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December 2, 2015

The Honorable Michael B.G. Froman
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Froman:

In accordance with section 5(b)(4) of the Bipartisan Trade Priorities and Accountability Act of 2015, and section 135(e) of the Trade Act of 1974, as amended, I am pleased to transmit the report of the Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC-3) on the Trans-Pacific Partnership Trade Agreement, reflecting consensus on the proposed Agreement.

Sincerely,

Vincent M. DeLisi

V.M. (Jim) DeLisi, Chairman
ITAC-3

The Trans-Pacific Partnership Trade Agreement

Report of the
Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products
and Services

December 2, 2015

Date: December 2, 2015

Subject: Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC-3): Advisory Committee Report to the President, the Congress and the United States Trade Representative on the Trans-Pacific Partnership Trade Agreement (TPP).

- **Purpose of the Committee Report**

Section 5(b)(4) of the Bipartisan Trade Priorities and Accountability Act of 2015, and section 135(e)(1) of the Trade Act of 1974, as amended, requires that advisory committees provide the President, the U.S. Trade Representative, and Congress with reports not later than 30 days after the President notifies Congress of his intent to enter into an agreement.

Under Section 135 (e) of the Trade Act of 1974, as amended, the report of the Advisory Committee for Trade Policy and Negotiations and each appropriate policy advisory committee must include an advisory opinion as to whether and to what extent the agreement promotes the economic interests of the United States and achieves the applicable overall and principle negotiating objectives set forth in the Trade Act.

The report of the appropriate sectoral or functional committee must also include an advisory opinion as to whether the agreement provides for equity and reciprocity within the sectoral or functional area.

Pursuant to these requirements, the Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC-3) hereby submits the following report.

- **Executive Summary of Committee Report**

Our members believe that many of the negotiating objectives and priorities of ITAC-3 regarding the TPP have been met. Many of our members have concerns about the agreement that was reached on intellectual property impacting the pharmaceutical industry as well as the agreement on Rules of Origin. We are very pleased that all tariff lines eventually go to zero, especially the fact that almost all of the tariff lines in our sector in Japan go to zero upon entry into force.

We are very pleased that the United States made negotiating a Free Trade Agreement (FTA) with this group of countries, which represent almost 40% of world trade, a priority.

We are concerned about the fact that there will be inevitable conflicts between the TPP and our existing bi-lateral FTA's with Australia, Singapore, Peru, Chile, and NAFTA. We urge USTR to carefully detail how these agreements will interact. In addition, since in many instances the agreements will run "side by side", we urge USTR to prepare a matrix comparing the benefits of

each agreement. This matrix would be especially useful for SME's (Small & Medium-sized Enterprises) wishing to understand how best to take advantage of the market opening this new agreement represents.

We also regret to report that ITAC-3 had requested that *“USTR utilize a communication strategy that has proven valuable in the past. Included should be secure ITAC calls during the negotiating sessions and the posting on the secure website of negotiating positions and documents as soon as possible. We also request that whenever an issue is raised that could potentially impact our sector that our DFO be promptly contacted so that a suitable response can be forthcoming.”* Unfortunately, in many instances, this did not happen and therefore we were surprised at some of the details learned after the release of the full texts.

III. Brief Description of the Mandate of ITAC-3

ITAC – 3, the United States Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services, represents the following product sectors and subsectors:

Adhesives and Sealants	Rubber and Rubber Articles
Specialty Chemicals	Soaps and Detergents
Industrial Chemicals	Plastics and Compounded Products
Organic Chemicals	Composite Materials
Inorganic Chemicals	Biocides
Crop Protection Chemicals	Forest and Paper Product Chemicals
Pharmaceuticals	Rare Earth Metals
Biotechnology	Radioactive Chemicals
Dyes and Pigments	Enzymes, Vitamins, and Hormones
Paints and Coatings	Cosmetics, Toiletries, and Fragrances
Petrochemicals	Photographic Chemicals and Film
Fertilizers	Catalysts
Printing Inks	Animal Health Products
Electronic Chemicals	Medical Devices & Equipment
Public Health	

The sector coverage as listed above for ITAC-3, includes the products and substances classified in the U.S. Harmonized Tariff Schedule (HTS) Chapters 28 – 40, as well as other specific chemicals found in HTS Chapters 13, 14, 15, 22, 23, 25, 27, 55 and 71 as well as medical equipment found in HTS Chapters 28, 30, 34, 38, 40, 42, 61, 63, 84, 85, 87, 90 and 94.

