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THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: ACHIEVING THE POTENTIAL

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BEFORE THE

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THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: ACHIEVING THE POTENTIAL

WEDNESDAY, OCTOBER 30, 2013

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 11:10 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Carper, Cardin, Brown, Casey, Hatch, Thune, and Isakson.

Also present: Democratic Staff: Mac Campbell, General Counsel; Rory Murphy, International Trade Analyst; Bruce Hirsh, Chief International Trade Counsel; Chelsea Thomas, Professional Staff Member; and Lisa Pearlman, International Trade Counsel. Republican Staff: Chris Campbell, Staff Director; Everett Eissenstat, Chief International Trade Counsel; and Jeff Wrase, Chief Economist.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

Benjamin Franklin, who helped negotiate the original trade treaties between America and Europe more than 2 centuries ago, gave the following advice, and I quote: "To succeed, jump as quickly at opportunities as you do at conclusions."

Franklin was our first ambassador, becoming the U.S. Minister to France in 1776, long before our Nation won its independence from Britain.

He saw an opportunity, an opportunity to build a strong relationship with a powerful ally. Thanks to his work, the United States and France signed treaties in 1778 that gave our young army critical support and laid out the framework for a successful trading partnership.

We are here today because we have another opportunity, an opportunity to boost America's economy, an opportunity to create thousands of new jobs across the United States. This opportunity lies in a new comprehensive trade agreement between the United States and the European Union. It is called the Transatlantic Trade and Investment Partnership, or TTIP. And it is an opportunity we must jump at quickly.

The U.S. and E.U. already enjoy the strongest economic relationship in the world. Together we make up half of global GDP and more than a third of global trade. Every day, the United States and the E.U. trade $2.7 billion in goods and services. We have invested nearly $4 trillion in each other's economies. Transatlantic trade supports 13 million U.S. jobs. We all know that we need more jobs and better-paying jobs. This new opportunity, this new trade and investment agreement, would deliver those jobs.

This new trade agreement could boost exports to the E.U. by a third and add more than $100 billion annually to U.S. GDP. It could support hundreds of thousands of new jobs in the United States.

Jobs related to exports pay 13 to 18 percent more than the national average, and jobs supported by foreign direct investment in the United States pay 30 percent more than non-FDI-supported jobs. When we lower trade barriers, we increase exports and attract foreign investment, and we provide America's economy the shot in the arm it so desperately needs.

The benefits of TTIP would ripple across our Nation. For example, in my home State of Montana, TTIP could grow exports to the E.U. by 19 percent and support nearly 2,400 new Montana jobs. Every State would have its own success story.

How would TTIP do this? It would lower tariffs on our enormous bilateral trade, increasing U.S. exports by double digits and saving families money on the goods and services they buy here at home.

It would cut red tape and reduce costs for businesses, such as automakers that currently face duplicative regulations in the E.U. and the United States. And it would spark investment in innovation that would bring jobs and growth on both sides of the Atlantic.

We are talking about a landmark opportunity. But for the TTIP to live up to its potential, we will first have to tackle a number of challenges. For example, we must address the E.U.'s unscientific and unjustified barriers to U.S. agricultural products, including beef and poultry.

While in Europe last year, I pushed their leaders to drop those barriers. U.S. beef has earned the top safety rating from the World Organization for Animal Health. And CODEX, another of the world's trusted authorities on food safety, has declared U.S. beef production methods to be perfectly safe. It is finally time for the E.U. to act.

I am confident that we can overcome that hurdle and others. The more challenges we address in negotiating the TTIP, the bigger the gains will be for our two economies, boosting exports, attracting new investment, and creating jobs.

The TTIP is just one part of the most ambitious U.S. trade agenda in a generation. Ninety-five percent of the world's consumers live outside of the United States. Our trade agenda today gives American farmers, ranchers, businesses, and workers more opportunities to reach them than ever before.

It means Dave and Cole Mannix, two proud family ranchers from Helmville, MT, can expand their market for some of the best-tasting beef I have ever had. It means global brewers, like Anheuser-Busch InBev, can use more Montana malt barley in their beer. It means international companies like Siemens can have even

more reason to work with educational institutions like Flathead Valley Community College to develop the skills of Montana's workforce.

Congress needs to be a full partner in the development and execution of this agenda, and the best way to do that is to pass Trade Promotion Authority and to do it soon.

The United States has numerous other trade opportunities. The Trans-Pacific Partnership, or TPP, is near completion. The TPP parties need to know in the clearest terms what Congress's priorities are. And Congress needs to set priorities as the administration starts negotiating with Europe. We can do that through Trade Promotion Authority. I am pleased that President Obama has requested TPA and that Ambassador Froman has been making the case for TPA.

It is time for us to do our part. We must introduce a bill and pass it quickly. Senator Hatch, let us work together to get that done as quickly as possible.

Ben Franklin counseled us to jump at opportunities. That is advice we must heed for very simple reasons. More trade means more American jobs, and more trade means a stronger economy. More trade means a more secure future. It is that simple.

So let us jump at this opportunity to expand the world's largest trade relationship. Let us do the hard work. Let us make sure that TTIP is as meaningful as we can make it.

[The prepared statement of Chairman Baucus appears in the appendix.]

The CHAIRMAN. Senator Hatch?

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Senator HATCH. Well, thank you, Mr. Chairman, for holding this hearing.

As we all know, expanding international trade is vital to our economic growth. Unfortunately, the United States has not conducted a new free trade agreement since June of 2007. Fortunately, the administration has a golden opportunity to change that in the near future.

Negotiations for a small package of trade-enhancing measures under the auspices of the World Trade Organization are really reaching a critical stage. According to Ambassador Froman, negotiations to conclude a Trans-Pacific Partnership are also in the, quote, "end game."

Meanwhile, interest in concluding the Trade and Investment Services Agreement continues to build. And, of course, there is the potential surrounding the Transatlantic Trade and Investment Partnership agreement, or TTIP, which we are here to discuss today.

TTIP negotiations are just getting underway. If successful, they will build on our already strong economic ties with the 28 member states of the European Union. Our economic relationship with the E.U. is one of the largest and most complex in the world. Together, our two economies account for about one-half of the world GDP and for nearly a third of world trade.

Our two markets are already deeply integrated. So, for TTIP to reach the full potential, the agreement must reflect an unprecedented level of ambition.

Tariffs between our two economies remain low, but the sheer volume of trade means that companies and consumers on both sides of the Atlantic are paying vast sums in unnecessary tariffs. For example, ICON Health, based in Logan, UT, manufactures home exercise equipment. Grown from a small company on the campus of Utah State University, ICON now employs over 3,000 people and sells its products all over the world. Yet, today, they still face tariffs in the E.U. averaging 2.7 percent. Elimination of these nuisance tariffs would help spur more economic opportunity on both sides of the Atlantic.

On February 12th of this year, Chairman Baucus and I sent a letter to Ambassador Kirk outlining our expectations for the TTIP negotiations. We highlighted the importance of strong market access for U.S. agricultural products, including the elimination of unjustified sanitary and phyto-sanitary standards. We also called for the agreement to be comprehensive, excluding no product or sector from the actual negotiations.

Finally, we called upon the administration to ensure that the agreement reflects the highest standards of intellectual property rights and does not jeopardize our ability to reach high levels of intellectual property protection in other negotiations or in other markets.

All of these goals still hold. But today I want to emphasize a few key points. First, for the U.S. economy to thrive, strong intellectual property rights protections are vitally important. Intellectual property-intensive industries support at least 40 million jobs and contribute more than $5 trillion to the U.S. economy.

For me to support a final agreement, it is absolutely essential that TTIP reflect the highest standards of intellectual property rights protection of any prior agreement. Indeed, the standards set in TTIP will be a model for the world. So we just have to get it right.

I also want to emphasize the importance of digital trade. The Internet has fundamentally changed the way in which consumers shop and businesses deliver their products and services. Businesses, especially small businesses, benefit through improved efficiency, lower production costs, and access to a wider range of markets, while consumers benefit from more choices and, I might add, improved access to products and services.

Given the importance of digital trade in the European market, there are several barriers to digital trade that I believe the agreement must address.

First, there are barriers that inhibit the free flow of digital data, including forced localization policies that, for example, require data servers to be located in-country or that require utilization of local content or technologies. The final TTIP agreement should prohibit these kinds of policies. The agreement should also prohibit discriminatory treatment of digital products and ensure that all technologies are given the chance to compete in the marketplace. In addition, audiovisual services must be included.

Regulatory coherence will also be critical to achieving a meaningful agreement. Inconsistent and duplicative regulations create enormous cost and inefficiency for U.S. exporters of goods and services to the E.U. These negotiations must strive for regulatory convergence and coherence to eliminate barriers to trade. In particular, we should seek identical standards for emerging technologies, such as nanotechnology and Internet technologies.

Finally, no sector should be excluded from our efforts to enhance regulatory convergence, including financial services. Financial services play an essential role in facilitating trade and investment flows between our two regions. Given the central importance of the financial sector to every other aspect of industrialized economies, I do not see how financial services regulation can be excluded from a meaningful TTIP agreement.

Of course, for this or any trade negotiation to succeed, the President must work with Congress to achieve renewal of Trade Promotion Authority, as the distinguished Senator has said, the chairman of this committee. Senator Baucus and I are currently working with our House counterparts to conclude a discussion on legislation to renew TPA. Once those efforts succeed, I hope that President Obama and his team will actively work with Congress to quickly seek Congress's approval.

Mr. Chairman, I want to thank you again for holding this hearing. I look forward to hearing from each one of our witnesses today.

Thank you.

[The prepared statement of Senator Hatch appears in the appendix.]

The CHAIRMAN. Thank you, Senator.

I am pleased to be here today with Michael Ducker, who is the executive vice president and chief operating officer of FedEx Express.

Following him is Mr. Ryan McCormick, president of the Montana Grain Growers Association, a grain farmer and small business owner near Kremlin, MT.

Our third witness is Dave Ricks, senior vice president of Eli Lilly and president of Lilly Biomedicines.

Our fourth witness is Mr. Bill Roenigk, senior vice president of the National Chicken Council.

Thank you all so very much for coming. And you are first, Mr. Ducker. Go ahead. And you know our rules here. Your statements will automatically be included in the record, and you have about 5 minutes to tell us what you think.

STATEMENT OF MICHAEL L. DUCKER, EXECUTIVE VICE PRESIDENT AND CHIEF OPERATING OFFICER, FEDERAL EXPRESS, MEMPHIS, TN

Mr. DUCKER. Yes, sir. Chairman Baucus, Ranking Member Hatch, and distinguished members of the committee, I do thank you for the opportunity to be with you today and to talk about TTIP, which we believe is an opportunity of enormous importance, and FedEx strongly supports that.

At FedEx, our business is trade, operating the world's largest express delivery network spanning 220 countries and territories, linking that 95 percent of global GDP that Chairman Baucus just

spoke about—all within 72 hours—along with other operating companies, creating jobs for more than 300,000 team members.

Our network handles more than 10 million shipments on an average day, and our customers range from individuals and small and medium-sized enterprises to the largest companies. Therefore, a trade agreement that creates opportunities for our customers to expand their businesses and generates increased demand for FedEx services will be an undeniable boon for the U.S. economy, as well as for our own company.

The U.S. and Europe, as you heard, account for close to half of global GDP, and our trade already exceeds $1 trillion each year. So, liberalizing the rules that govern trade and investment in that enormous economic area will inevitably result in unprecedented gains in jobs, competitiveness, and GDP.

But the TTIP opportunity, we believe, is even greater than that. By instituting ambitious, high-standard, comprehensive trade rules, including those which address emerging global issues, such as regulatory compatibility, state-owned enterprises, data flows, competition policy, and investor-state dispute settlement, the TTIP can pave the way for global trade in the 21st century to be governed by the shared values and mutually agreed regulatory standards of the U.S. and E.U., rather than alternative approaches favored by countries with different attitudes toward free markets and sensible regulation.

I want to talk about several pillars of TTIP. First of all, tariffs. Now, those are the traditional mainstay of trade negotiations and maybe the easiest ones to address in TTIP. Tariffs are already relatively low, however, in the U.S. and the E.U. So it should not be difficult to gain an agreement to get rid of those tariffs that remain. Nonetheless, the importance of eliminating those tariffs is very significant. Because of the enormous volume of trade across the Atlantic, even the generally single-digit tariffs still force costs of about $6.4 billion a year.

Second, as the world's largest express delivery carrier, the rules to be negotiated that will govern the services sector are of particular importance to us. In order for trade in services to realize its full potential, TTIP needs to reflect principles that are conducive to continued investment, competition, and innovation in the services sector. That would include full market access, national treatment, as well as disciplines to prevent state-owned enterprises from engaging in anticompetitive conduct. Because the U.S. and the E.U. both have strong global express delivery companies, it represents a unique opportunity to agree on high standards in that area that can eventually become a global standard.

Investment is the third area. It already totals about $3.9 trillion, resulting in $3 trillion in incremental annual sales for U.S. businesses and incremental employment for 3.5 million U.S. workers. We can take this opportunity of TTIP to enshrine the rules which can form the right to establish and operate investments on a nondiscriminatory basis and freely transfer funds and data, and establish high standards and disciplines regarding competition with state-owned enterprises and investor-state dispute settlement.

Regulatory compatibility is the fourth area. It lies at the heart of the TTIP negotiations and is likely to be one of the most chal-

lenging issues to tackle, but it really holds the greatest promise for economic gains.

To be successful, we do not really need fundamental changes in our respective regulatory approaches. It is about finding areas where unnecessary, redundant regulations or processes can be reduced to simplify trade and facilitate it while still maintaining very high standards of consumer, investor, and environmental protection. And it is about improving regulatory cooperation, transparency, and best practices to reduce regulatory barriers in the future. The rewards in this area could be substantial.

Improving trade facilitation is another area, and by getting rid of unnecessary red tape that raises the cost of trading across borders, we think that holds enormous potential. There are many things we can do in our border management and Customs clearance procedures to make trade simpler, faster, and more seamless. And one important example is the de minimis level, the threshold below which goods can enter the country duty- or tax-free. Ours in the U.S. is $200. And legislation is pending in both houses with bipartisan support to raise that de minimis level to $800.

In Europe, the de minimis level is around $200. But, in effect, de minimis on VAT is about $30 in most member states and as low as $13 in some. That means that companies, as Senator Hatch pointed out, selling into Europe will often face higher taxes and administrative costs than European companies that are selling into the U.S.

In sum, we believe the TTIP represents an unprecedented opportunity to promote economic growth on both sides of the Atlantic. Neither side can afford to forego this opportunity. And I know, also, the committee is interested in Trade Promotion Authority. FedEx fully supports the passage of TPA as soon as possible. Given the United States' ambitious trade agenda, getting that done quickly will be critical to bringing those agreements across the finish line.

I deeply appreciate the opportunity.

[The prepared statement of Mr. Ducker appears in the appendix.]

The CHAIRMAN. Thank you, Mr. Ducker, very much.

Mr. McCormick, you are next, and welcome to Washington, DC.

STATEMENT OF RYAN McCORMICK, PRESIDENT, MONTANA GRAIN GROWERS ASSOCIATION, GREAT FALLS, MT

Mr. MCCORMICK. Thanks, Max.

The CHAIRMAN. For the interest of everybody in the room, we just saw each other a week ago in Montana.

Mr. MCCORMICK. Not so long ago, yes, that is right.

The CHAIRMAN. That is right. Thanks very much.

Mr. MCCORMICK. Chairman Baucus, Ranking Member Hatch, members of the committee, my name is Ryan McCormick. I, along with my family, operate a successful agribusiness near Kremlin, MT.

On our farm, we raise hard red winter wheat, hard red spring wheat, durum, dried peas, and, most recently, mustard. I currently serve as the president of the Montana Grain Growers Association, am on the Board of Directors for the National Association of Wheat Growers, and I am the chairman of NAWG's Domestic and Trade

Policy Committee, which helps set NAWG's policy for international trade.

In a typical year, U.S. wheat farmers export about 50 percent of their production. In Montana, we export nearly 80 percent of our production. To say that trade is important to Montana is an understatement. Trade is just as important to Montana producers as tractors, fuel, and seed. Not only do we depend on trade, the world depends on us as a reliable supplier of high quality wheat.

The U.S. wheat industry supports the swift negotiation and ratification of a comprehensive, high standard TTIP. A successful TTIP must be completed in a single undertaking, with no exclusions or commitment to deal with tough issues at a later date.

First, the TTIP must eliminate all duties on U.S. wheat imports. The E.U. reduced the in-quota duty to zero on low- and medium-quality wheat in February of 2011. Due to this recent action to remove tariffs and taking into account the low U.S. tariff, the U.S. should push for complete, immediate, and permanent tariff and duty elimination.

U.S. wheat producers, many from Montana, compete against Canada for sales of durum and high-quality wheat. Canada and the E.U. just this month completed negotiation of their own free trade agreement. The outcome of the Canada-E.U. agreement will result in permanent zero wheat duty for Canadian producers to be phased in over 7 years. This will lead to future tariff differentials and a preference toward Canadian wheat. This increases the urgency to finalize this trade agreement so that we can stay competitive with our neighbors to the north.

Second, U.S. wheat producers strongly support science-based, least trade restrictive regulations. The E.U. and the U.S. are viewed as global scientific leaders, and our actions on sanitary and phyto-sanitary measures have a broad impact, making this a critical area of discussion. Increased cooperation on science-based SPS risk assessments, standards, processes, and implementations of least trade restrictive regulations would benefit U.S.–E.U. bilateral trade and positively influence SPS regulations in countries that look to the U.S. and the E.U. for guidance.

Third, the European Union must agree to a more predictable biotechnology approval process. The E.U.'s political approach in regulating crops enhanced with traits achieved through modern biotechnology procedures is a concern to U.S. wheat producers. The E.U. biotechnology approval process is slow and often influenced more by politics than science. Creating uncertainty and deterring new investment in wheat research, the slow biotechnology approval process puts future trade at risk.

Science should be the basis for biotech crop approvals, and the E.U. market should provide consumer choice for biotech and non-biotech products. Due to the slow approval process, the E.U. needs to implement a low level presence policy for food to avoid trade disruptions. A workable LLP policy and threshold for events approved by U.S. regulators would ensure that trade continues even when negligible amounts of approved biotech traits are inadvertently present in bulk shipments.

Finally, we urge Congress to renew Trade Promotion Authority. TPA renewal is essential to completion and ratification of a com-

prehensive TTIP agreement, as well as completing the Trans-Pacific Partnership and securing an eventual WTO agreement.

In conclusion, U.S. wheat farmers welcome the progress that has taken place so far in the TTIP negotiations and encourage Congress and the administration to work together to negotiate a comprehensive, high standard agreement.

Mr. Chairman, Ranking Member Hatch, members of the committee, thank you for allowing me the opportunity to be with you today to discuss the importance of this free trade agreement to wheat farmers. I would be happy to answer any questions you may have. And I wanted to let Max know that anytime he wants to, he would be welcome to operate my combine. [Laughter.]

[The prepared statement of Mr. McCormick appears in the appendix.]

The CHAIRMAN. Thank you, Ryan, very much. That is an inside joke that we talked about last week.

Senator HATCH. I do not know that I would trust him with that expensive equipment. [Laughter.]

The CHAIRMAN. Thank you, Ryan, very much.

Mr. Ricks?

STATEMENT OF DAVE RICKS, SENIOR VICE PRESIDENT, ELI LILLY AND COMPANY, AND PRESIDENT, LILLY BIOMEDICINES, INDIANAPOLIS, IN

Mr. RICKS. Thank you. That is hard to compete with.

Chairman Baucus, Ranking Member Hatch, members of the committee, we very much appreciate the opportunity to address the committee today on the TTIP arrangement, a negotiation of great importance to Eli Lilly and Company and, we think, the entire business community.

Now, Lilly is a 137-year-old global biopharmaceutical company headquartered in Indianapolis, IN—we are Hoosiers. We are a truly integrated transatlantic company with significant investments in R&D, in people, and facilities in both the U.S. and in Europe.

In addition to our more than 16,000 U.S. employees, our investments in Europe help support U.S. jobs, investment, and patient programs, including in the great States of Montana and Utah.

Through our membership in a number of industry and transatlantic organizations, we have advocated for the TTIP on both sides of the Atlantic as a comprehensive and ambitious agreement, offering many benefits to our company and our employees, to the U.S. economy, and to patients here and around the world who rely on our medicines.

I have a strong appreciation for the benefits of open trade and the concerns that occur when it is not there. As the leader of Lilly's largest business, spanning from Japan to Europe, formerly the head of Lilly's Chinese business and the Canadian business, I know how these barriers can affect trade and real investment.

Before commenting on the TTIP, however, it is important to first say that Lilly, our industry, and the business community believe that legislation to renew the TPA, or the Trade Promotion Authority, could provide an important opportunity to strengthen and grow the U.S. economy. I would like to acknowledge Chairman Baucus

and Ranking Member Hatch for their leadership on this issue and underscore that the business community stands ready to work with you and your staffs on a high standard TPA bill.

On TTIP, we strongly favor an ambitious, comprehensive, and high standard trade investment agreement. Lilly and the pharmaceutical industry believe that TTIP represents a unique opportunity to promote the highest standards of intellectual property, market access, and regulation, in particular for IP-driven sectors in which the U.S. and the E.U. enjoy today a global advantage. We believe the two governments should use the TTIP arrangement to work together to maintain and grow that advantage.

We believe the agreement must cover industrial goods, food and agriculture, services, investment, procurement, protection of IPR, and regulatory issues. We believe there should be no exclusion of specific sectors or commodities. We believe that the TTIP should set the highest possible standards for third countries to work toward in the areas of investment, IPR, competition policy, and SOEs, and should eliminate forced localization. As for the timeline, we would prefer that negotiators take the time needed, within reason, to achieve a comprehensive agreement rather than rushing to meet a self-imposed deadline.

I also want to underscore how critical it is that intellectual property rights be included in negotiations. For our company, for our industry, and for the broad business community, we believe it is essential that this agreement maintain and promote effective levels of IPR in the E.U. and globally. This is absolutely essential to continued investment in research, development, and commercialization of leading-edge technologies.

