AdvaMed
Advanced Medical Technology Association

COMMENTS REGARDING
THE ADMINISTRATION'S REVIEWS AND REPORT TO THE PRESIDENT
ON TRADE AGREEMENT VIOLATIONS AND ABUSES

Response to Docket Number USTR-2017-0010

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide the views of our members in response to the Federal Register (FR) notice seeking Comments Regarding the Administration's Reviews and Report to the President on Trade Agreement Violations and Abuses, USTR-2017-0010, Document number 2017-13610. We understand that USTR is seeking comments regarding the countries with which the United States has a trade agreement (Free Trade Agreement (FTA), Bilateral Investment Treaty (BIT), or some other trade relationship (e.g., preference program.)) The FR notice also seeks views on the performance of countries with which the Unites States does not have an FTA but trades under the rules of the World Trade Organization (WTO).

Our written comments are set out below. We are focusing our comments on FTAs in general, specific provisions in FTAs, and the function of the WTO. The Harmonized Tariff System numbers that cover our industry are included in the Annex I, and our aggregate trade with key trading partners is listed in Annex II. We would be pleased to respond to questions.

AdvaMed General Trade Policy

AdvaMed continues to endorse policies that open foreign markets and enact fair and predictable rules. Over 60 percent of the global medical technology market is outside the United States. Opportunities are good for further sales growth in foreign markets due to aging populations and rising needs in the largest markets of Europe, Japan and China, as well as many emerging markets. U.S. companies rely on dynamic global supply chains to manufacture and deliver products to patients in these markets. These supply chains allow manufacturers to operate closer to customers, better manage geographic risks, and provide benefits to customers and shareholders alike in the form of greater operating efficiencies.

The medical technology industry, an American success story, is responsible for nearly 2 million high-paying U.S. jobs and 9,800 manufacturing facilities, across the 50 states. Our industry's wages are an average of 30% above those of other manufacturing jobs. We are a research intensive industry, with some members spending as much as 20 percent of revenue on R&D to provide patients the most innovative technologies and to compete in a highly competitive global market. Our industry is the clear world leader and is one of the few manufacturing industries that has consistently run a U.S. trade surplus, with exports of almost $51 billion in 2016, and imports approaching $50.3 billion.

AdvaMed Position on Trade Agreements

WTO

AdvaMed supports U.S. trade-opening initiatives. The multilateral agreements reached under what is now the WTO, dating to the General Agreement on Tariffs and Trade (GATT) in 1948, have provided the foundation for stable global trade rules. Each successive "round" of multilateral trade negotiations expanded coverage of those rules and enabled trade to flourish among nations, culminating in the Uruguay Round (1986-94).

The agreements coming out of the Uruguay Round involved highly complex issues, including the Dispute Settlement Understanding (DSU). Under the DSU, the losing country to a WTO trade dispute has three options: (1) comply by changing its offending trade measure; (2) negotiate trade compensation acceptable to the winning country; or (3) refuse to comply, which allows the winning country to impose trade retaliatory action – e.g., increase tariffs on imports from the losing country. It is this last threat that often "forces" compliance.

AdvaMed supports the concepts of compliance embodied in the DSU but has concerns about its application. On the positive side, the threat of a potential WTO case against another trading partner can be used effectively to change discriminatory policies. However, an actual case involving the full process can take several years and is of questionable value for companies in the industry even if the outcome is favorable – as the offending party can continue to delay policy changes, and the firms in the industry receive no compensation. In addition, the government of the offending country sometimes threatens retaliatory action against the complaining industry.

We recommend changes that at least expedite the process. The DSU includes procedural timelines. The United States should push for those timelines to be met. There might be other improvements that can be made without renegotiation (which seems to be a political non-starter).

The WTO's fundamental problem is that world trade, and governments' involvement in trade within and outside their borders, have changed almost beyond recognition in the 25 years since the Uruguay Round concluded. Countries with no or little industry in the 1980s now have competitive power-houses. Some countries are much more sophisticated in the way they manage trade. Localization requirements have become much more prevalent.

