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AdvaMed
Advanced Medical Technology Association

May 10, 2001

Ms. Gloria Blue
Executive Secretary
Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Re: Trade Policy Staff Committee; Public Comments on Preparations for the Fourth Ministerial Conference of the World Trade Organization, November 9-13, 2001 in Doha, Qatar

Dear Ms. Blue:

On behalf of AdvaMed, the Advanced Medical Technology Association, we submit the following comments in accordance with the Notice published by the Office of the United States Trade Representative on April 5, 2001. See Trade Policy Staff Committee; Public Comments on Preparations for the Fourth Ministerial Conference of the World Trade Organization, November 9-13, 2001 in Doha, Qatar, 66 Fed. Reg. 18,142 (Apr. 5, 2001). This submission provides general comments as well as specifically provides AdvaMed's comments and suggestions with respect to Non-agricultural/Industrial Market Access, one of the specifically enumerated categories for which comments were sought.

The members of AdvaMed fully support continued multilateral trade negotiations to develop important substantive components of the World Trade Organization (WTO). Properly negotiated and comprehensive agreements in areas such as market access will enhance opportunities for U.S. businesses throughout the world by helping to reduce the

costs of doing business, expanding market access, accelerating economic growth in the region and reducing burdensome trade restrictions. Particularly, a liberalized framework that ensures equal and transparent market access and permits open competition in government procurement will open markets for America's medical technology manufacturers and also will greatly enhance the availability of the most technologically innovative and effective medical devices to patients throughout the world.

I. ITEMS OF GENERAL APPLICABILITY

A. Harmonization of Customs Rules and Procedures

Transacting business with facility and ease throughout the hemisphere must be a central benefit arising from any trade agreement. We encourage the U.S. government to continue to press for consistency and uniformity in the rules and procedures that guide customs professionals across the globe as they go about the day-to-day business of international trade.

In the area of standards, testing and conformity assessment, the elimination of redundant testing and certification requirements through the adoption of the 1-1SDoC principle would foster the flow of technologically advanced products and thereby support economic development. This principle should guide the negotiators in their discussions in these areas. Internationally accepted standards on performance criteria should be adopted whenever possible.

B. Early Adoption of Tariff Reductions

U.S. negotiators should continue to press for early reduction of tariffs in non-controversial areas and freezing of tariffs at current applied rates in all other markets. For some products, current bound tariff rates remain extremely high, which allow governments

to freely increase applied tariffs without repercussion under the rules of the WTO. The U.S. government should propose a freeze on tariffs for these particular products as a first, good faith step towards agreement in this sector, with similar efforts in other sectors as appropriate.

Many of our members feel that immediate steps can be taken to reduce tariffs in other, less controversial areas. We would suggest that the future negotiations on non-agricultural/industrial market access focus on achieving early success through the immediate elimination of "nuisance" tariffs of 5% or less. Further, we hope that the U.S. negotiators will press for early relief from the artificially high tariff rates imposed by certain WTO members, especially by Brazil, where some of our members continue to experience tariffs as high as 20 to 40 percent. In addition, U.S. negotiators should encourage participation and global support for regional tariff and non-tariff barrier elimination initiatives, such as the APEC Accelerated Tariff Liberalization (ATL) package, which will make significant strides in reducing tariff barriers in key Asian markets.

C. Transparency in Government Procurement

Procurements by the public sector continue to represent a very large opportunity for American businesses, as many key markets are still state-owned. AdvaMed applauds previous efforts of U.S. negotiators to address this issue, and urges continued efforts in this regard. Discriminatory government procurement practices continue to be a substantial barrier to growth throughout the world. We believe that the central tenets of any continued WTO negotiations on market access and government procurement should include:

- Fair and open international competitive bidding procedures that provide bidders with adequate notice and sufficient time to prepare bid submissions;

- Objective award criteria that are specific, published in bid documents and clearly followed in the selection process;
- Publishing of bid documents and specifications with the widest possible technical terms and in publications that afford the greatest breadth of availability;
- Adopting sealed tender procedures and public bid openings;
- Awarding contracts to the lowest compliant bidder on the basis of overall value; and
- Provision of remedies for non-compliance and dispute resolution.

II. RECOMMENDATIONS RELATING TO THE MEDICAL TECHNOLOGY SECTOR

AdvaMed strongly supports swift elimination of tariffs related to medical technologies. Elimination of these tariffs will expand opportunities for U.S. medical technology manufacturers – the global leaders in this sector. Tariff elimination will also ensure patients worldwide access to the best available medical technologies.

In the medical technology sector, governments, health care providers, patients and suppliers face a number of technical barriers to trade (TBTs) in areas such as transparency, national treatment and standards that should be addressed in future multilateral trade negotiations. Addressing these TBTs is important because trade liberalization can help WTO countries improve the efficiency and effectiveness of their health care systems and provide their citizens with timely access to high-quality, cost-effective healthcare products and services. Moreover, these important objectives can be achieved while respecting each country's sovereign rights and responsibility to ensure that health care products are safe and effective. The medical technology industry believes that WTO member governments'

regulatory agencies should make their policies and practices towards medical technology conform to relevant and appropriate international trading rules.

The member representatives from this industry believe that member economies should agree to make their medical device regulatory regimes conform to the following guiding principles:

- Acceptance of international standards;
- Conformity/provision of transparency and national treatment;
- Use of harmonized quality or good manufacturing practice inspections;
- Recognition of well-established, internationally recognized product approval processes (or the data used for those approvals);
- Development of harmonized auditing and vigilance reporting standards; and
- Use of non-governmental, accredited, expert third party bodies for inspections and approvals, where possible.

While the medical technology industry supports and encourages the use of non-governmental, accredited third party expert bodies for inspections and approvals, it does so with the recognition that these bodies must include an expert representative of the medical technology sector. Health care advisory committees that include only local industry representation tend to make decisions that benefit one country's suppliers over others. Currently, governments use these committees to advise them or even make decisions for them on matters related to the approval and reimbursement of specific new medical technologies, making it imperative that they be comprised of a mix of experts that will be fair to all suppliers. Governments should include or, at a minimum, consult with a

representative of the primarily affected industry, regardless of nationality, when making such decisions.

Many economies require purchases of medical technologies to take place through centralized and/or government-administered insurance reimbursement systems. To ensure timely patient access to the advanced medical technologies of domestic and foreign suppliers, member economies should agree to adopt these guiding principles regarding the reimbursement of medical technologies:

- Establish clear and transparent rules for decision-making;
- Develop reasonable time frames for decision-making;
- Ensure data requirements are sensitive to the medical innovation process;
- Ensure a balanced opportunity for the primary suppliers and developers of technology to participate in decision-making; and
- Establish meaningful appeals processes.

The medical technology industry encourages early WTO approval and implementation of the recently submitted APEC Early Voluntary Sector Liberalization package on tariffs, which included tariff reductions in the area of medical technology. These tariff reductions should be extended to all WTO members (e.g. Brazil), where possible.

In closing, AdvaMed's members are cognizant that the forthcoming fourth Ministerial meeting of the WTO presents a significant opportunity for continued development of market-liberalizing provisions. We stand to benefit, along with other sectors, from the broad-based liberalization measures that are being considered. As one of our nation's most competitive and productive industry sectors, we support and encourage

our government's representatives in their efforts to speed global market access and integration.

Sincerely yours,

Ed Rozynski

Edward M. Rozynski