We believe TTIP should set an ambitious standard for pharmaceuticals in the fields of regulatory standards, intellectual property protection and enforcement, and market access. For Lilly, this agreement represents a significant opportunity to address regulatory duplication, increase reward for innovation through raising the IPR standards, and address serious market access and transparency concerns we have.

As well, TTIP should improve alignment between the U.S. and the E.U. vis-à-vis third countries, to promote a high policy standard for pharma and improve access to innovation and new medicines throughout the world.

In conclusion, Lilly, along with the biopharmaceutical industry and much of the broader business community, sees TTIP as a once-in-a-lifetime opportunity to simplify transatlantic business, address longstanding trade issues, create new markets, and, most importantly, increase this country's competitiveness and improve U.S. jobs here.

We look forward to working with the committee and Congress to ensure that this agreement meets the expectations of the business community, creates jobs, and enhances the competitiveness of our two economies.

Thank you for the opportunity to testify today.

[The prepared statement of Mr. Ricks appears in the appendix.]

The CHAIRMAN. Thank you, Mr. Ricks, very much. I appreciate that.

Mr. Roenigk, you are next. Thank you.

STATEMENT OF WILLIAM ROENIGK, SENIOR VICE PRESIDENT, NATIONAL CHICKEN COUNCIL, WASHINGTON, DC

Mr. ROENIGK. Good morning.

The CHAIRMAN. Good morning.

Mr. ROENIGK. Thank you, Chairman Baucus, Senator Hatch, and members of the committee, for the opportunity for the National Chicken Counsel to share our thoughts and recommendations regarding the Transatlantic Trade and Investment Partnership.

This is an important hearing and very timely, as our negotiators continue to move forward to reach a conclusion and a final agreement. So we very much appreciate this opportunity.

I am Bill Roenigk with the National Chicken Counsel. The Counsel represents the vertically integrated companies that will produce and process over 95 percent of the chickens in the United States this year, and we will produce, as an industry, over 9 billion chickens, almost as many packages as Federal Express will deliver this year.

In my written statement, I have outlined how the European Union has excluded U.S. poultry from its market since 1997. At the same time, I can assure this committee that, if time permitted, you would have a long, almost endless list or stream of other witnesses from other parts of agriculture who could share with you their frustrations and their problems in trying to export their commodities and products to the European Union. These problems not only restrict or limit, but in our case, prohibit our exports to the E.U.

With tomorrow being Halloween, permit me to note that we in U.S. agriculture know the final agreement with the TTIP could be a trick or it could be a treat. We, of course, hope that it is a treat and not a trick. Time will tell, of course, how the final agreement looks to U.S. agriculture.

The E.U., since 1997, when it implemented the common agricultural policy, has used a bagful of scary tricks to severely hamper free and fair trade in U.S. agricultural products. One of the more irksome tricks in the E.U. bag has been the so-called precautionary principle, which, as I understand it, the E.U. uses when it is convenient as a call to approve an over-abundance of caution regarding food safety and similar issues, while, at the same time, having zero risk involved.

Having experienced some of our frustrations, I should note that there may be reasons to be hopeful. I am not going to use the word "optimistic," but there may be reasons to be hopeful with respect to a successful agreement being concluded.

First, it does appear the E.U. is somewhat willing to fully engage in negotiations in a serious way. More specifically, in the case of agriculture, we have examples where the E.U. may be changing. Export subsidies for poultry were discontinued last month. These subsidies or, as the E.U. calls them, export restitutions, have been an integral part of the common agricultural policy. So it was good to see the export subsidies being discontinued.

Another example in agriculture is the E.U., earlier this year, I think in February, approved lactic acid to be used on beef as a pathogen reduction treatment. Further, we now understand the E.U. is considering peroxyacetic acid as a pathogen reduction treatment on poultry. Peroxyacetic acid may be a scary name, but basi-

cally it is hydrogen peroxide and vinegar. And we are hopeful that this process will continue.

In 1997, the reason we were prohibited from the market was because we used hyper-chlorinated water to reduce the bacteria on our product. In 1996, U.S. poultry exports to the E.U. 15, at that time, totaled about $55 million, making it the 9th-largest market. If the current 28 countries were in the E.U. in 1996, our exports would have been $210 million, making the E.U., if it existed at 28 at that time, our 3rd-largest market.

U.S. poultry exports to the E.U., we believe, with a successful conclusion of an agreement, could be over $600 million and would make the E.U. the 3rd-largest market, behind Mexico and Hong Kong, China. The E.U. imports about $2 billion worth of poultry on an annual basis, so, if we were able to secure a market, we believe we would have about one third of that.

When U.S. Trade Ambassador Froman announced a launch of TTIP, he said he wanted to do it on one tank of gas. Now, he did not mention how big that tank of gas was or whether there was 10 percent ethanol in that gas, but I will leave the ethanol issue for another day and another hearing. But we are hopeful that that tank of gas will move along quickly and we will secure an agreement, a good agreement, sooner rather than later.

But at the point where we do have an agreement, we would be willing to support that agreement if it does include, as my fellow panelists said, inclusive, comprehensive benefits to all parts of U.S. business and agriculture. If the agreement does not, those of us in U.S. agriculture will need to consider our options.

Before I conclude, I would like to share what my fellow panelists said about Trade Promotion Authority. Not only is it critical for Congress, for this administration and future administrations, but we believe that if it was given to our negotiators now, it would strengthen their hand in terms of being able to be more successful at the negotiating table.

Chairman Baucus, Senator Hatch, members of the committee, we very much appreciate this opportunity and look forward to working with the committee to have a successful agreement.

I look forward to your comments and questions.

[The prepared statement of Mr. Roenigk appears in the appendix.]

The CHAIRMAN. Thank you, Mr. Roenigk, very much.

I might say, we were there about a year ago and talked to the E.U. folks about lactic acid as a pathogen reduction treatment, and we were a bit firm about it, and they backed off. And, as you might recall, that was one of the conditions we had in entering into negotiations with TTIP.

Mr. ROENIGK. That was a big breakthrough. We appreciate that.

The CHAIRMAN. You bet. The point being, if you are fairly precise and fairly firm and make it very clear, you are more likely to succeed. That was one area where we had some success.

I tend to think, in trade, that no country altruistically, out of the goodness of its heart, ever lowers a trade barrier. That is, you need leverage. There has to be an economic interest for them to do so. They are not going to do it out of the goodness of their heart. No country will.

So what leverage do we have here? That may be a little bit strong and crude, but what do we have that they want to help us get what we want? What do we want? We want lower tariffs, we want greater access, we want more direct investment in the U.S., we want regulatory transparency, scientific standards, et cetera. We want that.

Now, it could well be that many European business people want a lot of that too. But what do they want from us that we are going to have to think about as we work for what we want?

Who wants to first address that? Mr. Ducker, do you want to take a crack?

Mr. DUCKER. Yes. Yes, Senator. I could take a stab at it. I think most of us would agree that global economic growth has sort of languished over the last 5 years, and the reason I believe that the timing is so opportunistic is that both of these large trading blocs want to create job growth.

And I think that we have already demonstrated in the past that the greater the extent that we trade with each other, the greater jobs and the better jobs can be created. So I think the economic conditions have certainly given us greater leverage. Whether it is as a consequence of the DOHA round stalling or not, I think that people are taking the opportunity, and trade agreements like this one are proliferating. And I think that is a pent-up demand, and I think it can increase economic benefits on both sides of the Atlantic, and I think there is leverage on both sides.

The CHAIRMAN. So your basic point is, world demand is down a bit and this can help address that. That is the basic point.

Mr. DUCKER. Absolutely. Only a few times in the last 25 years has global trade grown slower than global GDP, and, usually, it is about 2½ times the pace. But we are significantly below that today, and one of the reasons, I think, is the failure of the DOHA round, the multilateral trading round, and the fact that we do not have good trading rules and a liberal trading environment.

And I think, in today's world of fast-paced commerce, we have to work really hard to get greater transparency, regulatory standardization, harmonization, and I think that it would increase global trade and, as a result, global GDP.

The CHAIRMAN. So do you think, to some degree, the Europeans have the same view, that this will help demand in Europe?

Mr. DUCKER. I think they do. My belief is, in discussion with some of my longtime colleagues there—and I have been managing that in one capacity or another for more than 20 years—that many of the businesses in Europe want to see greater trade with the United States and a free trade agreement that is a high standard free trade agreement.

The CHAIRMAN. Who else wants to address that? Mr. Ricks?

Mr. RICKS. I will jump in. I think in our industry and in other intellectual property-based industries, the U.S. and Europe lead the world. Our customers are, of course, among each other, but increasingly outside of these two economic zones as an export opportunity.

So, in the area of pharmaceuticals, there is not a lot of disagreement between companies on that side of the Atlantic and companies on this side of the Atlantic about the opportunities in TTIP to

raise intellectual property rights standards to be the highest in the world between the two economies so that, vis-à-vis other trade agreements, we can create leverage on the rest of the world to raise their standards and reward investment in research and development for new medicines.

The CHAIRMAN. I appreciate that.

Mr. RICKS. The other opportunity is to reduce regulation burden, which is—there are many duplications, which cause delay and excess cost in the business, and I think everybody would be for eliminating those.

The CHAIRMAN. Thank you very much.

Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Mr. Ricks, yesterday it was reported that Ambassador Froman, while speaking about the Trans-Pacific Partnership negotiations, suggested that there is a tension between protecting intellectual property rights for innovative medicines and ensuring access to medicines. I cannot disagree more. To the contrary, strong intellectual property protections spur innovation. They are, therefore, essential for providing access to innovative medicines.

Now, could you please comment on why strong intellectual property protection for innovative medicines is important and, also, what steps can be taken by these foreign governments to ensure access to lifesaving medicines that do not include diluting intellectual property rights for U.S. innovators?

Mr. RICKS. Thank you. Strong intellectual property protection is a key issue for us, but it is not a barrier to access to innovation in developing markets or anywhere. New products come from the incentive to develop them through the promise of reward through intellectual property. Without those rewards, it is difficult to see where these new medicines would come from to begin with.

On the other hand, there is a lot of evidence that market access to medicines does not have to do with intellectual property or pricing, but rather the way health systems function. In fact, 95 percent of the World Health Organization's, quote-unquote, "essential medicines" to treat populations are generic. There is no intellectual property associated with them.

So, more often than not, you are dealing with issues of how drugs get distributed, how care and diagnosis happen in a given country, and these are complex issues that have to do with the entirety of the health care system, not just a simple issue of IPR.

So we are aligned in the view that intellectual property is an important issue for our sector. It is where new medicines come from, but it is not related to market access for these medicines years after their invention. What is important there is collaborating with health systems, governments, and regulatory authorities to make sure the health systems work around the world.

Senator HATCH. Let me just add another question. In your testimony, you note that trade secret theft is a growing problem around the world. We know that China, in particular, is systematically stealing critical information from hundreds of U.S. companies. Now, this is an area where international standards for protection must be improved and where it is important for the U.S. and E.U. to work together.

Can you discuss why it is so important for our trade agreements to include strong provisions that safeguard U.S. trade secrets?

Mr. RICKS. Absolutely. And we have been very active in trying to strengthen our own company's systems to prevent this type of theft. But having a legislative and a regulatory framework between the E.U. and the U.S. on this point would be critical.

We both share an interest in knowledge-based industries, like the pharmaceutical industry and others. We simply cannot afford together to lose or have leakage of this to the rest of the world inappropriately and illegally. So we support that.

I believe there is an opportunity to include that in the TTIP arrangement, and we would support that as a key component for intellectual property-driven industries like ours.

Senator HATCH. Thank you.

Mr. Ducker, in your testimony, you talked about how the value-added tax, as levied in European Union countries, can significantly drive up the cost of U.S. goods and exports to the European Union, especially for small businesses.

In fact, the Utah company I mentioned in my opening statement, ICON, has to deal with this problem when exporting their exercise equipment into the E.U. How much of an impediment to U.S. exports are value-added taxes in the E.U. and should their elimination be a priority for the USTR as they negotiate the TTIP agreement?

Mr. DUCKER. Well yes, sir, it should absolutely be a priority, and it is an impediment for our exporters. I think I mentioned in my verbal testimony that it is not only the de minimis value, but on the value-added tax, some of those numbers are as low as $30, and it can even go lower on some of the newer entrants into the E.U., which means that any good that is shipped into Europe that is above the value on the VAT of $30 has to file unnecessary forms for a low value-added good.

In many cases, the value and the transaction costs to ship a good into the E.U. with these low de minimis standards can exceed the cost of the good itself. So we believe that de minimis values need to be raised across the board, and we need to have some regulatory harmonization between the two trading blocs on that.

So I think it has a big impact on small and medium enterprises, in particular terms, because large multinationals have the infrastructure in place to deal with more complex regulations. The small shippers and customers do not.

The CHAIRMAN. Thank you. Thank you, Senator.

Senator Carper?

Senator CARPER. Thanks. Again, welcome to all of you.

Just permit me a little bit to talk about Trade Promotion Authority, please. I understand it is not a slam-dunk that we are going to get it done. And I am going to ask each of you for just a little bit of audience participation.

If you will, on a scale of 1 to 10, 1 for not very important that we get it done, 10 for very important, each of you just give me some kind of idea what you think, starting with you, Mr. Ducker. Just briefly, just very briefly.

Mr. DUCKER. I believe it is hugely important that we get it done, and the reason that I believe it is important is——

Senator CARPER. No, no.
Mr. DUCKER. You want a scale.
Senator CARPER. Yes. Just answer my question.
Mr. DUCKER. Eight out of 10.
Senator CARPER. Thank you.
Mr. MCCORMICK. I would say similar, 9 out of 10.
Mr. RYAN. Nine-and-a-half.
Mr. ROENIGK. On a scale of 1 to 10, I would say it is 11.
Senator CARPER. Thank you very much. Those are the scales we use. Now give me the best argument, your one single best argument, very briefly, against Trade Promotion Authority, best argument against, and then rebut it, very briefly, please, same order.
Mr. DUCKER. Best argument——
Senator CARPER. Against, that anybody would give. What is the best, strongest argument against it, and then rebut it, just very briefly.
Mr. DUCKER. I think that anybody would say the best argument against it would be the lack of collaboration and participation from large groups of people. And I would rebut that argument to say that, at the pace that commerce and trade deals are moving around the world, that we have to have speed to market in this case for U.S. business and U.S. trade.
Senator CARPER. Thanks.
Mr. McCormick, same question.
Mr. MCCORMICK. I would say that probably the biggest thing is speed, and the reasoned argument against it would be that we would make rash decisions too fast, too swiftly. But speed is key, especially when Canada has just signed their free trade agreement.
So our neighbors to the north are competing against us. We need to have the ability to swiftly come in behind them with our own agreement.
Senator CARPER. Mr. Ricks, give us your strongest argument against TPA, then rebut it.
Mr. RICKS. I suppose the argument against it is to make sure all interests are well-represented, but I think, when one is negotiating, it is important to empower the people at the table to make the tradeoffs that are in the best interest of the country.
Senator CARPER. All right. Thank you.
Mr. Roenigk?
Mr. ROENIGK. I would not say it is legitimate, but I think they would argue this is a blank check given to Congress. Let us see the agreement, and then we will decide whether we want to sign the check or not.
Senator CARPER. All right. Good. We raise a lot of chickens on Delmarva, in Delaware. There are, I do not know, 300 or 400 chickens for every person in my State. So this is pretty important.
It used to be we did not export many of them. Today, I was talking with Senator Cardin earlier, and I think we export about 20 to 25 percent of the poultry that we raise.
You shared with us some numbers going back, I think, about 20 years, and I think you said, Mr. Roenigk, that the E.U. was number three if you put all those countries together, but our number-three market 20–25 years ago. Today, are they still in the top 10? I do not think so.

Mr. ROENIGK. We are prohibited from exporting to the E.U., so they are not an export market for us. But if we had access, we believe that total exports would be $600 million, making them the third-largest market.

So it would be very, very important not just for Delmarva, but for the entire industry.

Senator CARPER. You touched on this, but let me ask you to drill down on it. Could you just describe for us what the current poultry market is like in the E.U. and what other factors, besides addressing regulatory barriers, could be important to ensure that our poultry industry can achieve the kind of potential in the E.U. you have just mentioned to us?

Mr. ROENIGK. Some of the most expensive chicken in the world is in the E.U. So it is not an inexpensive place to enjoy chicken.

Senator CARPER. Is it the best chicken in the world?

Mr. ROENIGK. The best chicken in the United States—is the Senator from Georgia gone? [Laughter.]

Senator CARPER. But we are still here. We are still here from Delaware and Maryland.

Mr. ROENIGK. The best chicken in the United States is from Delmarva.

Senator CARPER. Thank you. That was good. I have no more questions.

Go ahead, finish your answer.

Mr. ROENIGK. I would just say the most expensive chicken is in the E.U., a few other places, but what we need is a climate, a regulatory climate, where the food safety and so on is based on performance, not on proscriptive regulations—the walls are white, but are they the right color white? So we need to get away from a proscriptive approach to inspecting chicken and some animal health issues, and, hopefully, the agreement will address those critical issues.

Senator CARPER. All right. Thank you very much. Thank you all.

The CHAIRMAN. Thank you, Senator.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman. Let me thank our witnesses.

I certainly concur in the observations of our witnesses for a TTIP agreement that includes the provisions you all have said. But let me just inject a little bit of reality here. The chairman's comment is that we never achieve what we need to easily, that the other side is always looking for something else.

Mr. Ducker, you mentioned the de minimis rule and our tax issues. I could expand that. We had our issues with Europe when we tried to get a better understanding on and a level playing field in corporate taxes, business taxes, and we tried to deal with that through some form of credit, only to find that Europe challenged us successfully under WTO rules.

So we do not have a level playing field on business taxes with Europe today. And the de minimis rule just underscores the challenge for small entities, but it does not deal with the underlying core problem that we should harmonize the tax agreement so that we have a level playing field in international trade. The last time we looked at a global trade update, Europe was very difficult on the agricultural sector, protecting its high-cost poultry, among

other commodities, and it ended up we were unable to get an agreement.

I guess my point is this. I hope we can successfully complete a TTIP agreement that does put us on a level playing field, and I know that it is going to have to be a give-and-take. But I hope that your testimonies here today will be consistent as we evaluate a TTIP agreement to make sure that it is worthwhile and that we are not just yielding to the pressure to get an agreement, but that we really do accomplish something positive for commerce between Europe and the United States.

If it is on a level field, I am very confident that American producers, manufacturers, and farmers will do just fine. But if we continue to make these unilateral concessions, then it is not in America's interest and not in the global interest.

So, on the poultry side, we have seen over and over again, it is not just the tariff but also the non-tariff issues, and I just really want to point out that the numbers you give could be much greater if we get science-based safety standards in Europe.

That is going to be one area that I think we really need to focus on as we look at the regulatory side. Europe, on agriculture, has used many creative ways in order to protect their farmers, and I hope you all will be very direct with us as to whether this agreement deals with a meaningful change that will allow an increase in market penetration by American agriculture, including the poultry industry.

So, Mr. Roenigk, I want you to know, we are going to be looking to you to be very clear with us and not just say, any trade agreement is okay. We really need to make sure that we have a trade agreement that will give us a more level playing field.

Mr. ROENIGK. If I could just say so, you have exactly hit the nail on the head. The creative ways they have used—it is our concern that those creative ways will continue, and that is what we have to be very careful about. We have to perhaps trust, but verify.

Senator CARDIN. Mr. Ducker, let me just underscore the point on the taxes. You mentioned the de minimis rule. I understand that. But for any American manufacturer or producer, they have to go through that process concerning the European VAT tax where there is no comparable burden on a European who exports into the United States. Is that fair?

Mr. DUCKER. No. I did not say it was fair. That is why I hope we can move the ball forward and advance it with some of these common rules in the trade agreement.

Senator CARDIN. The de minimis rule absolutely deals with those products that come in under that threshold, but it does not do anything for those above that threshold. Why are we not more ambitious?

Mr. DUCKER. Well, I think, as far as I am concerned, we can be more ambitious with that. We already have a bill moving through to raise it to the $800 level, on the de minimis levels. But I do not know if it is a part of TTIP at this point in time. That matter might be better served in another area.

Senator CARDIN. In another hearing, as the chairman knows, I will be bringing up tax legislation to try to give our producers and farmers and manufacturers a better break.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Brown?

Senator BROWN. Thank you very much. And to Senator Hatch and to especially the chairman, thanks for holding this hearing on this very important issue.

This is for both Mr. Ducker and Mr. Ricks. With respect to investment under TTIP, you advocated for the coalition's position that we needed a TTIP that has a "robust investor-state dispute settlement mechanism."

Why is that necessary in this kind of an agreement when we have two well-developed systems to safeguard intellectual property? And this is not an agreement with a country that is obviously less developed than ours. With the rule of law and the sort of sophistication and the intellectual property investment that we have developed in all of these countries, why is this necessary? And give me examples, if you would, of why we need it between the world's two most developed entities, if you will.

Mr. Ricks, do you want to start?

Mr. RICKS. Absolutely. Thank you, Senator.

It is necessary because the systems do not work identically and sometimes do not work well. I will give you an example under NAFTA which my company is working through right now with the Canadians.

We have a situation in Canada where a large number of patents on medicines are being thrown out by the courts, we think, in violation of the principles of NAFTA and TRIPS in the WTO intellectual property regime. We have exhausted all local options in the Canadian courts, including going to the Supreme Court on this issue, and we now have an investor-state action under NAFTA with Canada. This is really our only recourse to level the playing field to what we think is a global standard.

Those types of issues hopefully will not occur with Europe, but they could, and there are quite a number of differences in the patent system, as well as your rights to intervene and have early resolution, in Europe versus the U.S.

So these investor-state provisions are quite important to assure predictability over the long term.

Senator BROWN. Does it concern you, as an American citizen, living in a country of laws and democratically reached rules, regulations, and statutes, to allow a foreign investor to, in essence, challenge, to have the standing to challenge, a democratically attained rule or law in this country, sort of converse to what you were saying?

