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STATEMENT OF
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IN RESPONSE TO ADDITIONAL QUESTIONS FOR THE RECORD
THE U.S. – E.U. FREE TRADE AGREEMENT: TIPPING OVER THE REGULATORY BARRIERS

Submitted to

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

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Additional Questions for the Record

The Honorable Jan Schakowsky

1. **At the Subcommittee hearing on July 24, 2013, witnesses discussed various issues related to company data that is shared with regulatory agencies. What is the importance of this data to public health and consumer safety? Do you have any thoughts on proposals to implement more stringent standards on data protection and confidential business information through the Transatlantic Trade and Investment Partnership (TTIP) negotiations?**

Industry proposals to implement more stringent standards on data protection and confidential business information through the Transatlantic Trade and Investment Partnership (TTIP) negotiations would limit access to data and information, adversely affecting efforts to improve public health, consumer safety and the environment.

In the case of hazardous chemicals, inventors need access to information about chemical hazards and exposures to develop safer solutions. Consumers and downstream users need access to information about chemicals in products to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. And regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives.

Of particular concern to businesses is the need to protect confidential business information (CBI), including data. Industry's abuse of CBI privileges under U.S. laws designed to protect public health and the environment is well documented.[1] This abuse represents a serious barrier to the identification of hazardous chemicals and the development and entry of safer alternatives. Recent experiences show that the inability to access information can impede the development and adoption of safer alternatives. Incomplete information on potential alternatives enables "regrettable substitution," i.e. the transition from one hazardous chemical to a different hazardous chemical, instead of safer alternatives.[2]

While respecting the desire to protect legitimate CBI as a means of encouraging businesses to continue to innovate, policy makers around the world have long recognized the potential for the disclosure of information to promote additional innovation. Patents are based on this principle.

Recent changes to European laws that increase access to information on substances of very high concern are "the driver[s] for change at the present,"[3] according to a 2012 review of the impact of these stronger laws on innovation. For information to accelerate and steer innovation in a safer direction—and ensure the integrity, efficiency, effectiveness, and accountability of governments, institutions, and industry—health and safety information must be generated and access must be provided to that information.

Although U.S. laws for toxic chemicals and pesticides already recognize that health and safety information should never be CBI, they still have farther to go in properly balancing these interests. Despite limits to the type of information that may be claimed as CBI, regulators do not always require justification of claims of confidentiality or re-justification of claims after a period of time. Ingredients of pesticide formulations are not publicly disclosed, preventing the

development of safer alternatives, despite the potential for over 99 percent of the chemical to be an "inactive"—but not necessarily inert—ingredient. A further problem is the practice of allowing the identity of chemicals that are the subject of health and safety studies to be masked as CBI, impeding the identification of chemicals of concern. Unlike patents, which generally expire after twenty years, CBI can be kept confidential in perpetuity. The health and environmental risks of this approach are compounded when important information is inappropriately claimed to be CBI.

U.S. regulators have been taking steps to limit this abuse, and to afford protection only for legitimate CBI, raising concerns among the trans-Atlantic chemical industry.[4] But, despite their best efforts, proposals by regulators were delayed in ORIA review for years, and then abandoned. In the EU, court rulings to ensure consistency with obligations under the Aarhus Convention regarding access to information have been unjustly criticized by industry attorneys with blanket assertions of "threatening CBI protection."[5]

Proposals under TTIP by the European Chemical Industry Association (Cefic) react to these innovation-friendly developments, which would increase access to information about the potential risks of chemicals and products on the market today. Cefic's proposals would further limit the access of regulators, consumers and potential competitors producing safer alternatives to information relevant to determining the health and safety of chemicals to which workers and the public may be exposed, and the potential advantages of alternatives. Under current law, U.S. regulators have the power to compel the production of information by the chemical industry that is submitted to regulatory authorities abroad. ACC and Cefic propose to curtail this power by requiring that CBI that includes original study data--and thus goes beyond the "robust" summaries that industry prepares regarding the methods and conclusions of its own experiments--be shared only with the permission of the "owner" of the regulatory data.[6] Under EU law, chemical manufacturers produce these "robust" study summaries themselves with limited accountability and oversight, whereas under US law full study reports are required and robust study summaries are generally viewed as insufficient.[7]

TTIP is not necessary for U.S. regulators to access health and safety information regarding chemicals, and would in fact, as proposed, limit access to necessary information for U.S. regulators, progressive businesses, and consumers. Thus, industry proposals adversely affect ongoing efforts to improve public health, empower consumers and business, and protect the environment through enabling innovation in safer alternatives to hazardous chemicals.

2. **The primary federal law regulating chemical safety in the United States, the Toxic Substances Control Act (TSCA), differs greatly from its European counterpart (known as REACH) in that it takes a largely risk-based approach rather than the hazard-based approach employed by REACH. At the Subcommittee hearing on July 24, 2013, you commented that TSCA, which was passed more than 36 years ago, is not strong enough to respond to the alarming health risks that we now know certain chemicals pose. You also expressed concerns with one current Senate proposal to update TSCA, known as the Chemical Safety Improvement Act, and stated that this bill is not sufficient to bring the U.S. to the same level of protection that the E.U. is achieving. Others argued that the ultimate outcomes that result from consideration of chemicals' safety under REACH and TSCA are not markedly different from each other, and that, in some**

cases, current federal policies toward chemicals should not be adjusted through the TTIP process to better match their corresponding E.U. policies.

a. Did you have any concerns resulting from this discussion that you would like to share with the Subcommittee?

