



March 18, 2013

The Honorable Greg Walden

Chairman

Energy and Commerce Committee

Subcommittee on Communications and Technology

US House of Representatives

The Honorable Anna Eshoo

Ranking Member

Energy and Commerce Committee

Subcommittee on Communications and Technology

U.S. House of Representatives

Dear Chairman Walden and Ranking Member Eshoo,

Recent comments concerning the Medical Device Tax and potential harmful effects on job creation and innovation are interesting, but seem more like political speech rather than thoughtful analysis. Current technology such as smartphones and tablets, for which apps are being developed have also come under scrutiny as possibly being subject to the Tax and, therefore hindering innovation.

We are a small business with just over 50 employees. We manufacture our products right here in America. As with most such companies we are in business to make money. We are finally pulling out of the economic slowdown. We fully expect that in the next few years we will see a growth spurt due to more Americans having affordable health care. If we manage our business prudently we will welcome the increased sales and the positive effects there from. It is difficult to imagine that a responsible manager would not embrace growth even though there will be a tax imposed on it. Why would we not hire new people, buy new production equipment and increase space to have the resources to make more money? That is our job. To avoid growth to avoid a tax is not prudent management.

The same logic applies to development of new products whether they be new hardware based or app based. If the innovation would result in a saleable product it would make no sense for a responsible manager to not innovate. There are thousands and thousands of new products under development across the entire medical device industry. There seems to be no reduction in FDA applications for new products due to the ACA.

In terms of the applicability of FDA regulations to new smartphone and tablet devices we see no reason that current reasoning should not continue. The definition of a medical device is rather straightforward. The use of this definition could be easily applied to new app technology. If a device is simply used to record data and not used to actually generate the data or make a diagnosis based on the data, it would not fit the definition. If the



device were used to make measurements and/or diagnose from those data, then it would be regulated. We have all seen the effects of insufficient regulation. China which is well known to have had severe problems with lack of oversight has suffered from many cases of serious effects from contaminated food and drugs. Right here in Massachusetts there is an ongoing situation with a firm that produced products that were not regulated by the FDA and under regulated by the state. Americans deserve to have the confidence that products that can affect their health are safe and effective. We also need reasonable and logical debate on matters that effect laws and regulations that can produce that confidence.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Boyle".

Michael J. Boyle, President

SDI Diagnostics, Inc.

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