IV. Negotiating Objectives and Priorities of ITAC-3

In a letter to Ambassador Ron Kirk and Secretary Gary Locke, dated June 24, 2010, following a communication sent to Acting Secretary Wolf and Acting United States Trade Representative Ambassador Allgeier, that was dated February 12, 2009, ITAC-3 set out its priorities for these negotiations. We've chosen to detail these issues here to once again demonstrate the standards by which we intend to evaluate the results of this negotiation.

Please consider this initial advice on TPP from the newly re-chartered ITAC-3 as over-arching type principles and essentials. After ITAC-3 has an opportunity to review texts on the secure USTR website, we will be in a better position to provide additional advice.

Overview:

ITAC-3, the Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services believes that completion of TPP negotiations offers the chemical sector very significant new trading opportunities with an important group of countries proposed for TPP and those expected to be added later.

We encourage USTR to utilize a communication strategy that has proven valuable in the past. Included should be secure ITAC calls during the negotiating sessions and the posting on the secure website of negotiating positions and documents as soon as possible. We also request that whenever an issue is raised that could potentially impact our sector that our DFO be promptly contacted so that a suitable response can be forthcoming.

We also believe that a TPP agreement should serve as a springboard for expanded free trade between the U.S. and countries that are willing to assume high Free Trade Agreement (FTA) standards in the entire APEC region. We would especially be interested in having Japan become part of the TPP negotiations as soon as practical, and would strongly support the inclusion of Korea, once the U.S.-Korean FTA is fully implemented. To have other countries join in a future second or third “tranche” would be preferable once an acceptable model is reached with the first tranche of countries.

These negotiations are very timely and in fact critical since both the EU and China are rapidly negotiating FTAs in the APEC region. As you know, the EU embarked on negotiations with Vietnam a couple of weeks ago. If we are not successful in the TPP initiative, it is likely that the U.S. will lose its competitiveness in the Asia-Pacific region. This would be a costly outcome for the economic well-being of U. S. companies.

We understand that the TPP negotiating format is still under consideration, but trust that USTR and DOC will adopt an interactive procedure with all stakeholders, including the domestic industry. We consider the following points to be important considerations:

- As we understand it, 8 countries are currently participating: U.S., Australia, Brunei, Chile, Singapore, New Zealand, Peru, and Vietnam. The U.S. already has high standard FTAs with four of these countries. Some have higher standards than others. Adding complexity, in some instances, the standards vary from sector to sector.*
- The TPP Agreement should use each of the strongest individual provisions in our existing FTAs as the preferred standards.*
- The chemical sector places significant importance on appropriate sector specific rules of origin. Although not yet implemented, the U. S. proposed sector specific rules of origin*

for the chemical sector in the U. S.-Korea FTA would meet the high standard we believe necessary in the TPP Agreement.

- *Ideally, one of the results of TPP negotiations should be to allow for accumulation among all of the parties.*

It is vitally important to the chemical sector that the terms and conditions of the TPP Agreement not “backslide” from the hard fought “gains” in any of the our existing FTAs with Australia, Chile, Peru and Singapore, but instead build on these gains to achieve an even stronger TPP Agreement. FTAs currently in place and approved by the U.S. Congress should not be reopened for TPP negotiating purposes.

