S. HRG. 114–224

A FRESH LOOK AT THE IMPACT OF THE MEDICAL DEVICE TAX ON JOBS, INNOVATION, AND PATIENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

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A FRESH LOOK AT THE IMPACT OF THE MEDICAL DEVICE TAX ON JOBS, INNOVATION, AND PATIENTS

THURSDAY, APRIL 23, 2015

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:03 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Patrick J. Toomey (chairman of the subcommittee) presiding.

Present: Senators Grassley, Thune, Portman, Coats, Heller, Scott, Stabenow, and Cardin.

Also present: Republican Staff: Brad Grantz, Staff Director, Subcommittee on Health Care. Democratic Staff: Kim Corbin, Legislative Counsel; and Sarah Shive, Legislative Counsel.

OPENING STATEMENT OF HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE, COMMITTEE ON FINANCE

Senator TOOMEY. Welcome, ladies and gentlemen. The Senate Finance Subcommittee on Health Care will now come to order.

First of all, I want to thank Senator Hatch for encouraging us to begin this process of exploring the medical device tax with this hearing. I want to thank Ranking Member Stabenow for all of her leadership on health care issues generally, and her interest in exploring this topic as well.

I am very grateful to our witnesses for taking the time, and in some cases traveling a considerable distance, to be with us to share their expertise and their perspective on a really important issue. So, I will make no bones about it, my strong preference would be to have a full and permanent and complete repeal of the medical device tax, because it is my view that this tax is doing considerable harm—economic harm. I am concerned about the impact that it has on innovation in the medical device industry, and I am really concerned about the impact it has on individual patients—current patients and future patients.

So we will discuss this. I want to start with just a little illustration of some of the absolutely wondrous things that are being invented and developed in this space. I have in my hand, if you can see this, a ventricular assist device. This is a mechanical heart pump for those with congestive heart failure. This has kept 7,000 Americans alive while they await a transplant. Three hundred thousand people die every year in our country from heart failure. It took 5 years to get the FDA approval for this.

The company, HeartWare, that developed this product spent $200 million on research and development over the first 5 years of their existence as an American company, and they racked up $112 million of losses before they ever were able to begin to turn a profit, but think of the lives that were saved by virtue of this remarkable invention.

Here we have a spinal implant. For those who are not close enough to see, it looks remarkably like a vertebrae, but it clearly is not. It is used to mend bone fractures. This material is an alternative for over 400,000 people annually who have spinal fusion surgery to deal with severe and chronic pain in the lower back. It is made by a company called Synthes. The company employs hundreds of people in my State of Pennsylvania in Westchester.

Last, this is a vagal nerve stimulator. This is implanted in the chest, surgically implanted, this very device, and it sends an electrical current to the patient's brain, and it treats epilepsy and it treats treatment-resistant depression. Millions of Americans suffer from each of those maladies. The company that makes this also experienced, as so many start-up companies in the medical device space do, losses for years as they were in the stages of developing the product and bringing it to market and getting the approvals. In fact, they incurred $250 million in losses before they were able to turn around. Sadly, the CEO has announced that, in part to offset the costs of the medical device tax, they are going to build their next factory in Costa Rica rather than in the United States.

One of the big concerns is that this tax on sales is going to threaten America's global leadership in this space. The medical device industry is a huge economic contributor, not just in my State of Pennsylvania but across the country. The range of products is stunning, from pacemakers to orthodontics, hearing implants, surgical tools, knee braces, joint replacements. The industry employs over 400,000 people directly. There are another 2 million people who are indirectly employed because they are vendors or supplier companies to the medical device industry.

Interestingly, we had a big debate yesterday about trade policy, as Ranking Member Stabenow knows very well. The medical device industry, for the last 5 years, has run a substantial trade surplus. Because we are the leaders in the world, we make the best products, and we sell them all around the world, we have had a trade surplus, on average, over the last 5 years.

So it is a big, it is an innovative, it is a dynamic industry. It pays good wages above the averages. It improves the quality of our lives through the products that it makes, so it is really important, I think, to all of us that this industry thrives.

My view is that the medical device tax is not only onerus in its scale, but it is bad in its design. It is a tax on sales, not a tax on profits, so these companies that I alluded to that spent large sums of money making these products and bringing them to market, they were losing money for years.

Even when they started to have sales the initial years, those sales were not enough to be profitable. To impose a tax on those sales prior to there even being a profit just adds to the debt load that these companies have to carry, and there is only so much debt that can be financed. This is one of the concerns that I have. The design of this tax is very, very unfortunate.

I think we are going to hear from some of the witnesses that this has cost us jobs across the country already. Some companies have had to cancel plans to expand; others are looking to move to other places.

I want to read an excerpt from a letter from Carmel Therapeutics, which is a Pittsburgh-based company. The president and CEO is Alan West, and he sent me a letter last month in which he states that "it has also been"—the "it" he is referring to is the medical device tax—"a strong factor in discouraging venture capital from even considering medical device and early stage deals. Currently, the majority, 55 percent, of clinical trials are now being conducted overseas, and most novel medical devices are now launched outside the U.S. 4 to 5 years before they are available in the United States, according to the U.S. Department of Commerce. This is the complete opposite of the situation only a few years ago when the U.S. was taking the lead. As a case in point, my company, Carmel Therapeutics, conducted a clinical trial in South Africa and is planning to launch our first product next year in Europe."

As I said earlier, I am concerned that, of course, if we slow down the pace of new development of new medical devices, we will harm the patients who would benefit from these. So for these and other reasons, I am very hopeful that we will, in this Congress, be able to repeal the medical device tax. I am pleased that we have had bipartisan support for this concept. We had 79 U.S. Senators, obviously big majorities in both parties—every Republican and a large majority of Democrats—voting in favor of an amendment to the budget resolution in 2013.

I am delighted that we have bipartisan support for the bill to repeal it entirely. Again, I want to thank Chairman Hatch for his cooperation in this effort. I want to thank the members of the committee who are here, and the witnesses.

At this time, I would yield to our ranking member, Debbie Stabenow. Again, I want to mention how grateful I am for her leadership on health care issues in general, her leadership on this committee, and, at this time, I recognize her for an opening statement.

[The prepared statement of Senator Toomey appears in the appendix.]

OPENING STATEMENT OF HON. DEBBIE STABENOW, A U.S. SENATOR FROM MICHIGAN

Senator STABENOW. Well, thank you very much, Mr. Chairman. It really is an honor to be the ranking member on the Health Subcommittee. It was health care, which has been a lifelong passion of mine, that actually got me into public service. I will not say how many years ago, it makes me feel too old, but it is something that I have been involved with my entire life.

Thinking about last night, because it does feel like we never went home, I think the good news for your industry, from a trade standpoint, is that this tax does not apply to exports. So that is good news, because we want you to be here and be exporting. So, that is at least one good piece about this.

Today we want to hear testimony about the medical device industry and your feelings on the medical device tax, but also to focus on the vital purpose that you serve in the delivery of top-quality health care. I think that is really what the point is: creating life-saving technologies, which the chairman spoke about. I do not have anything to hold up, but it is amazing to look at these items.

From simple things like an insulin pump or the various supplies like our witness, Ms. Donisvitch, uses to control her diabetes, to an arsenal that another witness, Mr. Judge, and his doctors are relying on to combat his cancer, like imaging scans and surgical tools and radiation beams, the medical device industry's work and creativity really are a part of every medical success story and are so very important to health care, very important to our economy.

The industry does these things by investing in critical research and development that holds the promise of leading to the next medical breakthrough. I think it is also incredibly important to underscore the partnership—public-private partnership—in our country and the need to continue to invest in basic research, which then leads to the next steps for the industry to be able to move forward, as we move forward ourselves, debating things like, do we have sequestration caps, what is the budget going to look like? Investing in basic research is a very important piece of all of this if we want to continue to have those innovations.

So the next new technology could help a child to walk or hear better, or help heal our seniors' wounds, help our doctors and nurses give better, safer, more efficient care.

In addition to spurring innovation, this industry is helping to spur local and State economies all around the country. Because of key investments by the industry, American manufacturing is growing. This is a form of manufacturing.

We have lots of manufacturing in Michigan, and one of those types of manufacturing comes from great industries where, instead of an assembly line, someone is sitting at a desk doing that work, and on a very intricate, individual basis. I know firsthand—watching this innovation, the investments, and the exciting breakthroughs—because of what is happening in my home State of Michigan. Because of how important this industry is to Michigan, I helped lead the effort, when we were writing the Affordable Care Act, to actually cut the original proposed tax in half to the level that it is today as a step forward.

The good news I want to conclude with is that the Affordable Care Act is working and saving lives: 16.4 million Americans now have insurance thanks to the Affordable Care Act. Because of the premium tax credits that we all in this committee worked on so hard to secure to make it more affordable, more than half of consumers in the marketplace have a plan with a premium of under $100. Let me say that again: more than half of consumers in the marketplace have insurance plans that cost less than a cell phone plan or a cable television bill.

Because of the strong insurance market reforms, fewer Americans are going into bankruptcy due to medical bills. Because of Medicaid expansion, over 11 million additional Americans have coverage now under Medicaid or the Children's Health Insurance

Program, and that means millions of Americans now have access to lifesaving medical devices, things that had been financially out of reach for way too long.

So, Mr. Chairman, I remain committed to working with you and the medical device industry on this tax issue. It is also critical that, whatever approach we take, we protect the ability of people to be able to have the health care that they need and deserve, to have affordable insurance, and to keep access to medical devices. We all know how important it is that any solution be fiscally responsible and not add to our Nation's deficit.

The stories we are going to hear from Ms. Donisvitch and Mr. Judge are exactly the reason that we fought so hard, and continue to fight, for the Affordable Care Act and for the affordability provisions that finally put health insurance and critical medical innovations within reach of so many American families.

So I look forward to hearing from our witnesses, Mr. Chairman, and working with you on this issue.

Senator TOOMEY. Thank you very much, Senator Stabenow.

Would any other members like to make an opening statement? Senator Coats?

OPENING STATEMENT OF HON. DANIEL COATS, A U.S. SENATOR FROM INDIANA

Senator COATS. Well, thank you, Mr. Chairman. I will try to be brief. I do not want to repeat what has been said.

Indiana is the home to over 300 medical device companies, a major manufacturing industry in our country offering high-skilled jobs with literally 56 percent, on average, higher pay than other manufacturing jobs in Indiana. But more than that, more than what it does to our economy, what has already been mentioned, the improvements in health and lifesaving results of medical device innovation are truly, truly extraordinary.

We as a Congress, and we as a Federal Government, ought to be doing everything possible to encourage this industry for moral reasons alone, but for also a number of economic reasons and the fact that it is making a significant difference in people's lives.

The tragedy of what has happened here is that, while there is as much bipartisan support for this legislation as any other piece of legislation in the last 5 years within the Congress, we are unable to get to the finish line. There is one person standing in the way of our passing this on a bipartisan basis—79 votes in the last Congress, all 45 Republicans and 34 Democrats. I do not know what the ratio is now, but it significantly exceeds anything else that we have been dealing with.

Yet, the White House is reluctant to do this. It has been a pay-for, obviously, for a failed health care act. But it is an egregious tax that is not only costing a lot of companies a lot of money that they could have been putting into innovation, but has also denied people the ability to improve their lives and potentially save their lives.

In 2013, in testimony before the Senate Budget Committee, Cook Medical chairman Steve Ferguson stated, and I am going to quote because this, I think, reflects what the consequences of not taking action are: "Cook has made the difficult decision that without repeal of the medical device tax, we will move important new product lines outside of the United States. Our previous plans to open five new manufacturing facilities in American towns are now on hold as we have to use this capital intended for these projects simply to pay the excise tax."

It is more than time that Congress took up this legislation, passed a bill on a bipartisan basis, delivered it to 1600 Pennsylvania Avenue, and, if necessary, was prepared to override a presidential veto. We desperately need to move forward with this legislation and take action. We have had all the hearings that we need, and this one is important. This is part of our moving forward.

I have small companies in Indiana that are researching and pouring money into innovative improvements and yet are denied the opportunity to go forward. They are losing money in the research phase, which they cannot capture through the sales that they have because they are taxed not on profits, but they are taxed on sales. Excise tax is one of the most egregious taxes ever dreamed up by any form of government.

So, as you can tell, I am pretty exercised about this whole issue. I am really happy that you are having this hearing, and I want to move from this hearing, Mr. Chairman—and I would mention the ranking member also because this is a bipartisan effort. Let us get to the point where we no longer allow the executive branch to say, well, Congress has not moved on that. Let us move on this. Let us get a bill there, and, if necessary, let us override a veto and get this excise tax repealed.

Thank you, Mr. Chairman.

Senator TOOMEY. Thank you very much, Senator Coats.

Senator Heller?

OPENING STATEMENT OF HON. DEAN HELLER, A U.S. SENATOR FROM NEVADA

Senator HELLER. If I may. Mr. Chairman, thank you. And to the ranking member, Senator Stabenow, thank you very much for holding this hearing. I will be brief, but I probably will be repetitive. [Laughter.]

We are here to talk about the impacts of Obamacare's medical device tax on jobs, innovation, and, most importantly, patients. So let us begin with jobs.

This is an issue that is critical to my home State of Nevada, especially as we continue working to bring one of the Nation's highest unemployment rates down. At a time when one of our top priorities in Nevada is expanding and diversifying the economy, we need pro-growth policies, not new taxes on promising industries.

But the medical device tax does not create jobs or grow the economy. It funnels money into the general fund that could be spent on more employees or to continue research and development. In fact, the Medical Device Manufacturers Association reports that three-quarters of members' companies have slowed or halted the creation of new jobs thanks to this tax.

Second, we talk a lot about the ideas of promoting innovation here in Washington. The medical device industry is a perfect example of a sector where innovation is a fundamental part of its success. Yet, here we have an excise tax that stifles the development of new products that improve the quality of life for Americans, help us live longer and healthier lives. Excise taxes are often used to deter certain behavior, alcohol or tobacco consumption. In this case, the medical device tax deters innovation and the use of devices that can make our lives better.

Which brings us to the most important aspect of this discussion: how patients are harmed by this tax. Like nearly any tax, the burden ultimately falls on the consumer. Not only do patients end up paying more, their options are more limited, and they have to wait longer for new devices, or manufacturers are forced to cut back on their efforts. Medical device manufacturing represents a huge growing market, both in Nevada and throughout this country. We should be encouraging innovation in this sector, not stifling it.

Mr. Chairman, again, thank you for your efforts to bring attention to this critical issue, and I will look forward to what the witnesses have to say.

Senator TOOMEY. Thank you, Senator Heller.

Let me introduce our witnesses now. First, Bruce Heugel. Mr. Heugel is the senior vice president and chief financial officer of B. Braun Medical, Inc., which is a medical device, surgical, and pharmaceutical company located in Bethlehem, PA.

Mr. Heugel is a certified public accountant, has a master of science degree in management from Purdue University and a bachelor of business degree in accounting from the University of Toledo, where he graduated magna cum laude. Mr. Heugel, thank you for joining us.

Next is Mr. Quinton Farrar. Mr. Farrar is the founder of West Surry Strategies, LLC.

He currently holds more than 20 patents and has served in executive and engineering roles at multiple medical device companies, including Genzyme and Smiths Medical. Mr. Farrar holds a bachelor of science degree in mechanical engineering from Fairleigh Dickinson University and currently resides in New Hampshire.

Third is Alyra Donisvitch. Ms. Donisvitch is currently the assistant to the executive director at Maine Centers for Women, Work, and Community in Augusta, ME. She also has Type I diabetes.

Finally, Mr. Mark Judge. Mr. Judge is a patient advocate near Pittsburgh. He has been diagnosed with colon cancer and undergoes chemotherapy and radiation treatments.

Thank you to all of you for being willing to testify today and for joining us today.

With that, I recognize Mr. Heugel for 5 minutes of testimony.

STATEMENT OF BRUCE A. HEUGEL, SENIOR VICE PRESIDENT AND CHIEF FINANCIAL OFFICER, B. BRAUN OF AMERICA, BETHLEHEM, PA

Mr. HEUGEL. Good morning, Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Committee. I am honored, and I appreciate the invitation to appear before you to discuss the medical device tax.

I am Bruce Heugel, the CFO of B. Braun of America. We are proud to manufacture and distribute high-quality, safe, innovative, and life-saving medical devices and pharma-solutions that are used for the care of thousands of Americans every day.

In 2013, 79 Senators voted to repeal the tax. A 2015 bill, S. 149, to repeal the tax, was introduced by Senators Hatch, Klobuchar, Toomey, Casey, and many bipartisan members of the Senate. On behalf of our 5,000 American manufacturing employees, thank you. We respectfully encourage you to pass the bill now.

We are not alone, because 1,000 organizations, associations, and companies representing hundreds of thousands of jobs have also requested a repeal of the medical device tax.

A history of B. Braun of America. In the late 1970s, Professor Braun took a chance on America. His 140-year-old family medical company rescued a struggling company based in Bethlehem. This was good news for the thousands and thousands of people who were laid off due to the demise of the former industrial giant, Bethlehem Steel. The B. Braun focus on innovation, efficiency, and sustainability grew B. Braun of America from $6 million in revenue and 300 employees to $1.5 billion in revenue and 5,000 American employees, truly a success story. Bethlehem Steel had over 300,000 employees; now they have zero.

Our plant and office overlook the former Bethlehem Steel headquarters building, now an abandoned 20-story monument reminding us each day of the cruel realities of global competition, job loss, and the importance of sustainability. Sustainability is key to our company, B. Braun. We have the responsibility to our employees, our shareholders, and our community not to end up like Bethlehem Steel.