In our testimony before the Subcommittee, CIEL cautioned that TTIP would provide a vehicle by which the chemicals industry could manipulate the pace and direction of chemicals regulation on both sides of the Atlantic. A subsequent analysis of industry proposals for TTIP prepared by CIEL and ClientEarth, a not-for-profit legal organization based in the European Union, demonstrates that our concerns were warranted.[8]

While the U.S. Toxic Substances Control Act (TSCA) was a pioneering step in chemicals legislation when it was adopted in 1976, the Act has not been meaningfully updated in nearly four decades. At the same time, two forces have served to build a widening gap between the United States and international best practice on chemicals management. First, and significantly, significant gaps and design flaws in TSCA, which have been exploited relentlessly and successfully by industry for decades, have left many of its original intentions largely unrealized. Consequently, TSCA--and chemicals management at the federal level in the United States--have failed to evolve with the rapidly changing science--and public preferences--in this field. Second, and simultaneously, the European Union itself has adopted a series of reforms in its own chemicals laws that have transformed the EU from a follower to a global leader in chemicals management. As a result, chemical safety standards in the United States are now far below those of the European Union. Ironically, it is this gap, precipitated and exploited by the industry itself, which lies at the root of the alleged "trade barriers" posed by European chemicals standards.

As your question rightly observes, a fundamental difference between the two systems lies in the divergent approaches to addressing chemical threats. Under U.S. chemical laws, the United States employs a risk-based approach to chemical regulation, which requires projections for exposure level and other socio- economic considerations to be taken into account before chemicals are restricted. This approach has failed the public for decades, by allowing toxic chemicals to remain on the market despite overwhelming evidence of risk to human health or the environment, and providing no incentive for the development and adoption of safer chemicals outside of public pressure. The EU's hazard-based approach for certain chemicals enables a systematic transition away from carcinogens, mutagens and other chemicals of concern toward intrinsically safer chemicals.

Put simply, the United States' own regulatory inertia in the face of evolving scientific understanding of chemical hazards for human health and the environment, and in the face of declining willingness to accept those risk on the part of consumers in large parts of the world, has created a regulatory chasm between this country and the European Union, which has moved more aggressively to respond to both changing science and changing consumer preferences. Industry and trade agencies have responded by invoking "trade" as an argument to oppose further development of EU laws, notwithstanding the clearly expressed and scientifically justified preferences of the European public.

In light of this wide and growing gap, only a deep structural reform of US chemicals legislation could create a sound basis for regulatory cooperation between the United States and Europe. Notwithstanding calls by chemical industry groups for closer regulatory cooperation, neither the profoundly mis-named Chemical Safety Improvement Act nor subsequent bills championed by industry in Congress have come close to the reforms needed to close or even significantly narrow that gap.[9]

Recently, for example, 72 environmental, health and safety organizations, including CIEL, submitted a joint letter to Representative John Shimkus, Chairman of the House Subcommittee on Environment and Economy, analyzing the newly-released discussion draft of the Chemicals in Commerce Act.[10] The concerns expressed with that draft demonstrate the distance still to go in U.S. chemicals reform. Under the draft Chemicals in Commerce Act:

- The existing federal program is weakened in several areas, including oversight of new chemicals, confidential business information, and the ability to restrict unsafe chemicals in consumer products.
- EPA will remain unable to impose needed restrictions on unsafe chemicals. While the new draft clarifies the role of cost benefit analysis in the regulation of existing chemicals compared to the earlier draft, the legal burden for EPA to take action is effectively the same as the unworkable current law.
- The required assessments fall short of the mainstream recommendations made by the American Academy of Pediatrics and the National Academy of Science, among others, which call for aggregating the chemical exposures to vulnerable populations like pregnant women, developing children or workers and ensuring they are protected.
- The precise meaning of "significant risk" in the draft is unclear.
- The "low priority" category still creates the possibility that many chemicals will be treated as safe --- and proliferate in new products and applications--- though they have not been subjected to a thorough safety review.
- The preemption remains sweeping, thereby curtailing functioning state programs in exchange for a federal program that will continue to be dysfunctional. [11]

U.S. EPA agreed with this analysis in many respects during recent testimony before the House Subcommittee on Environment and Energy, noting "that the revised draft of [the] House Toxic Substances Control Act (TSCA) reform bill does not align with the EPA's stated principles for TSCA reform…and weakens existing law."[12]

In the absence of needed reforms, and as discussed more fully below, proposals for regulatory harmonization and mutual recognition under TTIP offer little prospect of improving chemicals management--or the health and safety of workers, consumers and families--on either side of the Atlantic.

b. I understand estimates vary as to what it costs chemical manufacturers to comply with REACH. What is your interpretation of these estimates, and what do you believe explains REACH compliance cost levels during the first few years it has been in effect?

Industry consistently over-states the expected costs of environmental regulations. For example, environmental laws to protect human health and the environment from vehicle emissions, acid rain, ozone depletion, airborne toxic substances all resulted in far lower compliance costs than originally estimated.[13] These and other examples of inflated estimates demonstrate that industry projections of regulatory compliance costs are not reliable predictors of actual costs and, accordingly, should be viewed with substantial skepticism absent external validation.[14]

The projected costs of the EU's REACH regulation are no exception. Regarding the impact to jobs, industry estimates for the impact of REACH projected the loss of over 3 million jobs in France and Germany.[15] GDP was projected to decline by 4.7 and 6.4 percent for France and Germany, respectively.[16] Notwithstanding such doomsday predictions, the evidence to date tells a much different story about the economic impact of REACH.

Since the adoption of REACH, Germany and France have increased GDP ever year except 2009, due to the global recession.[17] According to the European Commission's analysis, during the period of developing debating, adopting and implementing REACH, "the EU chemical industry grew slightly higher than the average rate for all manufacturing sectors, and has largely recovered from the [economic] crisis of 2008."[18] Since the adoption of REACH, the "EU chemicals industry remains the world's largest exporter and its turnover has increased in absolute terms."[19] A commissioned study of the impact of REACH on innovation conclude that as a result of the regulation "it is envisaged that over time the number and quality … of skilled human resources to industry will increase and be supportive of innovative activity."[20] And following the enactment of REACH, the European chemical industry continues to generate a positive trade balance and is particularly well-performing in high margin sectors of specialty chemicals.[21]

Nor is REACH likely to impose unbearable costs on domestic industry in the United States. Compliance costs for the U.S. chemical industry with REACH represent a modest 1% of the value of exports to the EU, and 0.0000035 of annual turnover.[22] Chemical industry executives acknowledge that the primary factors affecting the location of the chemical industry are proximity to feedstocks and manufacturing activity, not regulation.[23]

c. How do you believe differing U.S. and E.U. regimes for chemical safety affect innovation in chemical manufacturing industries? Is there a particularly strong connection between stringent chemical safety standards and how many new chemicals come to market?