Renegotiating provisions of the WTO does not appear to be feasible. The Doha Development Agenda failed after over a decade of effort. U.S. market access is so open that there are few concessions remaining to use as leverage. Most other countries seem content with the *status quo.*

The USTR should consider using the Chapter on Technical Barriers to Trade (TBT) more aggressively under certain circumstances. The TBT's core provisions of non-discrimination, non-imposition of "unnecessary obstacle" and regulations being no "more trade-restrictive than necessary" are sound principles. We suggest below how these provisions could be strengthened in U.S. FTAs and offer an example in KORUS that illustrates the TBT limitations even in an

FTA. Without trying to renegotiate this specific chapter of the WTO, we recommend that USTR interpret it more broadly and without being intimated by potential defensive concerns.

This interpretation would complement GATT Article III:9, which explicitly recognizes the prejudicial effects price controls can have on exporting countries. We are not advocating that USTR attack all manner of price controls – as that would likely provoke backlash. However, there are cases in which U.S. export interest severally suffers. For example, some governments implement price controls that drive prices so low that higher value and more R&D intensive medical devices and diagnostics cannot compete against products that are manufactured without such added costs at artificially low prices. Such measures are discriminatory against high-value medical devices and would appear to be "more restrictive than necessary" to achieve many governments' goals of improved patient care and lowering overall healthcare costs.

Furthermore, when countries like India insist that price-controlled products remain on the market, the manufacturer's intellectual property (IP) rights are undermined. The cost of developing the product often involves creating new IP. Forcing sales devalues the IP.

On a positive note, AdvaMed would support additional negotiations in the WTO that benefit our industry. For example, the Information Technology Agreement, involving over 50 countries, resulted in the elimination of tariffs on $10 billion of U.S. medical technology exports.

FTAs: General Provisions

The United States needs to conclude more FTAs to begin to bring the rules of global trade into the 21st century. The medical technology industry's supply chains are global. Governments need to recognize that our industry cannot invest in every country and, therefore, should not impose discriminatory measures that try to force domestic production. FTAs are effective mechanisms to deepen and expand disciplines of potentially discriminatory practices.

Our industry continues to face a wide array of barriers in overseas markets. We believe well-crafted FTAs can help knock down these obstacles, including:

- ***Localization:*** Governments impose requirements on companies to invest in their countries as a condition for market access.

- ***Regulatory:*** Governments use their approval procedures to delay or prevent foreign medical technology from gaining market access.

- ***Procurement:*** Governments increasingly purchase medical technology, using opaque procedures that artificially control prices driving out higher value innovative products or otherwise limit the ability of U.S. medical technology companies to compete - often preferring domestic products and sometimes even banning foreign products from being purchased.

- ***Other Measures:*** Governments impose a variety of other policies that impede market access, including local standards, burdensome customs clearance procedures, high

import duties, artificial price ceilings, unnecessary regulations, and arbitrary and discriminatory enforcement of anti-corruption or anti-monopoly laws.

Future provisions in FTAs – whether new agreements or renegotiated current agreements – should address these major issues. When doing so, we recommend the following general principles and some specific provisions.

(1) **Clarity:** FTA provisions should be unambiguous in their intent. While negotiators sometimes claim they need to resort to "softer" formulations in order to obtain agreement, this short-term victory often fades when the FTA partner is called upon to implement the obligation. At that point, compliance with the ambiguous text must depend on the good graces of the potentially offending partner.

(2) **Dispute Settlement:** All provisions should be subjected to the disciplines of dispute settlement. Excluding some provisions from this process gives them lesser weight and the impression that they can be ignored. While some commitments in an FTA are procedural – and, thus, the remedy would be to correct the process foul – this should not excuse the provisions from the potential for a formal dispute.

(3) Good Regulatory Practices: All FTAs should include provisions that require trading partners to implement regulations in a way that provides adequate notice and comment. The U.S. Administrative Procedures Act is an excellent model but need not be cited as the FTA objective but its core elements should be included. This foundation would improve the formulation of regulations to which the private sector must adhere.

(4) Technical Barriers to Trade: As noted above, the WTO TBT Chapter includes sound principles. However, such text cannot unambiguously cover all of the ways governments can impose overly restrictive or discriminatory trade barriers. The onus appears to be on the government (and, hence industry) alleging harm to demonstrate that other means can achieve the same regulatory results. We recommend in FTAs changing the burden of proof to the government imposing the regulations that no other feasible alternative could be implemented to achieve the desired level of protection (e.g, safety or public health) than the one imposed. For example, China imposes a requirement that a medical device first be approved in the country of origin (CoO) before that same product can begin China's registration process. Under our recommended approach, China would have to demonstrate why its own regulatory process is not adequate for imported medical devices, while it is for domestic medical devices – why the CoO is needed.

