Chairman Coats, Vice-Chairman Brady, Ranking Member Maloney, Senator Klobuchar and Representative Paulsen, I would like to thank you for this opportunity to testify. My name is Thomas Hoghaug and I currently hold the position of CEO for Signus Medical, LLC, and LockDown Surgical, Inc. It is an honor for me to be able to address this committee today and potentially shed some light on the extremely negative impact the Medical Device Tax has had on both of my companies and on similar small medical device firms. The issues and examples I will share are personal examples that are in no way unique to Signus Medical and LockDown Surgical. They are common experiences shared by a multitude of smaller device firms and have been conveyed and confirmed to me during meetings, committees and gatherings of medical device executives. Small device firms are primarily responsible for the majority of innovation and development of better and more cost effective treatment modalities for patient care in the U.S.

I have worked in the orthopedic medical device arena for over 27 years with extensive experience in both international and domestic product sales and distribution. Over the course of my career I have founded seven (7) medical device companies, the largest being California based Alphatec Inc., and assisted others in achieving critical sales mass in order to go public. The most notable being Minneapolis based Spine-Tech Inc. which is considered to be the most successful IPO and ultimate acquisition target in the orthopedic industry. In 2002, I acquired sole ownership of Signus Medical, LLC, a master importer, developer and distributor of spinal implants. In June of 2014 I accepted the concurrent position of CEO of LockDown Surgical Inc; an extremity company focused on joint ligament repair. LockDown Surgical was founded in February of 2012 with a single FDA cleared product for shoulder repair. It has been operating at an annual financial loss and expects to reach breakeven and finally begin to turn a modest profit in the fourth quarter of this year. It wound have been sooner if it were not for the device tax.

Since the economic disaster of 2008, the spinal implant industry has been one of the hardest hit in terms of downward pricing pressure, FDA clearance delays and regulatory scrutiny. We have seen end user pricing drop in excess of 70%, while the burden of compliance and reporting has increased dramatically. Signus Medical has managed to weather these storms but not without a negative impact on its top line sales and net profit.

With the introduction and implementation of the Affordable Care Act's Medical Device Tax, companies have experienced a multitude of unforeseen and crippling consequences of the tax including: layoffs, non-replacement of lost employees, disrupted or negative cash-flow, curtailing or elimination of R & D projects, reduced inventory expansion and effective tax rates which can exceed 100% of profit. Money that was once used to grow and reinvest in the expansion of the companies is now sent to the IRS every two (2) weeks. The AdvaMed response to the November 3, 2014

Congressional Research Service reports that these payments are in fact used in the Nation's general revenue stream and not used for healthcare reform under the ACA as was promised.

From the time of our first device tax payments the impact was felt immediately. We are required to pay the 2.3% tax on all invoiced sales approximately every two (2) weeks. This tax is assessed on all device sales billed within the previous two (2) weeks irrespective of profit, profitability, cash-flow or collections. At present, our collections average about 72 days from the date of surgery yet we are compelled to pay the IRS within 14 days or less. As a result, we are fronting the tax payment nearly 50 days in advance of actually collecting payment for our implanted devices. Representing two small device companies as I do, I was forced to lay off several employees in order to cover the initial shortfall and when several more key support personnel were lost through the course of normal job advancement, I no longer have the investment capital to re-hire those positions. Both Signus Medical and LockDown Surgical are privately held businesses with very close-knit groups of employees. One of the hardest tasks I have ever had to perform in my 27 year career is to personally layoff employees who have performed their jobs admirably, have families and homes of their own, employer paid healthcare, financial obligations and commitments based upon the strong wages and benefits we were able to provide. Solely and for no other reason but to pay for the Medical Device Tax. To date we have experienced a nearly 25% reduction in our staff and I see no near or long term opportunity to replace them while this tax is in effect. I have

had to implement a wage freeze since 2012 as the device tax cut into the profits and ultimately took more than 100% of both company's profits in 2014.