So, when the new medical device tax takes away $33 million through 2015, we are forced to launch painful countermeasures. As a CFO working for 37 years, we follow a simple rule: we balance our checkbook, and we do not spend money we do not have. The tax is enormous for B. Braun. Our Federal tax bill increased by 29 percent, and we are not alone.

The Federal tax liability for the entire industry has increased by 29 percent per the study I reference below, and some start-up product lines are not yet profitable, but we pay the tax because it is a gross receipts tax, not a tax on ability to pay, not a tax on profits. A gross receipts tax is just bad tax policy.

The tax also wipes out 29 percent of the entire United States industry's profit. Per the study I reference below, it reviewed U.S. medical companies employing 458,000 people. For many companies, those profits are typically reinvested into developing new products. There is no windfall. Some justify the tax anticipating a windfall in new patients. This has not been our experience, and studies document that we are not alone. In fact, our operating margins have declined in this industry.

But if there was growth in new patients using our new technology, then new Federal taxes would have automatically been generated without the new medical device tax, and the new tax is generated at the highest corporate income tax in the world. Please do not punish our American manufacturing jobs by double taxation.

The industry is cutting back on jobs, people, capital spending, research and development, and innovation. It has been well documented. The claims are real. In our company, we have launched painful countermeasures to balance our checkbook. For the first time in history, we did not provide raises for our workers. We did it twice. We are not proud of it.

We cut clinical trials; research; development; capital investment; product line expansion; building a new headquarters building, campus, and training center; important national sales meetings; trade shows; travel; and our pension plan. We cut people's pay, we cut the company's share of benefits, we cut most budgets.

We are in a hiring freeze, and new jobs have not been created. True, B. Braun has not launched a large workforce layoff. We are just hopeful that the tax will be repealed now. But our total American medical device workforce is down 200 through budget reductions. The impact on our employees, on our families, is real.

In closing, thank you, Senators, for listening. On behalf of our 5,000 American manufacturing workers and hundreds of thousands of jobs in our industry, please repeal the medical device tax, and please do it now.

Thank you.

Senator TOOMEY. Thank you, Mr. Heugel.

[The prepared statement of Mr. Heugel appears in the appendix.]

Senator TOOMEY. Mr. Farrar?

STATEMENT OF QUINTON J. FARRAR, PRINCIPAL PARTNER, WEST SURRY STRATEGIES, LLC, KEENE, NH

Mr. FARRAR. Thank you, Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Committee, for the opportunity to discuss the medical device excise tax's negative impact on innovation in the medical technology ecosystem.

I started in medical device research and development when I was a very young man, still in college and looking for a way to pay my tuition as I studied mechanical engineering. Little did I know that it would be my first step in my life's work dedicated to improving patient care and solving complex health care-related problems. The first product that I worked on was a dialysis system.

Through hard work, team work, and determination, I am proud to report that we built and installed the first central-delivery bicarbonate-based system in Senator Toomey's hometown region of Allentown, PA. That morning, when I woke up and that system switched on and I saw the benefits to the patients, I was absolutely hooked. The results were amazing.

From that first innovation, I knew what I was going to do with my life, and I was committed to finding better ways to treat patients and improve outcomes. I have been very fortunate to work on a range of very innovative medical technologies, such as developing the first self-contained insulin syringe.

This device freed diabetics from the need to carry big, bulky blister-packaged devices around. Anyone who has a loved one who is a diabetic knows just how important this was, and this technology is still utilized today in the configuration we designed. I have some samples of that first device with me here, which I can pass around later.

I also was part of the team that developed the post-operative cardiac auto-transfusion. This cutting-edge technology allowed patients to receive their own blood following heart surgery. It was developed at the very same time that HIV was discovered in the blood supply and there were no screening tests. Just imagine what this type of technology meant to the patients and providers at that very delicate time when we first learned about HIV.

I eventually joined a company called Smiths Medical to help expand their line of products and grow innovative platforms. The wide range of new products that we worked on there went from needle-stick devices to drug delivery pumps with advanced medication error prevention systems. In fact, the last product that I worked on for Smiths Medical was the Medfusion system, a drug delivery device that was shown recently on a "60 Minutes" segment detailing a very promising new clinical study being conducted at Duke using polio to treat brain cancer.

While at Smiths, we were grappling with managing the cost of the medical device tax. So, after 10 years at Smiths and 35 years of my life developing innovative life-saving devices, including obtaining more than 20 U.S. patents, my position was eliminated.

Of course, I cannot speak on behalf of Smiths Medical, but when the tax went into effect, I saw firsthand the challenges that the device tax was placing on our business. I understand that 200 other jobs across multiple sites have also been eliminated, and they have had to close three manufacturing facilities thus far since that tax has been in place.

All this comes on the heels of the implementation of this medical device excise tax. As a person who has been on the front lines of making these decisions on how, where, and when to make investments with precious R&D resources, I can tell you that the single largest costs are to employ the team. Simply put, if a company has to save $15, $20 million a year in additional expenses, R&D is going to be impacted. Medical technology innovators have no choice but to shelve R&D projects and move U.S. manufacturing to lower-cost regions to address this punitive tax.

When a huge hurdle such as the medical device tax is put before innovators, the net result is what we are all seeing. Promising next-generation life-saving, life-changing technologies are being shelved or unnecessarily delayed.

As someone who has led countless teams that have embarked on research projects, I know just how critical it is to have the proper resources available to take those leaps of faith. Oftentimes, quite frankly, we did not know if we would succeed, and many times we did not. But as innovators, we charged forward with knowledge that our life's work is making big differences in the lives of patients across the world. No one can ever know the totality of the medical device programs that are not getting funded because of this tax. They leave no footprint.

Regrettably, I can assure you that the impact on the future quality of care as a result of this device tax is real. We all treasure our loved ones, and surely many of us have faced our own health scares over the years. Would any of us want to know that even $1 that was to be invested in treating the condition or disease state that impacted our lives was somehow diverted?

Finally, I thank the committee and members for the opportunity to testify today, and I respectfully ask that the Senate take up and pass S. 149, the Medical Device Access and Innovation Protection Act, authored by Senators Hatch and Klobuchar. Thank you.

Senator TOOMEY. Thank you, Mr. Farrar.

[The prepared statement of Mr. Farrar appears in the appendix.]

Senator TOOMEY. Ms. Donisvitch?

STATEMENT OF ALYRA DONISVITCH, PATIENT, MANCHESTER, ME

Ms. DONISVITCH. Mr. Chairman, Senator Stabenow, and members of the committee, thank you for inviting me to testify on this very important hearing today.

My name is Alyra Donisvitch, and I am from Maine, and I am absolutely thrilled to be here to share my experience for receiving a life-saving medical device by enrolling in an Affordable Care Act marketplace health insurance plan.

I was diagnosed with Type I diabetes when I was 15 months old. Type I diabetes is an auto-immune condition. Having Type I diabetes means that my body killed my insulin-producing islet cells, thinking that they were foreign objects. Now my body no longer produces insulin on its own.

This means that I have to put insulin in my body and monitor my blood glucose levels to stay alive. Without good blood sugar management, I am at risk of damage to my heart, blood vessels, nerves, eyes, and kidneys. Without insulin, I would not be able to live.

When I was growing up, I used insulin injections to treat my Type I diabetes. When I was 10, my doctors transferred me to an insulin pump. The pump changed my life. I no longer worried about the roller coaster that came with being on insulin injections, as the insulin pump made the control of my diabetes much more accurate and simple to maintain.

Being able to have such good control of my blood sugars has helped me to prevent all of the side effects that normally come with this disease. Throughout my childhood there were periods when my family did not have insurance. Both of my parents are self-employed, and sometimes we could not afford coverage. Those times were scary for all of us.

Luckily, when I was a teenager, my family learned that I qualified for Maine's version of Medicaid, called MaineCare. I was able to stay on the program until I was 20. When I no longer qualified for MaineCare, I struggled to pay for the supplies I needed to keep myself alive.

At that time, I was a full-time college student, and I worked two jobs to pay for my medical supplies and living expenses. Even though I enrolled in programs to help with the costs, they only helped with the cost of insulin; they did not cover the expenses related to managing my diabetes. I was always worried that something was going to go wrong. There was no way I could afford insurance.

I finally hit a breaking point when the insulin pump I had been using for years began to fail and the warranty ran out. I looked at different options and found that it would cost over $9,000 to get a new pump. I did everything I could to keep my insulin pump running. A small crack began to appear near the reservoir cartridge. I held it together with nail polish, knowing that if the crack opened all the way, the entire pump would have died. There were days when I worried I would need to drop out of college so I could work and save enough money to purchase a new pump. The stress was constant and all-consuming.

When the Affordable Care Act's new health insurance marketplace opened in Maine, I looked for a plan that would meet my needs. It was important for me to find something that would cover my insulin, a new pump, and my endocrinologist. I was fortunate to find a plan, through Maine Community Health Options, that only cost $12 each month. I had a $200 deductible and a $500 out-of-pocket maximum. Shortly after my plan began on January 1, 2014, I used my marketplace insurance to replace my insulin pump. I only paid $500.

I cannot tell you how relieved I was to finally have coverage. For the first time since I was on MaineCare, I felt like I was in control of my diabetes. Thanks to the Affordable Care Act, I was able to finish my undergraduate degree without worrying about what might happen. I put the money I saved into buying a reliable car and towards paying off my student loan debt.

When I graduated, I was named one of two distinguished students at my university. That would not have been possible if I had been forced to leave school because of very high medical expenses.

Today, even though I have coverage through an employer-sponsored health plan, I no longer worry about what will happen if my insulin pump stops working or how I will pay for my medications. Because of the Affordable Care Act, I take comfort in knowing that I do not need to worry about the health complications that come with not being able to afford the care and medical devices I need to survive.

The Affordable Care Act has truly been life-changing for me. Thank you again for allowing me the opportunity to testify today and share my story.

Senator TOOMEY. Thank you, Ms. Donisvitch.

[The prepared statement of Ms. Donisvitch appears in the appendix.]

Senator TOOMEY. Mr. Judge?

STATEMENT OF MARK JUDGE, PATIENT ADVOCATE, PITTSBURGH, PA

Mr. JUDGE. Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Committee, thank you for the opportunity to discuss the medical device excise tax's negative impact on patients who are suffering from cancer.

My name is Mark Judge. I am from Pittsburgh, PA, and I have stage 4 terminal colon cancer. I was first diagnosed with colon cancer in January 2013. I had limited signs or issues as it related to cancer, but I had gone to be pre-tested for rotator cuff surgery. My primary care doctor noted that my iron level in my blood was unusually low, which would lead one to believe that somewhere there had been blood leaving the body.

Since I had no family history of cancer and up to that point I had never been sick, she suggested I get a colonoscopy. I was 46 at the time, and colonoscopies are not usually done until you are at least 50. Thankfully, we agreed to the test, and they found a tumor in my colon that was defined as stage 3B.

I immediately began 6 weeks of chemotherapy and 6 weeks of radiation. During this time, I was admitted to the hospital on two occasions with complications. One of these times, I was put on a Fentanyl patch, which is, if you are familiar with Fentanyl, 20 times more potent than morphine.

After completing the 6 weeks of chemo and radiation, I had resection surgery to remove the tumor in my colon. When I awoke from surgery, I was surprised to see that my intestines were sticking out of my gut. I had a colostomy bag. I had the bag for approximately 3 months, and then I had the reversal surgery in August of 2013. The recovery from that is still ongoing. They call it a new normal, meaning you are no longer able to go to the bathroom the way you used to go. There were times that I would have to go 60 to 70 times a day. Basically, I was a prisoner of the bathroom for many months.

During this time, I was deemed NED, no evidence of disease. I was scanned every 3 months, and on the second scan the doctors discovered some nodules in my lungs. After two biopsies, it was discovered that my cancer had metastasized to my lungs. The reality is, I was probably stage 4 all along. The cancer was always there. I fall into the 20 percent of cases where doctors cannot see the cancer in the blood, the way it worked out.

This was March 2014. The average life expectancy I was given is 3 years. In April of 2014, after another lung surgery, I embarked on 6 months of intense chemotherapy. I was on three different chemo drugs. I had surgery to place a port in my upper chest so they could administer the chemo and take blood easier. In December of 2014, I had my sixth surgery to remove the upper right lobe of my lung and to remove two other nodules.

In January of 2015, I again went on the three-chemo regimen. I have my seventh surgery scheduled this coming Monday to remove two more nodules from my left lung. Obviously, I am aware that every time they go into my lungs, they take more and more of my lungs out, and at some point I will need oxygen to breathe. I will probably be on chemo for the rest of my life.

I have accepted my situation for what it is. I am very thankful for the scans that have prolonged my life to this point. If not for them, I would not be here today. I am a success story from that standpoint. Unfortunately, many of my friends in cancer forums and advocacy groups have not been as lucky. Many of them have not had the access to scans, and for others it has been too late.

I am going to continue to fight for my life. I have an 11-year-old daughter who is my co-pilot in this journey, and I will not let her down. I need to see her grow up; I need to see her graduate and go on to college. I need to see her become a woman. These are not things that she or any child deserves to do alone.

The imaging devices that found this disease cost millions of dollars to develop. The additional taxation on these devices could prevent many health care providers from purchasing them. It also reduces the incentive for companies to invest in improving them, so cancer is detected earlier. The trickle-down effect is, this stops the innovation of new technologies.

I can only ask the question, what new technologies are there that could save my life and the lives of millions of others that are not going to be produced because of this tax? That is why I am here today. I cannot see the rationale for imposing a tax that will reduce investment in the very life-saving technologies that I and millions of others rely on and hope to see in the future.

With that, I respectfully ask the Senate to pass S. 149, the Medical Device Access and Innovation Protection Act, authored by Senators Hatch and Klobuchar. Thank you.

Senator TOOMEY. Thank you very much, Mr. Judge. Thank you very much for having the courage to come here and to tell this very, very painful story. I appreciate it.

[The prepared statement of Mr. Judge appears in the appendix.]

Senator TOOMEY. I am going to begin with the questions here, and I will keep to the 5-minute clock. I would like to start with Mr. Heugel. You touched on this briefly, but I wonder if you could elaborate a little bit, Mr. Heugel. The question is this: when this tax was being designed and being contemplated, it was assumed that most, if not all, health care providers, and medical device companies among them, would have a huge increase in business.

This was going to bring people into the conventional health care treatments that were not there before. The result would be a huge surge in sales. The huge surge in sales would result in far greater profitability, and so you could easily afford a tax on these sales. I think that was a big part of the rationale, this notion that you were going to get a big windfall.

But it seems that that is not the case with B. Braun, and you represent a large, sophisticated medical device company. Was it the case that you got a huge windfall from this or was it not, and what are your thoughts on that?

Mr. HEUGEL. I am glad you asked this question. In our case, first of all, I would say that if there was a windfall, it would be bad tax policy, because then we are getting taxed twice, once on our highest corporate tax rate in the world and then, additionally, on a new medical device tax that raises the tax rate by 29% for everyone in this industry, per the studies.

In our case, we were hoping for a windfall, we were hoping for a lot of patients, but we have not seen any. In our products, there has been no windfall, no bolus of patients coming into our industry, so that has not been our experience. There are a lot of studies out there that also indicate, in different types of medical treatments, there are no new patients or no new bolus of new patients, so they never showed up.

Senator TOOMEY. Thank you, Mr. Heugel.

Mr. Farrar, you touched on something that I think is really important but is difficult, and that is, it is very difficult to point to the product that never got invented. It is difficult to imagine the enormous benefits that would have occurred. You have spent your adult life, basically, in this industry.

If there is a reduction in R&D expenditures by medical device companies because their funds are being diverted to this tax, how certain are you that we will either see fewer new devices, new inventions, or that there will be a delay in the time in which they are available to patients?

Mr. FARRAR. Very short answer. First of all, I am absolutely certain many leaders in the medical device industry have come before this body, very honorable people, including Mr. Heugel here, and told you what is going to happen. I see firsthand the allocation of funds and investment decisions being prioritized toward activities to pay this tax—in other words, reducing costs, laying people off—as opposed to investing in things with higher risk and longer payback. So it is absolutely certain that R&D has been, and is continuing to be, cut. Again, as I said, leaders of this industry have come before you, have predicted what is going to happen, and it is in fact happening.

Senator TOOMEY. Thank you, Mr. Farrar.

Mr. Judge, as I understood your testimony, it was some very sophisticated medical imaging devices that were able to detect the spread of cancer, allow for the treatment of that, far earlier than it could have been otherwise detected—as I understand it. Is it your view that had you not had access to those scanning devices, had they not yet been invented, had they not been generally available, that the course of your treatment would have been different?

Mr. JUDGE. Yes. Flat out, I would not be here today if it were not for the medical devices that were used, the PET scans, the CAT scans, which I get periodically every 3 months, and sometimes more than that depending on my treatments. But I would not be here testifying today, so to answer your question: without question, medical devices have been pivotal.

Senator TOOMEY. Thank you.

Back to Mr. Heugel. You made the point that if there had been a surge in sales, which you never did see—it did not occur—but had it occurred, you presumably would have had a profit on that portion of sales, and you would have then been subject to the highest corporate tax rate in the world. But under the medical device law, of course, in addition to that, you would have yet another tax on the sales.

My question is, is it your view that this additional layer of tax that we impose on your industry, on top of the highest corporate income tax rate in the world, does that discourage the attraction of capital by this industry? Does that discourage investment in this industry?

