September 27, 2018

The Honorable Robert E. Lighthizer
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Lighthizer:

In accordance with section 105(b)(4) of the Bipartisan Congressional 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 on Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3) on the Trade Agreement with Mexico and potentially Canada, reflecting consensus on the proposed Agreement.

Sincerely,

V. M. (Jim) DeLisi

V.M. (Jim) DeLisi, Chair
ITAC 3

A Trade Agreement with Mexico and potentially Canada

Report of the
Industry Trade Advisory Committee on Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3)

September 25, 2018

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Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3)

ITAC 3 Advisory Committee Report to the President, the Congress, and the United States Trade Representative on the Trade Agreement.

I. Purpose of the Committee Report

Section 105(b)(4) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, and section 135(e)(1) of the Trade Act of 1974, as amended, require that advisory committees provide the President, the Congress, and the U.S. Trade Representative 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 principal negotiating objectives set forth in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.

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 on Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3) hereby submits the following report.

II. Executive Summary of Committee Report

ITAC 3 supports the revisions of NAFTA that are included in the US/Mexico Free Trade Agreement and applauds both USTR and the Administration for its efforts to modernize and rebalance NAFTA. We agree that the agreement offers equity and reciprocity within our sectors. We would have preferred that Canada be a part of this agreement from its inception and urge the Administration to use its best efforts to make this happen in order to maintain NAFTA as a trilateral agreement.

We are pleased to understand that NAFTA will sunset when this agreement is ratified.

We are interested to learn more about Canada's status should Canada not come to an agreement with the US in time to ratify this agreement. Should this occur, would the "old" US/Canada FTA

become the operative instrument? Our preference would be that the "old NAFTA" remain the operative instrument strictly between the US and Canada for whatever period is necessary for Canada to come "on board" with NAFTA 2.0.

III. Brief Description of the Mandate of (Committee)

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

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

ITAC 3 stated its support for NAFTA and the potential for a renegotiated NAFTA in various ways during this charter term as well as the last. Our objectives and priorities are summarized as follows.

Our primary objective was to be sure that any re-negotiation of NAFTA does not harm the excellent trading relationship that has grown between the parties. We support the negotiating objectives in Trade Promotion Authority, including opposition to price controls.

We recommend that NAFTA remain a trilateral FTA. After twenty years, supply chains have developed that rely on the ability to achieve a dynamic interaction among the NAFTA partners.

Outlined below are provisions which ITAC 3 requested be included in a renegotiated NAFTA. These provisions are important to all of the sectors we represent. Each has a role in our ability *to*

grow, improve everyone's lives, make positive contributions to the U.S. economy, and create and sustain jobs in the United States.

Import Tariffs

U.S. exports to Mexico and Canada enjoy duty free treatment, and vice versa. ITAC 3 opposes any change in these market access provision.

Rules of Origin and Origin Procedures

Rules of Origin are of particular importance to the chemical industry and have evolved over the years. Whenever the U.S. enters a free trade discussion with one or more trading partners, the Congressionally mandated rule is that eventually all tariffs, with very limited exceptions must fall to zero for materials that meet "territorial origin" criteria. In general, the chemical industry believes that the KORUS rules of origin for our sector are the "gold standard".

The key to these rules is they are easy to understand and are based on a hierarchical sequence, beginning with a tariff shift test. If a product does not meet the prescribed tariff shift, there are additional rules that allow a company to prove preferential origin, without resorting to value content criteria. The chemicals sector strongly opposes value content criteria because they are difficult to administer, difficult to enforce, and easily distorted.

There are several sectors in our industry that are very sensitive to such rules. There was one significant change in the TPP rules that was very problematic for some of our members. This change removed the requirement that territorial colorants (classified in 3204 through 3207) be used to produce inks, paints and coatings that are also classified in chapter 32 (3208 through 3215) in order to attain preferential origin. If such inks, paints and coatings are shipped between the parties and do not meet this standard, then normal duty rates are applied. NAFTA was fully negotiated before we began our efforts to strengthen the Rules of Origin that impacted the use of color in the downstream commodities. Colorant producers need a chapter shift rule of origin for the top half of chapter 32 to give the remaining U.S. manufactures of these products a better shot at survival.

Additionally, the chemical industry supports harmonization of rules of origin across all preferential trade agreements. Since the KORUS rules are similar to most of the other FTAs that the U.S. has negotiated, making the NAFTA rules compatible with KORUS would go a long way towards meeting this goal. Interestingly, the previous administration negotiated an update to the Chemical rules of origin in NAFTA that accomplished many of these goals, which was never enacted. It therefore should not be difficult to reach a consensus with Canada and Mexico that KORUS style rules are appropriate for our sector.

There are two minor modifications that we would like addressed in the KORUS to benefit US manufacturing:

- 2106.90: Please adopt the TPP rules of origin, including the de minimis language.
- Chapter 34: Please amend the language to allow for a subheading shift for this chapter.

The Medical Technology sector opposes "tightening" the rules of origin criteria for medical technology products. More stringent criteria coupled with strict application of content

requirements, including in public hospital tenders for medical devices for example, can adversely affect a company's ability to sell products in the NAFTA markets. Stricter criteria could be particularly problematic for companies that source multi-component products from a combination of different countries to be manufactured as final products in the NAFTA region.

In addition, more stringent rules of origin requirements have the potential to impose significant compliance costs in the industry. Such costs might outweigh NAFTA benefits, leading to manufacturers foregoing any tariff preferences, especially since almost all medical technology enters the U.S. on an MFN duty-free basis.

Duty Drawback

Duty drawback allows for the refund of Customs duties that are imposed on imported goods that are used as inputs in the production of manufactured products that are later exported, or where the imported good is substituted for the same or similar good that is later exported. This allows U.S. specialty chemical manufacturers and exporters to reduce the cost of inputs, and thus reduce manufacturing costs and remain competitive in pricing their goods when exported. The policy rationale supporting duty drawback is as simple as it is powerful: to increase the competitiveness of U.S. manufacturers that export and to create and maintain U.S. jobs. Such provisions go back to the days of President George Washington.