The payment terms and concept of what is essentially a 2.3% excise tax was, in my opinion, ill-conceived. The tax is on gross sales, cannot be passed on to consumers, is non-deductible and does not take into consideration the profitability or financial status of the company. In respect to LockDown Surgical, being a startup company, we have had to actually finance the device tax in addition to financing all of the initial costs associated with setting up and rolling out a new company and product. Investors look at the negative impact of the device tax; see how it pushes out the point of breakeven by literally years and are extremely hesitant to invest capital knowing much of it will be siphoned off to pay for a tax instead of used to grow and develop a company and new treatment therapies. No other industry is burdened with this government imposed barrier to market. Make no mistake it is a very real impediment to investment as was highlighted by a number of surveys conducted by LifeScience Alley, the Medical Device Manufacturers Association (MDMA) and AdvaMed. While presenting to Minnesota Governor Mark Dayton's Economic Round Table Forum in 2013, I expressed real alarm that the then effective tax rate on Signus Medical due to the device tax was 82%. Governor Dayton's financial advisor addressed my concerns by asking me, "Why on earth would you want to be in any business with such a high tax rate? I would never be in one." My response after the incredulous shock of that comment was that I have been in the spinal market since 2001. Our company has made commitments to providing the best treatment options to surgeons and patient care, providing our employees and their families with well-paying jobs and benefits. This company is my investment in my own future as well. Prior to 2012, the corporate playing field was essentially even and all companies just had to deal with some of the highest corporate tax rates in the world. I certainly didn't chose to selfimpose this excise tax on my companies.

To help put this in perspective, our CFO provided me with some very basic accounting examples of the impact of the tax. I am by no means a tax expert, but as CEO I am legally liable for all financial reporting and tax submissions. As such, I can certainly navigate through corporate Profit and Loss Statements and can clearly assess the impact the Medical Device Tax has on corporate bottom lines. In former times, pre device tax, a small company with \$8,000,000 in sales and

an average 6% pre-tax income would show a modest \$480,000 pre-tax profit. Using the National average state corporate tax rate of 8.5% or \$40,800 combined with the Federal Tax Rate of 35% on the adjusted taxable income or \$153,720 it would result in a total of \$194,520 in taxes paid; the Net Income After Tax would be \$285,480 which could be used to expand the business, service debt or develop new products. That represented a 40.5% effective tax rate. Now, add in the 2.3% Medical Device Tax on gross sales of \$184,000 and the total taxes paid on the same revenue dollars jumps to \$378,520 resulting in a Net Income After Tax of \$101,480 or in other words a 78.9% effective tax rate, which is a 94.6% increase in taxes and far less capital to reinvest.

Next, extend this same scenario to a startup or loss company and the effects are even more dramatic. A pre-device tax company with the same \$8.000,000 in sales and a modest -2% loss of -\$160,000 would only be subject to the average 1.5% of various State minimum taxes of \$2,400. Total Net Loss After Tax would be a -\$162,400. With the addition of the Medical Device Tax, this startup or loss company is liable for the same \$184,000 as the profitable company; its total tax liability is now \$186,400 thus resulting in a Net -\$346,400 loss. This loss, including the device tax, has to be financed somehow and pushes out breakeven and profitability. There is no return on investment when one is financing a government tax and fewer investors are willing to take on this financial burden. Furthermore, the Device Tax loss is not deductible and is therefore lost to any kind of recovery forever. The following page contains a simplistic visual example of the deleterious effect of this tax.

Comparison of effective Tax Rates

Effect of Device Tax

on a profitable company

on a startup or loss Company

		Former Law - no Device Tax	Device Tax is not Deductible for State or Federal Tax Purposes		Former Law - no Device Tax	Device Tax is not Deductible for State or Federal Tax Purposes	
These two fields may be changed, they are variables		Actual Invoiced Sales	Actual Invoiced Sales		Actual Invoiced Sales	Actual Invoiced Sales	
Sales		\$8,000,000	\$8,000,000		\$8,000,000	\$8,000,000	
- Pre-Tax Income (% of Sales)	6.00%	\$480,000	\$480,000	-2.00%	-\$160,000	-\$160,000	
Device Tax	2.30%		\$184,000	2.30%		\$184,000	
- Adjusted Pre-Tax Income State Adjusted Pre-Tax Income Federal State Tax Effective Rate	8.50%	\$480,000 \$480,000 \$40,800	\$480,000 \$480,000 \$40,800	-1.50%	-\$160,000 -\$160,000 \$2,400	-\$160,000 -\$160,000 \$2,400	State minimum taxes
Adjusted Federal Taxable Income		\$439,200	\$439,200		-\$162,400	-\$162,400	
- Federal Tax Rate Total Taxes	35%	\$153,720 <u>\$194,520</u>	\$153,720 <u>\$378,520</u>	0%	\$0 <u>\$2,400</u>	\$0 <u>\$186,400</u>	
Net Income After Tax		<u>\$285,480</u>	<u>\$101,480</u>		<u>-\$162,400</u>	<u>-\$346,400</u>	<pre><<<< Has to finance device tax!!!!</pre>
Effective tax rate on Pre-Tax Income		<u>40.5%</u>	<u>78.9%</u>		<u>-1.5%</u>	<u>-116.5%</u>	
% Tax Increase to Effective Rate			94.6%			-387.5%	

