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AdvaMed
Advanced Medical Technology Association

November 15, 2004

Mr. Mark Mowrey
Deputy Assistant USTR for Europe and the Mediterranean
Executive Office of the President
600 17th Street, NW
Washington, DC 20508

Dear Mr. Mowrey,

I am writing in response to the Federal Register notice published August 17, 2004, requesting comments on the public dialogue on enhancing the transatlantic economic partnership (TEP) with the European Union (EU). This response represents the views of AdvaMed's members concerning medical technology products.

Issue for TEP to Address

Medical device companies doing business in EU Member States have been discouraged by the overreaching regulations and pricing policies they face. For example, the EU draft directive on the upclassification of orthopedic joint implants was not substantiated with scientific evidence and the process used to propose the upclassification was not handled in a transparent manner. Companies also face arbitrary price cuts and pricing controls throughout EU Member States. These regulatory and pricing policies discourage innovation and ultimately limit patient access to cutting edge technologies. We would welcome TEP discussion of the impact of European countries' reimbursement policies on trade and investment in innovative medical technology products.

We are encouraged by the EU-US Regulatory Cooperation and Transparency initiative and the progress it has made to date. We urge the USG to advance the initiative further by requiring Member States to adopt the initiative. This step would help create a level playing field for U.S. companies doing business in the EU and would be an important step toward encouraging innovation within Member States.

Background on AdvaMed and the Industry

AdvaMed represents over 1,300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed member companies are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, AdvaMed members manufacture nearly 90 percent of the $75 billion in life-enhancing health care technology products purchased annually in

the United States, and nearly 50 percent of the $175 billion in medical technology products purchased globally.

The medical technology industry is constantly innovating and producing products that can diagnose and treat diseases earlier, avoiding or saving long term health care costs. These products improve people's lives and contribute to economic progress. Moreover, in a world of shrinking healthcare resources, medical technology products are an investment in our most valuable resource – the health of our people. The return on that investment is the long term benefits that can be achieved when we provide the resources needed for the best medical care.

A few examples of the innovative products made by AdvaMed member companies include intraocular lenses, pacemakers, surgical supplies, magnetic resonance imaging equipment (MRI), vascular stents, joint replacements, ophthalmic implants and other diagnostic tests and equipment. These products span a full range of diagnostic, palliative and therapeutic medical interventions and can actually help lower medical costs by averting the need for higher-risk procedures. Patients and health care systems benefit when the most modern technologies are used – but access to these technologies can be jeopardized by policies that impede product development.

Medical device companies are dependent on a positive business environment which is conducive to innovation. A negative environment, on the other hand, discourages innovation. Companies are less inclined to introduce innovative products and procedures and patient access to these products may be limited. This could potentially leave patients and clinicians in Europe with more limited choices and reduced access to innovative therapeutic and diagnostic technologies.

Thank you for your consideration of these comments. We welcome the opportunity to discuss these issues with you further in the future.

Sincerely,

Michelle DeMoor

Michelle DeMoor
Director, Global Strategy and Analysis