NAFTA contains provisions that restrict duty drawback and duty deferral for goods exchanged between the U.S., Canada and Mexico. These rules allow the drawback claimant to receive only the lesser of (a) the duty paid on import of the finished good into the NAFTA partner; or (b) the duty paid on import of the input into the United States. All subsequent U.S. FTAs have no such restrictions on duty drawback and deferral. The result is that our U.S. manufacturers, workers and exporters are worse off when competing against Japan, China, India and other foreign competitors that can use these programs when exporting their goods to Mexico and Canada.

The NAFTA drawback and deferral restrictions must be repealed in order for U.S. exports to Canada and Mexico to be treated fairly, and to ensure that U.S. specialty chemical manufacturers, exporters and workers have the same export promotion programs fully available to them in order to compete on a level playing field with our trading partners and their competition.

Technical Barriers to Trade (TBT)

To address the challenge of non-tariff trade barriers, NAFTA should contain provisions that build on the WTO TBT Agreement. These improvements should ensure that standards-setting, conformity assessment procedures, and technical regulations are developed in a fair and transparent manner, with opportunities for "bottom-up" participation by stakeholders.

These provisions are designed to reduce unnecessary testing and certification costs and promote greater openness in standards development. They would call for governments to increase public participation in the development of technical regulations, standards, and conformity assessment procedures by government bodies. They should also require the parties to increase the transparency of government decision-making by publishing new technical regulations and

conformity assessment procedures, offering opportunities for public comment, and providing responses to substantive issues raised by comments.

TBT Medical Technology Annex

In as much as NAFTA is likely to serve as a precedent for future FTAs, we should seek a separate medical technology annex with the following regulatory provisions that would call on the parties to.

- improve the alignment of medical device regulations;
- consider relevant internationally-developed guidance documents when developing or implementing laws and regulations on the approval of medical devices;
- use a risk-based approach that distinguishes between classes of medical devices;
- base approvals solely on information related to safety, effectiveness, labeling, and design/manufacturing quality (and not pricing requirements);
- administer the approval process in a timely, reasonable, objective, transparent, and impartial manner; and
- allow decisions to be subject to an appeal process.

Regulatory Cooperation & Transparency

A more efficient and effective North American regulatory environment would provide a significant boost to innovation, growth and jobs, while ensuring that regulatory objectives are achieved to increase the overall health and safety for workers as well as end users of our products. For the chemical industry, a growing lack of regulatory coherence, particularly as governments amend or develop new chemical regulations, is increasing the costs of moving goods across borders. Likewise, for the medical device industry, redundant and increasing complex device approval processes add significantly to costs and slow the availability of important new technologies. The Parties should seek to improve alignment of their respective medical device and pharmaceutical products regulations and regulatory activities.

As tariffs and other "traditional" trade barriers are addressed, regulatory barriers to trade will become an increasingly important focus in future trade agreements. This is especially important issue for SMEs, for whom such growing regulatory costs represent a disproportionate burden.

In addition, a cohesive regulatory regime that is applied across all of North America would give the U.S. more weight in other international fora to fight for risk based regulations that are based on sound science rather than the hazards based approach that relies on the Precautionary Principle favored by the European Union.

Further, product safety is our industry's highest priority. In order to further this goal, we believe that NAFTA should incorporate the following:

- Sound science and a risk-based approach should serve as the basis for regulations that address hazard/risk analysis. International standards and scientific data should be

considered when developing new regulations. There should also be common approaches to risk assessment of chemicals in their respective regulatory frameworks.

- Manufacturers should have primary responsibility to assure the safety of products. Simple notification to authorities can be useful, but in-market supervision and enforcement is the most effective system of regulation.
- Approval processes should be transparent and equitable, with mutual recognition of other authoritative bodies' risk assessments and/or demonstrated safety based on history of use and within clearly defined timelines.

- Harmonization and/or mutual recognition/reliance of standards and regulations that provide the same level of protection needs to be a cornerstone of a new agreement.

- Regulations should avoid duplicative testing or approval requirements for products or ingredients that have already been evaluated based on sound science. Acceptance of a manufacturer's or supplier's Declaration of Conformity and one safety data sheet that is acceptable in all three countries will increase efficiency and reduce costs and strains on industry and government resources.

- Labeling regulations should be clear, concise and allow consumers to receive meaningful information about the safe use of products, while avoiding unnecessary requirements that provide little value to consumers. Labeling warning statements and contents should be aligned as closely as possible so consistent labeling can be used. For example: statements such as "See a doctor" in the US and "See a Health Practitioner" in Canada could be aligned to reduce the additional costs associated with creating a new label for the same meaning.
- Regulatory achievements made in the Regulatory Cooperation Council of Canada (RCC) and the High-Level Working Group for Mexico should be included. For example: aligned OTC monographs and GHS labeling requirements. An additional example could be extending the LCSA (TSCA reform)/CMP model for chemical regulation to Mexico. In doing so – the first step could be having Mexico adopt either the U.S. or Canada's chemical inventory instead of trying to compile their own.
- Mutual recognition of Good Manufacturing Practices (GMPs).
- Mutual recognition of pharmaceutical manufacturing facility inspections.
- Mutual recognition, aligned processes and common approaches for regulatory reporting requirements for the acceptance of new ingredients and new uses of chemical substances.
- Aligned definitions and nomenclature for ingredients and chemical substances as well as a common definition of filling tolerances in products that lose moisture would be very helpful.

Good Regulatory Practices – Medical Technology

We encourage the U.S. proposal to include a separate section which applies broadly to the development of regulations and other governmental decisions across the economy. This approach, similar to the U.S. Administrative Procedures Act, is designed to promote good governance through greater transparency, participation, and accountability in the development of

regulations and other government decisions. These provisions would go beyond NAFTA to require governments to promptly publish laws, regulations, administrative rulings of general application, and other procedures that affect trade and investment. They would also provide for policies that increase regulatory accountability and require evidence-based decision making. They should ensure opportunities for stakeholder comment on measures – and serious consideration of those comments by regulators – before they are adopted and finalized. Including such provisions in NAFTA would be an excellent foundation for other U.S. FTAs.