Mr. RICKS. It does not concern me, as long as it is quid pro quo; as long as we have the same rights in their system. And increasingly, companies like mine are global companies. We have an interest in many geographies. I think, if we agree under a trade agreement to certain provisions, that it is a reasonable standard to have the ability to have that enforcement from abroad.

Senator BROWN. These provisions—you mentioned NAFTA, and I think NAFTA was the first sort of prototype trade agreement to do this—do shift power, in reality, to a corporation to challenge a

sovereign government, something that we have not done previously.

But thank you for your answer.

Mr. Ducker, your thoughts?

Mr. DUCKER. Well, I have many similar thoughts, but the U.S. Government has been sued many times, and I do not know that we have lost any of those suits. And so I think gaining some predictability, especially for future agreements, as we go through, is an important element of a high quality and ambitious trade agreement, and my colleague gave some very good examples of it.

Senator BROWN. Anybody else? Do one of the other two of you want to comment on that; any thoughts?

[No Response.]

Senator BROWN. No. Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

One thought here. It seems to me—I would like your response—not only is a potential agreement good for all the reasons that you have all indicated, but also, it will help set world standards so that the United States can more easily trade with other countries, say the developing countries, India for example, and Brazil and so forth.

So the degree to which this is very successful, this TTIP, helps not only the United States and not only Europe, but also helps the United States and Europe in trading with a lot of other countries.

I think, therefore, that we should work very hard to make this a very successful agreement that sets very high standards worldwide. That is, for our two continents, which will help in other areas.

Thank you very much. You have been very helpful here. Thank you.

I am sorry. Senator?

Senator HATCH. Mr. Ricks, I am particularly concerned about the data exclusivity with regard to biologics. So I would like to have you weigh in on that and maybe send me a letter on it.

Mr. RICKS. We would love to, and we appreciate your support on that point.

Senator HATCH. Send it to the committee so everybody will see it, because that is an extremely important thing. And I have to say that Senator Kennedy stuck with me on that even though he felt the other way, because he knew doggone well it was right. And I would like to see us negotiate a much better situation there——

Mr. RICKS. We appreciate that.

Senator HATCH [continuing]. So that innovation is created and we move forward.

Mr. RICKS. Thank you.

Senator HATCH. Thank you.

The CHAIRMAN. The hearing record will be open, certainly until the end of this week, for other Senators to submit questions for the record.

Thank you very much. I appreciate it. The hearing is concluded.

[Whereupon, at 12:15 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Hearing Statement of Senator Max Baucus (D-Mont.)
Regarding the Transatlantic Trade and Investment Partnership
As prepared for delivery

Benjamin Franklin, who helped negotiate the original trade treaties between America and Europe more than two centuries ago, gave the following advice: "To succeed, jump as quickly at opportunities as you do at conclusions."

Franklin was our first Ambassador, becoming U.S. Minister to France in 1776, long before our nation won its independence from Britain. He saw an opportunity to build a strong relationship with a powerful ally. Thanks to his work, the U.S. and France signed treaties in 1778 that gave our young army critical support and laid out the framework for a successful trading partnership.

We are here today because we have another opportunity: An opportunity to boost America's economy – an opportunity to create thousands of new jobs across the United States. This opportunity lies in a new comprehensive trade agreement between the United States and the European Union.

It's called the Transatlantic Trade and Investment Partnership, or TTIP, and it's an opportunity we must jump at quickly.

The U.S. and EU already enjoy the strongest economic relationship in the world. Together we make up half of global GDP and more than a third of global trade. Every day, the U.S. and EU trade $2.7 billion in goods and services. We have invested nearly $4 trillion in each other's economies.

Transatlantic trade supports 13 million U.S. jobs, but we all know that we need more jobs, and better-paying jobs. This new opportunity – this new trade and investment agreement – would deliver those jobs we need.

This new trade agreement could boost exports to the EU by a third and add more than one hundred billion dollars annually to U.S. GDP. It could support hundreds of thousands of new jobs in the United States.

Jobs related to exports pay 13 to 18 percent more than the national average, and jobs supported by foreign direct investment in the United States pay 30 percent more than non-FDI supported jobs. When we lower trade barriers, we increase exports and attract foreign investment, and we provide America's economy the shot in the arm it so desperately needs.

The benefits of TTIP would ripple across our nation. For example, in my home state of Montana, TTIP could grow exports to the EU by 19 percent and support nearly 2,400 new Montana jobs. Every state would have its own success stories.

How would TTIP do this? It would lower tariffs on our enormous bilateral trade, increasing U.S. exports by double digits and saving families money on the goods and services they buy here at home. It would cut red tape and reduce costs for businesses, such as auto makers, that currently face duplicative regulations in the EU and the United States. And it would spark investment and innovation that will bring jobs and growth on both sides of the Atlantic.

We're talking about a landmark opportunity. But for the TTIP to live up to its potential, we'll first have to tackle a number of challenges.

For example, we must address the EU's unscientific and unjustified barriers to U.S. agricultural exports, including beef and poultry. While in Europe last year, I pushed their leaders to drop those barriers. U.S. beef has earned the top safety rating from the World Organization for Animal Health. And CODEX – another of the world's trusted authorities on food safety – has declared U.S. beef production methods to be perfectly safe. It's finally time for the EU to act.

I'm confident we can overcome that hurdle – and others. The more challenges we address in negotiating the TTIP, the bigger the gains will be for our two economies, boosting exports, attracting new investment, and creating new jobs.

The TTIP is just one part of the most ambitious U.S. trade agenda in a generation. Ninety-five percent of the world's consumers live outside the United States. Our trade agenda today gives American farmers, ranchers, businesses and workers more opportunities to reach them than ever before.

It means Dave and Cole Mannix – two proud family ranchers from Helmville, Montana – can expand their market for some of the best-tasting beef that I've ever had. It means global brewers like Anheuser-Busch InBev can use more Montana malt barley in their beer. It means international companies like Siemens can have even more reason to work with educational institutions like Flathead Valley Community College to develop the skills of Montana's workforce.

Congress needs to be a full partner in the development and execution of this agenda, and the best way to do that is to pass Trade Promotion Authority – and to do it soon.

The U.S has numerous other trade opportunities as well. The Trans-Pacific Partnership, or TPP, is near completion. The TPP parties just need to know in the clearest terms what Congress' priorities are. And Congress needs to set priorities as the Administration starts negotiating with Europe. We can do that through Trade Promotion Authority. I'm pleased that President Obama has requested TPA and that Ambassador Froman has been making the case for TPA.

It's time for us to do our part. We must introduce a bill and quickly pass it. Senator Hatch, let's continue to work together to get that done as quickly as possible.

Ben Franklin counseled us to jump at opportunities. That's advice we must heed – for very simple reasons. More trade means more American jobs. More trade means a stronger economy. More trade means a more secure future. So let us jump at this opportunity to expand the world's largest trade relationship, let us do the hard work, and let us make the TTIP as meaningful as we can.

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Michael L. Ducker
Executive Vice President & Chief Operating Officer
FedEx Express

TESTIMONY TO THE U.S. SENATE
COMMITTEE ON FINANCE
215 Dirksen Senate Office Building

"The Transatlantic Trade & Investment Partnership:
Achieving the Potential"

October 30, 2013

Thank you Chairman Baucus, Ranking Member Hatch, and distinguished members of the Senate Committee on Finance. My name is Mike Ducker, and I am the Executive Vice President and Chief Operating Officer for FedEx Express. Thank you for the privilege of testifying today to share FedEx's strong support for negotiation of the Transatlantic Trade & Investment Partnership (T-TIP) with the European Union.

FedEx is proud to be a founding member and Corporate Co-Chair of the Business Coalition for Transatlantic Trade (BCTT), an organization established to promote growth, jobs, and competitiveness on both sides of the Atlantic through an ambitious, comprehensive and high-standard trade and investment agreement between the United States and the European Union. The BCTT includes hundreds of companies and associations which recognize T-TIP's tremendous economic potential. While I'm testifying today solely on behalf of my own company, the themes reflected in my remarks comport with the positions endorsed by the Coalition.

The FedEx Perspective

It should hardly be surprising that FedEx is an enthusiastic supporter of the T-TIP. Trade is at the heart of our business, and expanding opportunities for trade enables FedEx to create more jobs for U.S. workers, more export opportunities for our customers, and increased value for our shareholders. FedEx provides individuals and businesses worldwide with a broad portfolio of transportation, e-commerce and business services. Our network connects 95% of global GDP within 72 hours. FedEx has more than 300,000 team members who serve our customers and run our global networks. FedEx Express is the world's largest express transportation company, providing fast and reliable delivery to every U.S. address and to more than 220 countries and territories, including all Member States of the European Union. We operate nonstop widebody all-cargo flights between our U.S. hubs and European gateway airports at Paris, Cologne, London, Frankfurt, and Milan, with connecting flights using dedicated aircraft between our European gateways and 39 additional European airports. FedEx works to provide its customers access to new markets, new consumers, and new opportunities around the world.

Our worldwide express network is a critical element of the global value chain infrastructure for thousands of U.S. and EU companies, from many small- and medium-sized enterprises (SMEs) to the

largest Fortune 100 companies, linking our customers with their suppliers, manufacturers, distributors, retailers, and consumers.

FedEx's U.S. operations, and our more than 230,000 American team members, support both our domestic services and our global express delivery network. Expansion of global trade strengthens FedEx and enables continued growth of our U.S. operations and workforce. As we grow around the world, we create jobs here in the United States. Without global trade, FedEx would be a shadow of our current operations, and our domestic work force would be dramatically smaller. Moreover, as our global network expands, we purchase new planes such as our new fleet of Boeing 777 freighters, new trucks, new equipment, new supplies and new services. We are constantly innovating to provide our customers the world's most advanced global air cargo, delivery and logistics network. Our growth abroad increases our demand for goods and services from our suppliers and vendors here in the United States, many of which are SMEs, helping them grow their businesses and work forces.

FedEx champions trade and foreign investment liberalization to help our customers reach new markets so they can grow their business and to increase demand for our services. Therefore, we strongly support trade negotiations and trade promotion agreements that create new commercial opportunities for our customers and in turn for ourselves. At FedEx we have seen the results from the trade promotion agreements currently in force, and we forecast similar positive impacts from the T-TIP negotiations. After implementation, two-way trade flows increase between the United States and its trade agreement partners, demand for our services to and from those countries increase, as do our package volumes, and we expand our operations in the United States and in the partner country to accommodate that growth – it really is as simple as that.

T-TIP Presents an Opportunity We Can't Afford to Miss

Because the U.S. and EU together account for almost half of global economic output, and the value of their trade already exceeds $1 trillion per year, the T-TIP is a trade initiative of unique and unprecedented magnitude. According to a report issued in September 2013 by the Bertelsmann Foundation in conjunction with the Atlantic Council and the U.K. Government, a comprehensive and ambitious T-TIP would lead to the creation of new jobs in every one of the 50 states, 740,000 new U.S. jobs in total, a figure equal to the entire working population of the State of New Hampshire. And as President Obama noted in June 2013 in announcing the launch of the T-TIP negotiations, this initiative will enable the U.S. and EU to "forge an economic alliance as strong as our diplomatic and security alliances, which, of course, have been the most powerful in history." The decision to pursue trade and investment liberalization with Europe is an obvious choice.

Moreover, the T-TIP has the potential, as a practical matter, to eventually set the standards to govern an even larger proportion of global trade, since other countries will likely see the benefit of conforming to its standards in order to gain access to this enormous combined market. Where the U.S. and Europe can agree on common approaches and high standard disciplines particularly with regard to such emerging issues affecting global trade as state-owned enterprises, cross-border data flows, and competition policy, T-TIP holds the promise of setting a high bar for international trade rules other countries will want to meet. High-standard transatlantic trade disciplines and standards which apply to close to half of the world's economy will have a powerful persuasive impact on both U.S. and EU trading partners by challenging those countries, some of which have adopted mercantilist trade and regulatory policies, to pursue trade agreements modeled after T-TIP, which are ambitious and comprehensive. Thus, our rules-based trading system will be strengthened, and all economies will benefit.

The T-TIP is distinct from many other recent trade agreements in that it will be between two highly advanced economies, both enjoying comparable standards of living, following broadly similar economic systems, and embracing democratic values. As a consequence, these negotiations are building from a position of considerable commonality on broad economic and political views. Therefore, it is less likely that it will be as difficult to reach consensus on many of the issues which have proven contentious in recent trade negotiations between developed and developing economies, such as environmental standards, labor standards, investment, services market access, and investor-state dispute settlement. Nonetheless, there is a host of other issues expected to prove sensitive in the T-TIP negotiations, including public procurement, state support for audio-visual and cultural industries, food and agriculture regulation and policy, and data privacy. Also, the T-TIP is expected to be far more ambitious than any earlier trade agreements in seeking to achieve greater compatibility of each side's regulatory regimes, such that producers of goods and services in both the U.S. and Europe can sell into each other's markets more efficiently and cost-effectively.

The T-Tip Pillars: Tariffs, Services, Investment, and Regulatory Compatibility

There are four principal pillars to the T-TIP: tariffs, services, investment, and regulatory compatibility.

Tariffs: Reducing tariffs, the traditional mainstay of trade negotiations, should be less problematic in the T-TIP context than in many other trade negotiations, because tariff levels in both the U.S. and EU are already relatively low. Nonetheless, given the massive volume of trade already occurring between the two partners, which will surely grow once the T-TIP enters into force, the economic consequence of eliminating even single-digit tariff rates will be enormous. It is estimated that U.S. businesses currently pay $6.4 billion each year in tariffs on goods exported to the EU. The simple stroke of a pen on the T-TIP agreement will eliminate this burden, immediately rendering U.S. exports that much more competitive in the European market. Moreover, approximately 40 percent of U.S. – EU trade is intra-company, which means that in many cases, companies are paying duties on both sides of the Atlantic for goods they're shipping to themselves.

Services: The U.S. and EU economies are increasingly dependent on services and major advancements in express delivery, computer networks, and telecommunications have driven this shift. The services sector generates 75% of GDP and employs 75% of the working population in both the U.S. and the EU. One of the great success stories of the U.S. economy is the global leadership American businesses in the services sector have achieved, including my own company, FedEx, which has become the world's largest express delivery carrier, but also many familiar brands in computer services, banking, securities, insurance, health care, education, management consulting, and other services industries. The services industry is a facilitator of trade, representing a growing share of value added in the manufacturing and agriculture sectors and enabling companies of all sizes, from SMEs to the largest corporations, the ability to transition from local establishments to international businesses that are able to participate in today's global value chains. During 2012, the U.S. exported $193 billion in services to the EU, representing 30% of total U.S. services exports, while the EU exported $149 billion in services to the U.S., accounting for 25% of its total services exports. Despite these impressive figures, trade in services represents only 36% of total trade between the U.S. and EU, trailing significantly the extent to which services are represented in the overall economy, and leaving us with ample room for future growth.

That growth is inhibited by the rules governing trade in services, which seriously lag behind those established in other sectors. In order for trade in services to realize its full potential, the T-TIP needs to reflect principles conducive to continued investment, competition, and innovation in the services sector. Such rules would provide for commitments to accord full market access and national treatment to service suppliers from the other jurisdiction, as well as providing disciplines for state owned enterprises that prohibit them from using their position to engage in anti-competitive conduct. The U.S. and the EU both have strong global express delivery companies and the T-TIP presents a unique opportunity for us to agree on high standard disciplines in this area that can eventually become the global standard.

Investment: With regard to investment, both the U.S. and EU have adopted measures which generally ensure a secure, stable, fair, and predictable legal environment applicable to direct investments. Pursuant to this regime, bilateral investment already totals a massive $3.9 trillion. The more than $2 trillion invested by U.S. firms in the EU represents approximately one-half of all U.S. foreign direct investment and generates $3 trillion in annual sales for U.S. business. Meanwhile, European investment in the U.S. creates employment directly for more than 3.5 million U.S. workers, and for many multiples of that number when supplier relationships are factored in. To capitalize on this already impressive bilateral investment relationship and lay the groundwork for even greater investment in the future, the T-TIP should incorporate a complete and ambitious investment promotion and protection chapter. This would include:

- A broad definition of investment;
- The right to establish and operate investments on a non-discriminatory basis, across the full range of economic sectors traditionally encompassed by trade agreements, including agriculture, mining, manufacturing, and services; this should be done on a "negative list" basis, with only limited and tightly defined exceptions;
- The right to transfer funds related to an investment;
- The right to transfer, process, store and manage data related to an investment;
- Allowing expropriation only for a public purpose, on a non-discriminatory basis, with due process, and with prompt, adequate and effective compensation for the fair-market value of the investment;
- High standard disciplines regarding competition with state-owned or state-controlled enterprises; and
- A robust investor-state dispute settlement (ISDS) mechanism.

Enshrining these principles in the T-TIP will enhance even further the favorable investment climate which exists in both the U.S. and EU, while also setting a strong example for third countries and for any multilateral framework that may be negotiated in the future.

Regulatory Compatibility: The subject of regulatory compatibility may hold the greatest potential of all for the T-TIP to confer economic gains, but is also likely to be one of the most difficult on which

to reach agreement. Most people believe that regulatory issues are the primary impediment to increased transatlantic trade and that if we can reduce these regulatory barriers to a substantial degree we can greatly increase our two-way trade. To be successful we don't need fundamental changes in our respective regulatory approaches. Regulatory compatibility is about finding areas where there are unnecessary and redundant regulations on both sides of the Atlantic that can be reduced in order to simplify and facilitate trade, while maintaining the same high standards of consumer, investor and environmental protections. Regulatory compatibility is also about improving regulatory cooperation, transparency and best practices in order to reduce regulatory barriers in the future. This will require that our regulatory agencies participate in the process and help identify and support areas where progress can be made. This will be difficult work and we hope that both sides are genuinely committed to tackling these issues constructively. The devil is in the details, and the benefits will be in the details as well. But the rewards will be substantial, in terms of making the transatlantic market that much more competitive.

Trade Facilitation: Low Hanging Fruit that Can Jump-Start GDP Growth

A subject that holds great potential to enhance the competitiveness of the U.S. and European economies and increase GDP on both sides of the Atlantic is trade facilitation. Earlier this year, the World Economic Forum, in conjunction with the World Bank and Bain & Company, issued a report which concluded that eliminating all remaining tariffs in the world would increase global GDP by less than one percent, while instituting best practices in terms of trade facilitation could increase global GDP by almost five percent. The reason this is possible is that tariffs essentially serve to reallocate resources from one location to another, while improving trade facilitation actually eliminates the waste of resources. Getting rid of unnecessary red tape that raises the cost of trading across borders holds enormous potential for economic growth on both sides of the Atlantic.

The "gold standard" for objectively measuring a country's trade facilitation practices is the World Bank's annual "Doing Business" Report, one of the sections of which specifically focuses on ease of trading across borders. According to the 2013 Doing Business Report, only one jurisdiction within the T-TIP area, Denmark, ranks among the top five countries in the world for trade facilitation best practices (the others making the top five were Singapore, Republic of Korea, Hong Kong Special Administrative Region, and the United Arab Emirates). The United States ranks 22nd out of the 185 economies studied in the Report – not bad, but leaving substantial room for improvement if we want to catch-up with the Singapore's of the world. Of the 28 EU Member States, ten rank higher than the U.S., and 18 rank below us, with three EU Members finding themselves in the bottom 50% of the world according to the study. So we in the U.S., as well as most of our friends in Europe, have a ways to go in this area to bring our competitiveness up to world class standards.

One particular reform which needs to be included in the T-TIP is a commitment to an ambitious and commercially meaningful "*de minimis*" level – the threshold below which goods can enter the country without the need for a formal customs entry or payment of duties and taxes. The principle underlying *de minimis* is that the total administrative cost of requiring low value shipments to comply with complicated customs entry procedures designed to apply to large commercial shipments, considering the burden on the shipper as well as the government in processing all of this paperwork, may actually exceed the amount of duties and taxes payable. Therefore, common sense calls for simply "waiving-in" such low value shipments. In the U.S., the current *de minimis* level is $200, and legislation is pending in both Houses of Congress, with bipartisan support, to raise it to $800. This would be in line with the amount returning travelers may bring back to the U.S. duty free, and would still be below the *de minimis* level of some of our trading partners such as Australia, which has a

1,000 Australian Dollar level (approximately $962 U.S. at current exchange rates). In Europe, the *de minimis* level with respect to customs duties is €150 (or $207 U.S.), but it is a mere €22 ($30.36 USD) with respect to taxes in most EU Member States, and as low as €10 ($13.80 U.S.) in some Member States.

Thus, a U.S. consumer or small business wishing to purchase goods online from a European-based web site can do so up to a value of $200 without having to engage a customs broker, pay duties or taxes, or otherwise incur the burdens of making a formal U.S. customs entry. But a European consumer or small business seeking to make a similar purchase from a U.S.-based web site finds that their transaction generally becomes subject to payment of value added tax as well as the need to involve and pay a broker in order to collect the tax, once the value exceeds $30. Engaging a broker to complete all this paperwork could easily double or triple the cost of a $30 or $50 purchase, thus making it much more expensive and thus less attractive to the consumer. In an economy where e-commerce every day plays a larger role in empowering consumers and businesses to comparison shop and secure the greatest possible value from the dollars or euros they have to spend, it is critical the continued growth of e-commerce not be stymied by *de minimis* levels set too low to be commercially useful.

All recent U.S. trade agreements, including those with the Republic of Korea, Panama, Colombia, and Peru, have included mutual commitments to establish *de minimis* levels of $200 – the *de minimis* level reflected in U.S. law at the time those agreements were negotiated. As noted previously, bipartisan legislation is pending in Congress to increase the U.S. *de minimis* level to $800. Accordingly, the Business Coalition for Transatlantic Trade is calling for the T-TIP to reflect mutual commitments by the U.S. and EU to institute an $800 *de minimis* level, a proposal which FedEx fully supports. Such action is needed to achieve competitive parity for online retailers selling into the other market, to spare consumers and SMEs from disproportionate administrative costs in making low-value purchases from sellers based in the other jurisdiction, and to position the economies on both sides of the Atlantic to maximize their global competitiveness. It is also a matter of reciprocity; if the U.S. is moving towards a higher *de minimis* level, our trading partners should at least be moving in the same direction.