Mr. HEUGEL. Very good question, Senator. It absolutely does. The tax rate is widely broadcasted throughout Europe. Last week, I was in Europe at a meeting with 26 different country managers. Everyone knows the U.S. tax rate is the highest in the world.

I have attended, where I spoke, an international trade event to try to recruit a business to Pennsylvania and the United States, and everyone in the audience always raises the question, you have the highest corporate tax rate in the world.

I have the PricewaterhouseCoopers study right here that says we have the highest corporate tax rate in the world. We also have a Canadian business up in Ottawa, and the good people to the north—where it was always at parity at 35 percent—they lowered their tax rate from 35 percent to 25 percent. It was so successful, they lowered it down to 15 percent and are asking, please come back up to Canada.

Our tax is 133 percent higher than theirs before you add the additional medical device tax burden which, per the studies by another Big Four firm, says it increases the Federal tax burden by

29 percent. So I can tell you, rest assured, from a person who has worked in 17 countries and lived in two, everyone knows our corporate tax rate is the highest, and it is uncompetitive.

We as a Nation have to be competitive in our technology, in our jobs, in what we do in our education. We have to be globally competitive in our corporate tax rates, and this does not help us at all. A 45-percent effective tax rate is too high. Thank you, Senator.

Senator TOOMEY. Thank you, Mr. Heugel.

Senator Stabenow?

Senator STABENOW. Well, thank you very much to all of you. I have lots of questions, actually, for all of you. First, Ms. Donisvitch and Mr. Judge, thank you so much for being here. Mr. Judge, thank you for sharing such a difficult story, and our thoughts and prayers go with you as you struggle going forward with this horrible disease.

I have to start, though, by saying, as somebody who wants to fix this, I have to get some facts out here on the record just because I think, if we are not careful here, it is going to be difficult to fix. We have to fix this based on accuracy.

First of all, let me just say that we had a debate last night about trade, Mr. Heugel. You should have been here. We were talking about Bethlehem Steel last night and globalization, because we are very concerned about the global economy, what is going to happen here as it relates to our trade laws, which is a whole different discussion.

Is it not true that in fact you can deduct the medical device tax as an ordinary business expense? There is not double taxation here. I just think, as someone who wants to fix this, it is very important that there not be misrepresentations. In fact, it is deducted as ordinary business expense.

Mr. HEUGEL. Thank you, Senator, for raising that question. Of course it is deducted as a cost, but it is still double taxation.

Senator STABENOW. I appreciate that. I mean, I appreciate what you are saying is double taxation, but, because it is deducted, I just think that that is important that we say that.

Mr. HEUGEL. May I add——

Senator STABENOW. Yes. I have limited time, but you are welcome——

Mr. HEUGEL. All right. Thank you, Senator. Of course it is deducted. If you look at the studies I have attached here, the average return on sales for the entire industry is 5.3 percent. As a result, if you take the medical device tax at 2.3 percent, add an effective corporate tax rate of 35 percent and lower it to 1.5 percent, you take 1.5 divided by the 5.3, and you have a huge tax increase of 29 percent for the entire industry, representing 458,000 workers.

Senator STABENOW. I appreciate that. I appreciate all the numbers. We are going through tax reform, and there is a broader issue that we need to address in tax reform. I also think that we have a medical device industry that is thriving in America. It would be very unfortunate to have the word go out that somehow this is an industry falling apart. That is certainly not true in Michigan.

In fact, it is important to say that—because this has to be credible if we are going to get this fixed—even in your own annual statement in 2013, the company said that continued growth is predicted for the U.S. health care market. In fact, when you say that you got no new customers, you got two of them sitting right here, two new customers as a result of the Affordable Care Act.

So, yes, we want to fix this, we want to do something that is fair. But I have to say that when we look at, even in your own instance, a $5.9-billion revenue increase, 2014 gained 5 percent from the year before, and there is projected growth in 2015 of 4 to 6 percent.

Certainly in Michigan and across the country, we are seeing growth. I just think we need to make sure that we support the industry by tackling, not just a 2.3-percent tax, but a whole range of things that we need to do to support innovation and to support growth in terms of other issues as well. And it is important to say that, according to a respected tax economist, Marty Sullivan, U.S. medical device companies are paying an average effective tax rate of about 7 percentage points lower than foreign competitors.

So I am not saying our tax rates on paper are not higher, but the effective rate is different. So again, when we go to what is competitive and where we need to do those things to be supportive, we just need to make sure that we are really sharing the same numbers here as we fix this.

So I want to make sure that what we are doing makes sense, but I think it is important also that people understand that we have a medical device industry that is growing and innovating in America. I hope you are not suggesting that this is going to devastate everything when there are so many other issues we need to work on together to grow the industry.

So just finally, I know I am out of time, but I do want to just say to our two folks here who are your customers, Ms. Donisvitch, it is my understanding that for you—I mean, I do not know what would have happened if the nail polish had not worked. That is a pretty scary thought.

But I am assuming that at this point, when you look at the fact that you are paying $12 a month and $500 instead of $9,000 for a pump, that for you, making sure what we do does not undermine the Affordable Care Act, I assume would be pretty important?

Ms. DONISVITCH. Yes, definitely. I mean, without the Affordable Care Act for me, in my circumstance, I would not have been able to get a new pump, and I do not even want to think about what would have happened when the nail polish failed, which it would have.

Senator STABENOW. Thank you. I know I am out of time, but, Mr. Judge, I just also want to say that it is my understanding right now that, because of your situation, you are also on Social Security Disability Insurance and on Medicaid, and we certainly understand that situation.

But, Mr. Chairman, I think that this story is also an example of why we need to be very careful about not cutting Medicaid. We just saw a budget come through this Senate, and one in the House, that would essentially devastate Medicaid, eliminating the expansion and making altogether about $1.2 trillion in cuts in Medicaid and potentially block-granting it to the States, as well as cuts in Medicare.

So, when we look at all of this, I just want to make sure that, in the end, we have a thriving industry, but also make sure that we are keeping our eye on the prize, which is making sure the people here today have access to affordable quality health care. Thank you.

Senator TOOMEY. Thank you.

Senator Portman?

Senator PORTMAN. Thanks very much for holding the hearing. Thanks for the testimony, some of which was very emotional, and some of which was very important information we need to have to be able to understand how to help our medical device companies deal with what is already a very competitive global marketplace.

Clearly, the combination of our tax structure that is not working and then this additional excise tax, which typically is something you put on things like cigarettes and alcohol—so-called "sin taxes"—is something that we have to deal with.

I am for eliminating it, because I see in my home State of Ohio the impact it has had. I have had the opportunity to visit a lot of medical device companies, and I plead with them to show me their books, and sometimes they do. What has happened is two things. One, companies in Ohio have been forced, because of the bottom line, to lay people off. I have looked at some of the, again, specifics of some of these companies.

To my colleague from Michigan, talking about how well the business is doing in some respects, in some areas of the country, I will just tell you, it would be doing a whole lot better if you did not have a tax, not on profits, but on revenues, that just makes it very difficult to be able to make the U.S. industry competitive.

So the second thing that is happening is, research is being cut back. What they tell me is, Rob, what we are going to do next year is change our budget for research, because, again, our bottom line is not as good because of this tax on our revenue. We do not want to lay people off, so we are going to try not to, but the only way to do that is to cut back on our seed corn, which is our research.

So it is happening. In my State of Ohio, there are 1,600 bioscience firms, over 400 focused on medical devices and equipment. They leverage an extensive supply chain of over 2,000 suppliers and service providers.

Mr. Heugel, I wanted to ask you a couple of questions quickly. In your testimony, you describe how B. Braun, similar to many companies in Ohio, has seen a decrease in operating margins and how the benefit from any new, increasing consumer demand for your products would be more than offset by the burdens imposed by the medical device tax and other taxes.

I guess what I would say is, kind of going to this issue of research, how does the excise tax, in comparison with other taxes, affect your firm's incentive to develop new products and do that research that we all want to see happen in order to do as Mr. Judge told us so poignantly, come up with these new devices to be able to handle some of the toughest diseases?

Mr. HEUGEL. Thank you, Senator. That is a good question. Basically, it is extra money going away. First of all, we balance our checkbook. So, when we add up the total budgets for our $1.5 billion company and recognize that we are going to have to pay, over this 3-year period, $33 million to balance our checkbook, we are forced with hard decisions.

That is why you see a lot of firms in Ohio and everywhere that are making those hard decisions. You will many times cut your clinical trials, cut your research and development, and cut a lot of your future. Why? Because you will not get paid, or those monies will not make a return to pay for those investments until 5 years, 8 years, 10 years, or longer.

So it is just basically that simple. We take the checkbook, see the cost increases due to the new tax, so therefore we have to reduce a cost from other parts of the business. That is why you see in my testimony all the cuts that we made. Thank you.

Senator PORTMAN. Mr. Farrar, you seem to have an interest in answering that question about research, too.

Mr. FARRAR. Yes. As Mr. Heugel said, R&D is sometimes—and you used the term "seed corn." It is viewed as discretionary and does not affect the immediate production of product and operations, and therefore, when you are under pressure like this, it tends to be the first thing that is deferred, because it is viewed as discretionary, future standard of living.

The other thing, why it is a tax on innovation, is because it is a dollar-one tax. It starts on the first dollar, and many new products lack scale efficiency in their early days. They cost more money, as my colleague just alluded to, with clinical studies to support them. To build on patient advocacy and those sorts of things, it costs more at the beginning, and therefore the returns are less, and it particularly affects new products and new initiatives, so you do less of them. That is the simple fact of how an excise tax works: it discourages investment.

Senator PORTMAN. So, Ms. Donisvitch, you talked about your experience; Mr. Judge, you talked about yours. I mean, what I am hearing from the companies in Ohio, and I think what I am hearing from you all today, is that part of the problem with the device tax being on revenue is that, not only do you have less research, as you say, things that are discretionary tend to go first, but also it just takes longer for the products or the technology to get to the patient so that some of these lifesaving devices are not going to be there in a timely way.

Can the two of you talk a little about that, in your experience: what difference it would have made to you not to have had the devices that you were able to take advantage of, and any information you have on sort of this time frame of how long it takes to go from the development stage to having something be available that can be used.

Ms. DONISVITCH. I mean, as far as the tax goes, I am not familiar with all of that.

Senator PORTMAN. Yes.

Ms. DONISVITCH. I mean, the insulin pump that I have is made by Tandem, and I do not know anything about that. I mean, I am glad I was able to get the insulin pump. I think what I would bring it back to is, if I did not have health insurance, I would not have been able to get it in the first place, so what is the point about making something, if it is not affordable for the consumer? So figure out the tax whichever way you want to, just please make sure that these devices are accessible and affordable for us.

Senator PORTMAN. Accessible. Yes.

Ms. DONISVITCH. That is what makes a difference to me.

Senator PORTMAN. Yes.

Mr. Judge, any thoughts on that?

Mr. JUDGE. Yes. Just to piggy-back on what Ms. Donisvitch said: without the scans, my doctors and myself would not have had any idea what was going on inside of me. As I mentioned to Senator Toomey, I would not be here today if I did not have those initial scans. In order for me to combat this, I need scans periodically.

Without the new technology, which is the PET scans and the CT scans—because I have cancer in there, but PET scans can only see the cancer at a certain size. It emits heat, so we want to get it as early as we can, because it is more affordable in the long term, but also for my sake, it will save my life. So that is basically where I am with that.

Senator PORTMAN. Yes. Thanks. My time has expired. I would just say, this is an economic issue, it is a tax issue, and it is also obviously a very personal issue, not just for the two of you, but for our constituents, so many of whom rely on America being at this cutting edge on providing these new innovations and devices and technologies. So we hope that the combination of coming up with a better solution here and our overall climate in this country, will allow us to continue to take the lead.

Thank you, Mr. Chairman.

Senator TOOMEY. I have to apologize to my colleagues. I did not realize that Senator Grassley had checked in, so I should have recognized Senator Grassley before Senator Portman. Let me recognize Senator Grassley now.

Senator GRASSLEY. I am not going to ask any questions, but I was chairing the Judiciary Committee and I wanted to show my support for this issue. I think a little bit of history is very important to understanding why this punitive tax was put on. This branch of medicine did not kowtow to the White House like the American Hospital Association or the pharmaceutical industry. This is a punitive tax just because they did not cave in.

Also, some of the history is, this tax would have been taken off last June. We had a bipartisan group, enough to override a presidential veto, with that many Democrats who were willing to support it. When this was going to pass, along with the pipeline bill, then the extenders tax bill was taken down by Senator Reid. He said, "We are not going to do that until after the election." So we have the support to get this passed, and I just want everybody to know that we ought to get it passed.

I associate myself with the remarks about the bad economic, as well as medical, impact this has had on the delivery of medicine. Many of us pointed out the flaws in this tax during consideration of Obamacare in 2009. At that time, the nonpartisan Joint Committee on Taxation was telling us that this tax would ultimately hit consumers of their products.

Our colleagues on the other side could not be bothered by a nonpartisan analysis and marched ahead with enacting a fatally flawed health reform legislation. We are now left with the consequences of this tax, and that is what is being discussed here. It has negatively impacted everyone, from manufacturers to small business people to patients, and it is time to repeal this tax once and for all.

I yield.

Senator TOOMEY. Thank you, Senator Grassley.

Senator Scott?

Senator SCOTT. Thank you, Mr. Chairman. Thank you to the panel for taking your time and investing your energies on illuminating such an important issue. This really is an issue about people, not products. I think, Mr. Heugel, your comments and your response to the question of deductibility of the tax—your numbers were quick, 5.3, 2.3, 35 percent, 1.5, 29 percent, so most folks probably did not have a chance to allow those numbers to get traction.

But let us just say it slower and differently so that we can help ourselves understand and appreciate what we are talking about. I am going to just give you a scenario, and please, let me know if I am right or wrong.

In order for the business to deduct something, you have to make something. So far, so good?

Mr. HEUGEL. Yes.

Senator SCOTT. All right. So if you make, at the end of the day, an 8-percent profit and you are going to take, not 2 percent of the profit, but 2.3 percent of the revenues generated to pay down your liability to the government, that 8.5-percent profit is slashed by about 29 percent.

Mr. HEUGEL. Yes, sir.

Senator SCOTT. So if you are taking that 29 percent and giving it to the government for some purpose, you probably cannot take that same 29 percent and use it for R&D.

Mr. HEUGEL. Yes, sir.

Senator SCOTT. If you cannot use it for R&D, the chances are innovation at the highest level will probably not happen.

Mr. HEUGEL. You get it.

Senator SCOTT. So the two folks to your left—not your immediate left, but beyond Mr. Farrar—are benefitting from the innovation and the creativity in an industry that is allowed to take the seed corn, the profit, or the revenue and reinvest that revenue in such a way that you actually are able to have more life-saving devices available on the market. As Ms. Donisvitch said, they have to be affordable to the consumer. Am I on the same page?

Mr. HEUGEL. Yes, sir.

Senator SCOTT. Sometimes we complicate the matter. If we do not appreciate and understand the absolute impact of paying a tax on gross revenues that then has to be translated out of the net profit, we do not necessarily understand the economic impact, not just on your company, but on an industry's ability to provide life-saving devices that are desperately needed. Of course, the industry is growing because people are living longer, because the medical devices are actually working. That does not necessarily make them less expensive, but it makes them more important, more valuable to all of us who want to see our friends and family members and neighbors live longer, healthier lives.

I think the stories that we have heard today are compelling stories. I have one at home in South Carolina where a lady named Kim Neal, who was diagnosed and then was victorious over breast cancer in 2006, decided to launch a small business, a small medical device business. She started seeing profits come in, she started doing pretty well. She thought—my words, not hers—the revenues that were coming in were not always profits, but they looked good when you were cashing the checks. You realize very quickly that you have to pay all your expenses, and you are left with what they call the bottom line. But unfortunately, the 2.3-percent tax eviscerated the bottom line, and it continues to do so.

So here you have a champion of champions, a breast cancer survivor, starting a medical device company, doing what she is passionate about doing, and the health care law starts, not to chip away, but to eliminate her seed capital to reinvest in such a way that she cannot innovate and create. This tax for other companies in South Carolina, smaller companies that have 35 employees, is in the range of $200,000 off the bottom line.

Now, Ms. Neal pays—in addition to the onerous tax burdens on the local level, the county level, the State level, the Federal level, and now the tax on medical devices—her own health care cost through Obamacare, which is $1,000 a month. She finds herself a little disillusioned by our political conversations about "just a 2.3-percent tax." It is not a 2.3-percent tax, it is a 29 percent, on average, elimination of resources to innovate, to create, and to extend the lives of Americans.

Have I missed something here?

Mr. HEUGEL. You have not, Senator.

Senator SCOTT. Mr. Farrar?

Mr. FARRAR. Very well said, sir.

Senator SCOTT. I think we should make this about what it really is about: two people who are alive, who are experiencing a higher quality of life, because of the innovation and the creativity of an innovative sector of our economy.

We should also realize that, if we are going to do the right thing—and Obamacare was supposed to cost $1.8 trillion; the latest number is down to $1.3 trillion, which is a drop of half a trillion dollars—I think we could figure out $29 billion.

Thank you, Mr. Chairman.

Senator TOOMEY. Thank you, Senator Scott.

I want to thank our witnesses for being very patient. We have been here for over an hour now. But I do have just a couple of quick follow-up questions, and I know Senator Stabenow does as well, so I hope you will be patient for just a little bit longer and be willing to share your time for a little bit longer.

Senator Stabenow raised, I think, a completely valid and important technical question about how this tax interacts with other taxes, and specifically she raised the question of whether the medical device tax is deductible from one's income for the purpose of determining one's income tax. My understanding is that, in fact it is deductible, and I think Mr. Heugel confirmed that.

