appeal to companies is equally unsurprising because ISDS affords “foreign” investors greater rights than domestic businesses. ISDS provides foreign investors the right to bypass domestic courts (including constitutionally-created Article III courts) and challenge the U.S. government directly before an international arbitration tribunal, if they feel that a domestic policy or government decision contravenes their expectations or threatens their expected future profits, a right that even domestic investors do not share.<sup>65</sup>

Proponents of ISDS also routinely ignore the regulatory chilling effect of real or threatened investor suites. The threat of ISDS suits can result in the dilution of many proposed laws on public health and environmental protection.<sup>66</sup> ISDS weakens the power of governments to regulate, despite the fact that they retain the “right” to do so. Governments must have the flexibility to put in place public interest policies without fear of costly trade litigation brought by well-resourced corporations.

Further, ISDS provisions undermine democracy and values of justice deeply embedded in both the U.S. and European systems. While the public interest laws at issue are the product of democratic processes, ISDS panels are not democratically selected, are not bound to consider basic principles of U.S. law such as sovereign immunity, and are not required to balance the public interest against alleged violations of an investor’s rights. Arbitrators often represent clients in different ISDS cases, and are above any meaningful degree of accountability, due in part to a dark veil of secrecy. Decisions of the tribunal—including legally incorrect decisions—are final and binding on countries, with limited exceptions. As arbitrators themselves are recruited from the international trade community to apply international trade rules to international trade agreement, the system is implicitly biased to elevate trade concerns above other societal values and policy priorities.<sup>67</sup>

Finally, ISDS suits place the public in a lose-lose situation. Each ISDS case costs American taxpayers an average of \$8 million, oftentimes to defend against meritless claims.<sup>68</sup> In the instance of a loss by the U.S. government, Americans must compensate corporations for less-than-expected profits. In the case where the law is weakened or abandoned to avoid the potential liability of an ISDS suit, the public may continue to bear the externalized costs of corporate activities, for example pollution.

**b. Both the U.S. and the E.U. have highly developed, well-functioning judicial systems. Why do some companies and industries want ISDS to be included in TTIP? Should consumers?**

While the inclusion of ISDS provisions is problematic in any trade agreement, traditional arguments for the inclusion of ISDS in trade and investment agreements are clearly without foundation in the context of TTIP. The United States and the EU have very strong domestic court systems and property rights protections, with the U.S. affording the same rights to foreign investors as domestic investors. European officials have stated publicly that ISDS is not necessary under TTIP for robust trans-Atlantic foreign investment, as the level of foreign investment is already very high.

ISDS is sought under TTIP by companies and industries because it offers corporations around the world a favorable venue to attack and undermine domestic laws and policies created through democratic processes, in order to maximize profits. ISDS grants foreign corporations the right to directly challenge government policies and actions in private tribunals, bypassing domestic courts and creating a new legal system that is exclusively available to foreign investors and multinational corporations. Typically a three-person panel composed of private attorneys oversees the case, with the power to award an unlimited amount of taxpayer dollars to corporations. For example, a crushing US\$2.3 billion, the highest compensation to date, has been awarded to U.S. oil company Occidental Petroleum against Ecuador, for the termination of an oil production site in the Amazon.<sup>69</sup> As the process elevates private firms and investors to the same status as sovereign governments, it amounts to a privatization of the justice system.<sup>70</sup>

For example, in one of the most notorious cases, U.S. tobacco giant Philip Morris launched investor-state cases challenging anti-smoking laws in Uruguay and Australia after failing to undermine the health laws in domestic courts.<sup>71</sup> In a recent case in which CIEL has been directly involved, a Canadian firm seeking to operate a gold mine in El Salvador, through a subsidiary registered in the Cayman Islands, abruptly closed that subsidiary and re-registered in Reno, Nevada in an effort to sue the government of El Salvador as a U.S. investor under the U.S.-Central American Free Trade Agreement.<sup>72</sup> Troublingly, the panel considering the case concluded that the firm's actions were permissible under CAFTA, despite the lack of any meaningful connection between its Salvadoran mining operation and the United States. The company was denied investor protections under CAFTA only after El Salvador successfully invoked another provision of the agreement to deny those protections.