As another example, the Korean Government is in the process of implementing a system of unique device identification (UDI) for medical devices. AdvaMed does not object, in principle, to a UDI system. The US FDA is in the process of requiring such a system. However, it is clear that Korea is coupling the UDI implementation with collection of pricing information with the intention to use it for the price control purposes. The current proposal appears to impose obligations to report transaction prices on a monthly basis, and imposes a fine for not doing so. UDI is a system designed and intended for device safety management purposes. Utilizing UDI for collection of pricing

information goes against this fundamental principle. Attempting to force over 5000 local manufacturers and importers, as well as over 5000 distributors to report monthly transactions prices, is an enormous practical challenge with significant additional cost and burden to doing business in Korea. Korea already has a system in place that collects pricing information from manufacturers, making price collection from UDI unnecessary and potentially trade restrictive.

(5) Adopt Principles for Tenders: We believe FTAs should include sound tendering procedures, incorporating 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;

- Ensure procurement specifications are appropriate to the particular technology and/or clinical issue to be addressed, and designated as flexible as possible to ensure that they support competition and do not inappropriately limit choice of technology or range of solutions − including to those products with components that might be researched, developed and/or made in multiple countries or regions with which NAFTA members have FTAs and which adhere to internationally-recognized quality processes and standards;

- 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 transparent and fair manner in contract selection, when appropriate; and

- Enable post-award performance monitoring of contracts as a mechanism to inform future procurements.

(6) Minimize Defensive Positions: Some provisions of FTAs are written ambiguously or are omitted because a U.S. regulatory agency can conjure up a situation in which their actions can be subjected to trade disciplines. Such concerns are sometimes exaggerated but can prevent U.S. negotiators from addressing the other trade partners' barriers. For example, a regulatory agency might have a very specific and legitimate concern with a trade provision that could be narrowly addressed – such as by a carve-out. Instead, the FTA text might use the phrase "to the extent possible," which would tend to excuse almost any violation and override the provision's commitment.

FTAs: Specific Concerns

AdvaMed supports the Korea-U.S. FTA (KORUS FTA), as generally beneficial to our industry. The FTA eliminated import tariffs on medical technology. In addition, KORUS has a chapter that specifically addresses reimbursement issues for our industry – "transparency and procedural fairness (TPF)" – and is designed to contribute to a more stable and predictable market. However, we believe this provision needs to be more effectively implemented and enforced.

Chapter 5 TPF for medical devices (and pharmaceuticals). In brief, this chapter is supposed to require Korea's reimbursement agency to consider free-market principles in determining payment levels and allow manufacturers to provide evidence to justify the value of their products. In practice, Korea has implemented price reductions on the basis of arbitration criteria completely unrelated to the value of the medical devices.

We would welcome the opportunity to work with USTR on developing text that clarifies Korea's obligations under Chapter 5. Some concepts we recommend developing are set out below. We believe these commitments are largely consistent with the current text and, therefore, could be implemented without a "renegotiation," but perhaps with a side letter.

(1) Principles for guiding government pricing and reimbursement, including
   (a) Transparency, procedural fairness, rules based, and data driven;
   (b) Strengthened definition of what it means to respect innovation and value, such as mechanism that reflect improved patient access, outcomes and affordability
   (c) Least-intrusive mechanisms allowing innovation and market differentiation

(2) Imposition of government limitations only when necessary to achieve legitimate and specifically defined healthcare goals

(3) A dispute process that:
   (a) Requires the government imposing the price/reimbursement measure to submit a detailed written report on how the measure is the least burdensome way to achieve legitimate healthcare goals;
   (b) Calls for the creation of an independent expert panel, selected according to agreed criteria, to evaluate the government's written submission.

Conclusion

Millions of overseas patients are alive today because of U.S. medical technology. We support policies that remove trade barriers and allow us to continue to serve patients around the world.