Another perhaps unforeseen but very significant impact of the Medical Device Tax is disruption of both of my companies' cash-flow. As mentioned earlier, payments are made within 2 weeks of posting sales but collections are running upwards of 70 days. These payments strip both firms of ready cash which was previously used for day to day operations, payroll and payments to vendors. Since 2012, our monthly cash-flow has been negative due to the tax and we have slowly used up all cash reserves and creative reductions of inventory to now find ourselves in arrears with suppliers. Banks and investors are clearly aware of the effects of this tax and are reluctant to extend lines of credit or further loans citing no desire to finance government taxes. As of last year, I shelved two major R&D projects because I could not guarantee that cash, which at one time was budgeted and deemed available, would in truth actually be available. Instead, we are looking at how we will simply manage through the cost of introducing several new products in 2015 which would, under pre-device tax conditions and expectations, return Signus Medical to nominal profitability and expand LockDown Surgical products into other areas of the body where there is a very real and significant patient need.

I am very proud to be actively involved in the medical device arena. It has historically been a shining star in the US economy and has supported some of the highest paying jobs when compared to all other business sectors and average wages. The advancements in treatment and improved patient outcomes is commonly a direct result of smaller and more nimble device companies, such as Signus Medical and LockDown Surgical, reinvesting profits and resources into the development of new and more cost effective surgical and non-surgical solutions. What many are unaware of, however, is the very high physical cost of supporting each and every case performed on a daily basis across this huge nation of ours. Using spinal surgery as an example, Signus Medical must supply the hospital and surgeon sufficient implants and redundant backup inventory to address every potential size and possible complication one might face in surgery. Literally dozens of implants, like shoes in a shoe store, must be provided in order

to actually implant and sell only one device and the cost of this inventory is born by the company. Hospitals no longer purchase or stock specialty instruments and implants so they must be shipped in and tracked for every single case. The FDA and HIPAA compliance burden for the location of each and every implant, their corresponding lot numbers, all associated instrument sets and ultimately which implants are used is staggering for a company of any size. The costs associated with increasing even one surgical customer are so significant that it may take many months to upwards of a year just to recoup the investment of the supporting implants and instrumentation. We at Signus have become a model of "Just In Time" shipping and inventory control in order to work around the much needed expansion capital which has been used instead to pay the device tax. Efficiency alone has its limits and I have been faced with the unenviable choice of slowing or turning down business to ensure patient safety. Patients, their safety and surgical outcomes are a priority shared by all medical device companies. This is something I will not and cannot compromise on.

With the inclusion of the Medical Device Tax into the 2014 operational budgets, both Signus Medical and LockDown Surgical posted effective tax rates in excess of 110%. This is not sustainable for any business, large or small. I fear once again I will be facing employee downsizing and further elimination of development projects and thus new clinical therapies to patients in the United States in order to just remain in business and pay the device tax. Even as the business improves, so do the pre-payment of device taxes and it is extremely difficult to actually ever catch up. Money required for reinvesting in expanded infrastructure including employees, new inventory and promising R&D projects is no longer available. Again, these problems are not unique to my two companies and are clearly felt across the entire medical device industry. I do believe however that smaller and startup companies are more severely impacted by the device tax given their inherent size and inability to spread or defer to cost over non-device products being sold by larger and more vertically integrated companies.

In conclusion I would like to thank Chairman Coats, Vice-Chairman Brady, Ranking Member Maloney, Senator Klobuchar and Representative Paulsen for this opportunity to testify before this committee. I sincerely hope that the information and personal experiences I have shared help to enlighten you as to the true negative impact the ACA's Medical Device Tax has had on the Medical Device Industry as a whole and smaller and startup companies like Signus Medical LLC, and LockDown Surgical Inc in particular. Growth, innovation and new job creation come from small medical device firms. The Medical Device Tax threatens to kill off or at the very least considerably curtail this segment of our industry.