CIEL examined trends in chemicals regulation and patent filings to evaluate the impact of stronger rules for hazardous chemicals on the innovation of new chemicals products. Looking at examples from within the United States and abroad, our study *Driving Innovation*[24] found that

stricter regulation of hazardous chemicals can not only drive innovation, but also create a safer marketplace. As overwhelming evidence continues to grow about the financial costs of inaction on the hazardous cocktail of substances to which Americans are exposed daily, the need to direct our effort on innovation toward safer chemicals is particularly pressing.

While certain chemical manufacturers publicly insist that "there is no evidence that stricter chemical laws promote innovation,"[25] our study found clear evidence that the prospect of stricter rules on toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stricter rules to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new rules to protect people and wildlife from certain phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Thus, notwithstanding that the EU and its Member States led the global community in taking action on these phthalates, the impacts on innovation were positive.

Innovation hinges on the adoption of inventions into the market. In the case of chemicals, 15,000 new chemicals are registered daily, with little evidence these figures have been negatively affected by regulation.[26] In our view, the key question is not the number of new chemicals that enter the market, but rather the growth of safer chemicals on the market today. The future of the U.S. chemical industry is not in bulk chemical manufacturing but rather in the development and adoption of safer alternatives.

Our case studies highlight how stricter rules for hazardous chemicals can accelerate this process, not only sparking the invention of new chemicals, but—critically—enabling safer chemicals to overcome currently existing barriers to entry. Barriers exist that often prevent the adoption of safer alternatives, such as economies of scale, the externalization of costs, and the lack of information about chemicals and products on the market today. In some cases these are new chemicals, but they may also be previously known chemicals. Overcoming the market inertia imposed by entrenched toxic chemicals typically requires the exercise of governmental regulatory authority. Stronger laws for toxic chemicals help to overcome this inertia, creating incentives that help to pull safer inventions into the market, and turn invention into innovation.

3. Several witnesses at the Subcommittee hearing on July 24, 2013, discussed their desire to have the proposed U.S.-E.U. trade agreement serve as the default standard for all future trade agreements. If you were to assume for a moment that this agreement were in place, do you have any thoughts on how it would affect the ability of other nations, such as the BRICS countries, to address concerns unique to their locale?

The European Commission has stated that TTIP will not only set standards for the US and the EU, but will lay the foundation of normative expectations for all actors in the global economy.[27] If the EU–US trade agreement results in weaker levels of protection in the areas of human health, safety and the environmental regulation, which it is likely to do as currently envisioned, TTIP will likely have chilling effects on the development of stronger public interest regulations in

other regions as well, including the BRICS countries.

Businesses and industry associations have expressed an explicit interest in using TTIP as a regulatory template in other regions. For example, Procter and Gamble has stated that "[a]n ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries' regulatory systems, in particular of BRIC[S] countries."[28] Recent industry proposals clearly demonstrate that the chemical industry views TTIP as an opportunity to establish a global standard for chemicals regulation at the national or regional level by decreasing regulatory divergence between two of the most important players in global chemical markets.

Chemical manufacturing is expected to double between 2010 and 2030, with over 71% of this expansion expected to occur outside of the OECD and amongst the BRICS countries.[29] The U.S. has already been working to prevent REACH-like chemical regulation in areas outside of the EU that are engaged in significant chemical production, such as China, Japan, Australia, Korea, Turkey, Taiwan, Vietnam, and Malaysia. For example, in the development of K-REACH, Korea's version of EU REACH, the US government lobbied to seek revisions to draft proposals, such as an increase in the *de minimis* production volume exclusion from 0.5 tonnes to 1.0 tonnes.[30] This revision poses a potential impediment to accessing information about specialty chemicals, such as manufactured nanomaterials, that may be manufactured in commercially significant volumes while still falling below the minimum tonnage requirements, therefore affording less protection than the original provision. As other free trade agreements are concluded by the U.S., EU and/or the BRICS countries, there is a significant risk of creating a complex and onerous web of consultation processes for environmental, health, and safety standards, which would likely hinder the elevation of standards in the BRICS and elsewhere.

In addition, TTIP, together with Canadian and trans-Pacific trade and investment agreements could increase pressure for BRICS to adopt regulatory and legal standards that do not reflect their domestic needs and circumstances. For example, to address the need for access to life-saving medicines, the BRICS countries have advocated for flexibilities in intellectual property laws to help fight cancer and HIV in developing countries. Just as troublingly, trade rules have proven a significant barrier to efforts by developed and developing countries alike to spur the growth and deployment of healthy domestic renewable energy industries. By slowing progress to address the threat of climate change, these barriers present a risk not only to the environment within these countries, but to the global environment as a whole.

4. Fuel efficiency standards in the United States and the European Union differ greatly from each other. Do you have any thoughts on these divergent standards, and on how various stakeholders have proposed trade negotiators treat them under TTIP?

Fully addressing the differences between the US and EU for fuel efficiency standards and potential implications of TTIP would require additional research that we are unable to complete at this time., We would be happy to submit a response at a later point in time if requested.