Annex I

Medical Technology Harmonized Tariff Numbers

Medical Devices – HTS Codes
Refer to http://hotdocs.usitc.gov/docs/tata/hts/bychapter/0701c90.pdf

HS Heading	HS Description
3005 .10.1000 .10.5000 .90.1000 .90.5010 .90.5090	Wadding, gauze, bandages and similar articles for medical, surgical, dental or veterinary purposes
3006.10	Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure and similar sterile material
3006.20	Blood-grouping reagents
3006.30	Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient
3006.40	Dental cements and other dental fillings; bone reconstruction cements
3006.50	First-aid boxes and kits
3407 *Excluding 3407.00.2000 (modeling clay)*	Preparations of dental wax or dental impression compounds; other dental preparations of plaster
3821	Prepared culture media for development of micro-organisms
3822	Diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents
4015.11	Surgical gloves, of vulcanized rubber other than hard rubber
4015.19.0510	Medical gloves, of natural rubber
4015.19.0550	Medical gloves, other
4206.10.30	Articles of gut for use in the manufacture of sterile surgical sutures
6115.12.00, 6115.12.10	Surgical panty hose of synthetic fibers
6115.19.00, 6115.19.20	Surgical panty hose of other textile materials
6115.92.00, 6115.92.30	Surgical stockings of cotton
6115.93.00, 6115.93.30	Surgical stockings of synthetic fibers
6307.90.60, 6307.90.65, 6307.90.68, 6307.90.72	Surgical drapes of fabric, paper, or man-made fibers.
6307.90.8610, 6307.90.8710, 6307.90. 89, 6307.90.9010	Surgical towels
8419.20	Medical, surgical or laboratory sterilizers
8419.90.5040, 8419.90.9040	Parts and accessories for medical, surgical or laboratory sterilizers
8543.89.85	Electrical machines and apparatus for electrical nerve stimulation

8713	Carriages for disabled persons, whether or not motorized or otherwise mechanically propelled
8714.20	Parts and accessories of carriages for disabled persons
9001.30	Contact lenses
9001.40	Spectacle lenses of glass, unmounted
9001.50	Spectacle lenses of other materials
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences, and electro-medical apparatus and sight-testing instruments; parts and accessories thereof
9019.20	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories thereof
9020.00.60, 9020.00.80, 9020.00.90	Breathing appliances and gas masks; parts and accessories thereof
9021	Orthopedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability; parts and accessories thereof
9022 *Excluding 9022.19.0000, 9022.29.4000, 9022.29.7000, and 9022.29.8000 (non-medical equipment; smoke detectors and parts thereof)*	X-ray equipment
9025.11	Liquid filled clinical or veterinary thermometers
9025.19.00.40, 9025.19.80.40	Other clinical thermometers
9402	Medical, surgical dental or veterinary furniture and parts thereof
9810.00.85.00	Cellulosic plastics materials for use in artificial kidney machines or apparatus by a hospital or a patient (by prescription)

Annex II

Medical Technology Trade Flows with Selected Countries

Country	U.S. Exports	U.S. Imports	Trade Balance
Japan	$ 5,205,549,044	$ 2,560,642,446	$ 2,644,906,598
Canada	$ 3,997,827,257	$ 1,442,019,505	$ 2,555,807,752
EU28	$ 19,414,678,880	$ 17,666,625,452	$ 1,748,053,428
Brazil	$ 1,091,802,328	$ 134,966,114	$ 956,836,214
Korea	$ 1,094,670,388	$ 569,425,132	$ 525,245,256
India	$ 714,433,305	$ 248,820,590	$ 465,612,715
Taiwan	$ 440,128,447	$ 485,374,062	$ - 45,245,615
Vietnam	$ 126,254,653	$ 251,662,521	$ - 125,407,868
Indonesia	$ 104,044,718	$ 298,734,224	$ - 194,689,506
Thailand	$ 254,944,366	$ 779,198,769	$ - 524,254,403
Switzerland	$ 1,354,722,827	$ 2,601,717,352	$ - 1,246,994,525
Malaysia	$ 211,724,876	$ 1,810,537,933	$ - 1,598,813,057
China	$ 4,346,148,776	$ 6,009,817,077	$ - 1,663,668,301
Mexico	$ 3,495,441,459	$ 7,670,558,715	$ - 4,175,117,256
Total U.S.	**$ 50,932,590,745**	**$ 50,275,570,882**	**$ 657,019,863**