Following are some specific issue comments:

Tariffs:

We support a comprehensive and balanced TPP Agreement based on full reciprocity in tariff levels. We support immediate elimination of all tariffs in Chemicals (chapters 28-39) upon full implementation of the agreement provided that all other TPP partners offer the same concessions in their tariff levels within the chemical sector. However, to the extent that others request staging of their tariff phase-outs on particular products, the U.S. should request similar staging periods for the same or other products on a trade-weighted basis as appropriate, to ensure balanced reciprocity in market access under the agreement. In general, minimum coverage in all sectors should be consistent with existing WTO and FTA rules.

The domestic chemical industry should have the right to reserve/nominate a list of import sensitive items that should receive the maximum tariff phase-out period offered, primarily based on the criteria used for determining import sensitivity by the TPP negotiating teams.

We strongly support efforts to maintain full rights to duty drawback in this and all other FTAs.

Non-Tariff Barriers (NTBs):

We support the complete elimination of all NTBs in the trade facilitation area (like those currently being negotiated in the DOHA Round), and especially those involving Pharmaceuticals and Agricultural Biotechnology, upon implementation of the TPP Agreement. We look forward to working with U. S. negotiators on identifying such NTBs.

Rules of Origin:

Product specific rules of origin in free trade agreements are vitally important for the chemicals sector. The rules we support are hierarchical in nature, starting with the concept of “tariff shift” as the test for determining whether there has been a substantial transformation of a product that will confer origin. Where a substance does not meet the tariff shift rule, the second test should be the chemical reaction rule. If, following these two tests, the product’s origin is

still in doubt, a third set of tests based on additional rules for mixtures, purification, separation, and so forth as are outlined in Annex I to this statement.

We strongly support harmonizing rules of origin across all trade agreements and preference programs, particularly within the chemical sector. The domestic chemical industry is not in favor of “value content” rule of origin. We find “value content” rules of origin to be very burdensome, inefficient and not suitable for meeting the intent of substantial transformation in the chemical sector.

We therefore strongly support the use of sector specific chemical rules of origin proposed in the yet to be implemented U.S.-Korea FTA. These product-specific Rules of Origin concerning chapters 28 – 39, the General Rules of Origin and Origin Procedures, and the Customs Administration and Trade Facilitation rules, without substantial change could serve as the model for this agreement.

We also believe that origin rules for both preferential and non-preferential purposes should be the same in the TPP and all trade agreements.

It is vitally import that the rules effectively eliminate the potential for transshipment of goods so that the full benefits of the agreement accrue only to the parties of the agreement.

An even simpler approach to product specific rule of origin supported by the domestic chemical sector is attached as Annex I in a document titled “simplified rules of origin.” It has been widely agreed among many chemical industry representatives that these simple rules should be the basis for the chemical sector in all trade agreements and preference programs negotiated by the U.S.

Intellectual Property Rights (IPR):

Effective protection for intellectual property is vital for the chemical sector HTS chapters 28 - 39. We strongly advocate the TPP Agreement should reflect the U.S. standards in this area. Enforcement of IP rights should be a priority. The TPP Agreement should contain severe penalties for violations.

We also believe that the agreement needs to include provisions for private sector engagement in the development of IP policy and the subsequent enforcement of that policy. It would be helpful if it also has a strong emphasis on the enforcement of IP rights, the timely adjudication of those rights, and on imposing stricter IP penalties to combat theft, piracy, and illegal commercialization of foreign technology.

We also will be looking for practical, science-based approaches to the establishment of IPR protection for agricultural biotechnology. The TPP Agreement needs to emphasize enforcement of IP rights and adherence to the principles of the WTO and the existing TRIPS agreement as they relate to IPR.

In addition, we encourage USTR to obtain strong commitments from all of the TPP participants to take effective action at their borders to address trade in illegal, pirated, and counterfeited goods. Such measures are particularly important where counterfeit products can result in injury or death of those who end up using the products.

The agreement should also encourage increased efforts to educate the public and raise awareness about damages done by counterfeiting and piracy by increasing the allocation of government resources toward combating piracy and counterfeiting.

Data Recognition & Exclusivity:

The right to market many of the products in the chemical sector is subject to various government controls requiring the submission of voluminous data files. Such data needs to be protected in the region in accordance with current U.S. standards and statutes.