To be clear, these provisions are important to the medical technology industry because the development of regulations is always a work-in-progress in NAFTA members, as well as in most countries around the world. Having a sound foundation of good regulatory practices greatly helps structure improved regulatory systems for medical technology.

As an example of a specific regulatory issue, we urge that labeling regulations be clear, concise and allow consumers to receive meaningful information about the safe use of products, while avoiding unnecessary requirements that provide little value to consumers. Labeling statements and contents should be aligned as closely as possible so consistent labeling can be used.

Regulatory Conformity Assessment – Medical Technology

Medical technology products must be evaluated for safety and effectiveness in each of the three countries. Each country has a regulatory authority that oversees these requirements – U.S. FDA, Health Canada, and COFEPRIS. We believe all regulatory authorities could benefit from closer regulatory harmonization, which would reduce regulatory redundancy and industry's costs.

The United States and Canada are participating in a Medical Device Single Audit Program (MDSAP). ITAC 3 supports the MDSAP program, as it is being implemented in the context of the International Medical Device Regulators' Forum and believes it should be included in the NAFTA. The single audit program for quality management systems would reduce time and cost of inspection with a single audit rather than separate audits to satisfy each country.

We believe that the three NAFTA partners could go further and adopt a mutual recognition agreement, allowing mutual recognition of their respective approval procedures. The ultimate objective should be a single North American market, in which a medical device approved in one of the NAFTA partners are accepted in all. Recognizing that Health Canada and U.S. FDA are more advanced than COFEPRIS, there could be a transition period for the latter.

Transparency and Procedure Fairness (TPF) – Pharmaceuticals and Devices

Governments make decisions on whether to pay for specific products and, if so, the reimbursement levels for those products – i.e., the price the government is willing to pay, either directly or to the providers – for a specific device. In many cases, the government decision is not based on objective criteria but simply on a perceived need to save funds by cutting prices. Such decisions can adversely impact patient access and companies' ability to sell the product.

The purpose of a TPF chapter for medical technology is to give the manufacturer the opportunity to understand the basis for a reimbursement decision and to provide evidence to the government body making the reimbursement decision. Consistent with previous ITAC 3 positions, we should seek provisions that are designed to provide transparency to the process by which national (but not state or provincial) health care authorities in the NAFTA countries set reimbursement rates for medical devices at the national level. In the case of Mexico, these provisions should also apply to the Government's decisions about which products to list on its national formulary, as no national reimbursement rate is possible until the product is listed.

The NAFTA should also include as an objective that the value of the medical technology be taken into account and that market forces would be allowed to influence prices. However, the agreement would not require that covered products be reimbursed or that reimbursement be set at specific levels. It would simply provide for procedural transparency and general criteria.

The procedures should require that:

- Countries act within a reasonable time period in making reimbursement decisions;
- The rules they use to make these decisions are made public;
- Applicants can provide comments at appropriate times in the decision process;
- The basis for decisions is made available to the applicants; and
- An appeals process be available to the applicants.

Government Procurement – Pharmaceuticals and Devices

ITAC 3 supports a government procurement (GP) chapter that opens further the Mexican and Canadian markets. We believe such a provision is necessary not only for the NAFTA but also as a sound precedent for future U.S. FTAs.

A GP chapter should be based on the most recent U.S. FTAs – so that NAFTA is updated accordingly – and should: (1) allow NAFTA parties to participate actively in each other's government procurement purchases on a non-discriminatory basis; (2) ensure that government hospitals' procurement of medical technology is not excluded from coverage; (3) reduce the threshold to no greater than $7,700 for each contract (the current FAR threshold) for medical devices and diagnostic; (4) maintain the commercially available off-the-shelf items (COTS) flexibility; and (5) allow other services provided in the delivery of healthcare by any of the NAFTA parties, which Canada currently excludes.

We recognize that many U.S. states are concerned about expanding government procurement to foreign participation, and that states and provinces were not covered in the NAFTA (only in the WTO GPA). However, state governments purchase very little medical technology compared to the size of the U.S. market. Also, because medical technology tends to be purchased more by governments outside the United States than the U.S. government purchases here, the medical technology industry would greatly benefit from the U.S. precedent of comprehensive sub-federal level coverage.

Finally, we believe the NAFTA tendering procedures, which are generally good, could be updated to incorporate WTO Government Procurement Agreement provisions and along the following lines on the basis of new World Bank procurement principles:

- Ensure procurement opportunities are transparent and publicly accessible and stated in advance to prospective bidders;
- Enable the use of early market engagement with industry and key stakeholders (such as patient groups and physicians) in a process that is fair and transparent to identify the mechanisms best suited to address the particular problem and to ensure the procurement specifications are unbiased, fair and incorporate value for money principles;
- Ensure procurement specifications are appropriate to the particular technology and/or clinical issue to be addressed, and designated as high level as possible to ensure they do not inappropriately limit choice of technology or range of solutions;
- Ensure value for money concepts (such as health/clinical outcomes, life cycle costs, quality, training and other factors beyond initial purchase price or cost) are utilized in contract selection criteria and processes;
- Enable the use of expert panels in a transparent and fair manner in contract selection, when appropriate; and
- Enable post award performance monitoring of contracts as a mechanism to inform future procurements.

Investment

Investment protections are important in order for companies to create their global supply chains. For example, a firm might need to invest in R&D, local call or support centers, and manufacturing facilities in another country as a way to maximize efficiencies. If so, that firm should expect to be treated in a non-discriminatory way – either in terms of nationals of that country or other countries — and not be subjected to expropriation. In addition, it should be free to transfer its earnings out of the country. Similarly, the company should not have to use any specific percentage of domestic content or services. Finally, the firm providing the service should be free to determine its senior management and board in the other NAFTA parties.