5. During the Subcommittee hearing on July 24, 2013, you were asked about several topics relating to the proposed trade agreement between the United States and European Union. If you would like to elaborate on your comments regarding any of the following topics, please do so:

- **The impact of regulatory harmonization or the mutual recognition of standards on the health or safety of American consumers.**

Regulatory harmonization or the mutual recognition of standards would weaken or lower stronger standards for the health or safety of American consumers in those instances where they exist, and delay the development of stronger standards on both sides of the Atlantic. Although EU trade negotiators state that they have no intention of lowering EU standards for protecting people and the environment from chemicals under TTIP, the European Union's negotiation mandate states that the elimination of regulatory obstacles that may restrict the potential profits of transnational corporations operating in EU and US markets is a top priority for TTIP.[31] Tools for regulatory cooperation like harmonization and mutual recognition could be used to remove or reduce public health, environmental, labor, consumer, and other public-interest regulations including toxic chemical regulation and food safety rules.[32]

As noted in CIEL's testimony to the Subcommittee last July, and discussed more fully in response to question #2 above, it is difficult to envision any degree of harmonization with respect to certain environmental, health and safety standards due to a wide divergence in regulatory approaches and regulatory outcomes. The European Commission acknowledged in documents prepared for TTIP that "US requirements [for chemicals] are less strict" and that, in the view of the EU, "neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU."[33] Given both the substantial differences in approaches between the EU and U.S. and the fact that recent bills to reform TSCA in the United States bear no resemblance to EU laws, the likelihood of harmonization or mutual recognition between the U.S. and EU resulting in a "highest-common denominator" outcome to chemicals management is very unlikely, if not impossible.[34]

Nonetheless, proposals by the pesticide and industrial chemical sectors continue to advocate for harmonization or mutual recognition, both through targeted proposals to either U.S. or EU approaches deemed more favorable to industry, or via a permanent, overarching framework for trans-Atlantic regulatory cooperation.[35]

The Center for International Environmental Law and the European NGO Client Earth analyzed these industry proposals, and their potential impact on chemical safety in the United States and Europe, in the report *Toxic Partnership: A Critique of the ACC-CEFIC Proposal on Transatlantic Chemical Cooperation*. We found that the chemical industry's proposals for harmonization and mutual recognition would undermine more protective policies by the EU for workers, communities, consumers and wildlife, as well as necessary policies to compel the production of health and safety information for tens of thousands of chemicals on the market today.

For example, proposals by ACC and Cefic would undo the centrepiece of modern EU policies for industrial chemicals: to require basic health and safety data for over 30,000 of the most widely used industrial chemicals in order for these substances to retain market access, i.e. the principle of "no data, no market."[36] U.S. law does not require any information be generated by the chemical industry in order to gain or retain market access. In addition, the chemical industry's proposals for cooperation around priority chemicals for risk assessment by regulators on both sides would drastically reduce the number of chemicals to be assessed for potential public health and environmental concerns, and thus potentially subject to approval for certain uses of chemicals with intrinsic hazards.[37] Regarding pesticides, joint proposals by industry call for the EU to jettison precautionary policies that prohibit the use of pesticides that are carcinogens, endocrine (hormone) disruptors, and have other adverse intrinsic properties, and to raise minimum residue levels for certain chemicals on agricultural products.[38] These and other proposals by industry would place the public at greater risk by lowering relatively strong EU standards for toxic chemicals.

The industry groups disingenuously assert that they "are not proposing any changes to current regulations under TTIP." While the TTIP proposals might not change the letter of existing chemical safety rules in the United States and the European Union, they would severely affect the implementation of those rules. Implementation is the key for any legislation, whether it is at the state, national or international level. The EU's REACH regulation is many years away from being fully implemented. The final data call for health and safety information under REACH for tens of thousands of chemicals is not until 2018, and nearly 70% of previously submitted dossiers examined by the European Chemicals Agency (only about 5 % of the total number) are not in compliance. It could be said that US TSCA has never been implemented as intended for over 60,000 existing industrial chemicals over the past 38 years.

In addition, proposals to create an overarching institutional framework to minimize regulatory divergence between the U.S. and EU could freeze progress in protecting the health and safety of American consumers. Leaked position papers of the European Commission reveal an intention to alter lawmaking processes in the United States, subjecting both the states and federal government to new and additional obligations throughout legislative and regulatory processes [39]

Specifically, the EU has proposed the establishment of an overarching "Regulatory Cooperation Council (RCC)" to oversee the development and implementation of the vast majority of laws that protect public health, consumers, workers, the integrity of our banks, and the environment in both the EU and US. The U.S. Trade Representative is also calling for an institutional framework with similar objectives. As proposed, the RCC would hold regulatory dialogs between counterparts across the Atlantic throughout the lawmaking processes; create new and additional opportunities for industry to influence decisions under the guise of "transparency;" and carry out trade impact assessments for essentially every significant regulatory or legislative proposal. Without the added burden of trade impact assessments, onerous cost-benefit analyses have frozen the implementation of key provisions of the primary US law for toxic chemicals by regulators. These and other procedures proposed would fundamentally alter—and delay—the development and implementation of new and existing legislation in the EU and US. As discussed more fully below, TTIP would pose a particular barrier to regulations addressing new and emerging toxic hazards, including the hazards posed by endocrine (hormone) disrupting

chemicals and nanomaterials. Just as importantly, the processes envisioned for regulatory cooperation under TTIP would pose a particularly heavy burden on regulators at the state level in the United States and the individual member level in the European Union, where most regulatory innovations begin.

Thus, because of the widely divergent levels of protection in the EU and US, and different approaches to chemicals, harmonization and mutual recognition through either targeted changes to EU and US laws or the creation of an overarching institutional framework for regulatory cooperation would result in lower standards for the health and safety of American consumers.

- **The level of stakeholder input Americans are likely to have in regulatory harmonization or the mutual recognition of standards, compared to the level of input they are currently afforded for domestic laws and regulations.**

The ongoing and severe lack of transparency in the TTIP negotiations, discussed more fully below, makes it impossible to fully assess the level of input Americans would be afforded to regulatory harmonization and mutual recognition processes that result from those negotiations. Nonetheless, the limited evidence that has been released--or, more often, leaked--from the negotiations strongly indicates that ordinary Americans will have far lower levels of input in the harmonization and cooperation processes established by TTIP than they are currently afforded for domestic laws and regulations.

