

1200 G Street NW, Suite 400  
Washington, DC 20005-3814  
Tel: 202 783 8700  
Fax: 202 783 8750  
www.AdvaMed.org



**AdvaMed**  
Advanced Medical Technology Association

**WAYS AND MEANS COMMITTEE**  
**HEARING ON**  
**THE U.S.-DOMINICAN REPUBLIC-CENTRAL AMERICAN**  
**FREE TRADE AGREEMENT**

**APRIL 21, 2005**

**TESTIMONY**  
**SUBMITTED FOR THE RECORD**  
**BY**  
**THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)**

The members of AdvaMed join other companies in their strong endorsement of the U.S.-Dominican Republic-Central American Free Trade Agreement (CAFTA). This FTA will benefit the United States economy, the economies of our friends in the Dominican Republic and Central America, and our member companies that export and produce in this region.

AdvaMed represents over 1300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members manufacture nearly 90% of the \$83.4 billion in health care technology products purchased annually in the U.S., and nearly 50% of the \$175 billion in medical technology products purchased globally. Exports in medical devices and diagnostics totaled \$22.4 billion in 2003, but imports have increased to \$22 billion - indicating a new trend towards a negative trade balance for the first time in over 15 years.

The medical technology industry is fueled by intensive competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Accordingly, our US industry succeeds most in fair, transparent, global markets where products can be adopted on their merits.

### **Global Challenges**

Innovative medical technologies offer an important solution for nations that face serious health care budget constraints and the demands of aging populations. Advanced medical technology can not only save and improve patients' lives, but also lower health care costs, improve the efficiency of the health care delivery system, and improve productivity by allowing people to return to work sooner.

To deliver this value to patients, our industry invests heavily in research and development (R&D), and US industry is a global leader in medical technology R&D. The level of R&D spending in the medical device and diagnostics industry, as a percentage of its sales, more than doubled during the 1990s, increasing from 5.4% in 1990, to 8.4% in 1995, to 12.9% in 1998. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. This level of spending is on par with spending by the pharmaceutical industry and more than three times the overall US average.

However, patients benefit little from this R&D investment when regulatory policies and payment systems for medical technology are complex, non-transparent, or overly burdensome, causing significantly delays in patient access. They can also serve as non-tariff barriers, preventing U.S. products from reaching patients in need of innovative health care treatments.

### **Utilize Regional Forums to Eliminate Tariff and Nontariff Barriers to Trade that Unnecessarily Increase the Cost of Health Care**

AdvaMed supports international trade initiatives, including bilateral, regional and global trade negotiations, such as the Free Trade Area of the Americas (FTAA) and the Doha Development Agenda in the World Trade Organization (WTO). We encourage Congressional and Administration efforts to eliminate significant tariff and nontariff barriers to trade for medical technology maintained by many countries, particularly developing countries. Such barriers represent a self-imposed and unnecessary tax that substantially increases the cost of

health care to their own citizens and delays the introduction of new, cost-effective, medically beneficial treatments. For example, the medical technology sector continues to face tariffs in Latin America of 15-20% in Mercosur countries and 9-12% in Peru and Colombia.

We strongly endorse the Administration's effort to gain Congressional approval for legislation implementing the CAFTA. Under this free trade agreement, our trading partners in the Dominican Republic and Central America will grant U.S. exports of medical devices duty-free treatment upon entry into force. This would immediately eliminate tariffs of around 10-15% applied to medical devices in these nations. Since the United States already grants imports of almost all products from these countries duty-free entry under the Caribbean Basin Initiative, we view the CAFTA as a way to level the playing field for U.S. exports.

Congressional approval of CAFTA legislation would pave the way for progress on other international trade agreements. Under the WTO negotiations, AdvaMed, working with other trade associations, is seeking the elimination of tariffs on medical devices and other related health-care products. The result would be substantially expanded access for our products in many developing countries, where tariffs are still quite high. Lowering tariffs on health-care related products would reduce the cost of those products to patients in developing countries and improve their access to products that enhance, prolong, and save lives.

International trade agreements, such as CAFTA, provide a vehicle for Administration negotiators to address other trade-related issues. FTAs create a council which generally allows the parties to raise a range of trade-related issues. AdvaMed believes the USTR, Department of Commerce and Congress should monitor regulatory, technology assessment and reimbursement policies in foreign health care systems and push for the creation or maintenance of transparent assessment processes and the opportunity for industry participation in decision making. We look to the Administration and Congress to actively oppose excessive regulation, government price controls and arbitrary, across-the-board reimbursement cuts imposed on foreign medical devices and diagnostics. The councils established by a free trade agreement could provide a forum to address these types of issues, which are usually not explicitly contained in the FTA themselves.

## **Conclusion**

AdvaMed appreciates the shared commitment by the President and the Congress to expand international trade opportunities and encourage global trade liberalization. We look to the President and his Administration to aggressively combat barriers to trade throughout the globe, and support the adoption of the U.S.-Dominican Republic-Central American Free Trade Agreement. AdvaMed is fully prepared to work with the President, the office of the USTR, the Department of Commerce, and the Congress to monitor, enforce and advance regional, multilateral, and bilateral trade agreements – including those with our current key trading partners.