

October 6, 2009

VIA ELECTRONIC SUBMISSION

Senator Max Baucus, Chairman
Senator Chuck Grassley, Ranking Member
United States Senate, Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Baucus and Ranking Member Grassley:

The Medical Device Manufacturers Association (MDMA) commends the Senate Committee on Finance for its efforts to enact broad-based, comprehensive health care reform. Our members share the goals of improving efficiencies in the delivery of care, ensuring affordable coverage, and reducing fraud, waste and abuse in Federal healthcare programs. MDMA represents hundreds of small to mid-size medical technology companies that develop innovative medical therapies. Our members also recognize the important part they play in advancing health care reform and believe the technologies they produce will help achieve these shared goals.

MDMA remains concerned about the proposed fee for medical device manufacturers in the Chairman's conceptual mark of the America's Healthy Future Act. After hearing about negotiations between the Committee and large device companies, MDMA met with Committee staff in July to discuss our concerns over a broad-base device fee or tax. At that time, we also discussed areas of the bill that would result in significant reductions to medical technology costs, including proposed cuts of approximately \$155 billion to hospitals, reductions in imaging and clinical labs, and other provisions that would likely result in less utilization of medical products. Beyond the concerns we raised to the existing cuts in the bill, and the prospect of a device fee or tax, we discussed our willingness to consider targeted cuts in the medical device industry related to fraud, waste, and abuse. For example, we offered a repeal of the safe harbor afforded to group purchasing organizations under the Medicare anti-kickback statute. With the repeal of the GPO safe harbor, we proposed legislation that could potentially achieve cost savings of nearly \$4 billion annually for the Medicare program.

Although efforts to strike the device tax were unsuccessful during the Committee mark-up, we urge you to reconsider eliminating this provision as it moves forward in the Senate. It is important to remember that the medical device industry is comprised primarily of small to mid-size companies, many of which require tens, if not hundreds, of millions of dollars to commercialize a single product. The proposed fee provides little, if any, consideration to the size of the company, profitability, and the practical impact that it would have on the medical technology industry. For example, given the significant investment required to bring a product to market, a company can have annual revenues of \$100 million and still not be profitable. Requiring this type of company to pay a fee would result in the company reducing R&D and likely reducing its workforce by twenty percent.

In conclusion, MDMA would like to reiterate its steadfast opposition to the proposed medical device tax. Furthermore, we would like to clarify that the creation of a new fee, no matter what the amount, **is not a proposal supported by the overwhelming majority of the device industry**. MDMA looks forward to working with the Committee to address this critical issue and will continue to offer other options and ideas to achieve costs-savings in Federal health care programs. However, we cannot support any fee on the industry that will stifle medical innovation, limit patient access, prohibit research and development, and force companies to reduce their workforce. Unfortunately, the proposed fee will achieve all this if it is enacted.

Sincerely,

A handwritten signature in black ink that reads "Mark B. Leahey". The signature is written in a cursive style with a long, sweeping underline.

Mark B. Leahey
President & CEO
Medical Device Manufacturers Association