In the absence of publicly disclosed information from our own government regarding the nature of TTIP's evolving regulatory cooperation framework, we must look to other sources of information for insight into the likely impacts of TTIP on public participation.[40]

The most detailed of these sources, introduced above, is the EU's proposal of an overarching institutional framework, the "Regulatory Cooperation Council", to "… monitor the implementation of commitments made and consider new priorities for regulatory cooperation." As proposed, this body would have no accountability to the broader public at the sub-national, national and regional levels. This body would consist of the heads of the most important EU and US regulatory agencies and would monitor the implementation and development of legislation and regulation by the U.S. Federal Government and states. While the proposal explicitly envisions opportunities for input from transnational business groups in the policy-making process, neither the broader public nor civil society groups reflecting broader societal interests are afforded the same access, giving industry undue influence throughout the regulatory process.

EU proposals also outline substantial bi-lateral consultation requirements. Based on the EU position paper, both legislators and regulators in the US would have to undergo onerous consultations with trans-Atlantic counterparts, including time-consuming and unreliable trade-impact (cost-benefit) analyses.[41] Specifically, the EU has proposed that US legislators and/or regulators: (1) respond to EU proposals and comments; (2) provide periodic reviews of upcoming legislation; (3) maintain continuous dialogue with regulators across the Atlantic throughout the rulemaking process; and (4) fully disclose and explain all impact assessment/cost-benefit analyses to the EU Commission. This final point also risks the potential prioritization of

trade liberalization at the expense of environmental and social goals through cost-benefit analysis (i.e. impact assessments).

EU position papers indicate that proposals from stakeholders would be considered, but no further elaboration on the level of public participation or transparency is provided. Significantly, these requirements would apply not only to Congress and national regulators, but also to legislators and regulators at the state level, where international consultation requirements could pose an even heavier burden on comparatively smaller regulatory resources.

In addition, position papers point to the increased use of voluntary instruments to achieve regulatory objectives.[42] Together, these elements have the significant potential to delay or dilute rules needed to protect human health or the environment, with little to no public input.

- **Whether regulatory harmonization or the mutual recognition of standards would make it more difficult, in general, for the United States and the European Union to promulgate new regulations in the future – including on emerging threats to health or safety.**

Yes, regulatory harmonization and mutual recognition would make it far more difficult for the US and the EU to promulgate new regulations in the future, especially in response to emerging science regarding threats to health or safety.

In the 1970s and 80s, the US was the global leader in chemical safety, leading global effort to minimize the use of ozone-depleting substances, polychlorinated biphenyls (PCBs), and other chemicals of concern, with the EU following the U.S. lead. However, over the past few decades, the role of global leadership has shifted to European countries on a myriad of issues, including bisphenol A (BPA), phthalates, toxic flame-retardants, and numerous other chemicals of concern, with states in the U.S. and occasionally the federal government following European leadership.

Such regulatory divergence is how we have made progress on most environmental issues, with one jurisdiction going beyond the status quo, often to increase public protections through stronger regulations — resulting in divergent standards. Yet, it is in this critical regulatory arena that TTIP poses the most significant risks.

The example of endocrine disrupting chemicals is instructive. Nearly 800 chemicals are known, or suspected, to be capable of interfering with the normal function of our hormone systems which are crucial in laying the foundation for a healthy adult life. In 2012, the United States, European Union, over a hundred other countries—and industry—recognized hormone disrupting chemicals as being a global threat due to clear linkages with increased rates of a myriad of diseases which cannot be explained by genetics or lifestyle choices alone.

Member States have advocated for the EU to be a global leader in acknowledging scientific evidence of emerging threats in chemicals management, such as endocrine disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. However, the U.S. Trade

Representative and various industry groups have lobbied extensively against the promulgation of new regulations and criteria to address these emerging and known threats to health and safety.[43]

The longstanding and deep opposition that US diplomats have shown for pragmatic chemical policies by the EU has not been secret. An alliance of US Government officials and the chemical industry lobbied against these EU policies from 2002 until 2013, and continues today with debate over TTIP. A recent joint EU-US chemical industry proposal claims that emerging scientific issues present the EU and US with opportunities to align regulations and prevent divergence prior to their enactment. However, adding another regulatory consultation and co-ordination layer would delay that progress within the EU whilst alignment of regulation was considered. Indeed, CIEL's analysis of the chemical industry's proposal indicates that increasing such delays is an implicit objective of industry in seeking increased regulatory cooperation.[44]

Significantly, TTIP would pose a barrier to addressing emerging threats not only in Europe, but here in the United States as well. Just as U.S. industry and trade agencies have demonstrated strong opposition to REACH, European industry and trade agencies have expressed strong concerns with the more than 30 states that have enacted state-level measures to protect people and the environment from toxic industrial chemicals, due to the inability of the U.S. federal system to fill this role. Much of what is proposed under TTIP by the EU is an attempt to further limit the ability of states to regulate to address the concerns of their constituents. In doing so, TTIP would threaten progress by California, Maine, Washington and other states that have emerged as leaders in enacting measures to reduce exposure to toxic chemicals in products, food, water and the environment.

To reduce the likelihood that TTIP will hinder important public health and safety goals related to chemicals, TTIP must ensure that both the EU and U.S. retain the right to determine their own levels of protection for people, wildlife and the environment, and to develop measures to reduce exposure to hazardous chemicals and nanomaterials as they deem appropriate.

- **Whether regulatory harmonization or the mutual recognition of standards would diminish the regulatory sovereignty of the United States and the European Union, *i.e.*, constrain the ability of the two entities to promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens.**

Yes, regulatory harmonization or the mutual recognition of standards would diminish the regulatory sovereignty of both the United States and the European Union, both at the highest levels of government and, critically, at the subnational and subregional levels where regulatory innovations most often originate. Negotiators have stated that TTIP would not affect the right of the U.S. and the EU to regulate; however, TTIP would affect the ability of these Parties, including states and Member States, to exercise this right.