In response to the egregious corporate abuse of the investor-state system in sidestepping domestic court decisions, several countries have started to turn away from investor-state dispute settlement. South Africa, Bolivia, Ecuador, Venezuela, and Indonesia have begun phasing out existing bilateral investment treaties.<sup>73</sup> Additionally, Ecuador, Bolivia and Indonesia have withdrawn from the International Centre for the Settlement of Investment Disputes (ICSID).<sup>74</sup> In the U.S., the National Conference of State Legislators, representing all 50 U.S. state parliamentary bodies, has declared that it "will not support any [trade agreement] that provides for investor-state dispute resolution" because it interferes with their "capacity and responsibility as state legislators to enact and enforce fair, nondiscriminatory rules that protect public health, safety and welfare, assure worker health and safety, and protect the environment."<sup>75</sup>

On an international level, UNCTAD has prioritized its attention on reforming the system to provide for more transparency, preserve appropriate regulatory space for host countries, and balancing the rights and obligations of States and investors, as well as assessing the options available for countries to terminate existing treaties.<sup>76</sup>

In 2013, the United Nations Commission on International Trade Law (UNCITRAL) adopted new rules designed to bring greater transparency to international investment disputes.<sup>77</sup> While these rules represent an improvement in the status quo with respect to the transparency of such disputes for agreements completed after April 2014, the rules will not apply retroactively to existing agreements unless State parties to those agreements consent thereto. Nor do they remedy the many and fundamental challenges of ISDS discussed in the foregoing pages.

## Notes

<sup>1</sup> Government Accountability Office (GAO), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

<sup>2</sup> Center for International Environmental Law (CIEL), *Driving Innovation: How stronger laws help bring safer chemicals to market* (2013).

<sup>3</sup> Centre for Strategy & Evaluation Services, *Final Report, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU Chemical Industry*, (hereinafter "REACH Innovation Report") pp. xii (emphasis added) (June 14, 2012), available at: [http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report\\_en.pdf](http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf)

<sup>4</sup> U.S. Environmental Protection Agency (EPA), Confidential Business Information (webpage, last accessed May 5, 2014), available at: <http://www.epa.gov/oppt/tsca&e/pubs/confidentialbusinessinformation.html> (describing proposed changes by Administrator Lisa Jackson in 2010 to increase transparency).

<sup>5</sup> Chemical Watch, *Court ruling threatens CBI protection* (Global Business Briefing, Nov. 2013)

<sup>6</sup> Cefic, *Cefic response to Commission's request for further details on joint ACC-Cefic proposal for enhanced regulatory cooperation on chemicals under TTIP* (March 7, 2014). The question of ownership is critical in this context, and requires careful analysis. Trade secrets are a "non-core" intellectual property right in 27 of 28 EU member states, unlike the U.S. where trade secrets are generally protected under laws of unfair competition, creating fundamental distinctions between the rights conferred to "owners."

<sup>7</sup> Cefic, *Cefic response to Commission's request for further details on joint ACC-Cefic proposals for enhanced cooperation on chemicals under TTIP* (March 7, 2014), available at: <http://www.cefic.org/Documents/PolicyCentre/TTIP%5BTTIP%5D%20Cefic%20response%20to%20Commission%20ACC-Cefic%20proposal%20on%20TTIP%207%20March%202014%20%28web%20and%20click-in%29.pdf>

<sup>8</sup> CIEL & Client Earth, *Toxic Partnership: A critique of the ACC-CEFIC proposal for trans-Atlantic cooperation on chemicals* (2014) [hereinafter Toxic Partnership], available at: [http://ciel.org/Publications/ToxicPartnership\\_Mar2014.pdf](http://ciel.org/Publications/ToxicPartnership_Mar2014.pdf)

<sup>9</sup> Statement of Daniel Rosenberg, Natural Resources Defense Council before the United States Senate Committee on Environment and Public Works at hearing on Strengthening Public Health Protections by Addressing Toxic Chemical Threats (July 31, 2013), available at: <http://www.nrdc.org/health/files/drosenberg-13111401a.pdf> (describing the numerous shortcomings of S.1009, the Chemical Safety Improvement Act, and the problems with TSCA that it fails to address)

<sup>10</sup> Civil Society Organization Letter to Representative John Shimkus, Chairman of the U.S. House Subcommittee on Environment and Economy, Committee on Energy and Commerce (April 28, 2014) (on file with author).