While establishment of an ambitious *de minimis* level is perhaps the most compelling trade facilitation measure the T-TIP needs to address, other commitments which should be incorporated include:

- adopting a risk-based, multi-layered approach to customs processes, harmonized among all EU Member States, which facilitates legitimate trade while impeding illicit activities;
- committing to separate physical release of goods from payment of any duties and taxes owing;
- committing to pre-clearance of imports based on advance data submission;
- establishing a "single window" for border clearance whereby all government agencies with responsibility for entry of goods coordinate their actions and consolidate their data submission requirements;

- enhancing coordination and mutual recognition of "trusted trader" programs such as U.S. Customs & Border Protection's Customs-Trade Partnership Against Terrorism (C-TPAT); and

- committing to a separate and expedited procedure for clearance of express shipments.

Conclusion

The T-TIP presents a once-in-a-generation opportunity to boost economic growth, create jobs, and raise standards of living, for both the U.S. and our European partners. The U.S. and Europe have much in common, but we also have differences which, if appropriately reconciled in an ambitious and comprehensive T-TIP agreement, will provide a solid foundation for future economic growth, and assure the leadership of our two economies in establishing a trade regime that serves as an example to the world of a truly 21st century "gold standard" trade agreement. I urge the United States and the European Union to seize the moment to negotiate and conclude as promptly as possible such an agreement. FedEx stands ready to fully support the Administration's support for this important initiative.

I would also add that FedEx fully supports passage of new Trade Promotion Authority (TPA). An ambitious trade agenda is critical to America's economic growth and vitality and TPA is an important part of that agenda. Much has changed since 2002 when TPA was last updated. A new TPA will give us an opportunity to update our trade objectives to better fit the rapidly evolving global economic and commercial landscape.

Chairman Baucus, Ranking Member Hatch, and distinguished members of this Committee, thank you for the opportunity to share FedEx's views on this critically important initiative. I would be happy to respond to any questions you may have.

STATEMENT OF HON. ORRIN G. HATCH, RANKING MEMBER U.S. SENATE COMMITTEE ON FINANCE HEARING OF OCTOBER 30, 2013 THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: ACHIEVING THE POTENTIAL

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, delivered the following opening statement today at a committee hearing examining the opportunities and challenges of the Transatlantic Trade and Investment Partnership (TTIP) Agreement:

As we all know, expanding international trade is vital to our economic growth. Unfortunately, the United States has not concluded a new free trade agreement since June 2007.

Fortunately, the Administration has a golden opportunity to change that in the near future.

Negotiations for a small package of trade-enhancing measures under the auspices of the World Trade Organization are reaching a critical stage.

According to Ambassador Froman, negotiations to conclude a Trans-Pacific Partnership are also in the "end game."

Meanwhile, interest in concluding a Trade and Investment Services Agreement continues to build.

And, of course, there is the potential surrounding the Transatlantic Trade and Investment Partnership Agreement – or T-TIP – which we are here to discuss today.

T-TIP negotiations are just getting underway. If successful, they will build on our already strong economic ties with the 28 member states of the European Union. Our economic relationship with the EU is one of the largest and most complex in the world. Together, our two economies account for about half of world GDP and for nearly a third of world trade.

Our two markets are already deeply integrated. So, for T-TIP to reach its full potential, the agreement must reflect an unprecedented level of ambition.

Tariffs between our two economies remain low. But the sheer volume of trade means that companies and consumers on both sides of the Atlantic are paying vast sums in unnecessary tariffs.

For example, ICON Health, based in Logan, Utah, manufactures home exercise equipment. Grown from a small company on the campus of the Utah State University, ICON now employs over 3,000 people and sells its products around the world. Yet, today they still face tariffs in the EU averaging 2.7 percent.

Elimination of these nuisance tariffs would help spur more economic opportunity on both sides of the Atlantic.

On February 12, 2013, Chairman Baucus and I sent a letter to Ambassador Kirk outlining our expectations for the T-TIP negotiations. We highlighted the importance of strong market access for U.S. agricultural products, including the elimination of unjustified sanitary and phyto-sanitary standards.

We also called for the agreement to be comprehensive, excluding no product or sector from the negotiations.

Finally, we called upon the Administration to ensure that the agreement reflects the highest standards of intellectual property rights and does not jeopardize our ability to reach high levels of intellectual property protection in other negotiations or in other markets.

All of these goals still hold.

But, today, I want to emphasize a few key points.

First, for the U.S. economy to thrive, strong intellectual property rights protections are vitally important. Intellectual property-intensive industries support at least 40 million jobs and contribute more than $5 trillion to the U.S. economy.

For me to support a final agreement, it is absolutely essential that T-TIP reflect the highest standard of intellectual property rights protection of any prior agreement.

Indeed, the standards set in T-TIP will be a model for the world. We must get it right.

I also want to emphasize the importance of digital trade.

The Internet has fundamentally changed the way in which consumers shop and businesses deliver their products and services. Businesses, especially small businesses, benefit through improved efficiency, lower production costs, and access to a wider range of markets, while consumers benefit from more choices and improved access to products and services.

Given the importance of digital trade and the European market, there are several barriers to digital trade that I believe the agreement must address.

First, there are barriers that inhibit the free flow of digital data, including forced localization policies that, for example, require data servers to be located in-country or that require utilization of local content or technologies. The final T-TIP agreement should prohibit these kinds of policies.

The agreement should also prohibit discriminatory treatment of digital products and ensure that all technologies are given the chance to compete in the marketplace.

In addition, audiovisual services must be included.

Regulatory coherence will also be critical to achieving a meaningful agreement. Inconsistent and duplicative regulations create enormous cost and inefficiency for U.S. exporters of goods and services to the EU.

These negotiations must strive for regulatory convergence and coherence to eliminate barriers to trade. In particular, we should seek identical standards for emerging technologies, such as nanotechnology and Internet technologies.

Finally, no sector should be excluded from our efforts to enhance regulatory convergence, including financial services. Financial services play an essential role in facilitating trade and investment flows between our two regions. Given the central importance of the financial sector to every other aspect of industrialized economies, I do not see how financial services regulation can be excluded from a meaningful T-TIP agreement.

Of course, for this, or any trade negotiation to succeed, the President must work with Congress to achieve renewal of Trade Promotion Authority (TPA). Senator Baucus and I are currently working with our House counterparts to conclude a discussion on legislation to renew TPA. Once those efforts succeed, I hope that President Obama and his team will actively work with Congress to quickly seek its approval.

Mr. Chairman, thank you again for holding this hearing. I look forward to hearing from each of our witnesses.

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Testimony of Ryan McCormick
Wheat Farmer from Kremlin, Montana,
President of Montana Grain Growers Association
before the United States Senate Committee on Finance
Hearing to Review Pending Free Trade Agreement with the European Union
Wednesday, Oct. 30, 2013

Chairman Baucus, Ranking Member Hatch, members of the committee, my name is Ryan McCormick. I, along with my family, operate a successful agribusiness near Kremlin, MT. On our farm we raise hard red winter wheat, hard red spring wheat, durum, dry peas and most recently mustard. I would like to thank you for the opportunity to represent my fellow wheat producers and share my thoughts on the importance of this trade agreement with the European Union.

I currently serve as president of the Montana Grain Growers Association (MGGA); on the board of directors for the National Association of Wheat Growers (NAWG); and chairman of the NAWG's Domestic and Trade Policy committee, which helps set NAWG's policies on international trade.

Free and open trade is critical to wheat farmers, in both Montana and around the country. We are the largest exporter of wheat in the world. In a typical year, U.S. wheat farmers export about half of the product we produce; in Montanta this number runs as high as 80 percent. Not only do we depend on trade, the world depends on us as a reliable supplier of high-quality wheat.

Nearly 96 percent of the world's consumers live beyond U.S. borders. The remaining 4 percent, those who live within the U.S., do not consume enough wheat products to fully utilize the abundance of our nation's farms. In 2010, Montana growers produced more than 200 million bushels of wheat, while the U.S. Census listed our state population at 989,415 people. We simply do not have a large enough consumer base to support our state's large agricultural production. In fact, if Montana citizens were required to consume all of the wheat we produce within our borders, every person would have to eat 400 loaves of bread every day. As growers of an export-dependent commodity, MGGA and our national

association, the National Association of Wheat Growers, welcomes every opportunity to reduce costs for our international customers, reduce non-tariff barriers and compete on an equal playing field with our competitor suppliers.

In marketing year 2012/2013, the EU was the United States' sixth largest customer. The EU imports three classes of wheat from the U.S., soft red winter, hard red spring and durum wheat. The most often exported classes—hard red spring and durum—are grown in Montana. The EU was the fifth largest market for hard red spring and our top market for durum wheat in 2012/2013.

NAWG's sister organization, U.S. Wheat Associates, has maintained an office in Europe since 1958 to conduct market development activities in partnership with USDA, utilizing the Foreign Market Development program and Market Access Program authorized in the farm bill. U.S. wheat exports to the European Union in the last 20 years peaked at just over 2.0 million metric tons (MMT) in 2004, though the five-year average trade volume of more than 1.2 MMT remains significant and important. One concern to future export competitiveness is that U.S. wheat exports could face increased competition and a less preferential tariff status when the European Union implements its just-completed free trade agreement with Canada. Montana-grown wheat competes directly with wheat grown just north of the border in Canada. Further, the EU and Ukraine recently finalized discussions on an Association Agreement that will provide preferential access for Ukrainian wheat. While the details of this agreement are not fully known, any new access for Ukrainian wheat would compete with U.S. wheat exports.

The U.S. wheat industry supports the swift negotiation and ratification of a comprehensive, high-standard Transatlantic Trade and Investment Partnership (TTIP). A successful TTIP must be completed in a single undertaking, with no exclusions or commitment to deal with tough issues at a later date. The countries comprising the European Union have been valuable buyers of U.S. wheat, and a successful agreement will enable us to maintain and grow sales and market share.

We have identified several key issues for negotiation that will make U.S. wheat more competitive and enhance trade between the two largest economies in the world.

First, the TTIP must eliminate all duties on U.S. wheat imports. Eliminating duties on low- and medium-quality protein wheat will expand market opportunities for U.S. wheat producers. In January 2003, the European Union implemented a tariff rate quota for these two wheat types, which are designated by the EU as having below 14 percent protein. The United States has a special low-duty quota allocation and

can also participate in a worldwide quota. The duty for in-quota wheat is 12 euros per metric ton (MT), and the out-of-quota rate is 95 euros per MT, rates that are much higher than the U.S. wheat import tariff level of $3.50 per MT for WTO member countries. The European Union reduced the in-quota duty to zero on low- and medium-quality wheat in February 2011, which will remain in place through June 30, 2013. Due to this recent action to remove tariffs, and taking into account the low U.S. tariff, the United States should push for complete and immediate tariff elimination.

The European Union also operates a Margin of Preference (MOP) import system for durum and high quality wheat that results in variable import duties for WTO member countries. Since early 2008, high wheat prices have resulted in duty-free access for U.S. wheat that meets the EU specification for high quality and durum wheat. This zero duty level should be made permanent.

U.S. wheat producers, many from Montana, compete against Canada for durum and high quality wheat. Canada and the European Union just this month completed negotiation of their own free trade agreement. The outcome of the Canada-EU agreement will result in a permanent zero wheat duty for Canadian producers to be phased in over seven years, which will lead to future tariff differentials and a preference toward Canadian wheat. Given the many years of zero duties already in effect and Canada's negotiations, securing a permanent zero duty for U.S. wheat is achievable and would provide increased certainty to U.S. producers and EU importers. Given the seven year phase-in period for the Canadian agreement, a shorter implementation period under TTIP would increase U.S. wheat competitiveness.

Second, U.S. wheat producers strongly support science-based, least-trade restrictive regulations. The European Union and the United States are viewed as global scientific leaders, and our actions on sanitary and phytosanitary (SPS) measures have a broad impact, making this a critical area of discussion. Increased cooperation on science-based SPS risk assessments, standards, processes and implementation of least trade restrictive regulations would benefit U.S.-EU bilateral trade and positively influence SPS regulations in countries that look to the United States and European Union for guidance. Similar to TPP, the TTIP must include SPS commitments that go beyond those agreed to at the WTO, and these provisions must be fully enforceable and subject to dispute settlement.

U.S wheat producers also recognize that transparency and cooperation are critical when it comes to SPS measures, as the application of scientific risk assessments by our countries differ. The European Union

takes a highly cautious approach while U.S. regulators try to apply the least trade restrictive measures possible. These differing implementing procedures can result in a variation of applied SPS measures that create the potential for trade disruption. SPS issues that have arisen throughout the years between the United States and the European Union for wheat include Karnal bunt requirements, as well as mycotoxin and heavy metal allowances.

The United Kingdom and Greece currently have requirements to test U.S. wheat for Karnal bunt upon arrival. These tests have not generated confirmed Karnal bunt presence, but have resulted in delivery delays and a number of false positives, which in turn cause EU buyers to consider U.S. wheat a higher risk for arrival delays than from other origins. The European Union argues that the U.S. Karnal Bunt standard does not provide adequate risk protection, even though their many years of testing have failed to detect wheat that does not meet their requirements. The USDA Karnal bunt declaration is accepted by virtually all other countries around the world, and we are not aware of any new Karnal bunt case throughout the world that can be attributed to U.S. wheat exports. Continued cooperation and movement towards European Union acceptance of the USDA Karnal bunt statement would eliminate unnecessary testing of U.S. wheat shipments upon arrival, removing exporter and importer uncertainty.

This is similar in the case of mycotoxins. The U.S. Federal Grain Inspection Service (FGIS) currently offers official mycotoxin testing services that follows rigorous sampling and testing procedures to provide independent third-party assurance to buyers of their contract specifications, but the European Union does not accept the validity of FGIS approved tests. Destination testing at discharge ports adds a layer of uncertainty. Buyers in Italy have even encouraged U.S. wheat exporters to seek a pre-certification program for mycotoxins due to this additional risk. FGIS recently agreed to start bilateral discussions with their counterparts in the EU on this issue, and we encourage an outcome that reduces burdens for wheat exports. However, if agency discussions fail, this should be addressed during FTA negotiations.

Third, the European Union must agree to a more predictable biotechnology approval process.
The EU's political approach in regulating crops enhanced with traits achieved through modern biotechnology procedures is a concern to U.S. wheat producers. The EU biotechnology approval process is slow and often influenced more by politics than science, creating uncertainty and deterring new investment in wheat research. The slow biotechnology approval process puts future trade at risk. Science should be the basis for biotech crop approvals, and the EU market should provide consumer

choice for biotech and non-biotech products. Due to the slow approval process, the European Union needs to implement a low level presence policy (LLP) for food to avoid trade disruptions. A workable LLP policy and threshold for events approved by U.S. regulators would ensure that trade continues even when negligible amounts of approved biotech traits are inadvertently present in bulk shipments. The just-completed FTA between Canada and the EU did include provisions relating to biotechnology. Unfortunately, a discussion forum on biotechnology provides no assurances that the EU will begin adhering to timelines set out in their biotechnology approval process. A successful TTIP must include binding language which ensures timely, science-based approvals in the EU as laid out by their own regulations.

Finally, we urge Congress to renew trade promotion authority (TPA). TPA renewal is essential to completion and ratification of a comprehensive TTIP agreement, as well as completing the Trans-Pacific Partnership and securing an eventual WTO agreement. Current trade negotiations, such as TTIP and TPP, involve important, 21st century trade issues, such SPS enforceability and commitments relating to biotechnology regulations, that have evolved since TPA was last implemented. TPA provides assurances to our trading partners that once an agreement is reached, it will not be unnecessarily held up in Congress or amended to include provisions that may be unpalatable.

While TPA is essential for the Administration to successfully complete new agreements, it also empowers Congress. TPA negotiating objectives and procedures also lay out a structured framework and pathway for addressing issues important to Congress, and consultation requirements ensure that Congress remains aware of their negotiating status. Once a successful agreement is reached, TPA lays out the process for swift ratification by Congress.

In conclusion, U.S. wheat farmers welcome the progress that has taken place so far in the TTIP negotiations, and encourage Congress and the Administration to work together to negotiate a comprehensive, high standard agreement. Competition with Canadian wheat in the European market is looming and U.S. wheat farmers do not want to lose customers in this critical market.

Mr. Chairman, Ranking Member Hatch and Members of the Committee, thank you for allowing me the opportunity to be with you today to discuss the importance of this free trade agreement to wheat farmers. I am happy to answer any questions you have.

Prepared Statement

By Dave Ricks

Senior Vice-President and President Lilly Biomedicines

Before the

SENATE FINANCE COMMITTEE

On

"The Transatlantic Trade and Investment Partnership: Achieving the Potential"

October 30, 2013

Chairman Baucus, Ranking Member Hatch, and members of the Committee, I very much appreciate the opportunity to address the Committee on the Transatlantic Trade and Investment Partnership (TTIP) – a negotiation of great importance to Eli Lilly and Company, the innovative biopharmaceutical industry, and the business community.

Eli Lilly and Company is a global biopharmaceutical company headquartered in Indianapolis, Indiana. Our company was founded in 1876. In addition to our global presence, we are truly an integrated transatlantic company. We have approximately 38,000 employees worldwide, including 9,000 in Europe. More than 7,700 of our global employees, or 20%, are engaged in research and development. In 2012 we invested over $5.2 billion in R&D, representing 23% of our revenue. Over the last decade our R&D investment in Europe has doubled to over $600 million. One third of our clinical trials take place in Europe, which represents a total investment of nearly $170 million. We have research and development facilities located in eight countries including the UK and Spain. We have manufacturing plants located in 13 countries including France, Ireland, Italy, Spain and the UK. Our products are marketed in 125 countries. Our European facilities alone export to more than 100 countries. In the U.S. we employ more than 16,500 people. Our European investments also support U.S. jobs, and demonstrate the importance of transatlantic trade to our business.

Lilly and the biopharmaceutical industry believe that TTIP represents a unique opportunity to promote the highest standards of intellectual property protection, market access and regulation in particular for the IP driven sectors in which the EU and U.S. enjoy a global advantage. We also believe that the two governments should use TTIP to work together to maintain and grow that advantage.

As such, Lilly has been focused on the possibility of a transatlantic trade agreement for some time. We serve as Co-Chairs of the Business Coalition on Transatlantic Trade (BCTT), and I personally am the incoming U.S. Co-Chair of the Trans-Atlantic Business Dialogue. Lilly is an active member of the Transatlantic Business Council (TABC), the US Chamber of Commerce, the National Association of Manufacturers (NAM), The Business Roundtable (BRT), The Pharmaceutical Researchers and Manufacturers of America (PhRMA), and the Biotechnology Industry Association (BIO), among others. Through our membership in these organizations, Lilly has advocated for and promoted the TTIP on both sides of the Atlantic and is a vocal supporter of a comprehensive and ambitious agreement.

During my remarks, I will address the broad list of issues that have been put forward by the business community and will provide you with some specific real-world examples of how the completion of an ambitious TTIP agreement could benefit companies like Lilly, our employees, and the patients that rely on our medicines -- both present and future.

I would like to note that in light of both the ongoing Trans-Pacific Partnership (TPP) negotiations and Transatlantic Trade and Investment Partnership (TTIP) agreement talks, the consideration of legislation to renew Trade Promotion Authority (TPA) could provide an important opportunity to strengthen and grow the U.S. economy by identifying policies to advance trade liberalization. Principally, we believe that our nation's trade policy should seek to maximize U.S. companies' access to overseas markets, secure strong IP rights, and to minimize the use of tariff and non-tariff barriers as well as broad open-

ended exceptions to obligations. It should be the policy of the United States to ensure that our trading partners do not condition market access on forced localization policies, including the transmission of intellectual property rights or the building of business infrastructure in their markets. Equally important, TPA legislation should safeguard against policies such as government price controls and cost containment measures that operate as non-tariff barriers and can dramatically impact U.S. companies' ability to enter and compete in new and existing markets. These objectives should be supported and advanced by all U.S. government agencies with expertise in the areas of international trade, as well as the regulation of pharmaceuticals. I would like to acknowledge Chairman Baucus and Ranking Member Hatch for their leadership on this issue and underline that the business community stands ready to work with you and your staff on a high-standard TPA Bill.

One of the ways that Lilly is working to achieve the potential we see in TTIP is through serving as a Co-Chair on the Business Council for Transatlantic Trade's (BCTT) Steering Committee with other significant players in the in the transatlantic economy. The BCTT also includes many of the major multi-sectoral industry organizations. These sector-specific industry associations have been joined by dozens of other companies in coalition working groups tasked with defining the priorities of the business community in these negotiations.

The members of the BCTT support an ambitious, comprehensive, and high-standard trade and investment agreement between the United States and the European Union. We understand that while there is considerable enthusiasm on both sides of the ocean for TTIP, the sheer scale of the negotiations could lead to one side or the other trying to damper expectations. In contrast, the BCTT and other business organizations believe strongly that this agreement must meet several key expectations. By "ambitious," BCTT members urge negotiators to find creative ways to address emerging opportunities in the 21st century economy, such as trade in digital goods and services, as well as longstanding challenges in such areas as sanitary and phyto-sanitary (SPS) barriers, technical barriers to trade (TBT), trade facilitation, and regulatory barriers to trade and investment. By "comprehensive," we believe the agreement must cover trade in industrial goods, food and agricultural goods, services, investment, procurement, protection of intellectual property rights (IPR), and regulatory issues. BCTT members believe that there should be no exclusion of specific sectors or commodities. By "high-standard," we entreat that TTIP set the highest possible standards for third countries to work towards in the areas of investment, intellectual property rights, competition policy, treatment of state-supported enterprises, and elimination of localization requirements, among others.