The proposed institutional framework for regulatory cooperation would be composed of representatives from both Parties, and cover "any planned and existing regulatory measures of general application" and "extend to regulations by US States and EU Member States." It would have the unstated power to constrain the ability of the either Party to exercise its right to

promulgate regulations it deems uniquely appropriate for the specific threats to the health and safety of their respective citizens. Some of the key elements of this implicit power include:

- The use of "harmonization, recognition of equivalence, or mutual recognition" as tools for regulatory "cooperation" (see answers in questions 2 and 5 for additional details regarding their negative effects on regulatory sovereignty);
- The use of "cost-benefit" and "trade impact" analyses for proposed regulatory or legislative initiatives, with a special focus on international trade impacts, to be published with the proposed final measure;
- A requirement for "regulatory dialogues," with trans-Atlantic governments;
- The creation of a trans-Atlantic scientific body to guide regulatory decision making ; and

The right of "stakeholders" to table "substantive joint submissions" for this body to consider. These types of provisions are designed to weaken or delay the development and implementation laws that specifically address priorities of either U.S. or EU citizens that might not be reflected across the Atlantic. For example, the recent decision to abandon the EU's Fuel Quality Directive, which sought to curb the use of dirty energy sources and encourage renewable, was abandoned due to U.S. government and industry interference over the potential trade-related impacts.[45] An institutional framework would create a permanent avenue for foreign interference with the development and implementation of laws and policies sought by the public in the U.S. or EU to reflect their own values, judgments, circumstances and policy choices.

- **The level of transparency in ongoing U.S.-E.U. trade negotiations, particularly compared to previous trade negotiations in which either entity was involved.**

The level of transparency in ongoing U.S. and EU trade negations remains abysmal, has not improved relative to past agreement to any meaningful degree, and is wholly inappropriate given the focus of negotiations on U.S. and EU regulations and lawmaking processes. CIEL has addressed the systematic challenges to public participation imposed by the current U.S. Trade Advisory System in a statement made by Daniel Magraw before the U.S. House of Representatives Committee on Ways and Means Subcommittee on Trade on July 31, 2009.[46] Recognizing that these challenges have remained unresolved since we delivered that testimony, we attach it hereto and incorporate it herein by reference.

Because trade and investment between the EU and the US are already highly integrated, the main focus of TTIP will be to achieve regulatory convergence by removing non-tariff barriers to trade. Eighty percent of TTIP's expected benefits will come from addressing present and future barriers to trade. Thus, TTIP has much less to do with traditional trade issues such as tariffs, than with U.S. and EU regulations and standards that affect every single aspect of citizens' daily lives – from the quality of the food we eat to the safety of chemicals we use, the energy we consume, or the impact of financial services on each of us. This makes the need for transparency and public participation correspondingly greater, requiring at least the same level of transparency afforded to domestic lawmaking processes.

The creation of new stakeholder advisory groups for the negotiations by both the EU and U.S. – do not address this need. Members of the group will have limited access to the negotiating texts under strict confidentiality rules, with no access for nearly all civil society groups and citizens, as well as most policy-makers. Indeed, the creation of the new U.S. committee may actually result in a further erosion of the status quo.

The newly established Public Interest Trade Advisory Committee (PITAC) will be separated from the existing Industry Trade Advisory Committee process as are the current "tier two" committees for labor and environmental groups.[47] As a function of this separation, members of the Committee will be unable to attend meetings of any of the ITACs, unlike the ITAC members. The creation of a new segregated committee for the public interest does not address the problems and consequences of the wildly skewed composition of the current US Trade Committee System, which is overwhelmingly dominated by corporate and industry interests. According to a recent Washington Post article, representatives of industry and trade associations make up a total of 85% of the composition of trade committees.[48] In CIEL's own analysis, out of roughly 600 committee members, fewer than 90 members across all committees that represent State governments, local governments, standardization organizations, academics, research institutions, think tanks, labor unions, and nonprofits of all kinds. The remainder (approximately 85%) represent individual corporations, industry associations, or trade advocacy groups.

Ironically, USTR's decision, supposedly aimed at "providing a cross-cutting platform for input in the negotiations," would serve to further marginalize civil society organizations by placing them in a single group that cannot provide adequate representation for the diversity of issues that concern multiple sectors of civil society. The scope and breadth of issues facing the committee will likely result in the dilution of the committee's position with regards to specific issues, which will limit the committee's efficacy.

ITAC members have insisted on segregating public interest viewpoints from their committees because "when they were in attendance, it made life very difficult."[49] For more than a decade, industry has argued that ITACs should be limited to industry membership and reflect only industry voices. The idea behind segregating public interest groups originated from a 2010 meeting to review the membership of the ITACs and to determine whether to expand membership beyond industry representation--a proposition the ITAC members have unanimously rejected.[50]

The emphasis on segregation makes clear USTR's vision of the advisory system as a vehicle for sector-specific advocacy rather than a forum for a balanced, multi-sectoral discourse regarding policy objectives. Just as the inclusion of a single public interest representative on a committee comprising dozens of industry members cannot be said to fulfill FACA's requirement that advisory committees be "fairly balanced," the creation of a single segregated committee comprised of public interest representatives cannot counter the input from 16 industry trade advisory committees and a separate suite of agriculture advisory committees in the creation of a balanced US trade policy.

Segregating the committee would continue to shield the ITACs from any public interest oversight of communications between ITACs and negotiators.[51] Although the PITAC will

have access to negotiating texts, it will not be privy to the informal oral advice that often guides negotiation, rendering the process more reactive than interactive.[52] Public interest representatives should be able to participate fully on every level, and balance is necessary in each committee. The PITAC does not address these critical needs.

The skewed nature of representation in the trade advisory system has concrete implications for public participation in the TTIP negotiations. At the start of the fourth round of TTIP negotiations, CIEL and ClientEarth issued a detailed critique of a document submitted to TTIP negotiators by the two main chemical industry lobbies, the American Chemistry Council (ACC) and the European Chemical Industry Council (Cefic). The industry document contained specific proposals and wording to affect the pace and direction of chemicals regulation through TTIP.[53]

The document, which as of this writing remains publicly available only on CIEL's and ClientEarth's websites, was leaked after the third round of negotiations in December 2013. This industry submission illustrates the significant disparities between public and industry access to trade negotiations--and to the negotiators themselves.