<sup>11</sup> *Id.*

<sup>12</sup> ChemicalWatch, *US EPA says TSCA bill not in line with its reform principles: Industry, NGO positions remain unchanged* (April 30, 2014), available at: <http://chemicalwatch.com/19495/us-epa-says-tscas-bill-not-in-line-with-its-reform-principles>.

<sup>13</sup> ChemSec, *Cry Wolf: Predicted costs by industry in the face of new regulation* (2004), available at: [http://www.chemsec.org/images/stories/news\\_publications/Cry\\_wolf\\_report\\_040422.pdf](http://www.chemsec.org/images/stories/news_publications/Cry_wolf_report_040422.pdf)

<sup>14</sup> ChemSec, *Cry Wolf: Predicted costs by industry in the face of new regulation* at 5.

<sup>15</sup> ChemSec, *Cry Wolf: Predicted costs by industry in the face of new regulation* at 11 (citing Arthur D. Little GmbH, *Economic Effects of the EU Substances policy* (2002); and Mercer Management Consulting, *Study of the Impact of the Future Chemicals Policy* (2003)).

<sup>16</sup> ChemSec, *Cry Wolf: Predicted costs by industry in the face of new regulation* at 11 (citing Arthur D. Little GmbH, *Economic Effects of the EU Substances policy* (2002); and Mercer Management Consulting, *Study of the Impact of the Future Chemicals Policy* (2003)).

<sup>17</sup> World Bank data, available at: <http://www.google.com/publicdata>

<sup>18</sup> REACH review 2012, available at <http://eur-lex.europa.eu/legal-content/EN/ALL/?sessionid=D8RSTIZDSxsxZzMvHML9JDNpSvyGqc1NtVBwWhxChG2d0yLJ1y11-1073287639?uri=CELEX:52013DC0049>

<sup>19</sup> REACH review 2012

<sup>20</sup> *Id.* pg 94.

