

Opening Statement for the Record
Congressman Leonard Lance
Subcommittee on Communications and Technology
“Health Information Technologies, Harnessing Wireless Innovation”
March 19, 2013

Thank you Mr. Chairman and thank you to the witnesses who have all come to share their experience and expertise with us today.

The mobile app market place is growing at an exponential pace. We are seeing more innovative new apps on the market every day that help American consumers with innumerable daily tasks. This is one space where we are truly seeing fast paced development and where new, tech savvy entrepreneurs can quickly make their brainstorm into a reality and bring it to the market almost immediately upon completion.

There is a significant sector of this market aimed at helping Americans live healthier lives; this is the mobile health sector. A simple search for health and fitness apps for the iPhone produces page after page of options ranging from heart rate monitors, to calorie counters, to exercise apps and so much more. These technologies, as well as more advanced equipment and programs that are being used in doctor’s offices and hospitals every day are helping to improve consumers’ health and well being and in my cases bring down the overall cost of providing health care in this country.

Unfortunately, the prospect of arduous regulatory processes, or worse, the prospect of being subject to a poorly thought out regressive tax loom as potentially chilling barriers for some new entrants into this market. There rightly is a role for the FDA to have a regulatory role with many of these new technologies but they must be clear about what kinds of apps and devices will be required to undergo their full regulatory review and what others would be exempt. Some of our witnesses point out that FDA is still finalizing many of its regulations that determine what is a “medical device” and what is not and that this final analysis may have a significant impact on what qualifies under Obamacare’s medical device tax. Uncertainty like this is one of the largest drags on our nescient economic recovery.

This brings me to the Medical Device Tax itself. I, like many of my colleagues on both sides of the aisle, view the imposition of the 2.3% tax on the medical device industry as arbitrary and wrongheaded. Mr. Ford makes that case pretty succinctly in his testimony in my opinion. This \$20 billion tax should be repealed as soon as possible. The fact that there is any question as to whether or not a mobile device like an iPhone, iPad, or blackberry may be subject to this regressive tax would be comical if it weren’t such a potentially serious issue.

I have a constituent back home in New Jersey who is working with companies on the leading edge of some of this innovation. John Letko is President & CEO of U.S. Healthcare Supply located in Milford, NJ. His company provides care for roughly 150,000, most Medicare beneficiaries with diabetes. Mr. Letko is currently working with another company in development of a new glucometer that attaches to a smartphone and a corresponding app to help

patients with diabetes monitor and track their glucose levels and seamlessly share that information with caregivers or family members. Fortunately for him, recent IRS guidance appears to put this new device under the so called retail exemption from the medical device tax and hopefully the same applies to the app. However, he recently wrote me a letter expressing serious concerns he has with the medical device tax's possible effect on his industry. He rightfully points out that for a company like his, the President's sequester has already resulted in a 2% cut the provider side of Medicare and recent cuts to the reimbursement for mail order diabetes supplies have created a very challenging environment. A further 2.3% tax could be very damaging to the industry.

While my colleagues and I work to finally repeal this damaging tax provision I would encourage the FDA to carefully consider how it regulates these new and innovative technologies. We must ensure safety but should not impede technological progress unnecessarily. We must find the right balance between protecting consumers and harnessing the power of America's innovators to ensure that the U.S. remains at the forefront of the boom we are seeing in the development of such technologies.