The NAFTA contains provisions that should be preserved and probably updated for greater clarity. These provisions ensure that investment disputes are handled in a transparent and rules-based manner. They establish rules that provide basic protection against discrimination, such as requirements for national treatment (treatment no less favorable than a party country provides to its own investors or investments) and most-favored-nation treatment (treatment no less favorable than the party provides to another country's foreign investors or investments). These provisions also prohibit specified performance requirements, including local content requirements, export requirements, and technology transfer or technology localization requirements.

Services

Parties to the NAFTA commit to national treatment and schedule their cross-border services commitments on "negative list" approach — i.e., the sector is assumed to be covered unless it is

listed for exclusion under a "non-conforming measure (NCM). ITAC 3 supports this system, as it ensures the maximum liberalization over time. (medtech companies in ITAC 3 recognize that government procurement provisions are treated in a separate chapter of NAFTA.)

However, all of the NAFTA parties exclude medical services from their services commitments (as well as in the WTO) if the service is delivered as a social service for public purposes. This means that U.S. medical technology companies' protection under NAFTA's national treatment obligations is subject to debate: if they sell their healthcare services: (1) from the United States into the other NAFTA parties; (2) to a Mexican or Canadian in the United States; or (3) to a Mexican or Canadian who has a presence in Mexico or Canada.

Many medical technology firms provide some services with the sale of their products. For example, firms selling cardiovascular or orthopedic implants train physicians on the latest surgical techniques. Capital equipment manufacturers maintain and repair and/or train local representatives. Some firms provide credit financing for purchases of their products. These services are "traditional" in the sense that they are provided as part of the sale of the product. Temporary entry of business people would also appear to be under the Parties' NCMs, if the services are for "public purpose."

An increasing number of U.S. medical technology companies are combining the provision of a range of services and the sale of products. This "new" model involves the medical technology company providing services, some unrelated to the sale of a specific product (and which the company did not manufacture), with the objective of improving the efficiency of the hospital setting. Annex II provides an indicative list of the services companies might provide — all not directly tied to the sale of the manufacturer's own products. Some of these activities would involve visiting the foreign country (temporary entry) and some would require data transfers across borders.

NAFTA provisions should ensure that services can be provided under both the "traditional" and "new" models. However, given the ambiguity in the NCMs' terms (e.g., "public purpose") and governments' sensitivity about services in the healthcare sector, we recognize the difficulties involved in explicitly covering some healthcare-related services. A possible approach might be to indicate in the overall services commitments (i.e., not a separate healthcare chapter) the specific and limited types of healthcare-related services that could be covered — i.e., a positive list of non-exclusions to the NCMs. Of course, whatever services covered under the NAFTA would have to conform to the regulations and standards in the receiving NAFTA party and not in any way undermine safety and effectiveness requirements.

Medical technology firms represented on ITAC 3 recognize that some ambiguity might be a better approach than precise clarity, as the latter might force a government to be more restrictive in the NAFTA than otherwise. If companies are not experiencing problems selling their goods and services, seeking specific NAFTA provisions might highlight and cause concerns about practices that would otherwise be implicitly permitted. We would welcome the opportunity to work with USTR on the most effective way to introduce some degree of security for their services under NAFTA.

Trade Facilitation

Our members are highly supportive of any efforts that can be made to facilitate trade. It is important to do everything possible to shorten the time it takes to cross the border, especially in Mexico where there is a long history of theft and damage while trucks sit in long lines or are parked awaiting their turn to cross the border.

ITAC 3 recommends that the U.S. should pursue a WTO Trade Facilitation Agreement "plus" approach to customs and trade facilitation efforts under a modernized NAFTA. This includes:

- updating paper filing and auditing requirements to allow for electronic filing and digital signature;
- establishing mechanisms to provide for the free flow of cross-border data;
- targeting infrastructure projects to remove bottlenecks on the movement of exports (e.g. Michigan-Ontario bridge, cross-border pipelines);
- modernizing transport security requirements to allow for the same drivers or single forms of transport across borders;
- harmonizing clearance procedures within NAFTA, e.g. information required, and standardizing documents such as CBP434;
- expanding the unified cargo processing program between the U.S. and Mexico;
- unifying low value shipment criteria to minimize inconsistencies across members;
- extending the validity period of blanket certificates beyond one-year – three (3) years would be advantageous especially if the originating process is static;
- instituting a pre-clearance pilot program to increase border crossing TIP.
- promoting efforts to ensure that digital documentation is accepted on both sides of the border.
- Establish a trusted trader program to expedite crossings for no/low risk shippers.
- Publication of Laws, Regulations, and Procedures – importance of publishing customs laws, regulations, and procedures online and, if possible, in English.
- Release of Goods – committing to ensure that goods move through borders as quickly as possible, and, to the extent possible, are released within 48 hours of arrival.
- Advance Rulings – require NAFTA partners to provide decisions on key customs matters, including customs valuation, before goods are shipped. Also includes commitments to issue rulings no later than 150 days after receiving a request, with rulings remaining in place for at least three years.

- Express Shipments – requires expedited customs treatment to express shipments, including streamlined documentation and timely release of goods.

- Penalties – requires customs penalties to be administered in an impartial and transparent manner – as they are in the U.S. – and requires countries to avoid conflicts of interest in administering penalties.

- Customs Cooperation – promotes assistance between TPP countries to enforce customs laws and regulations.

Intellectual Property Rights & Data Protection

ITAC 3 supports the goal of modernizing NAFTA to ensure broad, effective and balanced intellectual property protections and enforcement regimes that reflect U.S. IPR standards.

ITAC 3 members representing the interest of Innovative Biopharmaceutical companies view NAFTA modernization as an excellent opportunity to resolve outstanding NAFTA implementation issues, including data protection in Mexico and the promise doctrine in Canada. Furthermore, it should provide an opportunity to improve all biopharmaceutical IPR standards, including data protection for biologics in Mexico and Canada similar to U.S. standards. This should be a primary objective of modernizing NAFTA.