<sup>21</sup> REACH review 2012

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- <sup>22</sup> See Massey et al. <http://econpapers.repec.org/paper/daedapap/06-06.htm> (chemical industry's annual turnover estimated at 4 trillion)
- <sup>23</sup> KEMI, *The Influence of Legislation on the Location of the Chemical Industry* (2013).
- <sup>24</sup> CIEL, *Driving Innovation: How stronger laws help bring safer chemicals to market* (2013), available at: [http://ciel.org/Publications/Innovation\\_Chemical\\_Feb2013.pdf](http://ciel.org/Publications/Innovation_Chemical_Feb2013.pdf)
- <sup>25</sup> Pat Rizzuto, *Law Center Says Strict Chemical Controls Foster Innovation, Markets, Protect People*, Chemical Regulation Reporter, 37 CRR 194 (Bloomberg BNA, Feb. 18, 2013), available at: [http://ciel.org/Chem/Innovation\\_BNA\\_18Feb2013.html](http://ciel.org/Chem/Innovation_BNA_18Feb2013.html)
- <sup>26</sup> Chemical Abstract Services, CAS Registry and CAS Registry Numbers FAQs (webpage, last accessed May 6, 2014), available at: <https://www.cas.org/content/chemical-substances/faqs>
- <sup>27</sup> Karel De Gucht, European Commissioner for Trade, 19 April 2013, The Transatlantic Trade and Investment Partnership: Global Impacts, available at: [http://europa.eu/rapid/press-release\\_SPEECH-13-343\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-343_en.htm)
- <sup>28</sup> Procter and Gamble, *P&G input into consultation on regulatory issues for possible future trade agreement between the EU and U.S.* (undated), available at: [http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/files/consultation/regulation/38-procter-and-gamble\\_en.pdf](http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/files/consultation/regulation/38-procter-and-gamble_en.pdf)
- <sup>29</sup> ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, OECD ENVIRONMENTAL OUTLOOK TO 2050: THE CONSEQUENCES OF INACTION (2012).
- <sup>30</sup> US Trade Representative (USTR), 2013 Report on Technical Barriers to Trade, 71 (2013)
- <sup>31</sup> "Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America," Brussels: Council of the European Union, 17 June 2013 (available as a leaked document).
- <sup>32</sup> John Hilary, *The Transatlantic Trade and Investment Partnership* (Rosa Luxembourg Foundation, 2014), available at: [http://rosalux-europa.info/publications/books/TTIP\\_EN/](http://rosalux-europa.info/publications/books/TTIP_EN/).
- <sup>33</sup> Note for the Attention of the Trade Policy Committee on the Transatlantic Trade and Investment Partnership, Annex 2--Initial Position Paper: Chemicals in TTIP, June 20, 2013, EC Trade Policy Committee (June 21, 2013) [hereinafter Chemicals in TTIP].
- <sup>34</sup> Chemicals in TTIP, *supra*.
- <sup>35</sup> See e.g. ACC-Cefic, Joint Proposal: Enhancing Regulatory Cooperation under TTIP (Dec. 2013), available at: [http://ciel.org/Chem/TTIP\\_10Mar2014.html](http://ciel.org/Chem/TTIP_10Mar2014.html); See also, CropLife America and European Crop Protection Association, Proposal on US-EU Regulatory Cooperation (March 2014), available at: <http://www.croplifeamerica.org/sites/default/files/ECPA-CLA%20TTIP%20Position%20-%20Paper%2010-03-14.pdf>.
- <sup>36</sup> *Toxic Partnership*, *supra*.
- <sup>37</sup> *Toxic Partnership*, *supra*.
- <sup>38</sup> CropLife America and European Crop Protection Association, Proposal on US-EU Regulatory Cooperation (March 2014).
- <sup>39</sup> EU Position paper – Chapter on Regulatory Coherence (Dec. 2013), available at: <http://corporateeurope.org/sites/default/files/ttip-regulatory-coherence-2-12-2013.pdf>; ACC-Cefic, *Joint Proposal*, *supra*.
- <sup>40</sup> Corporate Europe Observatory (CEO), Regulation none of our business? (2013), available at: <http://corporateeurope.org/trade/2013/12/regulation-none-our-business>
- <sup>41</sup> EU Position paper – Chapter on Regulatory Coherence, *supra*. See also, *Toxic Partnership*, *supra*.
- <sup>42</sup> EU-US Transatlantic Trade and Investment Partnership: Technical Barriers to Trade, EC (July 2013) [hereinafter TBT position paper], available at [http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc\\_151627.pdf](http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf).
- <sup>43</sup> USTR, 2014 Report on Technical barriers to Trade; USTR, 2013 Report on Technical Barriers to Trade; See e.g. ACC submission to USTR stakeholder consultation (May 10, 2013); Dow Chemical, submission to USTR stakeholder consultation (May 10, 2013); and Eastman Chemical, submission to USTR stakeholder consultation (May 10, 2013).
- <sup>44</sup> *Toxic Partnership*, *supra*.
- <sup>45</sup> EurActiv, The tar sands mystery and the TTIP smoking gun (April 15, 2014), available at: <http://www.euractiv.com/sections/energy/tar-sands-mystery-and-smoking-ttip-gun-301552>
- <sup>46</sup> Statement of Daniel B. Magraw Jr., Center for International Environmental Law, before the U.S. House of Representatives Committee on Ways and Means Subcommittee on Trade, hearing on the Trade Advisory Committee system, July 21, 2009, available at: <http://waysandmeans.house.gov/media/pdf/111/magraw.pdf>

