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THE U.S.-EU FREE-TRADE AGREEMENT:

TIPPING OVER THE REGULATORY BARRIERS

WEDNESDAY, JULY 24, 2013

House of Representatives,

Subcommittee on Commerce, Manufacturing, and Trade,

Committee on Energy and Commerce,

Washington, D.C.

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.

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:]

******** COMMITTEE INSERT ********

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.

[The prepared statement of Ms. Schakowsky follows:]

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

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.

[The prepared statement of Mr. Lance follows:]

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Mr. Terry. Is there anybody else on our side that wishes 2-1/2 minutes?

Seeing none, the time is yielded back.

The chair recognizes the full committee ranking member, the gentleman from 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 prepared statement of Mr. Waxman follows:]

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Mr. Terry. The gentleman yields back. And I am going to introduce our --

Mr. Waxman. Oh, Mr. Chairman, before you do --

Mr. Terry. Yes?

Mr. Waxman. -- 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 RESEARCH 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; JEAN M. HALLORAN, U.S. LIAISON, TRANSATLANTIC CONSUMER DIALOGUE SECRETARIAT, SENIOR ADVISOR ON INTERNATIONAL AFFAIRS TO THE PRESIDENT OF CONSUMER REPORTS, ON BEHALF OF THE CONSUMERS UNION AND THE TRANSATLANTIC CONSUMER DIALOGUE; AND CARROLL MUFFETT, PRESIDENT AND CEO, CENTER FOR INTERNATIONAL 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:]

******** INSERT 1-1 ********

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 lifeblood 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:]

******** INSERT 1-2 ********

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 to 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 certain 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:]

******** INSERT 1-3 ********

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:]

******** INSERT 1-4 ********

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:]

******** INSERT 1-5 ********

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:]

******** INSERT 1-6 ********

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 a 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. Okay.

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

Mr. Dooley. Yeah, 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. Okay, 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. Okay. 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. Okay. And formularies?

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

Ms. Schakowsky. Okay.

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. Okay.

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. Okay.

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.

RPTS JANSEN

DCMN SECKMAN

[10:50 a.m.]

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 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 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. Okay. 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 -- you know, 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 thing -- 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, you know, 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 -- 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. U.S. -- 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 the -- 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 -- 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. Say that -- 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, you know, you know, it is clear that whether you are producing a chemical in the United States or the EU, and our companies are multinational, is that, you know, 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 parties -- 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 it 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. Okay. 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 return 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.

Dr. 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.

Dr. 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.

Dr. 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.

Dr. 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.

Dr. 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. 65 percent --

Mr. Long. U.S. 65 of the overall --

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

Mr. Long. Okay. That was my question.

I have other question for you. How to 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 -- 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. T.

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. Okay. 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 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, you know, 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 -- that the industry folks, at the answer there, and that was this notion that if you had, you know, 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 the 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 NTSA 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 technology -- Biotechnology Industry Association statement. There all being nine. And these have all been shared with the minority.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Terry. Now I -- 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 -- 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 follows:]

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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.]