It is especially important for Crop Protection Chemicals that the TPP re-enforce the need for authorities in the region to recognize data meeting U.S. standards and that such authorities emulate the ten-year data exclusivity requirements established under US law.

Technical Barriers to Trade:

Commitments in this area are a vital component to ensure that standards and regulations do not erode the enhanced market access achieved under the TPP Agreement. Strict compliance with rights and obligations under the WTO TBT Agreement should be the base line of this chapter in the TPP. The agreement should contain strong transparency provisions, including advanced notice and a meaningful opportunity for private sector interests to participate in the development of standards and technical regulations procedures.

Transparent, risk based regulatory regimes are a necessary element for business to prosper and serve as a fundamental basis for giving companies the freedom to operate.

Investment:

The chemical sector believes that the inclusion of an “Investments” chapter in any FTA is a priority and should provide strong investment protection rules for U.S. companies investing abroad.

Among the elements that we advocate that should be covered in an “Investment” chapter are:

- *The defining of investment in a comprehensive manner;*
- *The guarantee of the better of either MFN or national treatment;*
- *The provision for, and the assurance of, the free transfer of profits and capital;*
- *The adequate dealing with issues affecting the movement of key personnel;*
- *The disciplining of the use of performance requirements;*

- *The prohibition of expropriation, except in the case of a public purpose and only with the payment of prompt, adequate and effective compensation;*
- *The guarantee that investment will receive fair and equitable treatment, with full protection and security, consistent with the principles of international law; and*
- *The assurance that investors have access to an effective mechanism for the settlement of investor-state disputes within the provisions of the FTA and that dispute settlement is consistent with our “Model BIT”.*

Conclusion:

We urge careful consideration of each of the concerns we have identified in this letter, and in particular that sector specific rules of origin for the chemical sector (as outlined herein) be included in the TPP Agreement and all future trade agreements.

In a follow-on communication to Ambassador Kirk and Acting Secretary Blank, dated June 22, 2012, we re-emphasized many of the same points, excerpts follow:

We especially hope that USTR will bring back an agreement that recognizes that for our sector to thrive, we need:

- *An agreement that sets a very high standard for the protection of intellectual property based on the WTO TRIPS rights and obligations to ensure an effective and balanced approach to IP rights among our TPP partners.*
- *Since our sector is highly regulated, we need an agreement that contains a robust statement on regulatory coherence. Therefore, we believe that the TPP should include a transparent, effective, enforceable, and mutually coherent regulatory coherence chapter which is both risk and science based, adheres to international best practices, and ensures high levels of collaboration among governments and their stakeholders.*
- *We strongly support separate provisions to address the unique regulatory and reimbursement obstacles faced by the medical technology and pharmaceutical industries.*
- *We strongly support the elimination of all tariffs in our sectors upon entry into force of the agreement*

NAFTA has been functioning, for the most part to our benefit, for almost 20 years. It is our understanding that NAFTA would continue in full force after the TPP, including Mexico and Canada, entered into force. Further, it is our understanding that in areas of “conflict” the later agreement would prevail. In other instances, such as Rules of Origin, a “conflict” can be considered a “choice” so a trader could choose to use the provisions most beneficial for each individual circumstance. With this understanding, we believe that the TPP should contain language that clearly delineates which agreement will prevail on topics where there is a prior agreement in place.

The unintended consequences of leaving in place an agreement that was concluded almost 20 years ago, based on an agreement negotiated with Canada almost 30 years ago, are impossible

to predict. An illustrative list of topics that would be problematic for our sector if not carefully defined to follow the TPP template includes:

- *Duty drawback: NAFTA does not permit duty drawback. It is likely that the TPP will permit this procedure, which we strongly support, to remain viable.*
- *Free trade zones: There are severe restrictions on the use of such beneficial zones in NAFTA. It is likely that the TPP will be silent on this issue, which means that such restrictions might remain in effect, to the detriment of our exports.*
- *Rules of origin: The chemical sector rules of origin in NAFTA are definitely incompatible with all of the FTA's that have been negotiated since except for the agreements in the Middle East that have modified GSP rules. Our sector needs consistent, easily understood, modern rules, similar to that which is found in KORUS. Such rules are much more "user friendly" and helps assure us that the participants in the treaty receive the benefits. We also believe that value content, the basis for the NAFTA rules in our sector, is an inappropriate method of determining origin.*
- *Mexico provides only 5 years of data protection for agrochemicals while all FTAs since NAFTA provide 10 years of protection for these products. We expect that the TPP will maintain the higher standard of 10 years of data protection for Agrochemicals.*

V. Advisory Committee Opinion on Agreement

Chapter 1. Initial Provisions and General Definitions: We note that article 1.2 is entitled "Relations with other Agreements". ITAC-3 strongly believes that USTR needs to construct a matrix, paragraph by paragraph so that all can understand the rights and obligations under this agreement and how they mesh or differ with our existing FTAs, including NAFTA, Peru, Singapore, Chile and Australia.

Chapter 2. National Treatment and Market Access: We support the results of the negotiations in this chapter. USTR reached our goal of being sure that all of the tariffs in our sector eventually go to zero. USTR also succeeded in bringing most of the tariffs in our sectors down to this level upon entry into force of the agreement. A job very well done.

Chapter 3. Rules of Origin and Origin Procedures: We applaud USTR's success in making sure that "process rules" were included in this agreement. However, we are disappointed with certain results achieved in this chapter. USTR agreed to value content rules of origin in 3004, 3006.50, 3505.20, 3808.50 – 3808.99 as well as 3901 through 3915. ITAC-3 has been on record as strongly opposing the imposition of value content Rules of Origin in our sector for many years. In addition, USTR severely weakened the rules of origin for 3207 through 3212 and 3215 allowing for the use of non-territorial colorants in Inks, Paints and Coatings. This change will have a significant negative impact on US producers of both inorganic and organic colorants in the USA. These changes will also serve to undermine hard fought results in our existing FTAs with Peru, Singapore, Chile and Australia.

Chapter 4. Textiles and Apparel: No Comment

Chapter 5. Customs Administration and Trade Facilitation: ITAC-3 supports the outcome of the negotiations in this chapter.

Chapter 6. Trade Remedies: ITAC-3 supports the outcome of the negotiations in this chapter.

Chapter 7. Sanitary and Phytosanitary Measures: ITAC-3 applauds positive outcomes in support of market access and removal of barriers to US bio-technology products.

Chapter 8. Technical Barriers to Trade: ITAC-3 strongly supports the results achieved in the negotiations in the area, especially in regards to section 8.7 on Transparency. The strong language used in this paragraph should assure our exporters that they will not be “surprised” by new rules, laws and/or regulations in all of the countries that are part of this agreement. We are also pleased to see that the agreement recognizes the extensive burdens that regulatory barriers can place on both industry and consumers by including sector-specific chapters dedicated to regulated industries. This language further ensures opportunities for American exporters and investors to be able to comment and engage on draft regulation, which will be a substantial benefit to ensuring full market access.

ITAC-3 strongly supports the medical device-specific provisions in this chapter. These provisions require governments to adhere to important regulatory principles for medical devices specifically, including consideration for internationally developed guidance, use of risk-based systems, basing approvals solely on safety and effectiveness (not economics), and following reasonable timelines for reviews; We believe these provisions establish high standards that should greatly improve regulatory systems in TPP participating countries – especially those with emerging regulations.

ITAC-3 also supports the transparency and procedural fairness (TPF) provisions, with a reservation. This section specifies a process for seeking government review of reimbursement decisions, including a Japanese commitment, but is not as strong as KORUS provisions. We expect USTR to insist that TPP Countries that do not currently meet the criteria for covering their device reimbursement system will be required to fulfill TPF commitments when they do meet the criteria.