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- <sup>47</sup> Sean Flynn, USTR Accepts Business Proposal to Segregate Public Interest in Advisory Committees, 19 Feb. 2014, available at: <http://infojustice.org/archives/32248>
- <sup>48</sup> Christopher Ingraham, *Interactive: How companies wield off-the-record influence on Obama's Trade Policy*, The Washington Post Wonkblog, February 28, 2014, available at: <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/02/28/how-companies-wield-off-the-record-influence-on-obamas-trade-policy/>
- <sup>49</sup> Jim (V.M.) DeLisi, transcript of meeting of USTR Industry Trade Advisory Committee chairs, Public Session, at 18 (Oct. 12, 2010), available at: [http://www.ustr.gov/webfm\\_send/2449](http://www.ustr.gov/webfm_send/2449)
- <sup>50</sup> *Id.* at 11.
- <sup>51</sup> See Margot Kaminski, Fixing International IP Capture? Some Problems with the Public Interest Trade Advisory Committee, March 13, 2014, available at <http://www.concurringopinions.com/archives/2014/03/fixing-international-ip-capture-some-problems-with-the-public-interest-trade-advisory-committee-pitac.html>
- <sup>52</sup> *Id.*
- <sup>53</sup> *Toxic Partnership, supra.*
- <sup>54</sup> Corporate Europe Observatory (CEO), Regulation none of our business? (2013), available at: <http://corporateeurope.org/trade/2013/12/regulation-none-our-business>
- <sup>55</sup> *Id.*
- <sup>56</sup> Civil Society Letter to Ambassador Michael Froman re: Support for Public Consultation Process on Investment and Investor-to-State Dispute Settlement Policies, February 28, 2014.
- <sup>57</sup> United Nations Conference on Trade and Development, Recent Developments in Investor-State Dispute Settlement (ISDS), N. 1 (April 2014), available at [http://unctad.org/en/PublicationsLibrary/webdiaepcb2014d3\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiaepcb2014d3_en.pdf)
- <sup>58</sup> Civil Society Letter to Ambassador Michael Froman and Commissioner Karel De Gucht opposing inclusion of investor-state dispute settlement provisions in the Transatlantic Trade and Investment Partnership, December 16, 2013; see Public Citizen Table, *supra*.
- <sup>59</sup> Public Citizen, Table of Foreign Investor-State Cases and Claims Under NAFTA and other U.S. "Trade" Deals, February 2014 [hereinafter Public Citizen Table].
- <sup>60</sup> Nathalie Bernasconi-Osterwalder & Rhea Tamara Hoffman, *The German Nuclear Phase-Out Put to the Test in International Investment Arbitration*, October 2013, available at: <http://power-shift.de/wordpress/wp-content/uploads/2012/06/TNI-PowerShift-Somo-Paper-Vattenfall-ICSID-case-updated-2013.pdf>
- <sup>61</sup> Lone Pine Resources Inc. v. Canada, Notice of Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and Chapter Eleven of the North American Free Trade Agreement, Sep. 16, 2013, available at: <http://www.italaw.com/sites/default/files/case-documents/italaw1596.pdf>
- <sup>62</sup> In January 2014, CIEL and the International Human Rights Program (IHRP) at the University of Toronto published a Guide for Potential Amici in International Investment Arbitration which provides guidance for such non-governmental organizations who are concerned that a dispute before the International Centre for Settlement of Investment Disputes (ICSID) might implicate public interests that will not be adequately addressed or taken into account by the ICSID Tribunal hearing a dispute.
- <sup>63</sup> USTR, *Facts Concerning Investor State Dispute Settlement* (March 2014), available at: <http://www.ustr.gov/about-us/press-office/blog/2014/March/Facts-Investor-State%20Dispute-Settlement-Safeguarding-Public-Interest-Protecting-Investors>
- <sup>64</sup> Public Citizen, TAFTA Corporate Empowerment Map, The 75,000 Companies that Could Attack Clean Water Safeguards, Green Energy Policies, and Wall Street Reforms, available at <https://www.citizen.org/TAFTA-investment-map>
- <sup>65</sup> Public Citizen Table, *supra*.
- <sup>66</sup> See Kyla Tienhaara, *Regulatory Chill and the Threat of Arbitration: A View from Political Science*, in *EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION* (Chester Brown & Kate Miles, eds. 2011). See also, Canadian Center for Policy Alternatives, *NAFTA Chapter 11 Investor-State Disputes* (Oct. 2010).
- <sup>67</sup> Corporate Europe Observatory, *Still not loving ISDS: 10 reasons to oppose investors' super-rights in EU trade deals*, April 16, 2014, available at <http://corporateeurope.org/international-trade/2014/04/still-not-loving-isds-10-reasons-oppose-investors-super-rights-eu-trade>
- <sup>68</sup> Civil Society Letter to Ambassador Michael Froman re: Support for Public Consultation Process on Investment and Investor-to-State Dispute Settlement Policies, February 28, 2014, available at: [http://www.citizen.org/documents/letter\\_froman\\_public\\_consultation\\_investment.pdf](http://www.citizen.org/documents/letter_froman_public_consultation_investment.pdf)
- <sup>69</sup> ICSID, Award In the Proceeding between Occidental Petroleum Corporation and the Republic of Ecuador, Case