So I have two questions. Mr. Heugel, despite the fact that the medical device tax is deductible for Federal income tax purposes, is it still the case that the net effect of the combination of the deductible medical device tax and the ordinary income taxes is still a huge tax increase over where taxes were prior to the imposition of the medical device act, number one?

Number two, I know this does not apply to your company, but you are an accountant and a CFO, and I am quite sure you know the answer to this. If a company is operating on a very narrow margin, say less than 2.3 percent, prior to the imposition of the medical device tax, is it not the case that the imposition of the tax could drive that company from a modestly profitable to a loss-making company in time, the very survival of which would be threatened? So those are my two follow-up questions for Mr. Heugel.

Mr. HEUGEL. Thank you, Senator. Those are good questions.

On the first question, I would refer to some of the studies that I referred to, because those are Big Four accounting firms. They studied the entire industry, so I quote where they said that, for the entire industry, the tax liability was raised by 29 percent.

Then I will refer to the study, also by the same public accounting firm, where they looked at all companies in the United States, 458,800 employees. I can show you the documents where they refer to what is the average industrial profit. That is where the ROS comes in, so you can do the calculations. So, the tax deductibility has already been factored into the last study that I referred to.

As far as 2.3 percent wiping out some start-ups, yes, I know of a couple of companies. We looked at them because they never had it in their long-term business model. They never had it in their long-term business model when they started their R&D. They never had it in their long-term business model when they tried to get FDA approval. They never had it in this business model when they tried to build a plant.

Now they get this new tax of 2.3 percent on gross, and one company I know is bankrupt. So it is a very devastating tax, because it delays the break-even. As a financial advisor to companies, I will say, "Put your money in the stock market; do not invest in this technology."

We have some technologies where we have invested over $100 million, $150 million 9 years ago, and we have not sold one because it takes so long. So, when you are paying tax on your gross revenues, it just makes it not a good economic decision. Thank you.

Senator TOOMEY. Senator Stabenow?

Senator STABENOW. Thanks very much.

I wanted to ask, Mr. Farrar, as an inventor and innovator yourself, I know you look at a lot of different ways to try to solve problems. That is really the business that you are in. I wonder when we look at the best approach to take in terms of the medical device tax or if there is a way—you talked a lot about the structure of this.

Is there another way to approach this in terms of the medical device industry being part of the Affordable Care Act, or is there another structure that you suggest? I am just curious if there is another approach.

Mr. FARRAR. So, first of all, thank you for the question, Senator. I am a mechanical engineer by training, and I have to defer to others on tax policy. I do not even do my own income taxes. So first of all, I think, as has been well discussed here today, an excise tax on sales is not a good idea. I think we all agree in a bipartisan way that discouraging innovation in the medical device industry is not a good idea.

So in terms of alternatives, I am not in a position where I can offer comprehensive tax advice to the Senate Finance Committee. I wish I could.

Senator STABENOW. I appreciate that. Yes, I appreciate that.

Mr. Heugel, as someone more in the tax realm, we are looking broadly at tax reform. We are looking at a whole range of things—of course, the R&D tax credit, which I believe needs to be made permanent. I think we have bipartisan support for that as well. I mean, I think it is important as we look at all this, where are the pressure points, and how do we put this together right?

But, in your perspective, is there any different way to structure this or a way to do this that is not going to add to the deficit so that as we are struggling—as a Budget Committee person, I also am in many, many meetings right now where we are trying to figure out how not to add to the national deficit. So, any creative ideas?

Mr. HEUGEL. Thank you, Senator. That is a very good and challenging question. I would look at it this way, since you asked for my advice. One of the things about the Affordable Care Act, as you have said, is it has provided people with more care.

I would sleep at night knowing that if there is more care out there, that those companies providing that care would already be taxed at the highest corporate tax rate in the world. So you can balance that by saying, if there is more patient care, this is a good thing because we are going to get more tax revenues.

In addition, I would look at it that the companies have two options. They either can try to pass it on, and we were really unsuccessful. We have long-term contracts. In fact, over 50 percent of our contracts are longer than 4 years. Over 15 percent are 7-year contracts. So we are unable to do that. But either (1), companies can do that, or they have to lay off people.

So I think I would rest at night peacefully knowing that I will prevent some layoffs, and that preventing layoffs will help the economy because it will mean jobs, and it will mean paying payroll tax, income tax, and what have you. In addition, I would recognize that if companies are successful in passing the expense on, and some of them are, you know what that does? That just increases the cost of health care, which is not what I think our policy is all about. We do not want to increase the of cost health care, so that is what I would say. Thank you.

Senator STABENOW. Thank you.

I would just ask, Mr. Heugel, do you support having more coverage in the Affordable Care Act, just without the tax? Let us say you take the tax away.

Mr. HEUGEL. I am a firm believer in health care coverage for the American people.

Senator STABENOW. Thank you very much.

Mr. Farrar, how would you respond to that?

Mr. FARRAR. Yes. So I think there are a lot of good things in the Affordable Care Act. There has also been a lot of discussion about things that could be improved upon. So I am generally in favor of care for folks, but this bill has some flaws that we already talked about, and I would like to see those fixed, starting with the medical device tax, of course.

Senator STABENOW. Of course, yes. Let me just conclude by saying the good news is, the ACA covers medical devices. So regardless of what happens, we do have people here who are covered now. I just want to thank, in conclusion, Ms. Donisvitch. You have been suffering with Type I diabetes for some 20-plus years now, and certainly Mr. Judge being diagnosed with cancer in 2013, that has to be just a punch in the gut to have to deal with all of this that is happening to you.

But I do want to say for the record that I am very proud of the fact that you both have access to affordable health care and that you are not being blocked because you have preexisting conditions, which would have happened if in fact we did not have the Affordable Care Act.

Ms. Donisvitch, as a woman in the marketplace, you probably would have been paying more for insurance if we had not guaranteed that that would not happen. And there would be annual and lifetime limits on the treatments, Mr. Judge, that you would have had, as well as the fact that, if we are not careful, people in your situation on Medicaid are going to be in a much, much more difficult situation.

So I appreciate everyone being here, and I appreciate the need for us to address this. I also want to make sure that folks can afford to buy what are very critical, life-saving innovations and products. So, thank you to all of you.

Senator TOOMEY. I want to thank you, Senator Stabenow, for your cooperation in joining us in this hearing. I am going to put you down as someone who is in favor of the Affordable Care Act, if I could.

Senator STABENOW. Yes.

Senator TOOMEY. That is an issue on which, broadly speaking, we are not in agreement. I am very deeply concerned about people losing the plans that they had and that they liked, and losing the doctors that they had preferred, the costs that have risen, and the general lack of freedom that results.

But, I appreciate the fact that we were able to focus on an area where I think there is a lot of agreement, and that is the flaws inherent in a tax that is imposed on sales on one industry that is such an important industry for our country and for the patients who benefit from the products that they develop.

I know you share the view that I have, that we want to encourage more innovation, further development of these wonderful, life-enhancing and life-saving and life-extending products. I know we are going to work together to try to achieve that.

I want to really thank our witnesses for taking the time to be here. Mr. Judge, Ms. Donisvitch, Mr. Farrar, and Mr. Heugel, your testimony was very, very helpful, and we are all very grateful.

The hearing is adjourned.

[Whereupon, at 11:28 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF ALYRA DONISVITCH,
PATIENT, MANCHESTER, ME

Mr. Chairman, Senator Stabenow, and members of the Committee:

Thank you for inviting me to testify at this very important hearing today. My name is Alyra Donisvitch, I am from Maine and I am absolutely thrilled to share my experience of receiving a lifesaving medical device by enrolling in an Affordable Care Act marketplace health insurance plan.

I was diagnosed with Type 1 Diabetes when I was 15 months old. Type 1 Diabetes is an autoimmune condition. Having Type 1 Diabetes means that my body killed my insulin producing islet cells thinking they were foreign objects, so now my body no longer produces insulin on its own. This means that I have to put insulin in my body and monitor my blood glucose to stay alive. Without good blood sugar management, I am at risk of damage to my heart, blood vessels, nerves, eyes, and kidneys. Without insulin, I would not be able to live.

When I was growing up, I used insulin injections to treat my Type 1 Diabetes. When I was 10, my doctors transferred me to an insulin pump. The pump changed my life—I no longer worried about the roller coaster that came with being on insulin injections, as the insulin pump made the control of my diabetes much more accurate and simple to maintain. Being able to have such good control of my blood sugars has helped me to prevent all of the side effects that normally come with this disease.

Throughout my childhood, there were periods where my family did not have insurance. Both of my parents are self-employed, and sometimes, we couldn't afford coverage. Those times were scary for all of us. Luckily, when I was a teenager, my family learned that I qualified for Maine's version of Medicaid, MaineCare, and I was able to stay on the program until I was 20.

When I no longer qualified for MaineCare, I struggled to pay for the supplies I needed to keep myself alive. At that time, I was a full-time college student, and I worked two jobs just to pay for my medical supplies and living expenses. Even though I enrolled in programs to help with the cost, they only helped with the cost of insulin, they didn't cover other expenses related to managing my diabetes. I was always worried that something was going to go wrong. There was no way I could afford insurance.

I finally hit a breaking point when the insulin pump I had been using for years began to fail and the warrantee ran out. I looked at different options and found out that it would cost over $9,000 to get a new insulin pump. I did everything I could to keep my insulin pump running. A small crack began to appear near the reservoir cartridge. I held it together with nail polish, knowing that if the crack opened all the way, the entire pump would have died.

There were days where I worried that I would have to drop out of college so I could work and save enough money to purchase a new pump. The stress was constant and all-consuming.

When the Affordable Care Act's new health insurance marketplace opened in Maine, I looked for a plan that would meet my needs. It was important for me to find something that would cover my insulin, a new pump, and my endocrinologist. I was fortunate to find a plan through Maine Community Health Options that only cost $12 each month. I had a $200 deductible and a $500 out of pocket maximum. Shortly after my plan began on January 1, 2014, I used my new marketplace insurance to replace my insulin pump. I only paid $500.

I cannot tell you how relieved I was to finally have coverage. For the first time since I was on MaineCare, I felt like I was in control of my diabetes. Thanks to the Affordable Care Act, I was able to finish my undergraduate degree without worrying about what might happen. I put the money I saved into buying a reliable car and towards paying off my student loan debt. When I graduated, I was named one of two Distinguished Students at my University—that would not have been possible if I had been forced to leave school because of very high medical expenses.

Today, even though I have coverage through an employer-sponsored health insurance plan, I no longer worry about what will happen if my insulin pump stops working or about how I'll pay for my medications. Because of the Affordable Care Act, I take comfort in knowing that I don't need to worry about health complications that come with not being able to afford the care and medical device I need to survive. The Affordable Care Act has truly been life changing for me.

Thank you again for allowing me the opportunity to testify today and share my story.

PREPARED STATEMENT OF QUINTON J. FARRAR, PRINCIPAL PARTNER, WEST SURRY STRATEGIES, LLC

Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Committee, thank you for the opportunity to discuss the medical device excise tax's negative impact on innovation in the medical technology ecosystem.

I started in Medical Device Research and Development when I was still in college, working at a company called National Medical Care. It began as a way to help pay my tuition as I studied Mechanical Engineering.

Little did I know that it would be the first step of my life's work dedicated to improving patient care and solving complex health-related problems.

I started my career developing the first center delivery biocarbonate based dialysis system. In those days Acetate was the buffer solution used in dialysis. The patient's body has to convert acetate, bicarbonate is the body's natural buffer, and in theory would be better tolerated but it is not stable in solution for long periods. Through hard work and determination, I am proud to report that we built and installed the first central delivery bicarbonate system, in Senator Toomey's hometown region of Allentown Pennsylvania. The results were amazing,

At that moment, I was hooked. From this point forward, I knew I wanted to spend the rest of my life researching and developing better ways to treat patients and improve outcomes.

I had the good fortune of joining a company called Becton Dickson and developed the self-contained insulin syringe. This device freed diabetics from carry big bulky blister packaged devices. Anyone who has a loved one who has diabetes knows just how important this was, and the technology today is still utilized in the configuration we designed.

I then progressed to Pfizer's Hospital Products Group, where over the course of 18 years I ran R&D, RA/QA, and Manufacturing Technology for the Deknatel Division.

The first technology we developed was postoperative cardiac autotranfusion. This cutting-edge technology allowed you to receive your own blood following heart surgery. It was developed at the same time HIV was discovered in the blood supply, and there was no screening tests yet developed.

Imagine what this type of technology meant to patients and providers at a very delicate time period when we were first learning about HIV.

I always had the entrepreneurial bug, and as a result some colleagues and I at this point invested in building a new company, Deknatel Snowden-Pencer. Here we developed devices that allowed surgeons to make bypass grafts on a beating heart. We also introduced a minimally invasive surgical system to allow the harvest of the saphenous vein eliminating the need to open fillet of the leg, one of the most painful aspects of the recovery from heart surgery.

I've also spent some of my career creating biomaterials, surgical implants to reduce painful adhesions following surgery for colon cancer and hernia repair. We applied this technology to orthopedics to provide lubrication to arthritic joints, reducing pain and improving mobility.

About 12 years ago, I joined Smiths Medical to help expand their line of products and grow innovative platforms they are proudly known for. The wide range of new products ran from needle stick prevention devices to drug delivery pumps with advanced medication error prevention systems. In fact, the last new product that I worked on for Smiths Medical was the Medfusion system, a drug delivery device shown in the recent 60 Minutes segment detailing the promising clinical study at Duke of using Polio to treat brain cancer.

Unfortunately, the Medfusion syringe pump was my last new product at that company.

While Smiths Medical was grappling with managing the costs of the medical device tax, after more than 10 years at Smiths Medical, with 35 years of my life developing innovative lifesaving medical devices, including obtaining more the 20 U.S. Patents, my position was eliminated.

Of course, I cannot speak on behalf of Smiths Medical, but when the tax went into effect, I saw first-hand the challenges the device tax was placing on our business. I understand 200 other jobs across multiple sites have also been eliminated and they have had to close three manufacturing facilities thus far since the tax has been out in place.

All of this comes on the heels of the implementation of the medical device excise tax.

At the facility where I was headquartered, in Keene, New Hampshire, they produced safety stick needle technology. Before I left the company, we projected we would have to pay $3 million annually on the medical device tax. With disposable technology like safety stick needles, the business was struggling to make up that revenue.

As a person who has been on the front lines of making decisions on how, where and when to make investments with precious R&D resources, the single largest costs are compensation related.

Simply put, if a company has to save $15–$20M a year due to additional expenses, the first thing you might define is discretionary spending not directly related to the current product and operating income.

All too often however, R&D is impacted.

I strongly believe this is why the largest source of lost jobs and investments are due to the medical device tax.

Medical technology innovators have no choice but to shelve R&D projects and move U.S. manufacturing to lower cost regions to address this punitive tax.

The tax depletes resources that should be invested in new promising cures or new manufacturing technologies. I can assure you firsthand that R&D requires significant investment, and long periods of time in the ecosystem before possibly ever seeing a return.

With my experience heading up R&D projects, sadly, I know that the billions of dollars this excise tax is diverting from innovators is now being taken largely out of compensation in the areas of R&D and U.S. manufacturing jobs.

The medical device tax starts with the first dollar of product sales and thus it reduces the incentive for growth investments. This effect is the same for every new product investment.

New innovative products tend to initially lack scale and efficiencies. This takes time, requiring cash investments at a higher percentage of sales then existing products. There are differences in a company's ability to offset the additional loses that the medical device tax imposes by siphoning money from other product areas.

Start-ups and small medical device businesses are particularly at a disadvantage as they lack the ability to redeploy operating income to offset an excise tax on sales. Put another way, when a huge hurdle such as the medical device tax is put before innovators, the net result is what you are seeing—cuts to R&D and promising, next generation of life-saving and life-changing technologies are now being shelved or unnecessarily delayed.

As someone who has led countless teams that embarked on research projects, I know just how critical it is to have the resources to take these leaps of faith. Often, quite frankly, we did not know if we would succeed. At times, we did not. But as innovators we charge forward with the knowledge that our life's work is making monumental differences in the lives of patients across the world. By Congress enacting policies that drains billions of dollars from American high-tech manufacturing, it is no surprise that these difficult choices are being made.

The medical device excise tax clearly increases the relative attractiveness and absolute urgency of large cost reductions programs for the base of existing products at the expense of investments in growth programs.

No one can ever know the totality of the medical device programs that are not getting funding because of this tax.

Regrettably, I can assure you that the impact on the future quality of care as a result of the device tax is real.

We all treasure our loved ones, and surely many of us have also faced our own health scares over the years. Would any of us want to know that even $1 that was to be invested in treating the condition or disease state that impacted our lives was diverted?

What future lifesaving device is not being developed today as a result of this excise tax? These difficult investment decisions are being made every day. I know we can all agree that reducing investments in the U.S. medical device sector is not a good idea. There should be no place for policies that reduce incentives for innovation in life saving technologies.

My life's work has been medical device development. I recently formed West Surry Strategies, LLC to help other medical device companies drive innovation and improve competitiveness. From kidney failure to diabetes to heart surgery and much more, I have been blessed to play a role in improving outcomes.

I live in New Hampshire and have spoken with both Senator Ayotte and Senator Shaheen and I am proud to say that New Hampshire enjoys bi-partisan support for the repeal of the medical device tax.

I respectfully ask that Senate pass S. 149, the Medical Device Access and Innovation Protection Act authored by Senators Hatch and Klobuchar.

Thank You.

