



UNITED STATES DEPARTMENT OF COMMERCE  
The Under Secretary for International Trade  
Washington, D.C. 20230

JAN 18 2011

The Honorable Amy Klobuchar  
United States Senate  
Washington, DC 20510

Dear Senator Klobuchar:

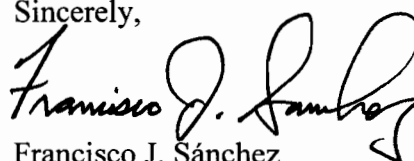
The Department of Commerce's International Trade Administration (ITA), through its Trade Agreements Compliance Program, recently helped Advamed, a medical device trade association representing over 1600 members, and QNET LLC, of Elk River, Minnesota, to gain improved market access in Italy for medical devices. Following our efforts, Italy agreed to reduce its duplicative registration requirements in accordance with the European Union (EU) single market law, which allows for medical devices to be registered in one point of entry in the EU rather than incurring costly registration fees in every member country.

In September 2009, QNET and Advamed raised concerns over Italy's new registration requirements for new-to-market medical devices. U.S. industry felt the requirement for a registered representative specifically in Italy was duplicative of the EU's single market representative requirement and more onerous than normal for class I devices. This posed possible concerns under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade. ITA communicated industry's concerns to the EU Commission and worked to seek clarification and a delayed implementation. In February 2010, Italy revised its law in response to EU Commission pressure: a new decree was adopted which brought about a much streamlined registration process for Class II and III devices and lifted the requirement that Class I devices be registered in Italy if the manufacturer has registered the Class I product in another EU member state. ITA's efforts helped preserve and possibly enhance U.S. medical technology exports to Italy, which total \$700 million annually.

Assisting U.S. exporters by ensuring foreign government compliance with trade agreements to which the United States is party is a top priority for ITA and a key pillar of the President's National Export Initiative. I am pleased that we were able to contribute to this success. We stand ready to assist your constituents facing foreign trade barriers through our Trade Agreements Compliance Program, and we urge you to refer any constituents facing unfair foreign trade barriers to us through the Trade Compliance Center Hotline, at <[www.trade.gov/tcc](http://www.trade.gov/tcc)> or (202) 482-1191.

If you have any further questions, or would like to receive a briefing on the work that the Trade Agreements Compliance Program does, please contact me or Peter Kaldes, Director of ITA's Office of Legislative and Intergovernmental Affairs, at (202) 482-3015.

Sincerely,



Francisco J. Sánchez



INTERNATIONAL  
TRADE  
ADMINISTRATION