Chapter 9. Investment This chapter appears to adequately meet our goals. By reference, we are incorporating the report of the IWG (ITAC Chair’s Investment Working Group) report that presents a very detailed review of this chapter.

Chapter 10. Cross Border Trade in Services: No comment

Chapter 11. Financial Services: No comments

Chapter 12. Temporary Entry for Business Persons: ITAC-3 supports the results achieved in this chapter.

Chapter 13. Telecommunications: No comment

Chapter 14. Electronic Commerce: We support the outcome of the negotiations in this chapter. We are especially pleased to see that it prohibits the imposition of a duty on the transfer of content electronically. We also appreciate the fact that it requires parties to make available and then receive trade related documents electronically. By eliminating the need for “paperwork”, this requirement should help enhance the international shipment of goods within the parties.

Chapter 15. Government Procurement: No Comment

Chapter 16. Competition: We support the outcome of the negotiations in this chapter and are especially appreciative of its direct language related to confidential business information.

Chapter 17. State-Owned Enterprises: We are especially pleased with the outcome in this chapter with the repeated use of the word “shall”. This chapter should effectively ensure that SOEs cannot exercise monopoly power over private enterprises in the sale or acquisition of commercially available goods and services.

Chapter 18. Intellectual Property - We support the overall goal of ensuring broad, effective and balanced intellectual property protection. We also support ongoing opportunities for further capacity building, especially in developing countries to ensure that IP protections offer an enforceable cover for American technologies and products.

Overall ITAC-3 supports the IP section since it raises the bar for many TPP member countries on issues which are relevant for our industry.

- Section 18.7 specifically requires a ratification of UPOV 91. This is a very positive development, because it will substantially improve the effectiveness of PVP rights in the member countries which are not yet at UPOV 91 level. Some member countries have been granted a 3 or 4 years delay in implementing, which does not seem abnormal since they will have to revise their national PVP laws. All in all, this is a very good achievement.
- Section 18.14 explicitly states that parties recognize the importance of improving the quality and efficiency of their respective patent registration systems. This is important since many of the member countries have a patent examination process which is not effective and also takes too long to come to a decision. The additional obligation to work together enables the US to provide training. Furthermore, the obligation to share research and examination results will enable the US to monitor progress on this front. This is very good.
- Section 18.6 on traditional knowledge (TK) makes an explicit link between TK and genetic resources, and is in principle limited to TK related to IP (explicit link through prior art). By doing so, it closes the door for an IP type protection on TK as such, which is a very political and contentious issue and has been discussed at WIPO for many years. This is a very good achievement.
- Section 18.37 clearly points out that patents need to be granted in all fields of technology.
- Section 18.37; 4) states that patents on plants may be excluded, but that these need to be available for inventions derived from plants. If this means that plant varieties can be exempted from being protectable by patents, this is in line with many existing national

patent laws, i.e. in Europe. Plant material should however remain patentable under this provision. In addition, there is an explicit reconfirmation of the TRIPs principles on exemptions and limitations.

- Section 18.47 imposing a minimum of 10 years of data protection for agrochemicals is very positive and a great achievement. There is a delay in implementation for some countries of 5 years.
- Section 18.78 imposes effective rules re the protection of trade secrets which is also a very good development.
- Pharmaceuticals - ITAC-3 is unable to come up with a consensus on the IP section of this agreement.
 - ITAC-3 members that represent the Generic Pharmaceutical sector are in support of the texts as agreed by the 12 TPP countries. The Generic Pharmaceutical sector are of the opinion that to a reasonable extent and with consideration of the broader impact of this agreement, the TPP Agreement, taken as a whole, is strong and promotes the economic interests of the United States (U.S.) and advances the overall and principal negotiating objectives with respect to intellectual property set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015. While there are elements which some ITAC-3 members would prefer to have strengthened, clarified or removed to conform better to the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 and previous bilateral free trade agreements (FTAs), the TPP intellectual property provisions generally modernizes standards of protection and enforcement, with particular importance for the five TPP partners with which the U.S. does not have FTA's, and enhance U.S. economic interests. ITAC-3 members representing the interests of Generic Pharmaceuticals therefore believe that the TPP deserves Congressional support as it is broadly consistent with the negotiating goals and objectives of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.
 - ITAC-3 members representing the interest of Innovative Pharmaceutical companies are of the opinion that portions of the TPP agreement do advance negotiating objectives with respect to intellectual property as set forth in section 102 of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015. However, there remain significant concerns about the provisions related to data protection for biologic medicines. The TPP agreement allows countries to provide protection that is “comparable” to eight years, a significant departure from current U.S. practice and the negotiating objective of 12 years of data protection for biologic medicines. The TPP agreement also accepts a definition of biologic medicines that is markedly narrower in scope than current U.S. practice. It is also unclear if even the lower level of 8 years of “comparable” protection that the TPP calls for can be adequately enforced via dispute settlement or implementation protocols. As a result of these differences with current U.S. practice, members of ITAC-3 representing the Innovative Pharmaceutical sector cannot agree that the TPP agreement as it stands now warrants Congressional support.