PREPARED STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

Good morning. I first want to thank Senator Toomey for arranging this important discussion and for your dedication and leadership in the bipartisan effort to repeal the medical device tax. Senator Toomey has been a long time partner and champion of fighting this ill-conceived tax. I truly appreciate his leadership along with Senators Burr, Portman, Coats, Crapo, Isakson, and Scott who have been key to building support on this.

The people of Utah and others that I hear from agree that the medical device tax harms American innovation, job growth, and the ability to provide innovative medical technologies to patients. Earlier this year, I re-introduced bi-partisan legislation to repeal the excise tax with 35 co-sponsors. If passed, the Medical Device Access and Innovation Protection Act will help ensure that Americans continue to have access to innovative, life-saving medical devices.

A strong medical device industry in the United States is critical to improve the health of Americans and the national economy. In the U.S., the industry employs over 400,000 American workers and pays about $25 billion in salaries. Medical device companies pay salaries that are 40% more than the national average. The technologies developed by these companies increase life expectancy, decrease mortality rates, and improve the quality of life for many Americans.

Although this industry is one of the engines of our economy and critical to patient health, President Obama decided to target it by implementing an excise tax on medical equipment and devices in Obamacare. Like many other provisions in Obamacare, the excise tax will ultimately increase the cost of health care for Americans. The Joint Committee on Taxation estimates that it will collect about $24 billion in taxes over the next 10 years. I have heard that the impact of the tax is particularly burdensome on innovative companies whose new products are not immediately profitable. As medical device companies face increasingly higher costs, some of that cost will inevitably be passed on to patients.

The tax is already having an adverse impact on job creation in the United States and harming U.S. competitiveness. A study by the Advanced Medical Technology Association (AdvaMed) found that the tax impacted approximately 33,000 American jobs in its first year, either through layoffs or forgone jobs that would have been created. The excise tax is likely to shift jobs overseas because it weakens the playing field for U.S. companies and gives their foreign competitors an unfair advantage in the global marketplace for medical devices.

For these reasons, it is my strong belief that Congress should act swiftly to repeal this excise tax to keep health care costs low for American patients, protect innovation, and protect American businesses.

I want to thank our witnesses for appearing today to help discuss the impacts of the medical device tax, and I look forward to this important discussion.

PREPARED STATEMENT OF BRUCE A. HEUGEL, SENIOR VICE PRESIDENT AND CHIEF FINANCIAL OFFICER, B. BRAUN OF AMERICA

Good morning. Chairman Toomey and Ranking Member Stabenow and members of the Senate Finance Committee, I am honored and I appreciate the invitation to appear before you to discuss the medical device tax. I am Bruce Heugel the CFO of B. Braun of America.

We are proud to manufacture and distribute safe, high quality, innovative and life saving medical devices and Pharma solutions that are used for the care of thousands of American patients every day.

In March 2013, 79 Senators voted to repeal the medical device tax. In January 2015, bill S. 149 to repeal the tax was introduced by Senator Hatch, Klobuchar, Toomey, Casey and many other bipartisan members of the Senate.

On behalf of our 5,000 American manufacturing workers we thank you, and we respectfully encourage you to pass the bill.

We are not alone, as 1,000 organizations, associations, companies, patients, providers and venture capital firms representing hundreds of thousands of medical technology jobs have respectfully requested a repeal of the medical device excise tax.[1]

HISTORY OF B. BRAUN OF AMERICA

In late 1970s Professor Braun took a chance on America. His 140 year old family medical company rescued a struggling company based in Bethlehem, Pennsylvania. This was good news as thousands were laid off due to the demise of the former industrial giant Bethlehem Steel. The B. Braun focus on innovation, efficiency and sustainability, grew B. Braun of America from $6 million in revenue and 300 employees to $1.5 billion in revenue and to 5,000 American employees. A true success story.

Bethlehem Steel had over 300,000 employees. Our plant and office looks over the former Bethlehem headquarters building, now an abandoned 20 story monument reminding us each day of the cruel realities of global competition, job loss and the importance of sustainability.

Sustainability is key to B. Braun. We have responsibility to our employees, shareholder and community not to end up like Bethlehem Steel. So when the new medical device tax takes away $33,000,000 through 2015, we are forced to launch painful counter measures. As the CFO we follow a simple rule: we balance our check book, and do not spend money we do not have.

ENORMOUS TAX

The tax is enormous for B. Braun. Our Federal Tax bill increased by 29%.

[1] January 13, 2015—letter to Majority Leader Hon. Mitch McConnell, Speaker of the House Hon. John Boehner, Minority Leader Hon. Nancy Polosi and Minority Leader Hon. Harry Reid. Letter attached.

We are not alone. The federal tax liability for the entire industry increased by 29%, per the study "Effect of the Medical Device Excise Tax on the Federal Tax Liability of the Medical Device Industry." [2]

Some start up product lines are not yet profitable, but we pay the tax, because it is a gross receipts tax, not a tax on profits. A gross receipts tax is bad tax policy.

The tax also wipes out 29% of the entire U.S. industry profit. Per the "Pulse of the Industry" study the U.S. Public medical companies employ 458,800 and had average profitability in 2013 of only 5.2%.[3] In comparison the new tax is 2.3% or 1.5% after tax (using federal statutory rate of 35%). As a result, the tax wipes out 29% of the profit for the industry.[4]

And for many companies those profits are typically reinvested into developing new products.

NO WIND FALL

Some justify the tax anticipating a windfall in new patients for the industry. This has not been our experience. And studies document we are not alone. In fact our operating margins are down in the last 2 years. The major driver of that decline is the tax.

But if there was a growth in new patients using our medical technology, then new federal taxes would automatically be generated, even without the new device tax. And the new federal tax generated is at the highest corporate income tax rate in the world.[5]

Please do not punish manufacturing jobs by double taxation.

PAINFUL COUNTER MEASURES

The industry is cutting back on jobs, on people costs, capital spending, research, development and innovation. It has been well documented.

The claims are real. At my company we have launched painful counter measures to balance our checkbook.

First time in our history we did not provide raises to our workers. And we did it twice. We are not proud of it.

We cut clinical trials.

We cut research and development.

We cut capital investment and product line expansion.

We cut building our new North American headquarters campus and training center.

We cut important National sales meetings, trade shows and travel.

We cut our pension plan.

We cut peoples' pay through reductions in deferred compensation.

We cut company share of benefits forcing our employees to pay more.

We cut most budgets.

We are on a hiring freeze, and new jobs have not been created.

True, B. Braun has not launched a large workforce layoff. We are hopeful the tax will be repealed. But our total American medical device workforce is down by 200 through budget reductions.

The impact on our company is real.

Thank you Senators for listening. On behalf of our 5,000 American manufacturing employees, and the hundreds of thousands of jobs in our industry, please act to repeal the medical device tax.

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[2] Effect of the Medical Device Excise Tax on the Federal Tax Liability of the Medical Device Industry by Ernst and Young November 2012, page 1, page 5.

[3] Pulse of the Industry. Medical Technology Report 2015, by Ernst and Young, page 35. United States Financial Performance calculated from Data $11.4/218.5–5.2%.

[4] Calculation: 1.5%/5.2% = 29%.

[5] March 17, 2015 Hatch Statement at Finance Hearing on Building a Competitive U.S. International Tax System.

CONTINUED TESTIMONY NOT SPOKEN

NO PRICE PASS THROUGH

The market for most medical technology is characterized by close competition. The highly price competitive nature of the market for medical devices is well established. Our customers have market power. As a result, raising prices is difficult even in the best circumstances. Most contracts between manufacturer and purchaser typically have terms of 5 to 7 years. There is no special mechanism to immediately pass the medical device tax forward. And when prices are negotiated during the bidding process for new contracts, the purchasers hold enormous leverage.

Some studies argue that the tax will be eventually passed on to the customer. But these studies assume a marketplace that is dominated by demand at the level of the individual patient. Medical devices, however, are not generally purchased by individual patients. Rather, the buyers are institutions. For our company, the main purchasers are GPOs and hospitals. In a highly competitive market such as the one for medical devices, these purchasers have the ability to refuse to accept price increases. In addition, they can delay or cancel large purchases or substitute alternatives.

Even if you assume a future scenario where the purchasers lack the market power discussed above, the end result would simply be to increase the cost of medical products and the cost of health care, which cannot be anyone's policy goal.

GLOBALLY UNCOMPETITIVE

Some say the tax does not unfairly treat U.S. companies as compared to foreign companies. I disagree. For one reason, IRS form 720 for paying the medical device excise tax can only be completed by U.S. companies. Further, as a general notion, companies develop medical devices for local markets first then export. U.S. manufacturers typically sell a larger portion of their technology in the U.S., meaning they are paying more tax than a foreign company whose U.S. sales may only represent a small percentage of their overall sales. Therefore, the U.S. manufacturer is absorbing a more significant cost on their sales.

I have spoken at numerous international economic development trade missions and forums. I have worked in 17 countries and I work for a global organization. I have first hand knowledge how the U.S. tax code is viewed by the world. The world knows that U.S. corporate tax system makes the U.S. uncompetitive. Let's not make it even worse by adding another tax, especially on an innovative, important industry like ours.

Most countries have lowered corporate tax rates to attract business and improve global competitiveness. Until recently, Canada, for example, was at parity to the U.S. at 35%. Canada then slashed the tax rate to 25%. It was so successful the tax was reduced a few years later to 15%. The U.S. tax rate is 133% higher than Canada.[6] Our goal should be to make the U.S. more competitive, not less. The tax makes the U.S. globally uncompetitive.

ABOUT B. BRAUN OF AMERICA

B. Braun manufactures and distributes medical devices, surgical instruments and Pharma IV solutions. Total revenues are $1.5 billion and there are 6,500 employees including 5,000 American employees. Our products are safe, high quality, innovative and FDA approved. We manufacture 70% of our products in the U.S. for the U.S. We also import and distribute, from the B. Braun Melsungen AG family of companies. B. Braun Melsungen AG is a 176 year old private family company, headquartered in Germany, and is our shareholder. The company's continued survival and success is driven by the B. Braun culture of innovation, efficiency and sustainability, under the Sharing Expertise umbrella.

January 13, 2015

The Honorable Mitch McConnell Majority Leader United States Senate	The Honorable Harry Reid Minority Leader United States Senate

[6] Calculation: 35% (USA)—15% (Canada)/15%.

The Honorable John Boehner Speaker of the House United States House of Representatives	The Honorable Nancy Pelosi Minority Leader United States House of Representatives

Dear Majority Leader McConnell, Speaker Boehner, Minority Leader Reid and Minority Leader Pelosi:

As the 114th Congress begins, we respectfully request that repeal of the medical device excise tax be addressed as a top priority. Implementation of this excise tax—now estimated to collect approximately $25 billion in taxes—is adversely impacting patient care and innovation, and will compromise patient access to cutting edge medical technologies. The Senate and House have both previously passed repeal legislation with strong bipartisan majorities. On behalf of the almost 1,000 undersigned organizations, associations, companies, patients, providers and venture capital firms representing hundreds of thousands medical technology jobs, we ask that you act to repeal the medical device tax during this session of Congress.

As you know, the medical device industry is a unique American success story—both for patients and our economy. The United States is the world leader in manufacturing life-saving and life-enhancing treatments, and the industry is an important engine for economic growth. The industry employs more than 400,000 workers nationwide; generates approximately $25 billion in payroll; pays out salaries that are 40 percent more than the national average ($58,000 vs. $42,000); and invests nearly $10 billion in research and development (R&D) annually. The industry is fueled by innovative companies, the majority of which are small businesses with 80 percent of companies having fewer than 50 employees and 98 percent with fewer than 500 employees.

Unfortunately, the health care law imposes tens of billions in new excise taxes on medical technology companies, which are stifling innovation and U.S. competitiveness. The tax is already having an adverse impact on R&D investment and job creation, jeopardizing the U.S. position as a global leader in medical device innovation. If this tax is not repealed, it will continue to force affected companies to cut manufacturing operations, research and development, and employment levels to recoup the lost earnings due to the tax. It will also adversely impact patient access to new and innovative medical technologies.

In short, this tax on innovation should be repealed for the following three important reasons:

- The tax stifles innovation and has already costs thousands of high-paying jobs. It has increased the effective tax rate for medical technology companies, thereby reducing financial resources that should be used for R&D, clinical trials and investments in manufacturing. The impact is especially hard on smaller companies whose innovations are not immediately profitable.
- The tax imposes an additional heavy burden on U.S. companies already struggling with an uncompetitive tax system and gives their competitors overseas an advantage in the global marketplace for medical devices.
- The tax is not being offset by increased demand for medical devices. In fact, it is important to note that there is no evidence suggesting a device industry "windfall" from healthcare reform. Unlike other industries that may benefit from expanded coverage, the majority of device-intensive medical procedures are performed on patients that are older and already have private insurance or Medicare coverage. Where states have dramatically extended health coverage, such as in Massachusetts where they added400,000 new covered lives, there is no evidence of a device "windfall."

At a time when the federal government is working to promote investment in U.S. industries of the future, it is inconsistent that a tax of this magnitude is placed on the medical device industry. We must do all we can to encourage and promote research, development, investment and innovation. Instead, increased taxes, such as this one on the medical device industry, coupled with the increased regulatory uncertainty the industry also faces, is leading to further job losses, hindering the development of breakthrough treatments and delaying patient access to medical technology.

We respectfully request timely action on legislation to repeal this over $25 billion excise tax.

.decimal
3D Medical Manufacturing, Inc.
3M Healthcare
A-dec
A.R. Hinkel Company
Abaxis
Abbott
Abiomed, Inc.
Acacia Research Corporation
Academy of General Dentistry
Accuitive Medical Ventures
Accuray Incorporated
Acelity
Acertara Acoustic Laboratories, LLC
Aciont Inc.
ACON Laboratories, Inc.
ActivaTek Inc.
Active Implants
Actus Medical
Acufocus
Acumen Healthcare Solutions, LLC
Adagio Medical, Inc.
Albright Technologies
Alcon, A Novartis Group Company
Aleeva Medical Inc.
Align Technology, Inc.
Alkaline Corporation
Allvivo Vascular, Inc.
ALPCO Diagnostics
Alphatec Spine, Inc.
Alps South LLC
Alta Partners
ALung Technologies, Inc.
AlvaMed Inc.
Ambio Health
Ambu, Inc.
Amedica Analogic Corp
America's Blood Centers (ABC)
American Academy of Facial Plastic & Reconstructive Surgery
American Academy of Pediatric Dentistry
American Academy of Periodontology
American Association of Endodontists
American Association of Neurological Surgeons
American Association of Oral and Maxillofacial Surgeons
American Association of Orthodontists
American College of Prosthodontists
American College of Radiology
American Dental Association
American IV Products, Inc.
American Society of Cataract and Refractive Surgery
American Society of Dentist Anesthesiologists
American Society of Plastic Surgeons
Amsino International, Inc.
Andersen Products
Andover Healthcare
Adept-Med International, Inc.
Adhezion Biomedical, LLC
ADM Tronics
Adroit Medical
Advanced Bionics
Advanced Circulatory Systems, Inc.
Advanced Medical Technology Association
Advanced Orthopaedic Solutions (AOS)
Advanced Surgical Instruments
Advanced Technology Ventures
AdvanDx
Aegis Surgical
Aerocrine, Inc.
Aesculap, Inc.
AescuLight
AestheTec, Inc.
Aethlon Medical, Inc.
AFC Tool
Affinity Capital
Agamatrix, Inc.
Agendia, Inc.
Alabama Dental Association
ARC Medical, Inc.
Ardiem Medical, Inc.
Argenta Advisors
ARIBEX, Inc.
Arizona BioIndustry Association
ArKal Medical, Inc.
ARKRAY
Arteriocyte
ARTHROSURFACE, INCORPORATED
Articulinx
Asante Solutions, Inc.
Aso LLC
Aspen Medical Products
Aspen Surgical
Associated Industries of Florida (AIF)
Associated Industries of Massachusetts (AIM)
Associates of Cape Cod, Inc.
Astute Medical
AtCor Medical Holdings, Ltd.
Ativa Medical
ATL Technology Utah
Atlanta BioMedical Corporation (ABC)
Atlas Spine, Inc.
Atos Medical Inc.
AtriCure, Inc.
Atrium Medical Corporation
Aurident, Inc.
Aurora Spine
Autonomic Technologies, Inc.
Auxogyn, Inc.
Avacen MOD Corporation
Avantis Medical Systems, Inc.
Avedro
Avinger
Axiobionics
Axiom Medical, Inc.
AxioMed Spine Corporation