Broadly-speaking, the business community has been united it its enthusiasm for an ambitious agreement. This negotiation will no doubt be complicated and challenging, but we know that the U.S. negotiators will be up to this task and we stand ready to work with them to provide solutions that overcome hurdles identified during the negotiations. While the agenda and stated timelines for TTIP are indeed ambitious, I believe I speak for many in our sector who would prefer that negotiators take the time needed, within reason, to achieve a comprehensive agreement rather than rush to meet an imposed deadline. On substance, the BCTT believes that the agreement should:

- Eliminate virtually all consumer, industrial, and agricultural tariffs upon entry into force, and for those that remain, specify phase-out periods that reflect scheduled tariff elimination under other U.S. and EU trade agreements.
- In the case of services, liberalize all modes of delivery and apply them to all sectors, including financial services.
- Facilitate the flow of goods in the supply chain by adopting common customs electronic data filing systems, minimizing inefficiencies in our security regimes and modernizing our customs and other government agencies' border clearance processes.
- Include disciplines on technical barriers to trade (TBTs) to ensure the least trade restrictive approaches to the regulation of goods.
- Support a common agreement on what constitutes an international standard.
- Include a binding chapter on SPS measures that reinforces the importance of science- and risk-based regulations and decision-making.
- Establish a framework for regulatory cooperation across all sectors, including financial services, to enable our regulators to become more efficient, transparent, and effective in fulfilling their mandate to protect consumers, investors, workers, and the environment. U.S. and EU regulators should determine where their regimes reach functionally equivalent outcomes that would allow a product or service sold in one market be made available in the other.
- Provide new tools and a governing process to guide cooperation on a horizontal and sector-specific basis. Regulatory cooperation is not about less or more regulation. We seek better processes that enable regulators to fulfill their statutory obligations in a manner that is not market-distorting.
- Create a binding framework with clear, consistent, and predictable rules on cloud computing and other ICT services, cross-border information flows, and prohibitions on requirements for local servers or infrastructure. Such a framework must allow for flexibility on the method used to achieve high levels of privacy protection and continue cooperative work on security matters. These provisions will not only bolster transatlantic digital trade, but will also serve as a global benchmark.
- Include a full investment promotion and protection chapter, reflecting at least the high standard of protections in the 2012 U.S. model Bilateral Investment Treaty (BIT). This includes a robust investor-state dispute settlement (ISDS) mechanism, which is essential to show the world our willingness to commit to the same set of rules that we urge trading partners to uphold.
- Commit both sides to further improve existing laws, regulatory measures, and standards regarding intellectual property rights (IPR) protection. Joint efforts to raise the standard of IP protection can also serve as the basis for promoting economic growth associated with robust IP protection and enforcement in third countries.
- Establish that all levels of government and public entities in the EU and the U.S. will commit to consider on a fully non-discriminatory basis bids to provide goods and services from firms based in the United States or the EU.
- Demonstrate unified transatlantic leadership in highlighting acceptable transparency and due process obligations with regard to competition enforcement proceedings, and in ensuring that

state-owned enterprises comply with their multilateral and bilateral trade and investment obligations.

In particular, IPR is a critical issue that should be included in the negotiations. As a company, an industry, and a business community, we believe it is essential that this agreement maintains and promotes effective and standard-setting levels of intellectual property protection.

Intellectual property rights are a critical driver of the American and European economies. As has been noted in numerous joint statements by the European Union and the United States, both partners recognize the importance of promoting effective and robust protection of intellectual property. The strong protections and enforcement provisions that both the EU and the U.S. currently provide in their domestic markets is evidence of this commitment and is an important foundation that should be recognized in the TTIP.

TTIP negotiators are fully aware that time and resources deployed trying to fully harmonize their IP systems are not well-spent. Instead, as the High-Level Working Group (HLWG) report notes, the Parties are willing to address and cooperate extensively on several issues of common concern that "would not only be relevant to bilateral commerce, but would also contribute to the progressive strengthening of the multilateral trading system."

An IP climate that establishes effective protection and enforcement mechanisms provides innovative companies -- of all sizes, and across sectors -- the incentives to commercialize and bring their products to market. This, in turn, facilitates the creation of jobs, continued innovation, public safety, and access to new technologies. In the United States alone, a U.S. Department of Commerce study found that IP industries support at least 40 million jobs, contribute more than $5 trillion or 34.8% to the GDP, and $775 billion in exports. Similarly, a September 2013 study Commissioned by the European Patent Office (EPO) and the Office for Harmonization in the Internal Market (OHIM) found that IP-intensive industries create 77 million jobs and generate 40% of the total economic activity throughout the EU - roughly 4.7 trillion Euros annually.

TTIP must protect and foster an IP climate central to strong economic growth. Conversely, the TTIP agreement must also address impediments to effective IP protection in the EU and globally. Effective protection and enforcement of intellectual property rights create an environment in which innovators receive the incentives to invest in the research, development, and commercialization of leading-edge technologies. Moreover, in such an environment, innovators are more likely to share their innovations and transfer technology voluntarily to others, knowing that the terms on which they do this will be respected and effectively enforced if necessary.

The TTIP is an important opportunity for the United States and the EU to improve upon specific issues affecting the innovation environment in both markets and to collaborate on improving global standards for IP. In the bilateral context, TTIP negotiators should ensure that this agreement does not undermine the rights of trademark holders or prevent the use of common names in international commerce.

Additionally, the TTIP is an opportunity to address practices in Europe that weaken intellectual property protection. This includes the inadequate protection of confidential commercial information submitted to marketing approval authorities from inappropriate disclosure. More specifically, the current and proposed policies of the European Medicines Agency (EMA) regarding disclosure of such data do not adequately protect patient privacy and do not protect confidential commercial information consistent with the EU's existing trade obligations. These policies must be addressed in order to implement responsible data sharing that effectively safeguards the privacy of patients, preserves the integrity of the regulatory system, and preserves incentives for investments in biomedical research.

The agreement should enhance global protection of trade secrets. This is one IP issue where the United States and EU share a mutual interest in developing a common positive agenda. Although some of a company's most valuable assets can be embodied in trade secrets, this type of IP often is subject to the weakest legal protections as compared to other types of IP. The entire economic value of a trade secret stems from the competitive advantage conferred by the confidential nature of the information. Once disclosed, trade secrets cannot be recovered because this form of IP does not give its owner an exclusive right (in contrast to a patent, for example).

Trade secret misappropriation is on the rise due to greater global competitiveness and a significant increase in the use of digital devices that process data on a nearly constant basis, which in turn increases the targets for cyber attacks. Moreover, some governments are requesting excessive amounts of confidential information as a condition of product approval, which raises a different kind of disclosure risk.

The TTIP should be used to develop a comprehensive, model trade secret protection system that can be promoted globally. This system should effectively (i) address trade secret theft, (ii) increase government to government cooperation to minimize cross-border incidences of trade secret theft, (iii) minimize increasing government requests for excessive and unnecessary confidential information (trade secrets) as a condition of product approval (market access), and (iv) address inadequate government procedures to protect the confidential information they receive.

Both the U.S. and EU governments are currently reviewing their respective trade secret laws to determine how they could be improved. A TTIP commitment to identify and adhere to the basic elements of a model trade secret law, and promote it globally, is especially important because the relevant obligations in Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights require only minimum levels of protection for trade secrets. Separate from model legislation effectively addressing trade secret theft, a comprehensive trade secret protection system also should require governments to justify requests for disclosure of trade secrets as a condition of product approval or market access.

I would now like to take the opportunity to address some specific areas of interest in the agreement for Lilly and the biopharmaceutical sector. My goal is to give you some context for what this agreement could mean for us as a global business and some context on what issues are most important to our industry.

As a company and as an industry, like many others, we are increasingly making products for the whole world, not just one single market. More and more, we are finding it difficult to include Europe as part of the business case to take a medicine forward, either due to market uncertainty, IP enforcement issues, or not receiving a fair price. In some cases, we terminate a new medicine's development because of this – presumably a medicine that could benefit Europe, the U.S., and probably many others. Because of the lack of alignment on a global standard for regulation, access or IP the result is that fewer treatments or cures reach the market. We believe that this represents a real tax on public health.

Because of this, we believe TTIP should set ambitious standards for pharmaceuticals in the fields of regulatory harmonization, intellectual property protection and enforcement, and market access. This is critical to ensure rapid access for patients to new medicines, the support of an industry that directly provides over 1.2 million highly skilled jobs in the transatlantic economy, and an appropriate benchmark for future trade agreements with other countries. For example, the innovative biopharmaceutical industry directly employed nearly 810,000 people and indirectly supported 3.4 million jobs across the United States in 2011. The industry generated nearly $51 billion in exports alone in 2012, and PhRMA member companies invested almost $50 billion in R&D for new medicines last year. At the same time, our industry faces substantial costs and risks in the course of bringing innovative medicines to market. Of five thousand to ten thousand potential compounds considered, only 250 compounds may show sufficient potential to undergo pre-clinical testing. Only five of those compounds, however, will enter clinical trials, and only one will ultimately be approved. Even then, only two out of every ten approved medicines will recoup R&D costs. Overall, it is estimated that developing a new medicine takes 10-15 years on average, and costs approximately $1.3 billion.

The TTIP agreement has the potential to facilitate further collaboration and create new markets and opportunities for the innovative biopharmaceutical industry to thrive. With the help of an ambitious, comprehensive, and high-standard agreement, our industry will create and market a generation of new medicines that will contribute to economic growth and prosperity in the U.S. and EU and will benefit patients around the world.

For Lilly, this agreement represents a significant opportunity to address regulatory duplication, increase stability and reward for innovation through the IP system, and address long-standing concerns about market access and transparency.

With regard to the biopharmaceutical industry, our industry believes it is critical that the TTIP agreement includes robust provisions, which:

Promote regulatory compatibility.

- Address regulatory differences and duplicative requirements that can impede efficiency in global drug development;
- Reduce redundant testing and optimize deployment of limited regulatory agency resources while preserving patient protections and encouraging expedited patient access; and

- Coordinate marketing application data disclosure policies to protect patients and preserve incentives for biomedical research.

Strengthen intellectual property protections.

- Ensure strong intellectual property protections, including 12 years of regulatory data protection for biologics;
- Clarify patentability standards and implement patent term adjustments necessary to incentivize further investment in biopharmaceutical R&D; and
- Adopt effective patent enforcement systems that allow for early patent dispute resolution.

Enhance market access.

- The further reduction of non-tariff barriers in both markets will spur tomorrow's innovations for the benefit of patients around the world. To this end, the Korean-U.S. Free Trade Agreement (KORUS) should be the foundation of the TTIP.

Ensure alignment between the U.S. and the EU as they engage with third parties, such as India, China, and Canada, thereby promoting high biopharmaceutical policy standards and access to innovative medicines throughout the world.

Regulatory Compatibility

The United States' innovative biopharmaceutical industry strongly supports efforts to address regulatory differences and duplicative requirements that can impede efficiency in global drug development, review, and evaluation. Addressing these important issues can help to enhance efficiency of drug development, reduce redundant testing, and optimize deployment of limited regulatory agency resources. At the same time, regulatory coordination can lead to expedited patient access to new, innovative, life-saving medicines.

Significant partnership already exists between the FDA and EMA, both bilaterally and internationally, through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH). The regulatory compatibility proposals outlined here build on those efforts. Indeed, a U.S.-EU agreement will be a unique opportunity to develop even greater streamlined processes and procedures, and to set high biopharmaceutical policy standards ensuring access to innovative medicines throughout the world. To this end, specific regulatory compatibility proposals that our industry would like to see pursued as part of the TTIP include:

- Coordination to reduce the regulatory burden for sponsors and agencies.
    - Recognize each other's Good Manufacturing Practices and Good Clinical Practices inspections.
    - Grant sponsors the right to receive parallel scientific advice upon request for all medicines.
    - If successful, formally adopt the current pilot program between the U.S. and EU agencies to conduct parallel assessment of Quality by Design applications.

- Addressing current and proposed data disclosure policies.
  - Disclosure of companies' non-public data submitted in clinical and pre-clinical dossiers and patient-level data sets (at the time of patient registration, drug approval, and discontinuation of research programs) risks damaging public health and patient welfare.
  - Engage with the EU to ensure responsible data sharing that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research.
  - Include provisions that adequately shield confidential commercial information from inappropriate disclosure.

- Increased collaboration under the auspices of the ICH.
  - U.S. and EU agencies should work together to achieve greater regulatory compatibility in the scope, content, and timing of submission of pediatric investigation plans (EU) and pediatric plans (U.S.), so that companies are required to prepare only a single plan for submission in both territories.
  - Seek greater collaboration on pharmacovigilance issues including post-market testing, risk management requirements and format, and deadlines for adverse event reporting through a specific "cluster" on this topic.
  - Revise existing guidance to reduce the requirements for duplicative local bridging requirements.
  - Develop a harmonized structural framework and methodology for benefit-risk assessments (agencies would retain authority to make different risk-benefit judgments under their individual approval schemes).
  - Develop a harmonized approach to post-approval variation submissions for manufacturing changes.

- Implementation of a collaborative process for developing therapeutic area guidelines.
  - The U.S. and EU should establish a procedure for developing scientific and other regulatory guidelines for specific therapeutic areas.

- Addressing falsified medicines/product verification issues. The EU and U.S. should work together to ensure that their national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary, harmonized international standards.

Intellectual Property Rights

The innovative biopharmaceutical industry, which supports millions of jobs in the U.S., relies on strong intellectual property rights protection and enforcement to recoup the substantial costs of developing lifesaving medicines. Recognizing that IP is the lifeblood of innovation, the EU, like the U.S., generally affords strong IP protections to innovative biopharmaceuticals within the rubric of its system, and any agreement between the U.S. and the EU must not dilute these protections. These protections and the underlying principles on which they are founded should be included by the U.S. and the EU in all future

trade agreements with other countries. Specific IP issues around which PhRMA and its member companies **strongly encourage the U.S. and Europe to secure greater convergence as part of the TTIP include:**

- Seeking similar IP protections to those afforded under U.S. law.
  - Negotiate strong regulatory data protection provisions. As per U.S. law, the U.S. should seek 12 years of regulatory data protection for biologics.

- Clarification of patentability standards.
  - Provide that the scope of patent eligible subject matter includes medical process inventions (such as methods of therapy) and plant or non-human animal inventions.
  - Impose no limits on improvement inventions beyond the normal standards applied to determine patentability.
  - Clarify the criteria that must be met to demonstrate novelty.
  - Stipulate that determinations of whether an invention is not obvious should be made on a case-by-case basis.
  - Elucidate that broad disclosures of compounds do not anticipate all specific molecules within their scope absent specific teachings or directions to one of ordinary skill in the art.
  - Provide greater clarity regarding what constitutes adequate disclosure of the invention and the nature of what additional information can later be presented to support the patent application.
  - Ensuring that the patent system provides an appropriate grace period.

- Restoration of lost patent life.
  - Delays at the patent office and the time taken during the marketing approval process reduce the effective patent life over which an innovative manufacturer can seek to recoup the significant investments required to bring a successful medicine to market.
  - The patent term should be adjusted and/or restored to compensate for both regulatory approval process and patent office delays (the EU currently addresses only the former).

- Ensuring effective patent enforcement.
  - Strict enforcement of IP protections is particularly important to the biopharmaceutical industry given the significant cost and time required to develop a new medicine – on average, over $1.2 billion over 10-15 years – and the relatively short remaining period over which a manufacturer can recoup this investment.
  - It is essential to adopt effective patent enforcement systems that allow for early resolution of patent disputes before a patent-infringing product is launched on the market. Allowing an infringing product to enter the market during a dispute harms the innovative manufacturer – very often irreparably.

The U.S. and EU should not impose trademark limitations other than those necessary to protect public health.

Market Access

Biopharmaceuticals face unique market access challenges. In most markets, access for biopharmaceuticals is dependent not only on manufacturers meeting strict regulatory approval standards, but also obtaining reasonable government pricing and positive reimbursement determinations. Both the U.S. and the EU have included specific pharmaceutical (and medical device) chapters in recent FTAs addressing these challenges. Those provisions were designed to ensure that the regulatory approval and reimbursement procedures for medicines are governed by transparent and verifiable rules founded on science-based decision making. These FTA chapters have also recognized that there should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies both in the development and specific implementation of all relevant laws, regulations, and procedures. Furthermore, applicants affected by a negative determination should be provided the right of appeal to an independent objective court or administrative body.

Building on the common provisions contained in the pharmaceutical and medical device chapters of the U.S. and EU FTAs with Korea, we strongly encourage the Parties to:

- Adopt meaningful general principles.
    - Recognize the value biopharmaceuticals can provide in reducing other more costly medical interventions and in improving the lives of patients;
    - Respect the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need;
    - Recognize the value of ethical interactions between biopharmaceutical representatives and health care professionals; and
    - Agree that any reimbursement controls/determinations should only apply to products dispensed and reimbursed in that country.

- Promote access to innovation.
    - Clarify that if a government entity of a Party establishes prices for patented biopharmaceuticals based on prices of the same product in other countries, it should only reference countries that are similar in terms of their socio-economic level, populations, disease burdens, and health care systems, and should never be set by reference to prices for the same product in countries in economic crisis; and
    - Provide that during the patent term of a biopharmaceutical product, the government price for that product should be based on the value of that product and should never be set by reference to prices for generic products.

- Ensure transparent government regulation.
    - Clarify that the pharmaceuticals chapter applies to laws, regulations, and procedures concerning all aspects of securing market access for biopharmaceuticals, including, but not limited to, health-technology assessments, demand-side measures, and "clawback" mechanisms;

  - Ensure that applications to the EU Member States are processed within a reasonable, specified period, i.e., per the timelines mandated in the EU Transparency Directive; and
  - Add similar language to that contained in Article 3.4(h) of the EU-Korea FTA requiring each Party to ensure that stakeholders with legitimate commercial interests have access to full information about each Party's pricing and reimbursement systems and processes (excluding confidential business information).

- Authorize dissemination of information to patients and health care professionals.
  - Permit manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites as long as the information is truthful and not misleading, includes a balance of risks and benefits, and is limited to indications for which the relevant regulatory authority has granted market approval for that medicine.

- Eliminate barriers to market access/patient access.
  - Respect the payment terms established by U.S. law and the EU's Late Payments Directive, respectively; and
  - Ensure that any "clawback" or rebate tax levied by a Party in response to an economic crisis should not disproportionately burden patented biopharmaceutical manufacturers (i.e., should be borne by the entire supply chain), and should be subject to a transparent, annual review process with an opportunity to comment. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

In conclusion, Lilly is one company among many within our industry and in the broad business community that believes TTIP is a once-in-a-lifetime opportunity to address longstanding trade issues, create new markets, and simplify transatlantic business. We look forward to working with the Committee and Congress to ensure that this agreement meets the expectations of the business community, creates jobs, and enhances the competitiveness of our two economies. Thank you for the opportunity to testify today. I welcome any questions that you may have.

David A. Ricks

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December 3, 2013

The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Hatch:

As requested during the Senate Finance Committee hearing on the Transatlantic Trade and Investment Partnership on October 30, I am responding in writing to your question regarding the issue of 12-years of data protection for biological drugs. I appreciate the opportunity to respond to this important issue and have cc'd the other members of the Finance Committee on this response as per your request.

As I mentioned during my testimony, Lilly is a 137-year old biopharmaceutical company based in Indianapolis, Indiana. We have grown over time to be one of the largest biopharmaceutical companies in the world. Our reach is truly global. We have grown through a relentless commitment to innovation. In fact, while many in our industry have decreased their research and development (R&D) investment in difficult economic times, our R&D investment continues to grow. Much of this investment in our pipeline is focused on biologic drugs.

Lilly is committed to innovation in biologic medicines because these medicines have resulted in and will continue to result in tremendous medical advances against the most challenging and costly diseases affecting patients in America and around the world. As you well know from your leadership role with Senator Enzi and then-Senators Kennedy and Clinton and with Representatives Eshoo, Barton, Inslee and Upton in the House, the Patient Protection and Affordable Care Act created both an abbreviated approval pathway for biosimilars as well as provided a 12-year period of data protection for innovator biologics. This provision received strong bipartisan support in both the House and the Senate and struck an appropriate balance between creating price competition and maintaining incentives for continued innovation.

Lilly

Data protection allows a biologic to be on the market for a fair period of time before a biosimilar can be approved based on the innovator's data and helps protect against the uncertainties caused by patent challenges early in a product's life which occur long after R&D investments are made. To advance the discovery of new biologics, the data protection period must be long enough to allow innovators, who undertake costly and risky R&D and must satisfy the FDA's exacting approval requirements, to earn a positive rate of return. Data protection of less than 12 years would multiply uncertainties about potential returns on investment and increase the risk that biologic products could not achieve a positive return, driving investment away from supporting the discovery of new biologics.

Patents alone are not always sufficient to create the environment needed to support large-scale investment in biologic discoveries. Effective patent protection for biologics often proves difficult to obtain. Many biologic products rely upon process patents or relatively narrowly drawn product patents. These may be susceptible to work-arounds, especially under a regulatory regime that may permit biosimilars to differ in their structural features from innovator products to a greater extent than U.S. law. This is of particular concern in countries where the balance in IP law is tilted in favor of state-owned enterprises or local companies. Furthermore, if a biologic's development time is extensive; there may be a very limited period of patent protection remaining once a product is approved. Adequate data protection recognizes the need for innovator to recoup their investment in R&D before biosimilar price competition commences.

The cost and risks characteristic of biotech innovation require strong data protection because large R&D investments must be made long before FDA approval and with uncertainty about post-approval patent challenges. The safety and efficacy data that must be provided by innovator companies to gain FDA approval of a biologic can take more than a decade to compile and conservatively require an average of more than $1.3 billion in pre-approval R&D. The estimates do not include the additional $250 to $450 million or more that innovator companies often spend on manufacturing facilities, which can take three to five years or more to construct. For example, a new biologics facility constructed recently in Indianapolis cost more than $1 billion.