While the industry associations assert that their proposals and positions have always been available on their website, the facts suggest otherwise. ACC and Cefic posted their joint proposal in October of 2012, before new bills to reform US law were introduced, and ACC published a further position paper in May 2013. While these positions were indeed released publicly, the document leaked in December 2013 went well beyond these publicly released positions. Those public statements, for example, did not include:

- Draft legal text for discussion by negotiators (and convenient verbatim adoption);
- Mutual recognition of notifications (under US TSCA) and registration (under EU REACH) – which would undermine the "no-data, no-market" principle of REACH;
- Procedural (bureaucratic) mechanisms, such as the establishment of a "Chemical Sector Joint Cooperation Committee and a "Transatlantic Scientific Advisory Committee (TSAC)" for required consultation on emerging issues or areas of concern prior to the enactment of any regulations; or
- Reliance on a yet to be concluded UN Harmonized List of Classifications.

ACC and Cefic allege that this draft language for TTIP was developed following a request from negotiators. If so, the question arises: In whose interests are US and EU governments negotiating? In order to develop their draft language, ACC and Cefic must have had prior knowledge of the EU position paper on Regulatory Cooperation, which was only disclosed to the public immediately prior to the December negotiating round.[54] That disclosure came not from the governments themselves, but from the European organization, Corporate Europe Observatory (CEO), which released a leaked copy.[55] The public never had access to this document before it was leaked.

These disparities will be further exacerbated if Congress abnegates its own constitutionally mandated role in regulating foreign commerce by conceding to the President's request for Fast Track negotiating authority.

Proposals advanced by industry and entertained by negotiators would lower standards and remove safeguards across the board. Government proposals, which only surfaced through leaked documents, would create onerous processes in order for either Party, including states and Member States, to exercise their right to regulate to protect people, the environment, our financial systems, and other important public interests.

Because proposals under TTIP would affect domestic regulations, standards and safeguards on each side, as well as the processes from which they arise, citizens have the right to know what is being proposed and negotiated. The standard legislative and regulatory processes of the U.S. allow for public scrutiny of nearly every step of policy-making as well as full involvement of elected representatives. Given their far-reaching effects on fundamental public policy choices, these negotiations should adhere to similar standards of openness. The process should also allow for public accountability of the U.S. Trade Representative, European Commission, and other negotiators for the positions that they take.

Without full transparency, there can be no accountability, or meaningful engagement of policymakers, civil society groups, and the public in a process that could fundamentally change the ability of our local, state and federal governments to exercise their right to regulate. Basic transparency requirements include making the following available for the public at the earliest possible stage and at regular intervals:

- The text of the negotiating mandates;
- Initial position papers tabled by the U.S. and EU;
- Additional papers submitted by the U.S. or EU in the course of the negotiations that detail or explain positions on topics, and that are being used in the course of the negotiations with the other party; and
- Draft and final versions of individual chapters as well as the whole agreement at all steps of preparation and evolution (and at least before closing the negotiations and initialing so that lawmakers and the public can still assess the outcome and make comments and recommendations).

If the U.S. and EU are serious about openness and engagement of the public in TTIP, communications between the negotiators and other regulatory agencies, institutional bodies, states and Member States, as well as third parties (including companies, lobbyists, and industry associations) should be made available.

As CIEL observed during our earlier testimony, the secrecy and opacity observed in other trade negotiations, including the negotiations for the Trans Pacific Partnership, are inconsistent with basic principles of good governance and with the public's right to informed, meaningful participation in what amounts to a public policy dialogue of profound national consequence on both sides of the Atlantic. Negotiations between the United States and the EU should demonstrate a clear commitment to public participation and should be conducted in an open, transparent and participatory manner.

6. **We have heard that in certain circumstances, foreign investment can have the unintended effect of providing advantages to foreign investors over domestic investors. An example of this advantage is the right of foreign corporations to bypass domestic state and federal courts and proceed to a form of international arbitration known as investor-state dispute settlement (or ISDS). ISDS mechanisms allow foreign companies to challenge U.S. laws that they claim unduly interfere not just with past or present operations but also with the expected future profits from their initial investment.**

   a. **Please elaborate on these investor state dispute settlement mechanisms and the effect they already have had on the United States. What is the impact of the inclusion of an ISDS mechanism in a trade deal?**

On February 28 2014, the Center for International Environmental Law (CIEL) joined 42 other American and international civil society and public interest organizations, as well as members of academia, in a letter to United States Trade Representative Michael Froman, calling for public consultation to review the costs and benefits regarding Investor State Dispute Settlement provisions in free trade agreements, particularly with regards to the TTIP negotiations.[56]

First, the inclusion of ISDS provisions under TTIP would dramatically increase risk of ISDS suits against the U.S. According to the United Nations Conference on Trade and Development (UNCTAD), U.S. and European companies account for 75% of all investor-state disputes known globally.[57] This fact is not surprising when one considers that, in addition to being the world's largest economies, the U.S. and E.U. member countries have negotiated approximately 3000 multilateral, regional and bilateral investment treaties containing investor protection provisions.

The number of investor-state cases worldwide has increased exponentially in recent years.[58] ISDS provisions have enabled businesses to claim more than $430 million in compensation, with $38 billion sought under fifteen pending claims for public interest and environmental laws and policies.[59] Cases against the U.S. include laws to protect people from the emission of a neurotoxin additive in gasoline (Methanex), and to require the restoration of mines (Glamis Gold). Other examples of ISDS claims for public health and environmental laws and policies include suits against: (1) Germany for U.S.$ 3.7 billion following a democratic decision to phase out nuclear energy;[60] and (2) Canada for CAN$ 250 million for lost profits by a *Canadian* company due to a moratorium on hydraulic fracturing (fracking) for shale gas.[61] Numerous legal and policy experts have voiced concerns over investment tribunals hearing such disputes, as they are unlikely to adequately take into account human rights, labor rights, and environmental or other public interest concerns.[62]

