MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

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Internal Revenue Service
CC:PA:LPD:PR (Notice 2010-89)
Room 5203
P.O. Box 7604
Benjamin Franklin Station
Washington, DC 20044

Attention: Ms. Natalie Payne

Dear Ms. Payne:

The Medical Device Manufacturers Association ("MDMA") is a national organization representing hundreds of innovative, entrepreneurial medical technology companies. MDMA's mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies. Our members will be significantly and negatively impacted by the new manufacturers excise tax on medical devices under Section 4191 of the Internal Revenue Code of 1986 ("Code").

MDMA remains steadfastly opposed to the new excise tax on medical devices because it will adversely impact patient care, innovation and job creation. Furthermore, the justification advanced by proponents of the tax that the "windfall" from the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act, will offset the costs of the tax on innovators is baseless and not supported by any evidence. Indeed, we believe that the additional burdens that the new excise tax will impose on the medical technology industry and the Government will only add to the federal deficit and increase the long term costs of healthcare. Although the only prudent step is the repeal of this new tax, we recognize that the Treasury Department and the Internal Revenue Service are charged with administering the tax as enacted by Congress. We raise our opposition to the new excise tax here because administrative guidance that does not reflect the complexities and unique nature of the medical device market will only worsen the severe impact that this new tax will have on healthcare in this country.

As a threshold matter, it imperative that the process for developing administrative guidance for the new excise tax involve a continuing dialog with affected manufacturers. Although MDMA fundamentally disagrees with the reasons for the enactment of the new tax, ambiguous, incomplete or ill-fitting rules will only ensure that the tax cannot be readily applied by affected manufacturers and effectively administered by the Service. This is a particular concern because, as suggested by Notice 2010-89, the existing rules for manufacturers excise taxes leave many questions unanswered with respect to medical devices, wholly apart from the critical question of what items are covered by the new tax. Our initial general comments are set out below.

Guidance should minimize the additional administrative burden on affected manufacturers. The medical technology industry is dominated by small businesses, which are the engine of job creation in this country. Approximately 80% of the companies in the medical technology industry have fewer than 50 employees, and 98% of the companies have less than 500 employees. Administrative guidance should minimize to the fullest extent practical any obligation to alter existing financial and recordkeeping systems and business practices, including the manner in which manufacturers interact with their customers. Otherwise, the financial burden of complying with the new law will divert precious resources away from the necessary investments these companies make in research and development that eventually lead to more effective and less costly healthcare for all Americans.

Guidance should avoid the double-taxation of medical devices. Generally speaking, existing Treasury regulations do not take into account the complex nature of the medical device supply chain and that various ways in which products are sold into the marketplace. This includes the fact that some technologies are combinations of drugs and devices and potentially could be subject to multiple taxes (e.g., medical device excise tax and brand prescription drug fee), and Congress did not intend a double-tax on these technologies. More traditional medical devices may move through the supply chain with other devices in a manner that, under the current framework, may subject them to multiple taxation absent guidance that takes into account how the medical technology industry operates and how these products are sold and consumed.

Guidance for the constructive sales price rules should take into account the unique nature of the medical device industry and market. The existing administrative guidance for the constructive sales price rules in the Code do not translate readily to the medical device market. We are very concerned that absent rules that can be readily applied by manufacturers and that result in prices (and, thus, excise taxes) that reflect economic realities, manufacturers may face tax burdens beyond those intended by Congress. In addition, given our concerns with the administrative burden that the new excise tax will impose, we recommend that administrative guidance for medical device manufacturers give significant weight to good faith efforts by a manufacturer to determine the constructive sales prices used to determine excise tax liability.

Guidance should take into account the unique nature and use of many medical device technologies. Many medical devices are unlike the commodity products that also are subject to manufacturers excise taxes. Some medical devices, for example, are provided to individuals as part of a clinical trial and are not commercially available to the public. Other products are leased or may require software updates and replacement parts. The often unique nature or use of many of these devices raises issues regarding which products (or portions of a product) should be subject to tax and when, which products should be exempt from tax, and how these distinctions should be made in a very dynamic and innovative industry. Existing administrative guidance dealing with more commoditized products are less useful when applied to the medical technology industry. We recommend that administrative guidance for the new excise tax not be issued until the Treasury Department and the Service have had sufficient time to understand and address the challenges posed by the nature of these products.

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The new manufacturers excise tax on medical devices is misguided and, if it goes into effect, will prove to be detrimental to any objective of improving the quality and cost-effectiveness of healthcare in this country. We are encouraged by and strongly support the current bipartisan efforts to repeal this new excise tax prior to its January 1, 2013 effective date. We nevertheless recognize that the Treasury Department and the Service have an obligation to develop administrative guidance for the new tax, and administrative guidance must not stifle innovation or unduly burden the dynamic companies, including many small businesses, that drive advances in medical care.

We hope that once the Treasury Department and the Service appreciate the difficult issues raised by the new excise tax – complexities that belie the brevity of Section 4191 of the Code – the Administration will support, if not the repeal of the new law, at least an additional one-year delay in the effective date. Although the new tax does not go into effect until 2013, we believe that meaningful, comprehensive and workable guidance will take far longer to develop. The harm from not having such guidance in place well in advance of the current effective date would be considerable, as affected manufacturers need time to develop procedures and systems to comply with the law. All of that effort will detract from more productive endeavors such as investing in research and development and job creation that will improve our healthcare system and our economy.

Respectfully submitted,

Mark B. Leahey
President & CEO
Medical Device Manufacturers Association

cc: Michael Mundaca, Assistant Secretary (Tax Policy), Department of the Treasury
Douglas Shulman, Commissioner, Internal Revenue Service
Jeffrey Van Hove, Tax Legislative Counsel, Department of the Treasury
Jeanne Ross, Attorney-Advisor, Department of the Treasury