U.S. jobs and future economic growth could be lost if the incentives for innovation are insufficient. The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing more than 20 percent of all domestic R&D funded by U.S. businesses. Investment in research and development by PhRMA member companies was an estimated $48.5 billion in 2013, remaining strong despite a challenging economic environment. Lilly alone invested $5.3 billion in R&D in 2012. This level of investment, together with increases in the number of medicines in development, is a strong indicator of the potential medical innovations to come – innovations that are being developed in the U.S. by American workers, including more than 16,500 who work for Lilly.

We believe that ongoing trade negotiations must recognize the need for strong IP protections. The U.S. innovation ecosystem should serve as a model for the world and the benefits of strong IP protections both in the TPP agreement and TTIP will spur innovation in all of our trading partners. These protections should include those afforded under U.S. law, including 12-years of biologics data protection. We commend USTR for tabling 12-years of data protection in the TPP negotiations, but it is now critical that

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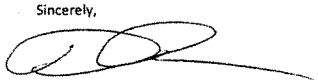
they bring it home in any final treaty. We understand that certain developing countries may require implementation periods during which they can build capacity in order to effectively implement their obligations, but these periods must be limited in time in order to ensure that the benefits of high standards of IP protection accrue to all TPP countries. We are categorically opposed to an approach that sets different milestones for IP based on per-capita GDP or some other arbitrary measure. The full impact of such a policy would directly benefit countries such as India and China who seek a lower standard for industrial policy reasons.

As I explained in my testimony, strong IP protections do not act as a barrier to access. Rather they drive access to new therapies. The biggest challenges facing developing nations are not IP protections, but the provision of basic medical services and infrastructure and overall investment in healthcare. In fact, 95% of the drugs listed on the World Health Organization's Essential Drug List have no IP protection, yet still more than one-third of the world's population has no access to these medicines.

Again, I appreciate the opportunity to respond to your question and would be happy to answer any further questions you or your colleagues may have on this issue.

Sincerely,



cc. Members of Senate Finance Committee

Transatlantic Trade and Investment Partnership: Achieving the Potential

Hearing of The United States
Senate Committee on Finance

William "Bill" P. Roenigk
Senior Vice President
National Chicken Council

Wednesday, October 30, 2013
215 Dirksen Senate Office Building
Washington, DC

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Good morning, Chairman Baucus, Ranking Member Hatch, and Members of the Committee. Thank you, Chairman Baucus, for the opportunity to participate in this critically important and most timely hearing on the Trans-Atlantic Trade and Investment Partnership (T-TIP).

I am William "Bill" P. Roenigk, Senior Vice President of the National Chicken Council. The Council represents the vertically-integrated companies that this year will produce and process over 95 percent of the more than 9 billion young meat chickens (broilers) in the United States. Member companies are proud to market on a very consistent basis the most wholesome, highest quality, affordable chicken in the world. Despite very tough competition from certain other countries, about 20 percent of the U.S chicken supply this year will be exported to 100-plus countries. Permit me to note that none of the 28 member nations of the European Union (EU) can be counted in the 100-plus countries.

Although I speak today about the EU prohibiting U.S. poultry from its market, I can assure the Committee that virtually every commodity and product exported by U.S. agriculture has their particular issues and challenges when they market, or try to market, to the EU. Difficulties range from tariffs, import quotas, sanitary/phytosanitary provisions, and other technical barriers to trade.

EU Has Prohibited U.S. Poultry Since 1997

Prior to 1997, the U.S. poultry industry was able to participate in the European market and had great, but, perhaps, naive hopes that the trade liberalization promised by the WTO Uruguay Round negotiations would further improve market access. Annual U.S. poultry exports in 1996 to the EU were $55 million, making the EU's 15 member countries at that time the ninth largest export market for U.S. poultry. If the current 28 countries were in the EU in 1996, the export market for these countries would have been $210 million, making that combination of countries the third largest poultry export market for the United States, behind Russia and Hong Kong.

Today, if U.S. poultry could be exported to the EU, sales would be in excess of $600 million on an annual basis, making it one of the top export markets. This revenue would generate significant economic activity in many parts of rural America; stimulate employment in more than 30 important poultry states, directly and indirectly; and provide for a more stable flow of income to hundreds of family farms who grow chickens.

From before World War I when canned U.S. poultry meat was exported to essentially all the countries in Europe, trade continued uninterrupted for the most part until 1997. In 1997, the EU erected a number of non-scientific and unjustifiable non-tariff barriers that have prohibited U.S. poultry from the European market for the past 17 years.

The United States and the European Union at the time were engaged in the so-called "Equivalency Negotiations" attempting to implement many of the provisions of the WTO Agreement on Sanitary and Phytosanitary Measures with respect to trade in meat and poultry products. The most difficult issue to resolve – indeed, the last issue to be resolved – in those negotiations was the issue to the terms and conditions for access for U.S. poultry. Despite United States insistence that the USDA system guarantees a safe, wholesome product and the

EU's failure to provide any evidence showing that the use of hyper-chlorinated water in poultry processing had any negative health effects or harm to the environment, the EU, nonetheless, very arbitrarily imposed its ban on U.S. poultry.

At the end of the negotiations, it was agreed that the United States would propose four alternative pathogen reduction treatments (PRTs) (that is, in lieu of hyper-chlorinated water) for use in poultry processing. Further, the European Union would present these proposals to its Scientific Advisory Committee for an opinion as to safety and efficacy. The EU promised to complete this review within a year's time. After many years this promise was eventually kept. Although the Committee determined the four PRTs posed no measurably food safety issue, the protectionist sentiment within the EU prevented the question of the alternative PRTs from coming before the European Food Safety Authority (EFSA) for more than ten years. The EU Scientific Advisory Committee's findings implied that the EU's precautionary principle had been met. When the question was finally submitted to EFSA, it took nearly two more years to study the question and render an opinion. Ultimately, EFSA did advise the EU that the use of each of the four proposed alternative rinses was, in fact, safe and efficacious. Further, it recommended that their uses be approved by the EU. When that advisory opinion was then presented to the Member States in support of an implementing proposal of the European Commission, the proposal was voted down 27-0. The EU Member States ignored the scientific facts and voted politically to continue to block imports.

Subsequently, the Office of the United States Trade Representative (USTR) announced that it was initiating consultations at the World Trade Organization with the European Union on this matter. When those consultations yielded no results, the U.S. government initiated dispute settlement process with the WTO. Both the United States and the European Union proposed panel members to hear the dispute, but were never able to agree on the composition of the panel. Under WTO rules, the United States was then entitled to request that the WTO Secretariat appoint panel members so that the dispute could be litigated. At that point, all progress on the case stopped without any explanation. The case has now lingered in the legal doldrums for five years without progress.

It should be noted, however, that despite the lack of progress via the WTO dispute settlement process, the Administration is working on the antimicrobial issue with the EU. Lactic acid for use on beef is now acceptable to the EU, according to an EU Commission Regulation published earlier this year. Following that favorable step, the Administration is now focusing on having the EU approve a PRT for poultry.

A recent application by USDA to DG SANCO, the EU's Directorate-General for Health and Consumer Affairs, was reportedly supportive of putting on the agenda the approval for the use of peroxyacetic acid as an anti-microbial treatment in the post-slaughter rinse water in U.S. poultry plants. DG SANCO, in turn, has forwarded the application to EFSA. Peroxyacetic acid is one of the four treatments previously approved by EFSA, but rejected by unanimously by a vote of the EU Commissioners. The others are chlorine dioxide, acidified sodium chlorite and trisodium phosphate.

Not using a pathogen reduction treatment is not an option for U.S. poultry plants operating under federal inspection. PRTs are used to reduce bacteria, enhance food-safety, and meet USDA's requirements for pathogen reduction which is an integral component of each processing plant's Hazard Analysis Critical Control Points (HACCP) program.

USDA's Food Safety and Inspection Service, Health and Human Service's Food and Drug Administration, and other government agencies deem the use of hyper-chlorinated water to be both safe and efficacious. About 45 billion pounds of U.S. poultry this year will be processed using hyper-chlorinated water or similar antimicrobials. U.S. poultry processed with the use of hyper-chlorinated water is consumed every day by millions of American citizens and by millions-more consumers in 100-plus countries where the United States exports its product. For more than four decades such treatments have been used in the United States.

U.S. Poultry Industry Strong Supporter of International Trade

The U.S. poultry industry has been and continues to be one of the strongest voices in U.S. agriculture for trade liberalization and international market opening. It has unquestioningly supported the efforts of the United States to achieve greater multilateral trade liberalization through the General Agreement on Trade and the World Trade Organization during the Tokyo and Uruguay Rounds, and supported further efforts to initiate the Doha Round talks. It supported U.S. efforts in the free trade agreement for the U.S./Canada, NAFTA, CAFTA, Morocco, Bahrain, Chile, Colombia, and Panama. Our industry is on record as supporting the Trans-Pacific Partnership negotiations, especially with the inclusion of Canada, Mexico, and Japan in those negotiations. In short, the U.S. poultry industry has been a constant and adamant supporter of trade liberalization efforts by the United States over the past four decades.

In the case of the T-TIP, however, the U.S. poultry industry is, very frankly, much less enthusiastic. We have serious concerns – even serious doubts – that any new trade agreement with the European Union will result in real and meaningful access for U.S. poultry exports to the European market. Our experience with the European Union's actions to block U.S. poultry imports – even in contradiction of the advice of its own scientists – tells us that Europe is unwilling to allow imports that would compete with European product, and that Europe will not live by the commitments that it makes in this respect. We are also concerned, based on lack of progress in the WTO case initiated several years ago, that the U.S. government will not insist on implementation of the terms of market access negotiated. We have been assured on a number of occasions by our trade negotiators that our industry's issues will not be traded-off for some other issue on the EU side. We trust our negotiators will secure the most favorable outcome possible, but at the risk of being redundant, we will want to be doubly-assured that the end product is worthy of our support.

Attached to my comments are two letters. One letter is dated May 4, 2013 addressed to then U.S. Trade Representative Ron Kirk. In this letter 64 agricultural organizations and agribusiness firms congratulated the Administration for its decision to launch the T-TIP negotiations. The letter also urged an ambitious and comprehensive commitment to achieving a successful final trade agreement. The other letter dated May 20, 2013 and was addressed to Michael Froman who at the time was headed-toward becoming the new U.S. Trade Representative. In that letter signed

by 47 agricultural organizations, Mr. Froman was urged to prepare to counter the EU's demonstrated "inability to lift unjustifiable measures because of domestic political pressures" in the EU. The letter also noted "precaution" in the EU has become a pretext for import protection. Importantly, the letter states that "if selected sectors or measures are excluded from the T-TIP, or placed into a 'future negotiation' category, the T-TIP will fall short of achieving the Administration's goal for it to be a high-class 21st century agreement, and it will likely fail to win the overall support of the food and agricultural sector that will be needed to ensure final passage of this agreement."

Trade Promotion Authority Should Be Approved Soon

If and when there is a final agreement for T-TIP or the Trans Pacific Partnership, Congress, of course, will be asked to consider the agreement. Such consideration to be most meaningful should be done under the Trade Promotion Authority. The National Chicken Council and essentially all other major agricultural organizations have urged Congress to act on renewing the Trade Promotion Authority. This Administration and future Administrations need this authority. Having Congress act before the next agreement is finalized will strengthen the hand of U.S. trade negotiators and demonstrate more strongly to the international trade community that the United States is most serious in continuing to be the world leader to building trade, increasing economic activity, and providing for more workers to benefit from the hard-fought agreements.

Conclusion

The U.S. poultry industry has always been a strong advocate of liberalized trade and a strong supporter of U.S. trade initiatives. However, after more than 17 years of being unfairly shut out of the European market by unjustifiable non-tariff trade barriers, especially SPS and technical barriers to trade and after seeing that our rights to access to the European market would not be aggressively pursued and vindicated, the U.S poultry industry has serious concerns regarding T-TIP. We hope that we will, at some point, be able to strongly support this initiative. However, until there is a clear indication of how this agreement will result in real and meaningful market access with the elimination of all non-tariff trade barriers to our products, it will be difficult to see how the T-TIP is in the interests of our industry, our member companies, our workers, or the tens of thousands of family farmers who grow chicken. Having stated that serious concern, we are also aware of what a famous ice hockey player said about scoring and putting the puck in the net. He said "You miss 100% of the shots you don't take."

The National Chicken Council looks forward to working with the Committee and others in Congress to secure the most favorable outcome for the T-TIP.

I look forward to your comments and questions.

Attachments

March 4, 2013

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

Dear Ambassador Kirk:

The undersigned food and agricultural groups applaud the decision to launch negotiations with the European Union (EU) on a transatlantic free trade agreement (FTA) and commend you for your insistence that the agreement be comprehensive and ambitious. Individual organizations will be providing comments in the coming weeks, but there are a number of general considerations on which we all agree.

First, we believe that this agreement must fit the excellent model established with the Trans-Pacific Partnership (TPP) for 21st century agreements. The next trade agreement to be undertaken by this Administration should not fall short of this high standard for free trade agreements. This means no less than a negotiation that covers all significant barriers in a single comprehensive agreement.

With this in mind, we are compelled to express some apprehension over language in the final report of the High Level Working Group (HLWG) suggesting that an agreement ...

> "... should be designed to evolve over time – i.e., substantially eliminate existing barriers to trade and investment, while establishing mechanisms that enable a further deepening of economic integration, particularly with respect to the promotion of more compatible approaches to current and future regulation and standard-setting and other means of reducing non-tariff barriers to trade."

Clearly, an agreement that is allowed to evolve to meet new demands is welcome, but the idea should not be used as a means of avoiding critical decisions in certain areas. Accordingly, we seek your assurances that this is not the intent of this language, or of the U.S. and EU negotiators.

We are encouraged by the fact that a significant portion of the HLWG Report is devoted to dealing with regulatory issues (and other non-tariff barriers), especially the recommendation to negotiate an ambitious "SPS-plus" chapter based on science and international standards. However, we are very concerned by recent statements by EU officials raising doubts about whether the EU has any real interest in dealing with sanitary and phytosanitary (SPS) issues as part of the negotiations. SPS issues must be specifically addressed as part of the negotiations, not simply left to some future consultative mechanism, and SPS provisions must be enforceable. Examples of these issues include unjustifiable restrictions on production methods that negatively affect exports of U.S. meat, poultry, and fresh fruits; costly and ever changing political and regulatory barriers to agricultural biotechnology that restrict U.S. corn, soy, and processed corn and soy product exports; and imposition of arbitrary sustainability requirements on the production of feedstocks in the U.S. and other countries for biofuels used in the EU. Such unscientific measures have become the most challenging barrier to U.S. food and agricultural exports to the EU.

While EU officials have expressed opposition to addressing these difficult measures in the negotiations, they are nonetheless eager to seek the inclusion of new barriers to trade benefiting EU products. For example, the EU has made no secret that it will seek restrictions on the use of names that are commonly used for many products. Geographical indications (GIs) are a legitimate form of intellectual property and deserving of protection; the United States already provides the same robust protection avenue for GIs that

is available to other trademark holders. However, the EU wishes to reserve names for products that have been in common use around the world for many years. The United States is not alone in the world in its opposition to these efforts, and the proposed U.S.-EU FTA should not become the platform for the EU to gain legitimacy for its objectives on this and other such protectionist measures.

The undersigned organizations welcome President Obama's decision to pursue an ambitious, high-standard Transatlantic Trade and Investment Partnership. We strongly believe that a comprehensive and ambitious U.S.-EU FTA will generate economic growth, reduce market volatility, and create thousands of new jobs on both sides of the Atlantic. But such a momentous free trade agreement must be built on the foundation established by the U.S. in the TPP and other U.S. free trade agreements, which build, as you have said, "the best trade policy for the future."

Sincerely,

American Beekeeping Federation
American Farm Bureau Federation
American Feed Industry Association
American Meat Institute
American Peanut Product Manufacturers, Inc.
American Seed Trade Association
American Sheep Industry Association
American Soybean Association
BIO
Blue Diamond Growers
California Cherry Export Association
California Dried Plum Board
California Farm Bureau Federation
California Fig Advisory Council
California Pear Growers
California Strawberry Commission
California Table Grape Commission
California Walnut Commission
Commodity Markets Council
Corn Refiners Association
Grocery Manufacturers Association
International Dairy Foods Association
National Association of State Departments of Agriculture (NASDA)
National Association of Wheat Growers
National Barley Growers Association
National Black Farmers Association
National Cattlemen's Beef Association
National Chicken Council
National Confectioners Association
National Corn Growers Association
National Council of Farmer Cooperatives
National Grain and Feed Association
National Milk Producers Federation
National Oilseed Processors Association
National Pork Producers Council
National Potato Council
National Renderers Association

National Turkey Federation
North American Blueberry Council
North American Equipment Dealers Association
North American Export Grain Association
North American Meat Association
Northwest Horticultural Council
Pet Food Institute
Produce Marketing Association
Smithfield Foods
Sunsweet Growers Inc.
Sweetener Users Association
Tyson Foods, Inc.
U.S. Apple Association
U.S. Canola Association
U.S. Dairy Export Council
U.S. Grains Council
U.S. Livestock Genetics Export, Inc.
U.S. Meat Export Federation
U.S. Wheat Associates
United Egg Association
United Egg Producers
US Dry Bean Council
USA Dry Pea & Lentil Council
USA Poultry & Egg Export Council
USA Rice Federation
Valley Fig Growers
Western Growers Association

cc: The Honorable Tom Vilsack, Secretary of Agriculture

May 20, 2013

The Honorable Michael Froman
Deputy National Security Advisor for International Economic Affairs
The White House
Washington, DC 20510

Dear Mr. Froman:

The undersigned organizations and companies, representing the vast majority of U.S. food and agricultural producers, processors and exporters, registered strong support for the initiation of free trade negotiations with the European Union, now formally known as the Transatlantic Trade and Investment Partnership (TTIP), in a letter to then-Ambassador Kirk on March 4, 2013 (see attached). Our initial support for the TTIP was largely based on the Administration's insistence that the agreement be "comprehensive and ambitious." However, a resolution regarding the TTIP passed by the European Parliament on April 24 strongly expresses the intent of the EU to maintain the precautionary principle, which would undermine sound science and ultimately the agreement itself. The following section is both informative and unsettling, and it suggests that our optimism for the TTIP negotiations may have been premature or misplaced:

> *17. [The EU Parliament] emphasizes the sensitivity of certain fields of negotiations, such as the agricultural sector where the perception of Genetically Modified Organisms (GMOs), cloning and consumer health is divergent in between the US and the EU; sees an opportunity in enhanced cooperation in agriculture trade and stresses the importance of an ambitious and balanced outcome in this field; stresses that the agreement must not undermine the fundamental values of either side, for example the precautionary principle in the EU; calls on the US to lift the import ban on EU beef products as a trust-building measure ...*

The juxtaposition of issues in this section is most concerning. On one hand, the Parliament demands that the European Commission defend arbitrary and unjustifiable SPS barriers and the precautionary principle on which they were based, yet, on the other hand, it calls on the United States to lift its ban on EU beef, which resulted from the BSE crisis, "as a trust-building measure." At the core, the EU's non-scientific notion of "precaution" has led to the adoption of many trade-restrictive measures that have resulted in several high-profile WTO disputes in which the EU's defense of the precautionary principle has been ruled to be inconsistent with WTO rules. Such precautionary measures are often based on mere hazard identification – or worse, on public perception and political considerations – rather than proper, science-based risk assessments, as required by the WTO. And, even in cases where risk assessments are ultimately carried out, the EU has demonstrated an inability to lift unjustifiable measures because of domestic political pressures. "Precaution" in the EU has become a pretext for import protectionism under the pretense of consumer safety. As a result, U.S. exports have repeatedly paid the price.

Examples of such problems include unjustifiable restrictions on production methods that negatively affect exports of U.S. meat, poultry and dairy products, as well as fresh fruits; discriminatory and trade-restricting labeling requirements; political and regulatory barriers to agricultural biotechnology that restrict U.S. corn, soy and processed corn and soy product exports; and imposition of arbitrary sustainability requirements on the production of feedstocks in the United States and other countries for biofuels used in the EU.

Such non-science-based measures have become the most challenging barrier to U.S. food and agricultural exports to the EU. They must, therefore, be specifically addressed as part of the negotiations, not simply left to some future consultative mechanism as some EU parliamentarians have suggested. Furthermore, SPS provisions negotiated under this free trade agreement (FTA) must be enforceable.

The EU has also worked to accomplish in its other FTAs what it has been unable to achieve multilaterally. The EU has sought the inclusion of language on geographical indications (GIs) that would grant it exclusive rights to certain product names widely used outside of Europe for many years. This objective was also reinforced by the EU Parliament. It defies credibility to think that a trade agreement could actually make it more difficult for the United States to market its products both domestically and internationally. Such an approach would not be in keeping with the broader trade liberalization goals of TTIP.

TTIP negotiations in agriculture carried out on the terms mandated by the EU Parliament would be an enormous mistake. In its preferential trade agreements with other countries, the EU has been successful in maintaining its existing non-science-based SPS measures while in some cases also introducing other non-tariff measures restricting trade.

We believe that the best way to achieve an outcome on these matters that the food and agricultural sector can strongly support is to use the Trans-Pacific Partnership (TPP) negotiating structure as the template for the TTIP. The TPP is intended to be a comprehensive agreement, covering all sectors without exceptions; all topics are to be concluded as a "single undertaking," which means that nothing is agreed to until everything is agreed to; and there is to be an SPS chapter with strong and enforceable WTO-plus disciplines.

The negotiating approach the Obama administration has reportedly worked out with Japan in the TPP negotiations is directly relevant to negotiations with the EU in the TTIP. It is our understanding that the United States and Japan will pursue the talks with a three-pronged approach: parallel negotiations on tariff issues, non-tariff measures and the automobile sector, with negotiations not to be considered concluded until all significant non-tariff measures are satisfactorily addressed. This same type of approach should be undertaken with the EU.

As stated in our March 4 letter:

> "We strongly believe that a comprehensive and ambitious U.S.-EU FTA will generate economic growth, reduce market volatility, and create thousands of new jobs on both sides of the Atlantic. But such a momentous free trade agreement must be built on the foundation established by the U.S. in the TPP and other U.S. free trade agreements, which build, as you have said, "the best trade policy for the future."