ITAC 3 members representing the interest of the generic and biosimilars companies, view NAFTA modernization as an excellent opportunity to resolve outstanding NAFTA implementation issues – specifically IPR standards, including data protection for biologics, patentability, patent term linkage, and patent linkage/early dispute mechanism. These issues were effectively addressed and agreed to by the U.S., Canada and Mexico during the TPP negotiations; and as such, should be the standards adopted during the NAFTA negotiations.

It is important to the producers of agricultural chemicals that NAFTA be updated to include 10 years of data exclusivity and protection. This provision was part of the TPP, and all of our other FTAs post NAFTA, it hopefully should not be difficult to include such provisions in a revised NAFTA.

"PEMEX" Exclusion

When NAFTA was negotiated, a broad sector of the Mexican economy was protected by the PEMEX exclusion. This exclusion includes many basic petrochemicals. While Mexico is not currently collecting tariffs based on any of these materials, we strongly believe that this exception should be deleted from a revised NAFTA so that they could not revert to this practice in the future.

State Owned Enterprises

NAFTA reform should leverage established principles in recent trade negotiations to establish enforceable, transparent, market based mechanisms for disciplining State-Owned Enterprises (SOEs). Principles should include coverage, nondiscriminatory treatment, transparency,

immunity & impartial recovery, noncommercial assistance and enforceable dispute settlement mechanisms.

Digital Economy

A revised NAFTA needs to enshrine principles of open cross boarder data flows. Our sectors have a vested interest in the safety and security of cross boarder data transmission. Data includes employee information for development purposes; technical data for customers and business process operations; and customer data to promote global innovative relationships.

Medical technology firms and Pharmaceutical providers understand the sensitivity of private data and the need to protect privacy. In addition, confidential clinical data and proprietary business information must be protected. At the same time, the most efficient means to provide expert advice might be by sending data across borders – which is especially the case as healthcare relies more on "big data" and medical devices and diagnostics become even more connected to the cloud. The balance between smooth flow of data and protection of personal privacy should be struck in a way that allows efficiency and patient-centered outcomes to be realized in NAFTA.

Anti-Corruption

The NAFTA should contain robust and detailed provisions to combat corruption and support the rule of law. These provisions should discourage corruption including through enforcement of domestic anticorruption laws and regulations as well as through international anticorruption efforts. They should also call for the establishment of codes of conduct to promote high ethical standards among public officials.

V. <u>Advisory Committee Opinion on Agreement</u>

Chapter 1: Initial Provisions: no comments

Chapter 2: National Treatment and Market Access for Goods

We are very pleased that this agreement maintains duty-free treatment for originating goods – a high priority for many ITAC 3 members.

However, we are very disappointed that this agreement continues NAFTA's restrictions on the use of duty drawback on manufactured goods. NAFTA is the only US FTA that has such restrictions. In some instances, restricting duty drawback can inhibit our ability to export goods to either country, especially in instances where they have a lower third-party duty than ours on components that need to be imported from outside the region. Removing these restrictions was one of our "key asks" for this negotiation. This will be especially painful for US manufactures that are required to pay special 301 duties on imported products only available from China.

Chapter 3: Agriculture: no comments

3a: Proprietary formulas for packaged goods: no comments

3b: Beverage Annex: no comments

Chapter 4: Rules of Origin: Looks good except 7% is a very low minimum content level.

4a: The Chemical Rules of Origin

The Chemical Rules of Origin are very well done. They are simple and easy to understand and satisfy many of the concerns of the Chemicals Sectors in our ITAC. While we would have preferred that there be no mention of value content in our sector, the fact that the process rules were included in this agreement negates any issues we might have otherwise had with the inclusion of value content rules. However, we are disappointed that the agreement does not include our previous request to increase the de minimis content allowance from seven to ten percent.

There is one area that needs to be clarified. There are significant restrictions on the application of the Biotechnological process rules that could be problematic for our sector since it restricts the use of this rule in 2930 – 2942 as well as chapter 30. These restrictions would likely include most pharmaceutical active ingredients as well as anything consider a finished pharmaceutical. As we understand it, the Chemical Reaction rule contains a note that it includes Biotechnological processes. Normally in an agreement of this type, rules are "hierarchal", meaning that a rule with a higher number takes precedent over a rule with a lower number. It is our understanding that in this agreement, the Chemical Rules are not "hierarchal" and therefore each process rule "stands on its own". If this is the case, if the Chemical Reaction rule is met, then the resulting product would be territorial. Since it is not easily understood that these rules are not "hierarchal", it would be useful of there was a side note to confirm our understanding.

Chapter 5: Origin procedures

We are pleased that the agreement includes multiple methods of conferring origin, including the ability for the importer to meet this requirement. It is also useful that such a certificate of origin can be produced in a format appropriate for the individual producing the certificate, including in electronic format. It is also especially useful that the agreement allows for advanced rulings on origin.

Chapter 6: Textiles and Apparel: no comments

Chapter 7: Customs and Trade Facilitation

We are pleased the agreement includes obligations designed to minimize costs incurred by traders and enhance cross-border transactions by streamlining customs procedures and increasing transparency. We wish to highlight two helpful provisions within this chapter:

- A change in Article X.8 that increases Mexico's de minimis shipment value level for low-value shipments from U.S. $50 to U.S. $100. Customs entries at or below this threshold would be exempt from duties and taxes, and subject to minimal entry requirements; and

- The requirement in Article X.10 for Parties to establish, no later than Dec. 31, 2018, a single-window system to enable electronic submissions through a single entry point of customs documentation and data required by each Party for importation into their countries. This will greatly enhance trade by streamlining customs procedures, simplifying data requirements, and reducing border delays.

