AdvaMed
Advanced Medical Technology Association

October 31, 2012

To:

Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs

Jean-Luc Demarty
Director General
Director General for Trade

Daniel Calleja Crespo
Director General
Director General for Enterprise and Industry

Ambassador Miriam Sapiro
Deputy U.S. Trade Representative
Office of the U.S. Trade Representative

The Advanced Medical Technology Association (AdvaMed) would like to thank the European Commission and the U.S. Government for the opportunity to share its views on how to promote greater transatlantic regulatory compatibility. AdvaMed welcomes both governments' stated goal of reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape while respecting each other's right to protect public health, safety, welfare, and the environment. During this critical time for both our economies, we also share the view that greater transatlantic regulatory compatibility will help businesses to grow, create jobs, and compete globally.

The medical technology industry creates the medical devices and diagnostics that are central to modern health care. Not only is medical technology a source of life-enhancing and life-sustaining treatments and cures, as a major manufacturing industry, it is a driver of current and future economic growth in the U.S. and Europe. The future potential for global economic growth driven by medical technology is great. World-wide markets for medical technology will expand dramatically as populations age in countries around the globe and as hundreds of millions of people in countries like India and China enter the middle class and demand access to modern, quality health care. Given the huge potential of this sector, it is critical that the U.S. and the European Union make this sector a priority as bilateral mechanisms are developed to promote regulatory compatibility and enhance economic cooperation.

The European Commission and U.S. Government already participate in multilateral efforts to promote regulatory harmonization through forums such as the International Medical Device Regulators Forum (IMDRF) but more can be done bilaterally to ensure that our governments achieve their regulatory objectives in a more effective and efficient manner. In particular, we urge both governments to work together as the European Commission develops new regulations for medical devices and in vitro diagnostics, to identify specific where greater regulatory convergence would reduce the regulatory burden on US and European manufacturers and regulators, speed up the pace of innovation and bringing technologies to patients in a timelier

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manner. With this in mind, AdvaMed prepared the attached matrix with specific recommendations for regulatory cooperation between the EU and US in the medical device sector.

Thank you for your consideration and we look forward to working with both Governments on this initiative.

Yours truly,

Steve Ubl Serge
President and CEO
AdvaMed

AdvaMed Recommendations for U.S. EC Regulatory Compatibility – October 31, 2012

Names of the relevant regulatory agencies in the EU and US	**Issue / Citations to the relevant regulatory and/or statutory provisions for each jurisdiction**	**Description of the regulatory differences**	**Possible solutions for bridging these differences**	**Steps that the EU and/or the US should consider to address horizontal and/or sectoral differences**	**An assessment of the effects of enhanced regulatory compatibility the likelihood of these effects occurring, and the time period over which they would occur.**
U.S. Food and Drug Administration (FDA) and the European Commission (DG Sanco)	FDA's proposed rule for a Unique Device Identification (UDI) System and Article 24 (row 237) of the EC's proposed regulation for medical devices	An initial comparison is difficult since Article 24 is a general outline of a possible framework whereas the US has a long and detailed rule under review. Based on what the EC has laid out, traceability appears to be a major objective of Article 24; unlike the FDA's proposed rule. The EU market is different from the US, i.e. gray market is not a concern in the US.	The EC and US should work together through the International Medical Device Regulators Forum (IMDRF) and bilaterally to ensure that there is regulatory compatibility for each region's UDI regime.	Both governments need to ensure that required data elements are aligned. Data transmission protocols are also critical.	We expect that that the FDA final rule will be in effect, at least for Class III products, well before the EC has a an enforceable law.

U.S. Food and Drug Administration (FDA) and EU Member State's competent authorities and Notified Bodies	The US and EU system for manufacturer inspections and audits	Currently the US FDA and Member State competent authorities conduct independent inspections of medical device manufacturer facilities.	Both sides should consider a single audit system that would allow the relevant authorities to share inspection reports and reduce duplicative audits and inspections.	NA	A single or mutual recognition system for company inspections and audits would facilitate information sharing between the EU and US and reduce the burden on both regulators and industry. Greater efficiencies on both sides would facilitate market access to innovative products. A mutual recognition system should be considered as the EU finalized its new regulations for medical devices and IVDs.
U.S. Food and Drug Administration (FDA) and EU Member State's competent authorities and Notified Bodies	The use and recognition of relevant standards such as ISO 14971 in the FDA review process and the EU's CE Mark process.	FDA recognizes the 14971 standard as written. The recent EU action to harmonize the standard with a revised interpretation rejecting the use of the ALARP principle ("as low as reasonably accepted") to determine the acceptable risk level is counter to	The EU should reconsider this action. Otherwise many products will potentially become unavailable in the EU as a result of having a more severe, and in some cases impossible requirement regarding setting an acceptable risk level for certain medical devices.	The EU could confer with either ISO TC 210 or with the US FDA regarding a resolution path to return to the previously-held interpretation.	This issue should be addressed quickly before the disparity of this new interpretation reduces the viability of the EU market for certain medical devices.

		internationally accepted practice.			

Source: https://www.federalregister.gov/articles/2012/09/28/2012-23613/promoting-us-ec-regulatory-compatibility