No. ARB/06/11, Oct. 5, 2012, available at <http://italaw.com/sites/default/files/case-documents/italaw1094.pdf>

<sup>70</sup> Public Citizen Table, *supra*.

<sup>71</sup> See Position of REDES- Friends of the Earth Uruguay on the Recent ICSID Decision, *Bad news for Uruguay and the WHO Framework Convention on Tobacco Control*, July 10, 2013, available at: [http://www.redes.org.uy/wp-content/uploads/2013/07/Posicionamiento\\_Redes\\_eng.pdf](http://www.redes.org.uy/wp-content/uploads/2013/07/Posicionamiento_Redes_eng.pdf)

<sup>72</sup> See CIEL, Amicus Brief Highlights the Environmental and Human Rights impacts of Mining in \$77 million Investment Arbitration Case (March 4, 2011), available at: [www.ciel.org/HR\\_Envir/PAC\\_RIM\\_4Mar11.html](http://www.ciel.org/HR_Envir/PAC_RIM_4Mar11.html)

<sup>73</sup> <sup>74</sup> See UNCTAD, International Investment Policymaking in Transition, Challenges and Opportunities of Treaty Renewal, No. 4 June 2013, available at [http://unctad.org/en/PublicationsLibrary/webdiapcb2013d9\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiapcb2013d9_en.pdf)

<sup>74</sup> Corporate Europe Observatory, *Still not loving ISDS: 10 reasons to oppose investors' super-rights in EU trade deals*, April 16, 2014, available at <http://corporateeurope.org/international-trade/2014/04/still-not-loving-isds-10-reasons-oppose-investors-super-rights-eu-trade>

<sup>75</sup> An Open Letter From U.S. State Legislators to Negotiators of the Trans-Pacific Partnership Urging the Rejection of Investor-State Dispute Settlement, available at <https://www.citizen.org/documents/State-Legislators-Letter-on-Investor-State-and-TPP.pdf>

<sup>76</sup> See UNCTAD, International Investment Policymaking in Transition, Challenges and Opportunities of Treaty Renewal, No. 4 June 2013, available at [http://unctad.org/en/PublicationsLibrary/webdiapcb2013d9\\_en.pdf](http://unctad.org/en/PublicationsLibrary/webdiapcb2013d9_en.pdf)

<sup>77</sup> UNCITRAL, 46th session (July 8-26, 2013), A/CN.9/XLVI/CRP.3 (July 9, 2013) (as modified in negotiations). For a detailed discussion of the rules, see New UNCITRAL Arbitration Rules on Transparency: Application, Content and Next Steps (August 2013). Joint publication by CIEL, IISD and the Vale Columbia Center. Available at: [http://www.ciel.org/Publications/UNCITRAL\\_Transparency\\_Aug2013.pdf](http://www.ciel.org/Publications/UNCITRAL_Transparency_Aug2013.pdf)