Chapter 8: Energy: no comments

8a: Energy Performance Standards: no comments

Chapter 9: Sanitary and Phytosanitary Measurers

We applaud the fact that the parties agreed to use science-based rules and a reliance on international standards where possible. We also strongly support the concept of transparency in all agreed upon SPS measures and the use of the principle of "proposal and comment" for all new SPS regulations. We do wish clarification of certain articles within this chapter, including:

- Article 9.5 List of competent authorities: Aside from the international organizations referenced (e.g. WHO or IPPC) what other relevant organizations will be involved in SPS regulation (e.g. COFEPRIS, SEMARNAT, EPA)? Specific U.S. and Mexican based organizations involved with these measures should be identified within this section.
- Article 9.9 Equivalence: How will this be enacted? Whose SPS Measures will be used as the standard for comparison purposes?
- Article 9.17 Formation of Committees: We support the formation of joint SPS committees similar to the current NAFTA Working Group. Will industry have a seat on this committee? Who will comprise this committee and what will be the ultimate purpose of this committee? Will they have the authority to enact change in the current process?
- We assume SPS Measures apply to agricultural and biocidal regulatory processes. It would be helpful if a glossary of key terms was provided at the beginning of this chapter to ensure clarity of regulation and what industries are affected.

Chapter 10: Trade Remedies: no comments

Chapter 11: Technical Barriers to Trade

Our members strongly support the inclusion of provisions aimed at strengthening collaboration in the development of technical regulations, standards, and conformity assessment procedures to reduce potential non-tariff trade barriers. We note that a significant accomplishment is agreement on a provision requiring the Parties to give national treatment to other Parties' conformity assessment bodies.

The Technical Barriers to Trade chapter, together with the Chapter on Good Regulatory Practices, is an essential component of meaningful 21st Century trade agreements to minimize regulatory and non-tariff barriers including those related to standards and conformity assessment. To address the challenge of non-tariff trade barriers, the NAFTA 2018 contains provisions to ensure that standards-setting, conformity assessment procedures, and technical regulations are

developed in a fair and transparent manner, with opportunities for "bottom-up" participation by stakeholders.

They require NAFTA countries to increase the transparency of government decision-making by publishing new technical regulations and conformity assessment procedures, offering opportunities for public comment, and providing responses to substantive issues raised by comments. The NAFTA 2018 significantly deepens the requirements to more fully implement acceptance of international standards irrespective of the source. These provisions are designed to reduce unnecessary testing and certification costs and promote greater openness in standards development.

Chapter 12: Sectoral Annexes

12a: Information and Communication Technologies: no comments

12b: Pharmaceuticals

The Pharmaceutical Sectoral helpfully requires Parties to better coordinate inspections of pharmaceutical inspections with respect to manufacturing surveillance. In addition it requires marketing authorization decisions to be based on safety, efficacy and quality information and prevents use of sales, pricing and other economic data information in those decisions.

12c: Medical Devices

We consider the medical device section of this agreement to be a break though in terms of regulatory harmonization. If this language becomes the template for future bi-lateral agreements this will be a major step forward for SME's dealing with parochial, country specific approval processes.

At the outset of the negotiations, industry provided the U.S. government with recommendations to serve as the basis for the U.S. position. We are pleased that the U.S. government was successful in securing the inclusion of almost all industry priorities in the regulatory annex of the agreement, with the exception of preventing re-registration requirements. The NAFTA 2018 goes further than our initial requests by including a provision on the Medical Device Single Audit Program, which will help harmonize audits among NAFTA participants. This is the first-time provisions on regulatory commitments to the approval process are included in a U.S. trade agreement.

One of our members is concerned that small and especially micro-sized medical device industries have expressed concerns with using MDSAP, due to its much higher costs. It would be preferable for Mexico and the United State to adopt the initiative for internationally accredited ISO 13485 certification, especially since the US FDA has indicated it will be replacing its quality system regulation (Part 820) with international standard ISO 13485.

As Mexico is not an IMDRF member they cannot participate in MDSAP related activities. Mexico is however engaged with the Inter-American Accreditation Cooperation, which has

recently signed a multilateral recognition arrangement to support ISO 13485, which is also aligned with Accreditation Bodies operating in the United States, Europe and Asia. The NAFTA agreement should strengthen use of internationally accredited ISO certificates, whenever they are used for regulatory purposes.

Key regulatory provisions include:

- improving the alignment of medical device regulations;
- considering relevant internationally-developed guidance documents when developing or implementing laws and regulations on the approval of medical devices;
- using a risk-based approach that distinguishes between classes of medical devices;
- basing approvals solely on information related to safety, effectiveness, labeling, and design/manufacturing quality;
- administering the approval process in a timely, reasonable, objective, transparent, and impartial manner; and
- allowing decisions to be subject to an appeal process.

12d: Cosmetics

We are pleased to see that the Administration understands the increasing complexity of trade barriers that are impacting the cosmetic industry globally. By creating a sectoral annex in NAFTA, a precedent for future trade agreements will be created that will enhance future trade negotiations. The current annex strengthens the current practices followed by the U.S. and Mexico today and will help ensure that the industry will continue to thrive between the two countries. We would hope that the language that remains in brackets can be finalized and an agreement can be reached with Canada to achieve harmonization in those products that are at the interface of cosmetics and drugs.

12e: Chemical Substances

We believe it is vitally important for this agreement, as well as NAFTA (assuming Canada's support), to endorse a science- and risk-based approach to regulation. We are really pleased that this agreement includes this chapter and hope it will lead to science- and risk-based regulatory coherence between the Parties for chemicals and chemical substances.

US/Mexico side letter on Auto Safety Standards

Chapter 13: Government Procurement: no comments

Chapter 14: Investment

<u>Investment/Local Content Requirements</u>

The NAFTA 2018 contains an extensive set of provisions to ensure the fair treatment of companies that invest in NAFTA 2018 countries. These provisions ensure that investment disputes are handled in a transparent and rules-based manner. They establish rules that provide

basic protection against discrimination, such as requirements for national treatment (treatment no less favorable than a NAFTA 2018 country provides to its own investors or investments) and most-favored-nation treatment (treatment no less favorable than a NAFTA 2018 country provides to another country's foreign investors or investments). These provisions also prohibit specified performance requirements, including local content requirements, export requirements, and technology transfer or technology localization requirements.