The U.S. food and agriculture sector is not alone in this belief; it is one shared by EU decision makers like British Prime Minister David Cameron, who recently stated when discussing the TTIP: "... It makes no sense to exclude vital parts of the economy. Everything must be on the table. And we must tackle the really tough regulatory issues so a product approved on one side of the Atlantic can immediately enter the market on the other."

If, instead, selected sectors or measures are excluded from the TTIP, or placed into a "future negotiation" category, the TTIP will fall short of achieving the Administration's goal for it to be a high-class 21st century agreement, and it will likely fail to win the overall support of the food and agricultural sector that will be needed to ensure final passage of this agreement.

Attachment

Sincerely,

American Farm Bureau Federation
American Feed Industry Association
American Frozen Food Institute
American Meat Institute
American Sheep Industry Association
American Soybean Association
Animal Health Institute
Biotechnology Industry Organization
California Farm Bureau Federation
California Poultry Federation
Corn Refiners Association
Georgia Poultry Federation
Grocery Manufacturers Association
International Dairy Foods Association
Michigan Agri-Business Association
Michigan Bean Shippers
National Association of State Departments of Agriculture (NASDA)
National Association of Wheat Growers
National Barley Growers Association
National Cattlemen's Beef Association
National Chicken Council
National Confectioners Association
National Corn Growers Association
National Council of Farmer Cooperatives
National Grain and Feed Association
National Milk Producers Federation
National Oilseed Processors Association
National Pork Producers Council
National Renderers Association
National Sorghum Producers
National Turkey Federation
North American Equipment Dealers Association
North American Export Grain Association
North American Meat Association
North Carolina Poultry Federation
Northwest Horticultural Council
Pet Food Institute
U.S. Apple Association
U.S. Canola Association

U.S. Dairy Export Council
U.S. Grains Council
U.S. Livestock Genetics Export, Inc.
U.S. Wheat Associates
USA Dry Pea & Lentil Council
USA Poultry & Egg Export Council
USA Rice Federation
Western Growers Association

COMMUNICATIONS

SENATE COMMITTEE ON FINANCE

HEARING:

Hearing on the benefits of a Transatlantic Trade and Investment Partnership

October 30, 2013

STATEMENT FOR THE RECORD

SUBMITTED BY:

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

Introduction

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments on the Transatlantic Trade and Investment Partnership (TTIP) to the Senate Finance Committee. AdvaMed represents approximately 400 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed members range from the smallest to the largest medical technology innovators and companies. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality health care technology can make toward achieving those goals.

AdvaMed supports the negotiation of a comprehensive free trade agreement (FTA) between the United States (US) and the European Union (EU), under the framework of the TTIP. We would like to see provisions addressing issues affecting our industry in US-EU bilateral trade and in trade with third countries.

General Comments on Regulatory Cooperation

Although the US and EU use different approaches to determine the safety and efficacy of medical technology, studies have demonstrated that each system delivers similar results in terms of these basic objectives. AdvaMed supports cooperation between the regulatory agencies on both sides of the Atlantic as a way to promote understanding and reduce unnecessary regulatory burdens. Rather than attempting comprehensive "convergence" of these two systems, such as a mutual recognition agreement (MRA), we recommend focusing on specific areas of "convergence." We have provided USTR an explanation of these issues.

We also believe that there should be improved transparency in the regulatory process in the EU. Stakeholders should be provided regulatory proposals while there is still a possibility of making meaningful changes – which is usually before the proposals are sent from the European Commission to the Parliament and Council. The Commission should be required to recognize such contributions – much in the way US agencies operate under the Administrative Procedures Act. This process would improve the regulatory process.

AdvaMed also recommends that TTIP include a regular dialogue between the U.S Food and Drug Administration (FDA) and DG-SANCO, involving USTR and U.S. Department of Commerce, to exchange information on regulatory measures being considered by either party that could impact trade and determine areas for additional "convergence." In advance of these meetings, industry would be consulted to provide their views on regulators' proposals. This dialogue could be held under provisions similar to Korea-US FTA, but strengthened to ensure that future measures be explicitly discussed and industry has the opportunity to comment on non-confidential proposals and has access to the results of such meetings.

Additional Recommendations

In addition to regulatory cooperation, we urge both governments to address the following issues in the context of a comprehensive Free Trade Agreement. We have provided USTR our views on the eliminating border tariffs, improving Customs procedures, enhancing the single market in the EU for medical technology, reducing late payments to our members, and including provisions on transparency and procedural fairness in Member States' reimbursement systems.

Third Country Issues

Our industry faces an array of issues outside the US and EU. Our member companies source many of their products sold globally from the US and/or the EU. Therefore, governments in both the US and EU should be interested in ensuring that medical technology companies are treated fairly by third country governments. We ask that the TTIP include provisions that encourage the relevant agencies to work on behalf of our medical technology firms. We have provided USTR with a list of specific areas for cooperation on third country issues.

Center for International Environmental Law

Statement of Center for International Environmental Law (CIEL)
ON BEHALF OF CIEL, Center for Biological Diversity, Friends of the Earth and Sierra Club

Before The U.S. Senate Committee on Finance, hearing on "The Transatlantic Trade and Investment Partnership: Achieving the Potential"

October 30, 2013

Thank you, Chairman Baucus and Ranking Member Hatch for the opportunity to submit written testimony on the proposed Transatlantic Trade and Investment Partnership (TTIP) Agreement before the Senate Committee on Finance.

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

I. Summary of Key Messages

The current system for regulation of chemicals is wholly inadequate to meet the challenges posed by the modern chemicals economy. Cancer rates have increased. The amounts of chemicals in our bodies have increased. Absent greater regulatory action, they will continue to increase. This is an international public health problem that *remains unsolved*. Public health is one of the core responsibilities of a government to its citizens, and it is one that is currently not being adequately addressed with regard to chemicals. The scarcity of detailed information on TTIP, particularly from the United States, makes any assessment of its eventual impact inherently speculative. While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, experience with other trade agreements, together with the explicit intention of reducing regulatory barriers to trade, make it far more likely that TTIP will hinder important public health and safety goals related to chemicals. To reduce this likelihood, TTIP:

- must ensure that both the EU and U.S. retain the right to determine their own levels of health protection from toxic chemicals, and develop measures to reduce exposure to hazardous chemicals as they see fit;
- must not include provisions for investor-state dispute resolution;
- should not provide authority to a Regulatory Cooperation Council or equivalent oversight group for the chemicals sector and other sensitive sectors;
- should not include provisions for mutual recognition for the chemicals sector and other sensitive sectors;

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- should not impede the rights of states and local governments, or of governments outside the United States and E.U., to adopt new initiatives on toxic chemicals and other environmental issues, including their right to choose higher levels of protection for their citizens;
- should not impede regulatory efforts to address emerging issues of concern, such as nanotechnologies, endocrine disrupting chemicals or hydraulic fracturing; and
- must be negotiated in an open, transparent and participatory manner that safeguards the universal and fundamental public interest in the outcomes of the negotiations.

II. Introduction

For over twenty years, CIEL has advocated for a positive trade agenda, where increased market access does not undermine environmental protections or human rights. This submission addresses the environmental implications of removing perceived regulatory barriers to trade between the United States and the European Union (EU) through the Transatlantic Trade and Investment Partnership (TTIP). The focus of this submission is on the potential impact of the negotiations on regulations intended to protect people and the environment from toxic chemicals.

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

We focus this submission on the chemicals sector because of the significance of recent shifts in outdated chemical policies in the EU, and the potential benefits of implementing related laws in the EU on the health and environment of people around the world, including those in the United States.

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

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

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

As implied by the Final Report of the High Level Working Group on Jobs and Growth and explicitly recognized in the EU's position papers, the "[e]limination, reduction and prevention of unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP."[2] Industry submissions reflect a similar expectation that TTIP will serve primarily as an opportunity reduce non-tariff barriers to trade. Provisions on harmonization, equivalence, mutual recognition and other provisions that may be included in TTIP could weaken standards for human health and the environment in both the EU and U.S., preempt state laws in the United States, restrain the continued development of REACH in the European Union, and influence the development of chemical laws outside the U.S. and EU, in particular the BRIICS countries (Brazil, Russia, India, Indonesia, China, South Africa).

To facilitate regulatory cooperation, the EU's Trade Commissioner recently proposed the creation of a Regulatory Cooperation Council to "... monitor the implementation of commitments made and consider new priorities for regulatory cooperation."[3] This submission focuses on five specific issues: (1) Regulatory cooperation, including harmonization and mutual recognition; (2) investor state dispute settlement; (3) preemption of laws at the state-level in the United States and the national-level by EU member countries; and (4) influencing the development of laws outside the U.S. and EU.

III. Regulatory Cooperation

Various tools are available to facilitate regulatory cooperation, including harmonization and mutual recognition. Harmonization takes two or more differing standards or procedures and converts them into a single, uniform standard. Mutual recognition requires countries to recognize and accept the results of assessments performed by assessment bodies of consenting parties. The EU, U.S. and other industrialized countries have been developing these trade policy tools over the course of the last decade as part of their international trade liberalization efforts. While the purported objective of regulatory cooperation is to reduce perceived regulatory barriers to trade, they also have considerable potential to reduce existing levels of national health, safety, and environmental protection.

While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, the harmonization of regulatory standards to the "lowest-common denominator" has often been the result of recent U.S. trade agreements, decreasing the level of protection afforded to the public in favor of private interests.[4] Other agreements, such as the North American Free Trade Agreement (NAFTA), failed to harmonize standards between Mexico, the U.S. and Canada, which has resulted in the transfer of dangerous and environmentally unsound industrial activity to Mexico.[5] This poses a serious threat to the environment,

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

[3] Karel De Gucht, European Trade Commissioner, Transatlantic Trade and Investment Partnership (TTIP) – Solving the Regulatory Puzzle, Address before the Aspen Institute Prague Annual Conference (10 October 2013).

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

[5] For example, a disturbing trend involving the export of Spent Lead-Acid Batteries (SLABs) for recycling has developed over the last several years. While the U.S. battery recycling industry has increased safety standards and lowered emissions, developing countries, like Mexico, are not keeping pace. While the U.S. has strict regulations governing lead emissions and employee blood lead exposure, no similar comparable regulatory regime can be found in Mexico. The Blacksmith Institute estimates that more than 12 million people are adversely affected by lead contamination from improper processing of SLABs. Since NAFTA, an increasing number of SLABs are exported

working families, and communities. It is therefore imperative not only that regulations are harmonized upward, but also that any convergence of regulations serves as a regulatory floor that allows governments the flexibility to develop more ambitious environmental and public interest policies in the future.

In the case of certain regulations in the EU and U.S., it is difficult to envision any degree of harmonization. Regulations for chemicals management offer one such example. EU and U.S. approaches diverge significantly, with the European Commission acknowledging in documents prepared for TTIP that "US requirements [for chemicals] are less strict" and that, in the view of the EU, "neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU."[6]

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

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

Most existing chemicals still lack toxicity data relevant to hazard assessment.[7] Regarding exposure, data also are lacking on production volume and use, which are critical for determining the potential for human and environmental exposure and for risk assessments and prioritization. Human bio-monitoring data exists for only a hundred or so of the tens of thousands of industrial chemicals and pesticides that are regularly used and released into the environment. Moreover, with respect to new chemicals, roughly two-thirds of submissions for approval to manufacture the new chemical do not include test data on chemical properties, and almost 85% of submissions provide no data on health effects.

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

The proposed, but widely criticized, Chemical Safety Improvement Act (S.1009) would not close this gap between U.S. and EU regulatory approaches in the absence of significant improvements. As the EU's initial position paper on Chemicals highlights, "the draft legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation."[8]

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to Mexico from U.S. battery dealers and manufacturers. In 2012, 754 million pounds of used batteries were exported to Mexico, *see* SLAB WATCHDOG, http://www.slabwatchdog.com/problem/slabs-2/ (last visited July 23, 2013).

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

[7] Congressional Research Service (CRS) Report RL34118 at 17.

[8] Chemicals in TTIP, *supra* note 6.

Recently, the European Union has emerged as a global leader in acknowledging and beginning to address urgent issues in chemicals management, such as endocrine disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. Endocrine or hormone disruption is an intrinsic hazard of certain chemicals, linked to a myriad of adverse effects that have been on the rise over the past several decades. As there is no safe level of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that need to be phased out globally. Nanomaterials have unique physical and chemical properties that make them distinct from traditional substances. They are increasingly used in a wide-range of products, but assessment methods are still not attuned to the properties of nanomaterials and precaution is warranted. Mixture toxicity recognizes that we are exposed to hundreds of hazardous chemicals daily. Adverse effects have been observed by mixtures of chemicals at levels where the individual chemical is not expected to result in any adverse effects, i.e. the additive, synergistic or 'cocktail' effect of chemical mixtures. Submissions by the chemical industry highlight these as "current regulatory issues with potential for significant impact on trade."[9]

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

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

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

The regulation of chemicals in cosmetics offers another illuminating example of how little overlap there is between chemicals restricted from certain uses in the EU versus the U.S. The EU Cosmetics Directive (76/768/EEC) was revised in January 2003 to ban 1,328 chemicals from cosmetics; the U.S. FDA has banned or restricted only eleven.[10] More recent improvements in the EU include the explicit authorization of colorants, preservatives and UV-filters, including those that are nanomaterials. In addition to giving the Commission the power to require a full safety assessment of nanomaterials used in

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[9] AMERICAN CHEMISTRY COUNCIL, ACC SUBMISSION TO USTR, May 10 2013.
[10] Campaign for Safe Cosmetics, *European Laws*, CAMPAIGN FOR SAFE COSMETICS, http://safecosmetics.org/article.php?id=346%E2%80%8E (last visited July 21, 2013),

cosmetics when there is a reason for concern, nanomaterials must be specifically identified in the list of ingredients in cosmetics with the word 'nano' in brackets following the name of the substance.

Some have commented that thirteen chemicals overlap between the EU's candidate list and the U.S. EPA's work plan on existing chemicals and implied that this points to the possibility of convergence around prioritization of hazardous chemicals for regulatory action. It is important to bear in mind, however, that these thirteen substances are drawn from a much larger list of 144 Substances of Very High Concern listed today on the candidate list and 83 chemicals included in EPA's work-plan, and possibly over 1,400 in the coming years.[11] In reality, however, EPA's work plans have not produced legally-binding obligations on any chemical included, and thus the number of chemicals that overlap would be far fewer. The chemical industry is lobbying to weaken the candidate list to "better accommodate business needs."[12]

Mutual recognition in the chemical sector and other sensitive sectors involving public health, safety or the environment is wholly inappropriate.[13] For the chemicals sector, mutual recognition provisions would essentially erase the measures for chemicals that that are restricted in only one jurisdiction. Procter and Gamble states that mutual recognition would "allow[] for the production, sale and use of chemicals that are lawful in one continent to also be lawful in the other."[14] Such provisions would require the EU and U.S.to both decide that a chemical warrants restriction in order to protect people in one or both jurisdictions.

One of five regulatory components of TTIP is the creation of a framework for future regulatory cooperation, including an institutional basis. Position papers by the European Commission suggest the creation of sectoral regulatory cooperation working groups chaired by the competent regulatory authorities, which would in turn report to the recently proposed Regulatory Cooperation Council or committee. The proposals outline substantial bi-lateral consultation provisions.[15] In addition, position papers also point to the increased use of voluntary instruments to achieve regulatory objectives.[16] Together, these elements have the significant potential to delay or dilute the creation of adequate rules to protect human health or the environment.

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

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[11] *TSCA Work Plan Chemicals*, EPA, http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html (last visited July 23, 2013).

[12] BUSINESS EUROPE, EU LEGISLATIVE BURDENS ON SMES (Dec. 20, 2012), *available at* http://www.businesseurope.eu/content/default.asp?PageID=568&DocID=31123.

[13] TRANS ATLANTIC CONSUMER DIALOGUE, BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (2001)

[14] Procter and Gamble, *P&G input into consultation on regulatory issues for possible future trade agreement between the EU and U.S.* (undated), available at: http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/jobs-growth/files/consultation/regulation/38-procter-and-gamble_en.pdf

[15] *Trade Cross-cutting disciplines*, *supra* note 2.

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

IV. Investor-State Dispute Settlement

Investor-state dispute settlement would allow foreign corporations to bypass domestic courts and sue governments in private tribunals over laws and policies that the corporations allege reduce their expected future profits. The inclusion of such extreme provisions in prior trade and investment deals has enabled powerful interests, from tobacco companies to corporate polluters, to use investor-state dispute resolution to challenge and undermine consumer, public health and environmental protections. Investor-state tribunals have ordered taxpayers to compensate foreign corporations for the domestic, non-discriminatory enforcement of such protections.

Investment provisions in existing free trade agreements, including the North American Free Trade Agreement (NAFTA), have facilitated a proliferation of legal challenges to bans on toxic chemicals, mining regulations, energy regulations, and more.[17] These rules have been replicated in various U.S. free trade agreements (FTAs), including the Central American, Peru and Oman FTAs, and the recently passed deals with Korea, Panama and Colombia. The inclusion of very broad investor protections, such as a guarantee of "fair and equitable and treatment," could open the door to investment cases when governments put in place new or amend existing laws and policies designed to protect the public interest.

Over US $365 million in compensation has already been paid out to foreign investors in a series of investor-state cases under NAFTA-style deals.[18] This includes attacks on health and safety measures, natural resource policies, environmental protection, and more. Of the over US $13.1 billion in the 16 pending claims under NAFTA-style deals, all relate to public health, environmental, energy, land use and transportation policies – not traditional trade issues.[19]

Cases in recent years have demonstrated that companies are both willing and able to locate or relocate their foreign operations for the express purpose of choosing the most investor-friendly forum for potential trade disputes, regardless of whether they have a legitimate business nexus with the countries involved. The risk of such treaty shopping is compounded by the growing number of companies and individuals claiming, and receiving, investor protections on grounds that bear little resemblance to direct investment in a country.

To date, the United States has entered into more than fifty agreements according some form of investor protection. The EU member countries have concluded more than 1,200 such agreements. The Australian government indicated that it will discontinue investor-state dispute settlement mechanisms after tobacco control measures were challenged by Philip Morris.

Notwithstanding the demonstrated risks of specious litigation, treaty shopping and attenuated and costly claims of investor protection under these existing agreements, both parties have declared an objective to go beyond any previous agreement to afford even greater levels of investor protection under TTIP. The extensive and troubling record of abuse under the existing system should raise grave concerns regarding that objective.

To avoid such overreaching procedural and substantive investor privileges, greater than those afforded to domestic firms in either the United States or the EU, any deal must exclude investor-state dispute resolution.[20] If concluded, TTIP could be enforced through ordinary courts of the U.S. and EU. Because

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[17] *Table of foreign investor-state cases and claims under NAFTA and other U.S. trade deals: March 2013*, PUBLIC CITIZEN, http://www.citizen.org/documents/investor-state-chart1.pdf (last visited Apr.11, 2013).
[18] *Investor-State Attacks on the Public Interest*, PUBLIC CITIZEN, http://www.citizen.org/Page.aspx?pid=5329 (last visited July 23, 2013).
[19] *Id.*
[20] Letter to President Barack Obama, President José Manuel Barroso, and President Herman Van Rompuy from consumer and public interest organizations in the U.S. and EU, dated July 8, 2013, available at: http://www.citizen.org/documents/public-citizen-letter-to-obama-alerting-to-tafta-concerns.pdf.

U.S. and EU property rights laws and courts are robust, there is no pretext for granting foreign investors superior rights to domestic firms or subjecting our judicial systems to tribunals empowered to put the American public in a lose-lose situation. The inclusion of such provisions would have a chilling effect on the future development of regulations for public health, safety and the environment in the EU and U.S.

V. Preemption

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

In the United States, over 30 states have enacted different measures to protect people and the environment from toxic industrial chemicals, due to the inability of the U.S. federal system to fill this role. California, Maine and Washington State are a few of States that have emerged as leaders in enacting measures to reduce exposure to toxic chemicals in products, food, water and the environment. Several submissions received in response to the various public consultations on the TTIP report on EU exporters' difficulties with accessing and understanding the rules they have to comply with to gain access to the US market, in particular where multiple layers of regulation.[21]

According to initial position papers, the "EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered."[22] This expectation is set forth clearly and repeatedly as a central EU objective for the negotiated outcomes under TTIP. EU documents set forth a further position that the EU should be notified and consulted on any significant regulations at the sub-federal level that may affect trade, and that any such regulations should be held to a standard that avoids unnecessary interference with transatlantic trade. A range of state-level initiatives on toxic chemicals and other environmental issues could be preempted by various provisions of TTIP, which could also have a chilling effect on their future development. Indeed, a significant factor in this chilling effect could arise simply from the extensive and costly additional burdens such consulting obligations would impose on policymakers and regulatory authorities at the state and local level. In addition, provisions such as investor state dispute resolution could preempt sub-federal or sub-regional laws that are more protective of health, safety and the environment.

Regarding divergent approaches in the EU, the US Trade Representative and industry has complained about Member States interpreting provisions of REACH in ways that would lead to improved consumer protection. Efforts are also ongoing in EU Member States to take precautionary approaches to health, safety and environmental protection, for example in the creation of registers for manufactured nanomaterials and moratoria on the use of hydraulic fracturing for shale gas extraction or 'fracking.' For example, a French initiative is in force for a mandatory register for nanomaterials that covers the entire supply chain is being imitated and expanded by the Danish, Belgian and Italian governments. In terms of moratoria on fracking, France, Germany, Spain, Bulgaria, Romania, and the Czech Republic, have placed moratoria on the use of this technology as a precautionary measure. These and similar efforts taking place at the state level here in the U.S. or at national level in the EU are at risk of being preempted by possible provisions of TTIP.

