June 5, 2012

The Honorable Pete Sessions
U.S. House of Representatives
2233 Rayburn House Office Building
Washington, DC 20515

Dear Representative Sessions,

Thank you for taking time to visit with me last week regarding OsteoMed and my concerns about the significant "headwinds" we face, especially related to the 2.3% medical device tax that is scheduled for implementation in 2013. On behalf of OsteoMed's 400 employees, I thank you for your support of H.R. 436, which would repeal this onerous provision that otherwise will negatively impact innovation and job creation at a time when we can least afford it.

As president & CEO of OsteoMed, a dynamic, 20 year old surgical device manufacturing company based in your district, I confront the challenges that America's innovators face every day. In addition to challenges with the FDA and reimbursement, this 2.3 % excise tax – which is on gross sales, whether or not a business has any profits – will directly impact our ability to create new jobs, invest in research and development and effectively compete in the global market.

- OsteoMed formed a new subsidiary company a couple of years ago to develop an innovative spine product that greatly simplifies spine fusion surgery and improves patient outcomes. OsteoMed launched this product last year which quickly grew to almost $5MM in sales in 2011 and currently employs a number of highly skilled, high paid individuals. Due to the significant upfront investment and on-going development costs, this new company is not projected to make a profit in the near future but is nevertheless subject to the device tax which will further delay this subsidiary's success. As a result, OsteoMed has now delayed additional new product developments and personnel in order to make "ends meet" and achieve the returns initially envisioned when this company was created.
- OsteoMed's core business manufactures surgical implant systems for use in craniofacial, neurosurgical and small bone orthopedic (upper and lower extremities) surgeries. These systems require extensive, specialized instruments that are typically not sold, but are used to implant the devices that drive OsteoMed's revenue stream. The device tax will not only tax gross product revenues, but my understanding is it will also tax the instruments OsteoMed must invest in and place into hospitals at no charge thereby further reducing my company's profit opportunities and forcing expense reductions in other areas in order to achieve our profit goals.
- OsteoMed's products are sold through a variety of sales channels and will require a new level of administrative burden in order to track the "gross" revenues defined by this tax. This requirement, along with the recent challenges imposed by the Physician Payment Sunshine Act, force additional levels of administration and non value added expenses that make OsteoMed less competitive and viable.

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- The market in which OsteoMed competes is in turmoil and has become increasingly competitive with many new offshore competitors. As economics and recent government restrictions have largely removed surgeons from the surgical device purchase decision process, hospitals are now forcing increasingly price concessions. Despite increased raw material and labor costs, OsteoMed has been unable to raise product prices over the past several years and is now equally unlikely to simply pass along the device tax to our customers.
- Like any other responsible business, OsteoMed must carefully manage expenses in order to make profit and continue to grow and succeed. In order to cover the shortfall the new device tax will create, OsteoMed has already started to implement cut backs in its operations including the delay/cancellation of new product development projects and the hiring of additional personnel, including biomedical engineering positions. It should be noted that OsteoMed is also aggressively re-directing its business focus to international markets that provide a less cumbersome and lengthy regulatory pathway with revenue streams that are not subject to the medical device tax....immediately "saving" 2.3% in the process. In the past month, OsteoMed initiated the search for sales managers in China and the Middle East to supplement recent managers hired in Korea and Italy. Unfortunately, OsteoMed has already started to effectively trade U.S. jobs for overseas positions as a direct result of the medical device tax and other governmental involvement.

The medical device industry not only provides numerous highly skilled and attractive jobs across the U.S., but it also pays its workers on average 40% more than the typical job. We are a vibrant sector of the economy and one of the few remaining industries that produces a healthy export of products. Tragically, this industry has now become the focus of misguided and short-term government intervention and the growth and continued prosperity of this proud American industry now faces great hurdles.

Again, I thank you for your service to our country and specifically for your support of H.R. 436 to repeal this tax and to help America's innovators continue to improve patient care and drive job creation. I look forward to your ability to visit OsteoMed when you are back in Dallas so you can see firsthand our great employees and the innovative products they produce to help people around the world. Please do not hesitate to contact me to discuss this issue or any other issues impacting the medical device industry.

Sincerely,

Walter J. Humann
President & CEO
OsteoMed