The investment provisions also:

- provide basic protections against uncompensated expropriation of property so that property may not be seized by a government without the payment of just compensation;
- prevent denial of justice, by which Americans could be denied basic due process in criminal, civil, or administrative proceedings abroad;
- allow for the transfer of funds related to an investment covered under the Agreement, with exceptions to ensure that governments retain the flexibility to manage volatile capital flows;
- ensure that investors have the ability to appoint senior managers without regard to nationality, and that nationality-based restrictions on the appointment of board members do not impair an investor's control over its investment; and
- put in place strong safeguards to raise the standards around investor-state dispute settlement, for example by discouraging and dismissing frivolous suits and by making proceedings more transparent.

Annex D: no comments

Annex E: no comments

Chapter 15: Cross Border Trade in Services: no comments

Chapter 16: Temporary Entry: no comments

Chapter 17: Financial Services: no comments

Chapter 18: Telecommunication: no comments

Chapter 19: Digital Trade: no comments

Chapter 20: Intellectual Property

Overall, ITAC-3 members representing the interest of Innovative Biopharmaceutical companies generally support the IP section of this Agreement because it would raise the bar in Mexico and Canada on issues relevant to the sector. Our members seek and continue to believe that a twelve-year term of regulatory data protection for biologics, as found in U.S. law, is the appropriate standard internationally. We recognize, however, that the enforceable ten years recited in this Agreement would improve the situation in both Mexico and Canada and are materially better than the outcome achieved in TPP. In addition, the definition of biologics to which the ten-year term would apply is materially better in this Agreement than the definition of biologics in

TPP. Finally, the Agreement makes clear that patents must be granted for new indications when standard patentability criteria are met, an outcome that also will improve the IP environment, particularly in Mexico.

It is important that the agreement requires Parties to implement measures that give patent holders adequate opportunities to secure remedies before biosimilars or generic products are marketed or approved for marketing based on an innovator's safety and efficacy information and separately requires patent term adjustment for marketing approval delays. Timely and complete implementation, including meaningful opportunities for industry to express views on implementation will be critical.

ITAC membership representing the interests of generic medicine and biosimilar manufacturers believes that the provisions in the IP chapter extending monopoly protection for innovative biologics to ten years will slow development of biosimilars for use in the U.S. and will thus decrease the ability of biosimilars to decrease prescription drug prices in the U.S. Moreover, the IP chapter is not adequately balanced between encouraging innovation while promoting access to medicines as required by the Bipartisan Congressional Trade Priorities and Accountability Act of 2015.

We are also very pleased that this agreement includes 10 years of data protection for pesticides.

20a: Medpharma Annex

<u>Transparency and Procedural Fairness for Medical Device Reimbursement</u>

The NAFTA 2018 agreement includes provisions for procedural fairness in medical device reimbursement. These provisions are designed to provide transparency to the process by which national (but not state or provincial) health care authorities in the NAFTA member countries set reimbursement rates for medical devices.

The procedures require that countries act within a reasonable time period in making reimbursement decisions, that the rules they use to make these decisions are made public, that applicants can provide comments at appropriate times in the decision process, that the basis for decisions is made available to the applicants, and that an appeals process be available to the applicants.

While these procedures will benefit industry, they fall short of our initial recommendations, which were aligned with the Korea-US FTA. Under the NAFTA 2.0, participants indicate in their accompanying schedules whether their medical devices reimbursement system meets the NAFTA criteria -- national healthcare system with national reimbursement of medical devices.

<u>Transparency and Procedural Fairness for Pharmaceutical and Medical Device Reimbursement</u>

The NAFTA 2018 agreement includes provisions for procedural fairness in pharmaceutical and medical device reimbursement that are important for trade policy and precedent. These provisions are designed to provide transparency to the process by which national (but not state or

provincial) health care authorities in the NAFTA member countries set reimbursement rates for medical devices.

The procedures require that countries act within a reasonable time period in making reimbursement decisions, that the rules they use to make these decisions are made public, that applicants can provide comments at appropriate times in the decision process, that the basis for decisions is made available to the applicants, and that an appeals process be available to the applicants.

While these procedures will benefit industry, they fall short of our initial recommendations, which were aligned with the Korea-US FTA. Under the NAFTA 2.0, participants indicate in their accompanying schedules whether their pharmaceutical and medical devices reimbursement system meets the NAFTA criteria -- national healthcare system with national reimbursement of medical devices. We note that Mexico did not declare any national authorities that meet the NAFTA definition. We believe the following Mexican Authorities meet this definition: The Mexican Social Security Institute (ISSSTE); The Mexican Civil Service Social Security and Services Institute (ISSSTE); National Social Protection System for Health (Seguro Popular). While we recognize the text does not preclude use of the provisions of this annex even without this specific list, for greater clarity we would have preferred including these authorities.

Chapter 21: Competition Policy: no comments

Chapter 22: State Owned Enterprises

The NAFTA includes rules to ensure that private sector businesses and workers are able to compete on fair terms with state-owned enterprises (SOEs), especially when such SOEs receive government backing to engage in commercial activity. SOEs are increasingly competing with U.S. businesses and workers on a global scale, in many cases distorting global markets and blocking U.S. exports with cheap subsidies and preferential regulatory treatment.

Specifically, the agreement ensures that:

- SOEs make commercial purchases and sales on the basis of commercial considerations;
- SOEs that receive subsidies do not harm U.S. businesses and workers; and
- SOEs do not discriminate against the enterprises, goods, and services of NAFTA members.
- It also establishes rules that will provide transparency with respect to SOEs.

Chapter 23: Labor: no comments

Chapter 24: Environment

We recognize and support the inclusion of enforceable environmental obligations, including first-ever articles aimed at improving air quality, preventing and reducing marine litter, supporting sustainable forest management, and ensuring appropriate procedures for environmental impact assessments.

Chapter 25: Small and Medium Enterprises

The NAFTA includes the first-ever chapter in a U.S. free trade agreement specifically designed to address issues that create particular challenges for SMEs. We support the establishment of a new Committee on Competitiveness to promote further economic integration among the Parties, including facilitating regional trade and investment, enhancing a predictable and transparent regulatory environment, and encouraging swift movement of goods throughout the region.