Andrew Technologies
Anesthetic Gas Reclamation, LLC
Angel Medical Systems
AngioDynamics
AngioScore Inc.
Anulex Technologies, Inc.
AOTI Inc.
Apollo Endosurgery
Applied Dexterity, Inc.
Applied Research & Photonics, Inc.
Aptus Endosystems, Inc
Aqueduct Neurosciences, Inc.
Aqueous Biomedical, Inc.
AqueSys, Inc.
BeneChill, Inc.
Benvenue Medical, Inc.
Berlin Heart, Inc.
Berman Medical
Bio-Rad Laboratories
Bioanalytical Systems, Inc.
BioBusiness Alliance of Minnesota (BBAM)
BioCardia, Inc.
BioCare Systems, Inc.
BIOCOM
Biocompatibles Inc.
Bioconnect Systems, Inc.
BioDerm, Inc.
BioElectronics
BioFlorida
BIOforward
BioHouston
BioMedical Life Systems
BioMedix
bioMerieux, Inc.
Biomet, Inc.
BioMimetic Therapeutics, Inc.
Bionix Development Corporation
BioOhio
Biophan Technologies, Inc.
BIOSAFE, Inc.
Bioscale
Bioscience Association of Maine
BioSET, Inc.
Biotest Laboratories, Inc.
bioTheranostics, Inc.
BIOTRONIK, Inc.
Bioventus LLC
Birchwood Labatories Inc.
Blaze Medical Devices
Boston Healthcare Associates, Inc.
Boston Scientific Corporation
BrainScope Company, Inc.
Breathe Technologies
Breg
BTE Technologies, Inc.
Business Council of New York State
Busse Hospital Disposables
C.R. Bard, Inc.
Cadence, Inc.
Caldera Medical, Inc.
California Healthcare Institute (CHI)
B. Braun Medical, Inc.
Balchem Corporation
Banyan Biomarkers
BAROnova, Inc.
BaroSense, Inc.
Baxano Surgical, Inc.
Baxter Healthcare
BayBio
BD
BEACON (Biomedical Engineering Alliance & Consortium)
Beaver Visitec
Beckman Coulter
Belmont Instrument Corporation
Cardia Access
Cardiac Dimensions, Inc.
Cardiac Science
CardiacAssist, Inc.
CardiAQ Valve Technologies, Inc.
Cardinal Health
Cardinal Scale Manufacturing Company
CardioCommand, Inc.
CardioDx, Inc.
CardioFocus, Inc.
CardioKinetix Inc.
CardioNexus Corporation
Cardiovascular Systems, Inc.
CareFusion Corporation
Carmell Therapeutics Corporation
Carrot Medical
Carticept Medical
Cartiva, Inc.
Case Medical, Inc.
Catheter Connections, Inc.
Cayenne Medical
CEA Medical Manufacturing
Celleration
Center for Medical Device Innovations
Cepheid
CeQur
Cerebrotech Medical Systems
Cerephex Corporation
Cerevast Therapeutics, Inc.
Ceterix Orthopaedics
Checkpoint Surgical
HIP Solutions LLC
Christcot Medical Company
Cianna medical
Circadiance
City Hill Ventures, LLC
CivaTech Oncology
Claret Medical, Inc.
Clarity Medical Systems, Inc.
Claro Scientific, LLC
Clarus Medical, LLC
ClarVista Medical
Clear Ear Inc.
Cleveland Medical Devices Inc.
Clinical Research Consultants, Inc.
CoAxia, Inc.
Cochlear

Canaan Partners
Cannuflow Inc.
Cantel Medical Corp.
Cantimer, Inc.
Carbylan Biosurgery, Inc.
Command Medical Products, Inc.
COMPASS International Innovations
Compression Therapy Concepts
Concert Medical
Congress of Neurological Surgeons
ConMed Corporation
CONNECT
Consensus Orthopedics, Inc.
ConvaTec Inc.
Cook Medical
Coombs Medical Device Consulting, Inc.
Core Medical Imaging
Corgenix Medical Corporation
Corin USA Limited
Corindus Vascular Robotics
Corinthian Ophthalmic, Inc.
Cormatrix
Corventis, Inc.
COTERA, Inc.
Council for Affordable Health Coverage
Covalent Medical, Inc.
Covidien
Coy Laboratory Products, Inc.
Creatv MicroTech, Inc.
Critech Research
Critical Diagnostics
Cryothermic Systems
CSA Medical, Inc.
CurveBeam
CVRx, Inc.
CyberHeart
Cyberonics
Cynosure
Cytori Therapeutics, Inc.
CytoSorbents Corporation
D & D Video Specialists, Inc.
D&D Medical, Inc.
D&R Products
Dallen Medical
dataCon Inc.
DataPhysics Research, Inc.
DaVinci Biomedical Research Prod., Inc.
De Novo Ventures
DEKA R&D Corp.
Delcath Systems, Inc.
Dental Trade Alliance (DTA)
Denterprise International, Inc.
DERMA SCiENCES, INC.
DeRoyal
Design Mentor
Desmoid Tumor Research Foundation
Detroit Technical Equipment Company
Figure 8 Surgical
Fischer Medical Technologies, Inc.
Fisher Wallace Laboratories
Fjord Ventures
Cohera Medical, Inc.
Coherex Medical
Colorado Bioscience Association (CBSA)
Colorado Dental Association (CDA)
Columbus Chamber of Commerce
Devicix
DFine, Inc.
DG Medical
diaDexus
Digirad
Direct Flow Medical
Disposable Instrument Co., Inc.
DJO Global, Inc.
Domain Associates, L.L.C.
Domain Surgical, Inc.
Dynatronics
E. Benson Hood Laboratories, Inc.
EarlySense Inc.
eCardio Diagnostics
Echelon Biosciences, Inc.
Echo Therapeutics
Edwards Lifesciences
EKOS Corporation
Electrical Geodesics, Inc.
Electromed, Inc.
Elekta
Ellipse Technologies, Inc.
Ellman International
Emerge Diagnostics, Inc.
Emergent Medical Partners
Emerson Consultants, Inc.
Endo Health Solutions, Inc.
Endo-Therapeutics, Inc.
EndoChoice, Inc.
EndOclear, LLC
EndoGastric Solutions
EndoShape, Inc.
eNeura Therapeutics
Engineered Medical Systems/Pulmodyne
Entellus Medical
EnteroMedics, Inc.
EPIC Research & Diagnostics
Erchonia Corp.
Essex Woodlands
eVent Medical
Evergreen Medical Technologies
Exact Sciences
Exactech
Experien Group
ExploraMed Development, LLC
ExThera Medical Corporation
Eye Care and Cure, Inc.
Fallbrook Engineering, Inc.
FAST Diagnostics
FemCap Inc.
Ferris Mfg. Corp.
Fidia Pharma USA Inc.
Halyard Health
Harbert Venture Partners
Hausmann Industries, Inc.
Health Industry Distributors Association

Flexicath, Inc.
Flexuspine, Inc.
Flight Medical
Flocel Inc.
Florida Manufacturing Extension Partnership (MEP)
Florida Medical Manufacturers' Consortium, Inc.
ForSight Labs, LLC
ForSight VISION6, Inc.
Fortimedix USA, Inc.
FOUNDRY NEWCO XI
Freedom Meditech, Inc.
Fresenius Medical Care NA
Freshmedx
Frontier Scientific Inc.
FUJIFILM SonoSite Inc.
Fujirebio Diagnostics, Inc.
Functional Fluidics
Galil Medical
Galt Medical
Gambro
Gamma Medica Inc.
GE Healthcare
Geistlich Pharma North America Inc.
Genesis Plastics Welding
GENICON
Gentis Inc.
Genway Biotech, Inc.
Georgia Bio
Georgia Dental Association
GI Dynamics, Inc.
Gilero, LLC
Glaukos Corporation
Glenveigh Medical
Globe Composite Solutions, Ltd.
Globus Medical
Goodmark Medical, LLC
Gradient Technologies, LLC
Great Lakes NeuroTechnologies Inc.
Greatbatch, Inc.
Gregory, Sharer & Stuart, CPAs
Ground Zero Pharmaceuticals
GT Urological, LLC
Gulden Opthalmics
Haemonetics Corp.
Halo Healthcare Inc.
HALT Medical, Inc.
Infinium Medical
InfoBionic
Infraredx, Inc.
InfraScan, Inc.
InjectiMed, Inc.
Inogen
inSite Medical Technologies
Instratek, Inc.
Insulet Corporation
Insurance Office of America
Insurgical LLC
Intact Medical Corporation
Intact Vascular, Inc.
(HIDA)
Health IT Now Coalition
HealthCare Institute of New Jersey
Healthcare Leadership Council
HealthpointCapital
HeartFlow
HeartWare International, Inc.
Heidelberg Engineering
HEPCO MEDICAL LLC
Hill-Rom
Hispanic Dental Association (HDA)
HistoSonics, Inc.
HITACHI MEDICAL SYSTEMS AMERICA, INC.
Holaira
Hologic
Home Dialysis Plus
Hospira Inc.
HoverTech International
HTG Molecular Diagnostics
Hull Associates
Hycor Biomedical, Inc.
Hydrocision
Hygieia, Inc.
ibiliti
iCAD, Inc.
ICAP Patent Brokerage
Ichor Medical Systems
ICONACY Orthopedic Implants, LLC
ICU Medical, Inc.
Ikaria, Inc.
Illinois Biotechnology Industry Organization—iBIO
Illinois State Dental Society
IlluminOss Medical, Inc.
ImaCor
IMARC Research
Immucor, Inc.
ImpediMed
ImThera Medical, Inc.
in2being, LLC—Your Medical Device Development Partner
Incept LLC
Indiana Chamber of Commerce
Indiana Dental Association
Indiana Health Industry Forum
Indiana Manufacturers Association
Indiana Medical Device Manufacturers Council
Laurimed, LLC
Lead BioPharma Consulting, LLC
LeukoDx Ltd.
LFI Medical
Life Science Tennessee
Life Spine, Inc.
Life Technologies
Lifecore Biomedical, LLC
LifeScience Alley
LifeScience Plus, Inc.
LifeWave
Lightstone Ventures
Linde Healthcare

Integra LifeSciences
Integrated Sensing Systems Incorporated (ISSYS)
Integrity Digital Solutions
INTER–LINGUA
International Franchise Association
International Medical Industries, Inc.
International Sterilization Laboratory LLC
Intersect ENT
InterValve, Inc.
Interventional Autonomics Corporation
Interventional Spine, Inc.
IntraPace
IntriCon
Intrinsic Therapeutics
Intuitive Marketing Strategists
Intuity Medical, Inc.
Ionix Medical, Inc.
Iowa Dental Association
iRhythm Technologies, Inc.
Irvine Chamber of Commerce
iSonea, Limited
ISTO Technologies, Inc.
Ivantis, Inc.
Ivenix
Ivivi Health Sciences LLC
iWalk
J.H. Garver Consulting, LLC
Jabil
Jack Saladow & Associates
Jerichons, LLC
Keith & Associates LLC
KFx Medical Corporation
Kinamed Inc.
KRONUS, Inc.
Kspine, Inc.
L. VAD Technology, Inc.
Laser Peripherals, LLC
MediStim USA, Inc.
MedOne Surgical, Inc.
MedShape
MedTech Association of New York
MedWaves, Inc.
Megadyne
Menlo Park Associates
Mercury Medical
Merit Medical Systems, Inc.
Metric Medical Devices, Inc.
Metronom Health, Inc.
Mettler Electronics Corp.
Mevion Medical Systems, Inc.
MGC Diagnostics
Micardia Corporation
Micell Technologies
MichBio
Michigan Dental Association
Michigan Life Ventures, LLC
MicroCube
Microline Surgical, Inc.
Micronics, Inc.
MicroTransponder Inc.
LipoScience, Inc.
LogicMark, LLC
Logikos, Inc.
Lonestar Heart, Inc.
Louisiana Dental Association
Luminex Corporation
LuxarCare
Mack Medical
MacuCLEAR, Inc.
Magellan Technologies, Inc.
Magnolia Medical Technologies, Inc.
Maine Standards Company, LLC
Mammotome
Manufacturers Association of Maine
Mardil Medical, Inc.
MarketLab
Masimo
Massachusetts Dental Society
Massachusetts Medical Device Industry Council MassMEDIC
MassBio
Materna Medical
Mauna Kea Technologies
MB Venture Partners, LLC
MBio Diagnostics, Inc.
MBL International Corporation
Mectra Labs Inc.
MED–EL Corporation
Medbio, Inc.
MedDx Capital Advisors
Medenovo, LLC
Medical Device Manufacturers Association (MDMA)
Medical Engineering Innovations, Inc.
Medical Imaging & Technology Alliance
Medical innovations Intl. Inc.
Medical Polymers, Inc.
Mediclever
Medigroup, Inc.
Myomo, Inc.
MyoScience
nanoMAG LLC
nanoMR
Nasiff Associates Inc.
National Association for the Support of Long Term Care (NASL)
National Association of Manufacturers (NAM)
National Federation of Independent Business (NFIB)
Nativis, Inc.
Natus Medical Incorporated
NaviMed Capital
Naviscan, Inc.
NDH Medical
Nebraska Dental Association
Nelson Laboratories, Inc.
Neodyne Biosciences
Neograft Technologies, Inc.
NeoMetrics, Inc.
NeoTract, Inc.

Midmark Corporation
Mighty Oak Medical
Millar Instruments, Inc.
MIM Software Inc.
Minerva Medical
Minnesota Dental Association
Minnetronix
Mirabilis Medica, Inc.
Mirador Biomedical
Miramar Labs
Mississippi Dental Association
Missouri Biotechnology Association
MitraGen
Mitralign, Inc.
Modulated Imaging, Inc.
Molecular Detection, Inc.
Monebo Technologies, Inc.
Moog Medical Devices
Morgenthaler Ventures
Morris Innovative
Mound Laser & Photonics Center
MOXI Enterprises, LLC
Moximed
MPI Research
MPM Capital
MPR Product Development
Mustang Medical
Mustang Vacuum Systems
MyoCardioCare, Inc.
NVCA
nVision Medical
NxStage Medical, Inc.
NxThera, Inc.
Nypro Inc.
O.E. Meyer Co.
Obalon Therapeutics
OBMedical Company
OCTANe
OcuSciences, Inc.
Ohio Chamber of Commerce
Ohio Manufacturers' Association
OmniGuide Surgical
OMNIlife science, Inc.
On-X Life Technologies, Inc.
Onciomed, Inc.
OncoHealth
ONSET Ventures
Onyx Medical Corporation
OPHTEC USA, Inc.
OptiScan Biomedical, Inc.
Orange County Business Council
OraSure Technologies, Inc.
Oraya Therapeutics
Orbital Research Inc.
Orchid Orthopedic Solutions
Oregon Bioscience Association
Orlucent
Ortho Kinematics
OrthoCor Medical
Orthodontic Manufacturers Association
Orthofix International N.V.
Neuro Kinetics, Inc.
Neuronetics, Inc.
NeuroPace
NeuroTherm
NeuroTronik
NeuroVista Corporation
NeuroWave Systems Inc.
NeuWave Medical
Nevada Dental Association
Nevro
New Enterprise Associates
New Hampshire Dental Society
New Jersey Life Sciences Vendors Alliance
New Leaf Venture Partners
NinePoint Medical
Niveus Medical
Nocimed, LLC
Non-Invasive Medical Systems
Nonin Medical
Norris Capital, Inc.
North Carolina Biosciences Organization
North Carolina Dental Society
Nova Biomedical
NovaSom
Novocor Medical Systems
NRG
NuMED, Inc.
NuOrtho Surgical, Inc.
NuVasive
Nuvimedix LLC
Philips Electronics North America
Phillips Consulting Group, LLC
Phlebotics, Inc.
PhotoMed Technologies, Inc.
Physcient, Inc.
Pilgrim Software, Inc.
Pittsburgh Life Sciences Greenhouse
Pittsburgh Technology Council
Pivot Medical Inc.
Plasma Technologies, Inc.
PlasticsOne
Plexus Corp.
Portaero
Preceptis Medical, Inc.
Precise-Pak Inc.
Pressure Biosciences, Inc. (PBIO)
Presymtec Medical
Prism Plus Consulting
Prism VentureWorks
Prizm Medical, Inc.
Pro2Med Inc.
ProMedTek
Prosolia, Inc.
Prospect Venture Partners
Prospex Medical
Proteus Biomedical, Inc.
PuriCore
QHeart Medical Inc.
Qualcomm Life, Inc.
QualPro Consulting
Quasar Bio-Tech Inc.

OrthoForge, Inc.
OrthogenRx, Inc.
Orthopaedic Implant Company (OIC)
OrthoPediatrics Corp
OrthoSensor
OrthoWorx
OsteoMed
Ostial Corporation
Ottobock U.S. HealthCare
Owens & Minor
Palo Alto Health Sciences, Inc.
Paradigm Spine, LLC
PARAGON MEDICAL, INC
Pathfinder Therapeutics, Inc.
Patient Pocket, LLC
Penn-Century, Inc.
Pennsylvania Bio
Pennsylvania Dental Association
Penumbra, Inc.
Percutaneous Systems, Inc. (PercSys)
Rinovum Women's Health, Inc.
Robomedica, Inc.
Roche
Rochester Electro-Medical, Inc.
Rodman Media Corp
RODO Medical, Inc.
RoundTable Healthcare Partners
ROX Medical
Royal Oak Medical Devices, LLC
RTI Surgical
RxFunction, Inc.
s2a molecular, Inc.
Safeguard Scientifics, Inc.
SafeShower
Sakura Finetek USA, Inc.
Saladax Biomedical, Inc.
Salix Pharmaceuticals, Inc.
San Diego Regional Chamber of Commerce
SandBox Medical LLC
Sanofi
SCBIO
Scientific Imaginetics
SDRS LLC
Sebacia Inc.
Second Sight Medical Products, Inc.
Sekisui Diagnostics
Senseonics
Sequent Medical Inc.
SI-BONE, Inc.
Siemens Healthcare
Sight Sciences Inc.
SightLine Partners
SIGNUS Medical, LLC
Silere Medical Technology, Inc.
Silicon Valley Leadership Group
Silver Bullet Therapeutics, Inc.
Sirtex Medical Inc.
Skyline Ventures
Small Bone Innovations, Inc.
Smart Perfusion, LLC
Smith & Nephew, Inc.
Quidel Corporation
RBC Capital Markets
Redpoint Corporation
Regenesis Biomedical, Inc.
Regulatory & Quality Solutions LLC
Reichert Technologies
Reimbursement Strategies, LLC
Relievant Medsystems, Inc.
Research!America
ReShape Medical Inc.
ResMed
Respicardia, Inc.
Respira Therapeutics, Inc.
Respiratory Motion, Inc.
Respiratory Research, Inc.
Respiratory Technologies Inc.
Response Biomedical Corp.
ReVent Medical, Inc.
ReVision Optics, Inc.
Rhythmlink International, LLC
Richmond Products Inc.
South Carolina Dental Association (SCDA)
Southeastern Medical Device Association (SEMDA)
Southern California Biomedical Council (SoCalBio)
SPE Medical
SpectraScience, Inc
SpherIngenics, Inc.
Spinal Kinetics
Spinal Modulation, Inc.
Spinal Ventures, LLC
Spine Wave, Inc.
SpineAlign Medical, Inc.
SpineGuard
Spineology Inc.
Spinofix, Inc
Spiracur Inc.
Spiration, Inc.
SPIWay, LLC
Split Rock Partners
St. Jude Medical
STAAR Surgical Company
Stanmore Implants
STATKING Clinical Services
STD Med, Inc.
SteriPack USA, Ltd
Steris Corporation
Stimwave
Strada Consulting
Streamline, Inc.
Streck, Inc.
Strohl Medical
Stryker
Sunshine Heart
Surface Solutions Labs, Inc.
SurModics, Inc.
Svelte Medical Systems, Inc.
Swan Valley Medical, Incorporated
Sylvan Fiberoptics
Synapse Biomedical, Inc.