Of considerable concern in ongoing efforts to fix TSCA here in the U.S. is the inclusion of state preemption provisions in the Chemical Safety Improvement Act (S. 1009), the latest Senate proposal for reform, recently introduced by Senator Vitter and the late Senator Lautenberg. Likewise, provisions for investor state dispute settlement and other trade promotion measures, such as harmonization and mutual

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[21] TBT POSITION PAPER, *supra* note 16.
[22] *Id.*

recognition, can also result in the preemption of laws for public health, environmental protection and safety at the state level in the U.S. and national level in the EU.

VI. Influencing the development of laws outside the U.S. and EU

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

The chemical industry has not hidden its displeasure with REACH from government officials in the U.S. or EU, and continues to complain about its costs, burdens and complexity. During the Bush Administration, a U.S. Commerce Department paper recorded that "[i]ndustry . . . would like the [U.S. Government] to work to educate [other countries] so that they can join the United States in raising concerns."[23] In March 2002, Secretary of State Colin Powell sent a cable directing U.S. diplomatic posts to "raise the EU chemicals policy with relevant government officials" and to object to the REACH proposal as "a costly, burdensome, and complex regulatory system."[24]

In addition to contesting REACH in the EU, the U.S. government and industry has been working to prevent the expansion of REACH-like policies outside the EU, especially where countries propose to go beyond what REACH currently requires. Despite these efforts, elements of the EU's REACH legislation continue to be adopted by countries outside the EU. These countries include countries with significant levels of chemical manufacturing and chemical use, such as China, Japan, Australia, Korea, Turkey, Taiwan, Vietnam, and Malaysia. In addition, India and Indonesia are each drafting national legislation that includes elements of REACH. It is worth noting that over the next two decades, worldwide chemical production is projected to double from 2010 to 2030, with 71 percent of this new production expected outside the OECD, especially among the so-called BRIICS countries.[25] Many of these countries are among those drafting and adopting chemical legislation similar to REACH.

But, in the case of Korea's version of REACH, K-REACH, while intensive lobbying efforts did not prevent the adoption of a REACH-like system, they did result changes to the legislation that would otherwise have afforded greater protection than REACH itself.

Regardless of the adoption and ongoing implementation of REACH in the EU, the chemical industry is viewing TTIP as an opportunity to establish a global standard for chemicals regulation at the national or regional level by decreasing regulatory divergence between two of the three major chemical countries or regions of the chemical industry. Procter and Gamble states that "[a]n ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries' regulatory systems, in particular of BRICs countries."[26] To the extent that TTIP results in stronger levels of protection in the U.S. for human health, safety and the environment, and does not delay the implementation of REACH, this could be a positive development. Anything less, however, would have a chilling effect on the development of chemical regulations outside the EU that impose measures more stringent than the EU or U.S.

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

[24] *Id.*

[25] OECD ENVIRONMENTAL OUTLOOK TO 2050: THE CONSEQUENCES OF INACTION (2012).

[26] Proctor & Gamble *supra* n. 14.

VII. Conclusion

To conclude, While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, experience with other trade agreements, together with the explicit intention of reducing regulatory barriers to trade, make it far more likely that TTIP will hinder important public health and safety goals related to chemicals. Since NAFTA, the United States has conducted its trade negotiations with other countries and regions in a in a manner that does not satisfy the requirements of transparency in a constitutional democracy, despite the profound implications of these negotiations for public health, well-being and the environment. To date, negotiations between the United States and the EU have followed a similar path. Although the EU's public disclosure of its initial negotiation positions has been a small but positive step in the right direction, the EU's recent statements indicates the possibly of regression.

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

In their communications with the public, both the United States and the E.U. have communicated an interest in defining a "positive" trade agenda--one in which increased trade mutually supports environmental protection and social development, and does not come at the expense of environment or labor rights. The EU outlines a number of goals that might be achieved, and explicitly acknowledges as a fundamental element of sustainability the need to recognize "each party's right to define and regulate its own domestic levels of environmental and labor protection at the level deemed necessary."[27]

However, end of the day cost-saving to consumers from trade agreements that lower consumer and worker safeguards are modest at best, while the cost of inaction on health, safety, labor and environmental concerns borne by the public-at-large are staggering at present, and grow with each passing day.[28] Even using consistently over-estimated costs of regulation and benefits of deregulation or harmonization,[29] these estimates do not come anywhere close to the cost of inaction on public health, safety, labor and environmental issues that are at risk from a trade agreement that puts trade ahead of the public interest.

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

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[27] *Trade and Sustainable Development: initial EU position paper*, EC (2013), *available at* http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151626.pdf.

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

[29] *See e.g.* The International Chemical Secretariat, *Cry Wolf: Predicted Costs by Industry in the Face of New Regulations* (2004).

Toy Industry Association, Inc.

www.toyassociation.org

Toy Industry Association Statement for the Record

October 30, 2013 Senate Finance Committee Hearing: "The Transatlantic Trade and Investment Partnership: Achieving the Potential"

The Toy Industry Association (TIA) is generally supportive of efforts to pursue a comprehensive U.S.-EU transatlantic trade and investment partnership (TTIP). The U.S. and EU already have the world's largest commercial relationship. Increasing trade, investment and cooperation between the two markets will strengthen the relationship between the U.S. and the EU, enhance both economies and create jobs on both sides of the Atlantic. Moreover, a bilateral agreement that reduces trade barriers and fosters greater regulatory coherence would set a strong example for future trade agreements and help cement the U.S. and EU positions as leaders in the global economy.

As background, TIA has a membership of more than 600 businesses – from toy manufacturers, retailers and importers to inventors, designers and testing labs – all involved in creating and bringing safe toys and games to children. Our members account for 85% of the $22 billion U.S. toy market. The U.S. toy industry supports an estimated 533,177 jobs (FTE) generating $25.8 billion in wages for U.S. workers, with a total annual economic impact in the U.S. of nearly $81 billion.

Thank you for the opportunity to submit a statement for the record on TTIP and regulatory cooperation. The regulatory cooperation objectives highlighted in the Final Report of the High Level Working Group on Jobs and Growth could have a significant impact on the U.S. and EU toy industries. Our specific comments on regulatory cooperation are below.

Regulatory Cooperation

The toy industry in both the U.S. and EU has espoused the goal of greater regulatory cooperation for a number of years. Our experience, however, has shown that there are very significant political and other barriers to this very worthwhile goal. These challenges notwithstanding, we believe the process of seeking greater regulatory cooperation has the potential to yield positive results for the EU and U.S. economies, which are the largest toy markets in the world.

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While toys are regulated differently in the U.S. and EU markets, both regulatory systems provide strong and effective consumer protection. Another way to state this is that toys are safe in both markets, but the regulatory approaches to achieving this end differ between the two markets. Given the differences in regulatory approach, in order to sell in both markets, companies often have to make design and/or manufacturing changes to meet both sets of requirements and must at a minimum perform redundant testing in order to demonstrate compliance to both sets of requirements. These costs to the toy industry add up to an estimated US$3 billion annually – unnecessary and redundant costs of demonstrating compliance – and costs ultimately shared by consumers – without improving the safety of toys. As a result of our ongoing work to promote greater standards alignment, there already exists significant congruence between many of the over 100 separate tests and design specifications in the ASTM F963 and EN 71 toy safety standards. In fact, we estimate that standards are currently about 80% "aligned."

Achieving the current level of alignment has taken a tremendous amount of time and effort from all involved. In fact, within the 80% of those standards that are "aligned," only a small handful (about 10% of the EU and US physical and mechanical standards) are word-for-word identical. The other standards that are "aligned," though not identical, are fundamentally the same or functionally equivalent. In these situations, companies often still have to test to both standards to demonstrate compliance with ASTM F963 and to secure a presumption of conformity to the TSD by testing the identical parts to EN71.

Significant barriers to further alignment, namely politics and differences in regulatory approach, remain on both sides of the Atlantic. Our experience has also shown that politics and differences in regulatory philosophy are the root causes of differences in toy safety standards. Therefore, approaching regulatory cooperation as strictly a technical alignment effort will result in marginal benefits – *especially* considering the short time frame set to complete negotiations. While we recognize that addressing the political barriers to alignment will also be challenging, with support and commitment from senior officials and regulators on both sides of the Atlantic, we are optimistic that the TTIP negotiations may result in meaningful progress.[1]

The toy industry is not alone in pursuing and recognizing the benefits of greater regulatory cooperation. The European Commission's Directorate General for Enterprise and Industry (DG ENTR) and the U.S. Consumer Product Safety Commission (CPSC)

1 As an example of politics resulting in a difference in U.S. and EU standards, the Consumer Product Safety Improvement Act (CPSIA) of 2008 set a U.S. *total* lead content standard of 100 parts per million (ppm). However, prior to this, the EU toy safety standard had a 90 parts per million (ppm) soluble lead content standard. While the soluble approach is preferable because it more closely correlates with exposure and risk, there is no evidence that either limit is more protective than the other; in fact, products typically meet both standards, but the misalignment results in additional (and totally unnecessary) testing and compliance costs. This example also highlights the need for political support of greater regulatory cooperation as the U.S. would likely not be able to align nor recognize the EU standard without Congressional assent.

signed a Recognition of Mutual Interest (RMI) Agreement last year with the purpose to, "memorialize DG ENTR's and the CPSC's common understanding of the benefits of continuing and enhancing our cooperation on toy safety issues." The RMI further states, "Both sides are confident that pursuing such initiatives will ensure that the safety of toys sold on the EU and U.S. markets will be further enhanced." In fact, DG Enterprise and CPSC note that regulatory cooperation in the toy industry can inspire greater regulatory cooperation in other industries like electrical appliances and fireworks.

TIA views regulatory cooperation as two separate exercises: addressing current regulatory divergences and promoting greater alignment for future regulations.

General Principles

Any regulatory outcomes in the TTIP must adhere to sound principles of science, risk assessment and cost-benefit analysis. As mentioned above, regulatory differences are often politically motivated and these measures add burden to companies without introducing a significant difference in the level of safety. TIA believes this to be a flawed approach. Decisions should be based on sound science, rather than children's safety being used for political purposes.

Some decision-makers and EU Member States have recently proposed unscientific restrictions in an effort to be seen by citizens as "stricter" than their counterparts, thereby creating a "solution" that does not necessarily fit the situation. Industry is committed to meeting safety requirements, but such rules must be based on sound scientific evidence and risk assessments.

We regret that this approach has resulted in regulatory divergences where standards were once harmonized. As an example, projectiles requirements had to be changed in EN 71-1 some years ago, following a request from one EU national authority. Similarly, hemispheric toy requirements in EN 71-1 were also changed following requests from EU member states; Neither change had any valid scientific rationale, and as a result standards in both areas are no longer aligned with those in the US or elsewhere. In both of these cases, the changes were motivated by a desire to address problems not demonstrated to actually exist.[2]

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2 In July 2013, the chemical requirements of the Toy Safety Directive (TSD) go into effect once again moving the U.S. and EU toy safety standards further away from alignment. In 2011, ASTM F963 was updated to bring the U.S. standard's eight heavy metal limits into alignment with the EU toy safety standard. Unfortunately, the European Commission updated the Toy Safety Directive, effective 2013, making the current heavy metal requirements unnecessarily divergent from the currently aligned limits. The differing limits on the already regulated chemicals do not make the toys safer. CPSC noted in a status report, "Review of Metals in the Toy Safety Standard, ASTM F963" in March, 2012, "that the existing intake limits in ASTM F 963-07 and EN 71-3 are sufficiently protective of children who use toys that conform to the current standard." Additionally, the TSD added new requirements for 11 additional heavy metals – including metals like aluminum that have been determined safe for use in more sensitive applications such as food contact, like aluminum foil.

Additionally, we caution that the benefits of regulatory cooperation between the U.S. and the EU will be significantly lessened if EU national or sub-national, or U.S. state, local, and/or city governments enact different regulations that address the same risk of harm addressed by EU or U.S. Federal standards.

Addressing Current Regulatory Divergences

Addressing current regulatory divergences will be significantly more challenging than promoting greater future regulatory cooperation. This is because both sides' standards have been set through long-established procedures and each party has significant investment in their own process. However, since differences in methodology are due largely to political considerations, not technical or scientific ones, these differences do not result in differences in the safety of the regulated toy. As current regulatory divergences do not alter the underlying safety of the product, **when addressing regulatory cooperation between *existing* standards, it is important to focus on the regulatory outcomes (ensuring toy safety) and not the specific approaches of the regulations themselves.**

Experience has shown that achieving full regulatory alignment will be extremely difficult and may have some drawbacks (as discussed below) that may result in additional costs to businesses without benefiting consumer safety. Therefore, instead we ask that regulators pursue ***mutual recognition.*** This would mean that each jurisdiction would agree to accept suitable demonstration of conformance to the other's standards as presumptive evidence of an adequate level of safety and acceptability for importation and sale.

Seeking mutual recognition depends on the understanding, acknowledgment and acceptance of the fact that regulators on both sides of the Atlantic set *effective* toy safety standards based on a unified objective (to ensure that toys are safe) and consumers in *both* markets enjoy a high level of regulatory protection. *When one recognizes this, it naturally follows then that toys that are compliant with either the U.S. or the EU toy safety standard are safe – regardless of where the toy is sold.* Therefore, mutual recognition would not result in any reduction in toy safety.

Mutual recognition is ultimately a better and more realistic alternative than full regulatory alignment, at least for toys. Mutual recognition would not undermine either side's regulatory sovereignty nor should it mandate that one adopt the other's regulatory approach. Moreover, regulatory alignment could result in significant costs to businesses especially if regulators decide to simply adopt the most onerous standard regardless of effectiveness, or the risk of hazard. However, the most stringent standard is not necessarily a better or more protective standard, and is not necessarily one based on any underlying science. Frequently, standards that are stricter than their international counterparts are promulgated due to political influence or the (often

unstated) desire to erect technical barriers to trade, and not predicated by science or risk factors.[3]

Establishing a Framework that Promotes Greater Regulatory Cooperation for Future Regulations and Emerging Hazards

A significant deliverable that the TTIP can produce for EU-U.S. trade is to promote greater regulatory alignment for new standards and emerging issues. We believe this area is the most promising as there are already frameworks that exist that can be used as a basis for future regulatory cooperation between the U.S. and the EU.

As mentioned above, the U.S. and the EU have different processes for setting regulations which have resulted in differences in the regulations themselves. While the goal of regulatory cooperation is to limit these divergences and differences, this agreement does not need to rework current regulatory processes or undermine either the U.S.'s or EU's regulatory sovereignty. A mutual recognition agreement should respect both the U.S. and EU governments' respective standard setting and regulatory powers. Promoting greater alignment for future standards should simply build on past and ongoing alignment efforts by adding a formal, "international regulatory alignment" mandate in addition to domestic priorities of protecting the health safety and welfare of consumers. We envision such a framework as mandating alignment with an existing standard (or recognizing compliance with that standard) in the other counterpart market unless it can be demonstrated by evidence that it is inadequate to address the hazard concerned or is not evidence-based.

To a certain extent, ASTM International already engages in trans-Atlantic and international regulatory alignment. ASTM F15.22 (the Subcommittee on Toy Safety that is responsible for ASTM F963) regularly considers, as part of its standard operating process, opportunities to align with EN-71 and other international standards. The Subcommittee then proposes revisions to ASTM F963 to align the standard with its international counterparts where valid and possible. Additionally, as emerging issues are identified (something at which the ASTM Subcommittee has become particularly adept, given the nimbleness of the ASTM process and the access to CPSC data), the Subcommittee readily shares new standards and supporting information with its counterparts in CEN and ISO.

CEN also engages in international regulatory alignment (though not specific to ASTM F963) through the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement), which creates a framework for regulatory cooperation between ISO

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3 As an example, U.S. Consumer Product Safety Commission (CPSC) commissioned extensive academic study of anthropometry and strength characteristics of children and these data have been used to set various U.S. standards including the U.S. tension test at 15lbf. In contrast, the EU requirement of 90N (20.2lbf) is an historical artifact, incorporated from a predecessor standard with no valid underlying rationale, and requiring additional testing above that required for the U.S. market.

and CEN. The principles within the Vienna Agreement should be broadened to include other international standards development organizations, such as ASTM International. In addition, other preexisting international regulatory alignment efforts must be subject to the above presumptive mandate.

Whenever a standard setting body begins to consider a new regulation, it is important that its international standard setting counterpart is not only alerted but is continuously updated throughout the process. An 'open' standards process should allow active participation and input. Should the standards setting body diverge from a preexisting regulation, it should demonstrate a compelling need for divergence from that requirement, and demonstrate convincingly that the costs of that divergence do not outweigh the manifest benefits of alignment. The standard setting body must also consider whether the divergent regulation achieves the same regulatory outcome as the preexisting standard. If both standards adequately protect human health and safety, then the respective regulatory bodies should grant "mutual recognition" of regulations.

Finally, in order to implement, promote and enforce regulatory cooperation, an agreement should create a committee consisting of stakeholders from standard setting bodies on both sides of the Atlantic to mediate any disagreements. Enforcement of a regulatory cooperation agreement will be an important element as an agreement will not be useful if these bodies do not observe their obligation to follow its international alignment mandate.

Conclusion

Toy Industry Association is supportive of overall efforts to facilitate trade between the United States and the European Union. Mutual recognition could address most of the divergences in regulations that unnecessarily burden companies who sell to both markets while reinforcing consumer confidence that toys compliant with either standard can be trusted as safe for children. Moreover, establishing a strong regulatory cooperation agreement will assure a joint U.S.-EU leadership role in international regulations, provide a basis for future trade agreements and help provide a benchmark for third country standards development efforts.

Some economic facts on the toy markets in the EU and the US:

EU	US
▪ Significant differences in average price of toys in each country ▪ Estimated 1.4 billion units sold each year (2009) ▪ 73% of sales in France, Germany, Italy, Spain and UK (2010) ▪ US$21 billion in toy sales (2012) ▪ EU Toy Industry provides 220.000 EU jobs ▪ 25% of the global toy market (2010) ▪ 5000 companies (2012) ▪ 99% of producers are SMEs (2012)	▪ Average price of a toy is under US$8.00 ▪ Estimated 3 billion units sold each year (2012) ▪ US$22 billion in toy sales (2011) ▪ US Toy Industry provides 500,000+ US jobs ▪ Total annual economic impact of US$81 billion ▪ 27% of the global toy market (2011) ▪ 80%+ of producers are SMEs (2011)

Leading regulatory agencies in charge of toy safety:

EU	US
▪ European Commission, DG Enterprise, Unit C/1 Internal Market and its International Dimension (lead within the Commission) ▪ National and regional Governments (implementation, market surveillance) ▪ • CEN/CENELEC (standards)	▪ Consumer Product Safety Commission (CPSC) ▪ Food and Drug Administration (FDA) ▪ Federal Trade Commission (FTC) ▪ Customs and Border Protection (CBP) ▪ ASTM International (standards)

Main legislation on toy safety

EU	US
▪ Toy safety Directive 2009/48 Other relevant legislation includes: ▪ General product safety directive 2001/95 ▪ Regulation 765/2008 on requirements for accreditation and market surveillance ▪ Decision 768/2008 on the marketing of products ▪ Regulation 1907/2006 REACH (Registration, Evaluation and Authorisation of Chemicals) ▪ Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) ▪ Directive 2011/65 RoHS (Restriction on the use of certain Hazardous Substances in electric and electronic products) ▪ Directive 2012/19 WEEE (Waste Electrical and Electronic Equipment) ▪ Regulation 1223/2009 on Cosmetics ▪ Directive 2008/98 on waste ▪ Directive 94/62 on packaging and packaging waste ▪ Directive 87/357 concerning products which, appearing to be other than they are, endanger the health or safety of consumers ▪ Regulation 1935/2004 on materials and articles intended to come into contact with food ▪ Regulation 10/2011 on Food contact plastic materials and articles ▪ Directive 1999/5 Radio- and tele-terminal equipment (R&TTE) ▪ Directive 2004/108 Electromagnetic Compatibility (EMC) ▪ Directive 2006/66 Batteries ▪ Directive 2006/95 Low voltage	▪ Consumer Product Safety Improvement Act ▪ Federal Hazardous Substances Act ▪ Flammable Fabrics Act ▪ Child Safety Protection Act ▪ Consumer Product Safety Act ▪ Food, Drug and Cosmetic Act ▪ Fair Packaging and Labeling Act ▪ Country of Origin Marking Various State Requirements (Stuffed toy labeling, California Proposition 65, Illinois LPPA, Washington CSPA, Maine KSPA, etc.)

Plus a number of national restrictions applying only in some Member States.	

Standards on toy safety

EU	US
▪ EN71-1 Mechanical and physical properties ▪ EN71-2 Flammability ▪ EN71-3 Migration of certain elements ▪ EN71-4 Chemical experimental sets ▪ EN71-5 Chemical toys ▪ EN71-7 Finger paints ▪ EN71-8 Activity toys ▪ EN71-9 to 11 Organic chemical compounds ▪ EN71-12 N-Nitrosamines and N-Nitrosatable substances* ▪ EN71-13 Olfactory board games, cosmetic kits and gustative games* ▪ EN71-14 Trampolines* ▪ EN62115 Electric toys * under development	▪ ASTM F963 series under ASTM International

A concrete example

Below is an example of the rules with which a simple plastic toy is required to comply for both EU and US markets. All these requirements aim to ensure children's safety. However, due to legislative differences, however, these requirements oblige industry to carry out duplicative tests in order to comply with safety requirements which convey the same goal.

EU	US
	
▪ EN71-1 Mechanical and Physical Properties ▪ EN71-2 Flammability Requirements ▪ EN71-3 Migration of Certain Elements ▪ Total Cadmium Content, REACH Annex XVII ▪ Total Phthalate Content, REACH Annex XVII ▪ Total Benzene Content, REACH Annex XVII	▪ ASTM F963 / 16 CFR 1500 Physical and Mechanical Requirements ▪ 16 CFR 1500 Flammability Requirements ▪ ASTM F963 Soluble Migrated Elements Requirements ▪ Total Lead Content, Consumer Product Safety Improvement Act of 2008 ▪ Total Phthalate Content, Consumer Product Safety Improvement Act of 2008

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