These are general provisions and are not specifically aimed at the medical device industry. Nonetheless, they could prove helpful to small and medium-sized companies looking to export to NAFTA members and as a good example for other FTAs.

The SME provisions are designed to:

- streamline complex technical and administrative barriers that make it hard for small businesses to access new markets;
- promote digital trade and internet freedom to ensure that small businesses can access the global marketplace;
- help small businesses integrate into global supply chains;
- make it easy for SMEs to access to information on utilizing free trade agreements – a problem that SMEs have identified as a disproportionate challenge for them; and
- review how well SMEs are availing themselves of the benefits of NAFTA and consider recommendations on ways to further enhance the benefits of NAFTA for SMEs.

Chapter 26: Competitiveness

We support the inclusion of high-level provisions aimed at promoting further economic integration among the Parties by incentivizing production in the region, facilitating regional trade and investment, enhancing a predictable and transparent regulatory environment, encouraging the swift movement of goods and delivery of services, and responding to market developments and emerging technologies. Further, the inclusion of language to ensure that interested parties have regular opportunities to give input on issues related to enhancing competitiveness is very consistent with the goals and objectives of other chapters in the agreement related to promoting regulatory compatibility and transparency, as well as ensuring sufficient stakeholder engagement.

Chapter 27: Anticorruption

We support this Chapter. The NAFTA 2018 contains robust and detailed provisions to combat corruption and support the rule of law. These provisions seek to discourage corruption including through enforcement of domestic anticorruption laws and regulations as well as through international anticorruption efforts. They also call for the establishment of codes of conduct to promote high ethical standards among public officials.

Chapter 28: Good Regulatory Practices

We applaud USTR's efforts to address regulatory and technical barriers to trade in the agreement – specifically, implementing government-wide practices to promote regulatory quality through greater transparency, objective analysis, accountability, and predictability. We are very pleased to see that among the chapter's provisions are obligations to publish an annual list of anticipated new regulations and to initiate retrospective reviews of existing regulations, as well as provisions encouraging the Parties to make public comments on regulatory proposals publicly available and to use regulatory impact assessments.

The inclusion of these provisions in the final NAFTA 2018 agreement will provide substantial benefits for the medical device industry and should be considered a significant win.
The GRP Chapter contains provisions which apply broadly to the development of regulations and other government decisions across the economy. The Chapter is designed to promote good governance through greater transparency, participation, and accountability in the development of regulations and other government decisions. These provisions require governments to promptly publish laws, regulations, administrative rulings of general application, and other procedures that affect trade and investment. It also provides opportunities for stakeholder comment on measures before they are adopted and finalized. These provisions apply to all NAFTA parties.

The inclusion of these provisions in the final NAFTA 2018 agreement will provide substantial benefits for the medical device industry and should be considered a significant win.

Chapter 29: Publication and Administration: no comments

29a: Energy Regulatory Practices: no comments

Chapter 30: Administrative Institutional Provisions: no comments

Chapter 31: Dispute Settlement: no comments

Chapter 32: Exceptions & General Provisions: no comments

NME: no comments

Chapter 33: Macroeconomic & Exchange Rate Matters (Currency)

We are very pleased that this agreement includes this chapter as it is important that our trading partners not unfairly impact trade by manipulating their currency exchange rates.

Chapter 34: Final Provisions

The fact that this agreement has a 16-year term with a review meeting after 6 years is helpful to be sure that it is serving its purposes effectively. Our members believe this compromise appropriately responds to business community concerns about certainty and predictability in trade agreements, while ensuring timely review by the Parties at regular intervals.

Non-Conforming Measurers: no comments

Annex I & II: Consolidated Explanatory Notes: no comments

Annex III: Consolidated Formatting Notes: no comments

Annex III: Canada: no comments

Annex III: Mexico: no comments

Annex III: United States: no comments

VI. Membership of Committee

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

Mr. Adrian Krygsman, Vice Chair
Director, Product Registration
Troy Corporation

Mr. A.E. (Ted) May, Vice Chair
V.P. & General Manager
Andersen Products

Ms. Suzanne A. Bullitt
Director, Global Trade Strategy
Eastman Chemical Company

Mr. Harrison C. Cook
VP, International Government Affairs
Eli Lilly and Company

Mr. Donald E. Ellison
President
Government Relations LLC

Michael A. Fitzpatrick, Esq
Head of Regulatory Advocacy
GE Legal-Government Affairs & Policy

Mr. David R. Gaugh
Senior VP, Science & Regulatory Affairs
Association for Accessible Medicines

Mr. Edward Gibbs
Chief Executive Officer
North Coast Medical Equipment, Inc,

Mr. Vijay Goradia
Chairman
Vinmar International, Ltd.

Trevor J. Gunn, Ph. D.
Founder & Chairman
USA Healthcare Alliance, LLC

Mr. Ralph F. Ives
Executive VP, Global Strategy & Analysis
Advanced Medical Technology Association

Mr. Tonya L. Kemp
Senior Principal, Regulatory Policy
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Mr. Richard H. Ljeldgaard
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Mr. Paul A. Neureiter
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Amgen, Inc.

Mr. Christopher P. Pearce
Director, Government Relations
S. C. Johnson & Son, Inc.

Mr. Grant Ramaley
Director of Regulatory Affairs
Aseptico, Inc.

George L. Rolofson, Ph. D.
Consultant, Representing
Gowan Company

Mr. Richard I. Sedlak
EVP Technical & International Affairs
American Cleaning Institute

Mr. Kevin J. Tierney
Import Export Manager
IDEXX Laboratories, Inc.

Harry L. Vroom, Ph.D.
VP, Economic Services
The Fertilizer Institute

Mr. Thomas G. Zieser
President
JACE Systems

We really appreciate this opportunity to present our views on this important agreement. Please let us know whenever there is a chance that ITAC 3 might be of service.

Very truly yours,

V.M. (Jim) DeLisi

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

cc: Honorable Wilbur R. Ross
Secretary of Commerce