While USTR asserts that the United States has never technically "lost" an ISDS case,[63] this conveniently overlooks settlements with investors and the growing trend of companies restructuring (and in some cases relocating) their operations to sue as protected investors under particular regimes. Indeed, global legal and consulting firms have developed a robust cottage industry in advising multinationals on how to structure their operations to make strategic use of these protections. With 75,000 companies already cross-registered in both the United States and the EU, the financial exposure from future investor claims and litigation response costs could increase dramatically if ISDS are included under TTIP.[64]

That recourse to these mechanisms would appeal to companies is equally unsurprising because ISDS affords "foreign" investors greater rights than domestic businesses. ISDS provides foreign investors the right to bypass domestic courts (including constitutionally-created Article III courts) and challenge the U.S. government directly before an international arbitration tribunal, if they feel that a domestic policy or government decision contravenes their expectations or threatens their expected future profits, a right that even domestic investors do not share.[65]

Proponents of ISDS also routinely ignore the regulatory chilling effect of real or threatened investor suites. The threat of ISDS suits can result in the dilution of many proposed laws on public health and environmental protection.[66] ISDS weakens the power of governments to regulate, despite the fact that they retain the "right" to do so. Governments must have the flexibility to put in place public interest policies without fear of costly trade litigation brought by well-resourced corporations.

Further, ISDS provisions undermine democracy and values of justice deeply embedded in both the U.S. and European systems. While the public interest laws at issue are the product of democratic processes, ISDS panels are not democratically selected, are not bound to consider basic principles of U.S. law such as sovereign immunity, and are not required to balance the public interest against alleged violations of an investor's rights. Arbitrators often represent clients in different ISDS cases, and are above any meaningful degree of accountability, due in part to a dark veil of secrecy. Decisions of the tribunal—including legally incorrect decisions—are final and binding on countries, with limited exceptions. As arbitrators themselves are recruited from the international trade community to apply international trade rules to international trade agreement, the system is implicitly biased to elevate trade concerns above other societal values and policy priorities.[67]

Finally, ISDS suits place the public in a lose-lose situation. Each ISDS case costs American taxpayers an average of $8 million, oftentimes to defend against meritless claims.[68] In the instance of a loss by the U.S. government, Americans must compensate corporations for less-than-expected profits. In the case where the law is weakened or abandoned to avoid the potential liability of an ISDS suit, the public may continue to bear the externalized costs of corporate activities, for example pollution.

b. Both the U.S. and the E.U. have highly developed, well-functioning judicial systems. Why do some companies and industries want ISDS to be included in TTIP? Should consumers?

While the inclusion of ISDS provisions is problematic in any trade agreement, traditional arguments for the inclusion of ISDS in trade and investment agreements are clearly without foundation in the context of TTIP. The United States and the EU have very strong domestic court systems and property rights protections, with the U.S. affording the same rights to foreign investors as domestic investors. European officials have stated publicly that ISDS is not necessary under TTIP for robust trans-Atlantic foreign investment, as the level of foreign investment is already very high.

ISDS is sought under TTIP by companies and industries because it offers corporations around the world a favorable venue to attack and undermine domestic laws and policies created through democratic processes, in order to maximize profits. ISDS grants foreign corporations the right to directly challenge government policies and actions in private tribunals, bypassing domestic courts and creating a new legal system that is exclusively available to foreign investors and multinational corporations. Typically a three-person panel composed of private attorneys oversees the case, with the power to award an unlimited amount of taxpayer dollars to corporations. For example, a crushing US$2.3 billion, the highest compensation to date, has been awarded to U.S. oil company Occidental Petroleum against Ecuador, for the termination of an oil production site in the Amazon.[69] As the process elevates private firms and investors to the same status as sovereign governments, it amounts to a privatization of the justice system.[70]

For example, in one of the most notorious cases, U.S. tobacco giant Philip Morris launched investor-state cases challenging anti-smoking laws in Uruguay and Australia after failing to undermine the health laws in domestic courts.[71] In a recent case in which CIEL has been directly involved, a Canadian firm seeking to operating a gold mine in El Salvador, through a subsidiary registered in the Cayman Islands, abruptly closed that subsidiary and re-registered in Reno, Nevada in an effort to sue the government of El Salvador as a U.S. investor under the U.S.-Central American Free Trade Agreement.[72] Troublingly, the panel considering the case concluded that the firm's actions were permissible under CAFTA, despite the lack of any meaningful connection between its Salvadoran mining operation and the United States. The company was denied investor protections under CAFTA only after El Salvador successfully invoked another provision of the agreement to deny those protections.

In response to the egregious corporate abuse of the investor-state system in sidestepping domestic court decisions, several countries have started to turn away from investor-state dispute settlement. South Africa, Bolivia, Ecuador, Venezuela, and Indonesia have begun phasing out existing bilateral investment treaties.[73] Additionally, Ecuador, Bolivia and Indonesia have withdrawn from the International Centre for the Settlement of Investment Disputes (ICSID).[74] In the U.S., the National Conference of State Legislators, representing all 50 U.S. state parliamentary bodies, has declared that it "will not support any [trade agreement] that provides for investor-state dispute resolution" because it interferes with their "capacity and responsibility as state legislators to enact and enforce fair, nondiscriminatory rules that protect public health, safety and welfare, assure worker health and safety, and protect the environment."[75]

On an international level, UNCTAD has prioritized its attention on reforming the system to provide for more transparency, preserve appropriate regulatory space for host countries, and balancing the rights and obligations of States and investors, as well as assessing the options available for countries to terminate existing treaties.[76]

In 2013, the United Nations Commission on International Trade Law (UNCITRAL) adopted new rules designed to bring greater transparency to international investment disputes.[77] While these rules represent an improvement in the status quo with respect to the transparency of such disputes for agreements completed after April 2014, the rules will not apply retroactively to existing agreements unless State parties to those agreements consent thereto. Nor do they remedy the many and fundamental challenges of ISDS discussed in the foregoing pages.

Notes

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[75] An Open Letter From U.S. State Legislators to Negotiators of the Trans-Pacific Partnership Urging the Rejection of Investor-State Dispute Settlement, available at https://www.citizen.org/documents/State-Legislators-Letter-on-Investor-State-and-TPP.pdf
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