Smiths Medical
Soft Tissue Regeneration, Inc.
Solace Therapeutics
Solta Medical, Inc.
Solvonics Medical
Sonacare Medical
Sonendo, Inc.
Sonitus Medical Inc.
Sonoma Orthopedics
Sorin Group USA, Inc.
Sotera Wireless
Tarsus Medical Inc.
TearScience, Inc.
TEI Biosciences Inc.
TEKNA Manufacturing, LLC
Teleflex Incorporated
Temptime
Teratech Corporation
Terumo Cardiovascular Group
Terumo Medical
Tethys Bioscience, Inc.
Texas Healthcare and Bioscience Institute
The Eclipse Group
The Foundry
The Innovation Factory
The Plastics Industry Trade Association (SPI)
The Spectranetics Corporation
The Tech Council of Maryland
The Vertical Group
Theodosiou Consultants, Inc.
Therapeutic Resources, Inc.
TheraTogs, Inc.
Thermo Fisher Scientific
Therox
Thoratec Corporation
Three Arch Partners
ThreeWire
Thubrikar Aortic Valve, Inc.
TIDI Products
Tissue Regenix USA Inc.
Titan Spine, LLC
Toshiba America Medical Systems, Inc.
Tosoh Bioscience Inc.
Trademark Medical
Transcend Medical
Transcorp Spine
TransEnterix, Inc.
TransMedics, Inc.
Transonic Systems, Inc.
Trillium Diagnostics, LLC
Trillium Engineering
TriReme Medical, Inc.
TriVascular, Inc.
Twin Star Medical
TYRX, Inc.
U.S. Chamber of Commerce
Unilife Medical Solutions
Uptake Medical Corporation
Uresil
Urobiologics LLC
Urologix, Inc.
Synarc, Inc.
SynCardia Systems, Inc.
Synecor, LLC
Synergy Health plc
Synergy Life Science Partners
Syntermed, Inc.
Sysdyne Corporation
Sysmex America, Inc.
Tactile Systems Technology, Inc.
Tandem Diabetes
Targeson, Inc.
Target Discovery, Inc.
Urovalve, Inc.
USGI Medical, Inc.
Utah Dental Association
Utah Technology Council
Valeritas, Inc.
Validation & Compliance Institute
Valley Ventures
ValveXchange, Inc.
Vapotherm
Vascular Solutions, Inc.
Vector Resources
Vector Surgical, LLC
VectraCor, Inc.
Velico Medical, Inc.
Ven-Tel Plastics Corporation
VENITI, Inc.
Venous Health
Veracyte
Verax Biomedical Incorporated
Veritomyx, Inc.
Versant Ventures
VertiFlex®, Inc.
Vertos Medical Inc
Vesiflo/Personal Med
ViaDerm LLC
Viatronix
VIDA Diagnostics
Virginia Biotechnology Association
Virginia Dental Association
VirtualScopics, Inc.
Viscogliosi Bros., LLC
Vision-Sciences, Inc.
VisionCare Ophthalmic Technologies
Vital Images, Inc.
Vital Therapies, Inc.
Vital/Med Systems Corporation
Vitalcor, Inc.
Viveve
Volcano Corporation
VQ OrthoCare
VueTek Scientific, LLC
W. L. Gore & Associates, Inc.
Ware Disposal Inc.
Warsaw-Kosciusko County Chamber of Commerce
Washington Biotechnology & Biomedical Association
Water Street Healthcare Partners
Waters Corporation

Uromedica, Inc.
Uroplasty, Inc.
Wescor
White Pine Medical, Inc.
Wilson Sonsini Goodrich & Rosati
Wisconsin Dental Association
Woolfson Eye Institute
Wright Medical
Wyoming Dental Association
X-Spine
Zynex
WaveTec Vision
Welch Allyn
Wenzel Spine, Inc.
Xlumena
Yukon Medical
ZELTIQ
Zimmer, Inc.
Zoe Medical, Inc.
ZOLL Medical
Zyga Technologies

Prepared Statement of Mark Judge, Patient Advocate, Pittsburgh, PA

Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Committee, thank you for the opportunity to discuss the medical device excise tax's negative impact on patients who are suffering from cancer.

My name is Mark Judge, I'm from Pittsburgh PA, and l have stage 4 terminal colon cancer.

I was first diagnosed with colon cancer in January 2013. I had limited signs or issues as it related to cancer but I had gone in to be pre-tested for rotator cuff surgery. My primary care doctor noted that the iron level in my blood was unusually low. Since I had no family history of cancer, and up to that point I had never been sick, she suggested I get a colonoscopy. I was 46 at the time and colonoscopies aren't usually done until you're at least 50. Thankfully, we agreed to the test and they found a tumor in my colon that was defined as stage 3b.

I immediately began 6 weeks of chemotherapy and 6 weeks of radiation. During this time I was admitted to the hospital on two occasions with complications. One of these times I was put on a fentanyl patch. After completing the 6 weeks of chemo/radiation I had resection surgery to remove the tumor in my colon. When I awoke from surgery, I was surprised to see that my intestines were sticking out of my gut. I was to have a colostomy bag. I had the bag for approximately 3 months then I had reversal surgery in August of 2013. The recovery from that is still ongoing. They call it a new normal, meaning you're no longer able to go to the bathroom they way you used to go. There were times that I would have to go 60–70 times a day. Basically I was a prisoner of my bathroom for many months. During this time I was deemed NED ("no evidence of disease"). I was scanned every 3 months and on the second scan, the doctors discovered some nodules in my lungs. After two biopsies it was discovered that my cancer had metastasized to my lungs. The reality was I probably had stage 4 all along. The cancer was always there. I fall into the 20% of cases where doctors cannot see the cancer in my blood. This was March 2014 and the average life expectancy I was given is 3 years.

In April 2014, after another lung surgery, I embarked on 6 months of intense chemotherapy. I was on three different chemo drugs. I had surgery to place a port in my upper chest so that they can administer the chemo and take blood easier. In December of 2014 I had my sixth surgery to remove the upper right lobe of my lung and to remove two other nodules. In January of 2015, I again went on the three chemo regimen. I have my seventh surgery scheduled this coming Monday to remove two more nodules from my left lung. Obviously, I'm aware that every time they go into my lungs they take more and more of my lungs out and at some point I'll need oxygen to breath. I'll probably be on chemo the rest of my life.

I've accepted my situation for what it is. I'm very thankful for the scans that have prolonged my life to this point. If not for them I wouldn't be here today. I am a success story from that standpoint. Unfortunately, many of my friends on the cancer forums and advocacy groups have not been as lucky. Many of them haven't had access to scans and for others it was too late.

I'm going to continue to fight for my life. I have an 11 year old daughter Elly who is my co-pilot in this journey and I will not let her down. I need to see her grow up. I need to see her graduate and go on to college. I need to see her become a woman. These are not things that she or any child deserves to do alone.

The imaging devices that found this disease cost millions of dollars to develop. The additional taxation on these devices could prevent many health care providers from purchasing them. It also reduces the incentive for companies to invest in improving them so cancer is detected earlier. The trickle-down effect is that this stops the innovation of new technologies. I can only ask the question: What new technologies are there—that could save my life and the lives of millions of others—that are not being produced because of this tax?

That is why I am here today. I cannot see the rationale for imposing a tax that will reduce investment in the very life-saving technologies that I, and millions of others, rely upon, and hope to see in the future. With that, I respectfully ask the Senate to pass S. 149, the Medical Device Access and Innovation Protection Act, authored by Senators Hatch and Klobuchar. Thank You.

PREPARED STATEMENT OF HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA

Welcome, Ladies and Gentlemen; the Senate Finance Subcommittee on Health Care will now come to order.

First of all I want to thank Senator Hatch for encouraging us to begin this process of exploring the Medical Device Tax with this hearing. I want to thank Ranking Member Stabenow for all of her leadership on healthcare issues generally and her interest in exploring this topic as well. And I am very grateful to our witnesses for taking the time and in some cases traveling a considerable distance to be with us to share their expertise and their perspective on a really important issue.

So, I will make no bones about it. My strong preference would be to have a full and permanent and complete repeal of the medical device tax, because it's my view that this tax is doing considerable harm—economic harm. I am concerned about the impact that is has on innovation in the medical device industry. And I am really concerned about the impact it has on individual patients—current patients and future patients. So we'll discuss this.

I want to start with just a little illustration of some of the absolutely wondrous things that are being invented and develop in this space. I have in my hand, if you can see this, a ventricular assist device. This is a mechanical heart pump for those with congestive heart failure. This has kept 7,000 Americans alive while they await a transplant. 300,000 people die every year in our country from heart failure. It took 5 years to get the FDA approval for this. The company, HeartWare, that developed this product spent $200 million on research and development over the first 5 years of their existence as an American company and they racked up $112 million of losses before they ever were able to begin to turn a profit, but think of the of lives that were saved by virtue of this remarkable invention. Here we have a spinal implant—for those who aren't close enough to see, it looks remarkably like a vertebrae, but it clearly is not—it's used to mend bone fractures, this material is, this is an alternative for over 400,000 people annually who have spinal fusion surgery to deal with severe and chronic pain in the lower back. It's made by a company called Synthes. The company employs hundreds of people in my state of Pennsylvania, in West Chester. And last, this is a vagal nerve stimulator. This is implanted in the chest, surgically implanted, this very device. And it sends an electrical current to the patient's brain and it treats epilepsy. And it treats treatment resistant depression. Millions of Americans suffer from each of those maladies. And the company that makes this also experienced, as so many startup companies in the medical device space do, losses for years as they were in the stages of developing the product and bringing it to market and getting the approvals. In fact, they incurred $250 million in losses before they were able to turn around and sadly the CEO has announced that, in part to offset the costs of the medical device tax, they're going to build their next factory in Cost Rica rather than the United States. And this is one of the big concerns; one of the big concerns is that this tax on sales is going to threaten America's global leadership in this space.

The medical device industry is a huge economic contributor, not just in my state of Pennsylvania, but across the country. The range of products is stunning, from pacemakers to orthodontics, hearing implants, surgical tools, knee braces, joint replacements. The industry employs over 400,000 people directly. There are another 2 million people that are indirectly employed because they vendors are supplier companies to the medical device industry.

And interestingly—you know we had a big debate yesterday about trade policy as Ranking Member Stabenow knows very well—the medical device industry for the last 5 years has run a substantial trade surplus. Because we are the leaders in the world, we make the best products, and we sell them all around the world, we've had a trade surplus on average over the last 5 years. And so it's a big, it's an innovative, it's a dynamic industry. It pays good wages, above the averages. It improves the quality of our lives through the products that it makes. And so, it's really important, I think, to all of us that this industry thrives.

My view is that the tax, the Medical Device Tax, is not only onerous on its scale, but it's bad in its design. It is a tax on sales, not on a tax on profits. And so these companies that I alluded to that spent large sums of money making these product and bringing them to market, they were losing money years, even when they started to have sales. The initial sales those years were not enough to be profitable. To impose a tax on those sales prior to there even being a profit, it just adds to the debt load that these companies have to carry. And there is only so much debt that can be financed. This is one of the concerns that I have. The design of this tax is very very unfortunate.

I think we're going to here from some of the witnesses that this has cost us jobs across the country already. Some companies have had to cancel plans to expand. Others are looking to move to other places. I want to read an excerpt from a letter from Carmel Therapeutics, which is a Pittsburgh-based company. The President and CEO is Alan West and he sent me a letter last month in which he states that:

> It has also been (this "it" he's referring to is the Medical Device Tax) a strong factor in discouraging venture capital from even considering medical device and early stage deals. Currently the majority, 55%, of clinical trials are now being conducted overseas. And most novel medical devices are now launched outside the U.S. 4 to 5 years before they are available in the United States, according to the U.S. Department of Commerce. This is the complete opposite of the situation only a few years ago when the U.S. was taking the lead. As a case in point, my company Carmel Therapeutics conducted a clinical trial in South Africa and is planning to launch our first product next year in Europe.

As I said earlier, I'm concerned that of course if we slow down the pace of new development of new medical devices, we will harm the patients who would benefit from these. And so for these and other reasons I am very hopeful that we will, in this Congress, be able to repeal the Medical Device Tax. I am pleased that we have had bipartisan support for this concept. We had 79 United States Senators, obviously big majorities in both parties, every republican, a large majority of democrats voting in favor of an amendment to the budget resolution in 2013. I'm delighted that we have bipartisan support for the bill to repeal it entirely. Again, I want to thank Chairman Hatch for his cooperation in this effort. I want to thank the members of the Committee who are here and the witnesses. And at this time I would yield to our Ranking Member, Debbie Stabenow. Again I want to mention how grateful I am for her leadership on healthcare issues in general, her leadership in this Committee, and at this time I recognize her for an opening statement.

COMMUNICATIONS

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED)

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April 22, 2015

The Honorable Patrick J. Toomey
Chairman, Senate Finance Subcommittee on Health
248 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
Ranking Member, Senate Finance Subcommittee on Health
731 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Toomey and Ranking Member Stabenow,

I am pleased to submit this statement for the record on behalf of the Advanced Medical Technology Association (AdvaMed), representing over 300 medical device, imaging, and diagnostic technology manufacturers. I want to thank both of you for holding this important hearing highlighting the negative impact the medical device tax is having on American jobs, innovation and patients.

The medical technology industry is central to the development of medical devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future. Patient access to advanced medical technology generates efficiencies and cost savings for the health care system, and improves the quality of patient care. Between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and add five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half.

The industry is also an engine of economic growth for the U.S., generating high wage manufacturing jobs and a favorable balance of payments. More notably, the impact of medical technology on economic growth and competitiveness goes well beyond the jobs and economic activity associated with industry R&D and manufacturing. A recent study by the Milken Foundation examined four diseases and a limited number of technologies used to treat those diseases. It found significant increases in labor force participation and productivity directly attributable to the technologies' contribution to reducing the burden of illness.

Evidence continues to mount how the medical device tax is a drag on a high-technology, research-based manufacturing sector that provides life-saving, life-enhancing innovations. A recent survey of AdvaMed's membership underscores the need to repeal this tax as companies are forced to curtail R&D and other capital investments—cuts that may chill medical progress for decades to come. More than half of survey respondents (53 percent) said they had reduced R&D as a result of the tax, and 58 percent said they would consider further or first-time reductions in R&D if the tax stays in effect.

We commend the Committee for its interest in these issues and appreciate the opportunity to discuss the impact of this tax on the industry in more detail. We look forward to a substantive discussion today and to advancing legislation in the House and Senate to repeal the tax. There is strong bipartisan support in both houses of Congress for repeal, and AdvaMed looks forward to working with our industry colleagues, patients, providers, research organizations, and members of Congress to achieve this goal.

Thank you again for the opportunity to submit our comments for the record.

Sincerely,

Steve Ubl
President and CEO, AdvaMed

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April 30, 2015

The Honorable Orrin G. Hatch
Chairman
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Patrick J. Toomey
Chairman
Subcommittee on Health Care
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
Subcommittee on Health Care
Finance Committee
United States Senate
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Chairman Toomey, and Ranking Member Stabenow:

Alcon is the leading global manufacturer and marketer of products for vision care and treatment of eye disorders. Our comprehensive portfolio includes medical devices used by surgeons to treat eye diseases such as cataracts, glaucoma, and diseases of the retina.

Alcon Research, Ltd. has a manufacturing facility in Sinking Spring, PA for the production of disposable single-use medical devices for cataract and vitreoretinal surgeries. The Sinking Spring facility employs approximately 700 associates.

We have become aware that you will be holding a hearing on Thursday, April 23, 2015 to consider repealing the device tax.

The device tax went into effect on January 1, 2013 resulting in a daily, real world impact on medical device companies and patients. It threatens innovation and jobs across the nation. According to an industry survey, forgone hiring and layoffs have cost 33,000 industry jobs and as many as 165,000 jobs overall. As many as one-third of device manufactures have reduced their budgets as a result of the tax, hampering medical innovation and slowing medical progress.

The knowledge that Alcon has gained over decades of research, manufacturing, and experience with highly-skilled eye surgeons has guided us so that we meet the needs of patients with the most innovative technologies available today. Our work enables excellent outcomes of eye surgery, and it is only through continued investment and innovation that we will enable surgeons to offer even better outcomes in the future.