Chapter 19. Labor: No comment

Chapter 20. Environment: No comment

Chapter 21. Cooperation and Capacity Building: No comment

Chapter 22. Competitiveness and Business Facilitation: ITAC-3 would appreciate an opportunity to give input when the committee that this chapter creates meets.

Chapter 23. Development: No comment

Chapter 24. Small and Medium-sized Enterprises (SMEs): ITAC-3 supports the inclusion of this chapter in this agreement. We expect that even large companies will find the website that each country needs to construct to satisfy the requirements of this chapter useful.

Chapter 25. Regulatory Coherence: We support the inclusion of this chapter in this text. However, we wish that most if not all of the uses of the words “may” and “should” had read “shall”. We strongly encourage early set up of the Regulatory Cooperation Council’s envisioned in the agreement as part of the early implementation efforts, and look forward to working with USTR and other agencies of the US Government to develop sectoral approaches on regulatory cooperation.

Chapter 26. Transparency and Anti-Corruption: ITAC-3 strongly endorses this chapter. This chapter contains provisions to combat corruption and to support the rule of law. It also calls for a code of conduct to promote high ethical standards. Importantly, this chapter requires countries to publish all rules, laws, etc. In some instances, we are disappointed that in the use of the words “to the extent possible”. We would have preferred that this phrase was eliminated and replaced with “except under emergent circumstances, parties shall”.

Chapter 27. Administrative and Institutional Provisions: ITAC-3 urges that the Commission that is created by this chapter include representatives from the private sector, with full voting rights.

Chapter 28. Dispute Settlement: This chapter appears to satisfy our goals of having a clear path to resolves disputes under this agreement. We trust that USTR has an understanding of how issues that arise under this chapter will be resolved if there are any conflicts with the language in our existing FTAs including NAFTA, Singapore, Chile, Peru and Australia should disputes arise with these countries.

Chapter 29. Exceptions

Chapter 30. Final Provisions

Annexes: No Comments

Related Instruments: No Comments

VI. Membership of the Committee

Industry Trade Advisory Committee On Chemicals, Pharmaceuticals, Health Science Products and Services ITAC-3

Chairman

Mr. V. M. (Jim) DeLisi
President
Fanwood Chemical, Inc.

Primary Vice-Chairman

Mr. Adrian Krygsman
Director, Product Registration
Troy Corporation

Secondary Vice-Chairman

Mr. A. E. (Ted) May, III
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Mr. David R. Gaugh
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Mr. Edward L. Gibbs
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Mr. Vijay Goradia
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Trevor J. Gunn, Ph.D.
Founder and Chairman
USA Healthcare Alliance, LLC

Mr. Ralph F. Ives
Executive Vice President, Global
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Association

Ms. Tonya L. Kemp
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**Industry Trade Advisory Committee
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ITAC-3**

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Senior Advisor for Trade, Intellectual
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Mr. Thomas G. Zieser
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Mr. Paul A. Neureiter
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