We urge senate members to act to repeal the medical device tax and engage in a full discussion of tax reform and the right tax structure for Innovative manufacturing Industries like the medical device industry.

Sincerely,

Richard L. Patterson
Vice President, General Manager
Sinking Spring Operations

ALLIANCE FOR AGING RESEARCH
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United States Senate Committee on Finance, Subcommittee on Health Care
"A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients"

April 23, 2015

The Alliance for Aging Research submits for the record the following statement by its President and Chief Executive Officer Sue Peschin, MHS:

"The Alliance for Aging Research believes that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term. We support policies that advance medical research and innovation and address the needs of aging patients.

"For this reason, the Alliance for Aging Research is unwavering in our support of efforts to repeal the medical device tax. We believe the tax drains critical resources away from research and development of technologies that can improve detection and treatment of age-related diseases and conditions, as well as the way we provide care for the aging population.

"The unmet health challenges of older adults are an enormous financial and human burden. More resources—not less—are needed to address these challenges."

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS

UPDATE
neurosurgery

FOR IMMEDIATE RELEASE
April 23, 2015

Contact: Katie Orrico
(202) 446–2024
korrico@neurosurgery.org

Senate Finance Health Subcommittee Holds Critical Hearing on the Medical Device Tax

Neurosurgeons Urge Congress to Repeal the Device Tax

Washington, DC—The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) commend the Health Subcommittee of the U.S. Senate Committee on Finance for holding a hearing on the impact of the medical device tax on jobs, innovation and patients. This is a critical step to repealing this detrimental tax.

Created by the Affordable Care Act, the medical device tax is a 2.3 percent excise tax that applies to the gross sales of medical device products. This tax imposes over $30 billion in new taxes and is adversely affecting medical innovation and patient care.

AANS president, Robert E. Harbaugh, MD, noted, "Repealing the medical device tax is among neurosurgery's top legislative priorities and we applaud the bipartisan efforts of Congress to abolish this arbitrary tax, which is ill-advised and ultimately will negatively impact our patients."

According to a recent study published by the Advanced Medical Technology Association (AdvaMed), as many as 195,000 jobs may be lost due to the tax, either through layoffs or forgone jobs that would have been created.

"Our health care system needs innovation to improve patient care and save lives. Instead, this tax stifles innovation and reduces patient access to new lifesaving technologies," said CNS president, Nathan R. Selden, MD.

The AANS and CNS have endorsed both S. 149, the "Medical Device Access and Innovation Protection Act," and H.R. 160, the "Protect Medical Innovation Act," and look forward to working with the members of the Senate Finance Committee to develop policy solutions to better support medical innovation and increase treatment options for our patients.

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*The **American Association of Neurological Surgeons** (AANS), founded in 1931, and the **Congress of Neurological Surgeons** (CNS), founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. These groups represent over 8,000 neurosurgeons worldwide. Neurological surgery is the medical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the entire nervous system, including the spinal column, spinal cord, brain and peripheral nerves. For more information, please visit www.aans.org or www.cns.org or www.neurosurgeryblog.org.*

AMERICAN DENTAL ASSOCIATION® (ADA)

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April 22, 2015

The Honorable Orrin G. Hatch	The Honorable Ron Wyden
Chairman	Ranking Member
Committee on Finance	Committee on Finance
United States Senate	United States Senate
219 Dirksen Senate Office Building	219 Dirksen Senate Office Building
Washington, D.C. 20510	Washington, D.C. 20510

Dear Chairman Hatch and Ranking Member Wyden:

The American Dental Association (ADA), the nation's oldest and largest dental association, representing more than 157,000 dentist members, strongly supports the repeal of the medical device excise tax. The dental manufacturing industry estimates that the medical device excise tax will increase the cost of dental care by over $160 million annually resulting in harm to our patients and an increase in the overall cost of healthcare.

Good oral health is an essential part of an individual's overall health and well-being. An increase in the cost of oral health care as a result of the excise tax on medical devices—including restorative materials, instruments, impression materials and equipment—could make healthcare less affordable and act as a deterrent to patients seeking dental care.

As you know, health care professionals who operate solo or small group practices are economic engines for their communities. In 2010, the most recent year for which we have survey data, 96.2 percent of the dentists surveyed reported that they work in practices comprising five or fewer dentists. The nature of dental insurance plans means that a dentist's reimbursements may not keep pace with this tax and many offices will have to absorb most of the increased cost. Operating costs for dental practices, particularly specialties, are significant, and the ability to sustain or grow small businesses like dental practices will be further constrained under this new excise tax.

Again, we strongly urge you to repeal the burdensome excise tax on medical devices. If you have any questions regarding the impact of the tax on a dental practice or our patients, please contact Margo Klosterman at klostermanm@ada.org or 202–898–2437.

Sincerely,

Maxine Feinberg, D.D.S.	Kathleen T. O'Loughlin, D.M.D., M.P.H.
President	Executive Director and Chief Operating Officer

ARC MEDICAL, INC.
ANESTHESIA/RESPIRATORY CARE
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800–950–ARC1

Wednesday, April 22, 2015

Brad Grantz
Senate Finance Committee
Washington, DC

Ladies and Gentlemen,

The Medical Device Tax has severely limited the ability of my company to add jobs and the additional cost imposed by the tax has limited our ability to provide better pricing for new customers.

One additional result of the tax is the impact on the profit sharing plan of our company.

As the tax affects directly the bottom line of the company, there has been less profit to distribute to our employees for their future. This has caused considerable harm to the employees.

For the good of the cost of healthcare and the betterment of company employees, please repeal this onerous tax.

Best regards,

Hal Norris, President

ARC Medical, Inc.
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www.arcmedical.com

BIOCOM
ACCELERATING LIFE SCIENCE SUCCESS

April 22, 2015

The Honorable Orrin G. Hatch
Chairman
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Patrick J. Toomey
Chairman
Subcommittee on Health Care
Finance Committee
United States Senate
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
Subcommittee on Health Care
Finance Committee
United States Senate
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Chairman Toomey, and Ranking Member Stabenow:

Biocom represents the Southern California life science industry and leads advocacy efforts to positively influence the region's life science community in the development and delivery of innovative products. Biocom and our medical device member companies, who are dedicated to developing life-enhancing and life-saving technologies for patients in need, **are opposed to the medical device excise tax and support its full repeal.**

Over the past decades, the American medical device industry has given patients access to cutting edge, life-saving technologies, from insulin pumps and heart valves to pacemakers and artificial limbs. Such products have helped increase life expectancy while reducing the burden of chronic diseases, which represent more than 70 percent of health care costs. Today, over 8,000 medical device manufacturers in the United States invest nearly $10 billion in research and development (R&D) annually, and employ more than 420,000 Americans. In California, the medical device industry generates $50 billion in economic activity annually and supports over 80,000 jobs.

The tax, which took effect in January 2013, is expected to cost medical device manufacturers $30 billion over the next 10 years. Similar excise taxes are levied by the federal government on products such as alcohol and tobacco to discourage their use. In addition, the tax is assessed on revenue and, therefore, is particularly burdensome for innovative start-ups and small companies that are not yet profitable. Contrary to some assertions, the tax is not being offset by increased demand for medical devices as a result of health care reform because the majority of device-intensive medical procedures are performed on patients that are older and already had private insurance or Medicare coverage.

Since its implementation, the medical device tax has effectively stifled R&D investments and medical innovation, hampered economic growth and job creation, and jeopardized patient access to breakthrough devices and therapies. According to an industry survey,[1] 14,000 industry jobs have been lost in the tax's first year, along with the forgone hiring of 19,000, resulting in a total direct industry employment impact of approximately 33,000 jobs. In addition, companies have had to reduce R&D investments and/or relocate or expand manufacturing outside of the U.S. as the result of the tax.

The negative impact of the tax on medical innovation and the U.S. economy has been widely recognized and a repeal of the device tax has broad bipartisan support in both the House and the Senate. Biocom strongly supports a repeal of the medical device tax and stands ready to work with you to ensure that patients continue to have access to the most innovative technologies in the world.

Thank you for your consideration of our concerns.

Sincerely,

Joe Panetta
President and CEO
Biocom

CARMELL THERAPEUTICS CORPORATION
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April 22, 2015

The Honorable Patrick J. Toomey
Chairman
Senate Finance Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
Senate Finance Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Re: Statement for the Record:
Senate Finance Subcommittee on Health Care
Hearing on the Impact of the Medical Device Tax

Dear Chairman Toomey and Ranking Member Stabenow:

I have been involved in start-ups and small companies in the life sciences industry for over 35 years. Advances in technology during my career have enabled the development of important medical products that not only save lives and preserve a quality of life for patients, but also reduce the costs of treatment. But I have never experienced a more difficult time to start a company and raise working capital. The Medical Device Tax, while appearing on the surface to sound innocuous, has contrib-

[1] Impact of the Medical Device Excise Tax—A Status Report from AdvaMed.

uted much to this already difficult situation. Because venture capital in the U.S. has all but abandoned investments in pre-revenue life sciences companies, it is now imperative for such companies to achieve early revenues to demonstrate market acceptance and attract investment, even if those early revenues will not by themselves get the company to cash flow positive. This misguided tax makes that process even more tenuous. It has also been a strong factor in discouraging venture capital from even considering medical device and early stage deals. Currently the majority (55%) of clinical trials is now being conducted overseas (NIH), and most novel medical devices are now launched outside the U.S. 4–5 years before they are available in the U.S. (U.S. Department of Commerce). This is the complete opposite of the situation of only a few years ago when the U.S. was taking the lead. As a case in point, my company, Carmell Therapeutics,conducted a clinical trial in South Africa and is planning to launch our first product next year in Europe.

Senator Stabenow—you and I met a few years ago when I was CEO of the Michigan Tech SmartZone, a great program that has become a model not only for other Michigan SmartZones but other states as well. Senator Toomey—you and I met last year at Carnegie Mellon University, from where Carmell was spawned. I hope you both agree that this tax, instead of creating meaningful tax revenues as was its original purpose, has had the unintended consequence of dissuading institutional investment and discouraging entrepreneurship in a vital industry already under significant pressures. In my opinion, the Medical Device Tax is the proverbial straw that is breaking the backs of the medical device industry by dissuading innovation. Thank you for the opportunity to present my views.

Sincerely,

Alan I. West
President & CEO

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April 22, 2015

Senate Committee on Finance
Attn: Editorial and Document Section
Rm. SD–219
Dirksen Senate Office Building
Washington, DC 20510–6200

Re: Written Testimony for the Record before the Finance Subcommittee on Health Care Submitted by the Cook Group, Inc., for the April 23, 2015 Hearing Entitled, "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients."

Dear Chairman Toomey and Ranking Member Stabenow:

Thank you for the opportunity to submit written testimony for the record to the Senate Finance Health Care Subcommittee's hearing entitled, "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients." We are pleased to provide our thoughts on the impact of the medical device tax on jobs, innovation, and patients. This is a tax that affects not only U.S. manufacturing jobs, but also patient access to the latest in medical technology.

I submit these comments as the Chairman of Cook. It has been my privilege to be associated with Cook for nearly 50 years.

History of Cook

Since 1963, the company has grown from its birth in a spare bedroom in Bill and Gayle Cook's apartment to a world leader in advancing medical care for patients worldwide. There were many setbacks and countless challenges that threatened the success of Cook as our founder, Bill Cook, sought to build an innovative American company that would improve patient care. But Bill was resilient and had the same entrepreneurial spirit that makes this country so unique. These traits, combined with his focus on the patient, are the foundation of Cook's success.

Today, Cook is the largest, family-owned medical device manufacturer in the world. We are best known as a pioneer in the field of interventional medicine. Our products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. Cook sells more than 14,000 different product variations with 13,600 of these products serving markets of $1 million or less worldwide. The other 400 are large market technologies. These devices are used by physicians in the more than 40 medical disciplines and range from simple wire guides, needles and catheters, to grafts, drug-eluting stents and tissue engineering.

Cook is headquartered in Bloomington, Indiana with its U.S. manufacturing plants in Indiana, Pennsylvania, North Carolina, Illinois and California. I should note, Mr. Chairman, we have two Pennsylvania facilities just outside Pittsburgh: Cook Vascular and Cook Myosite. Between the two we employ more than 200 employees who are involved in pacemaker lead extraction technology, vascular access ports and flow probe monitoring technology, accessory tools for in vitro fertilization, and research involving the use of adult skeletal muscle-derived cells to treat patients with a variety of muscle-related disorders, such as female urinary incontinence, among other areas. Cook also has manufacturing facilities in Ireland, Denmark and Australia and has direct sales in most of the world where the health care system is developed.

Our company employs nearly 12,000 people around the world with approximately 8,500 of these employees based in the United States. In the U.S., women comprise approximately 76 percent of our device production.

Like many others in the device industry, Cook is a net-exporter. While 60 percent of our sales are outside the United States, we manufacture more than 75 percent of our devices in this country. We want to be able to continue doing this.

The Medical Device Excise Tax

The most significant barrier to our future U.S. job growth is the medical device excise tax. The Affordable Care Act of 2010 (ACA) contained a revenue provision that placed an excise tax of 2.3 percent on the sale of medical devices in the U.S. beginning January 1, 2013. While that does not sound like much, it is a tax on gross revenue. It comes off the top and not on earnings, and it is huge. Further, whether a manufacturer makes a profit or not, the excise tax applies. **For a company like ours, which pays about 31 percent of our U.S. earnings in federal and state corporate income taxes, the excise tax will increase our effective rate on those U.S. earnings to 41 percent—a 32 percent increase.** It is true that imported goods are subject to the excise tax when sold in the U.S.; however, corporate tax rates on manufacturing income earned outside the U.S. are much lower. It is also important to note that there is not a state corporate tax on top of the federal corporate tax in countries such as Ireland (at 12.5 percent). Everyone agrees we need to increase U.S. competitiveness by lowering the U.S. corporate tax rate. So, how can folks believe that an additional 30 percent increase in this industry's effective rate makes the U.S. more competitive?

Since its enactment, there have been frequent announcements about device companies freezing capital expenditures, reducing research and development, expanding overseas rather than in the U.S., and/or in many instances, laying off employees due to the excise tax. It makes no sense to encourage manufacturing in the U.S. and at the same time impose an excise tax on one of the few industries that exports more products than it imports. Start-ups that have not yet turned a profit still must pay the excise tax and over time this will serve to threaten investment in and the future of this innovative industry, which is the envy of the world. Why would we want to impose an excise tax on one of our fastest growing and most innovative industries—medical technology—that increases the federal tax burden on medical device manufacturers by 29 percent? (Ernst and Young, *Effect of the Medical Device Excise Tax on the Federal Tax Liability of the Medical Device Industry,* November 2012).

Myths About the Device Excise Tax

1) Device manufacturers will pass along the amount of the tax—False.

Some say that a new 2.3 percent tax will only lead device manufacturers to pass on the cost of the new excise tax to purchasers (generally hospitals). That simply is not true for most companies. Hospitals are under tremendous cost pressure today with 40 percent of hospitals operating in the red. The hospitals and group purchasing organizations are saying no. This is a very competitive industry and customers have many suppliers.

Furthermore, our company, like most in our industry, has experienced significant increases in operational costs: health care costs for employees, salaries and wages, utilities, raw materials, regulatory costs, etc. We have seen the unemployment insurance tax increase along with other state, local and property taxes. Companies simply cannot pass all those costs on, let alone a 2.3 percent tax on gross sales.

2) Device manufacturers will have an increased market of new patients as the uninsured now become insured and therefore seek out new treatments—False.

Many believe that the ACA will add more patients and device companies will make more money as a result. This, too, is a myth for the vast majority of device companies. According to The U.S. Department of Health and Human Services (HHS), 71 percent of the "new insured" are younger than 45 years, a great majority of whom will not need our technologies. I have seen no credible studies that indicate an increase in sales, and our research and other studies demonstrate that there will not be an increase in the sales of medical devices and there will be no windfall profits.

I must also point out that a 2012 Roth Capital survey of companies showed that their experience in Massachusetts after universal health care was enacted showed no increase in the rate of growth compared to the increase in growth of rest of the nation. Indeed, Cook's growth rate in Massachusetts trends slightly behind the national growth.

Impact of the Device Excise Tax on Cook

In order to offset a big expense like the excise tax, a company can only look to employees, research and development or capital. Cook has never had to lay-off an employee in our 50+ years of business, and we will not start now. However, we must make hard choices.

Cook has made the difficult decision that without repeal, we will move important new, device-related product lines outside of the U.S. Our previous plans to open up five new device manufacturing facilities in American towns continue to be on hold as we use capital intended for these projects to pay the excise tax.

The direct impact of this tax is squarely on U.S. jobs and because device manufacturing is performed mainly by a female workforce in many sectors, it will hit these workers hardest. Cook will adjust, but those that will be most affected by the device excise tax will be the potential future employees and patients who seek access in this country to innovative medical technologies. Make no mistake about it: we want to develop and manufacture our devices in the U.S., but this tax is preventing this growth in this country. It is a shame that potential employees in Indiana, Illinois, Pennsylvania, California, North Carolina and in other states who can compete with workers any place in the world based on their productivity, are going to be denied the chance by government. I emphasize that for Cook this is not about labor costs. Our industry needs an educated, skilled labor force and we have the best workers in the world here in the U.S.

This migration of manufacturing, coupled with the fact that most clinical studies are now being conducted outside the U.S., will result in new, self-sustaining medical technology clusters that will threaten the United States' global leadership position in medical technology, innovation and manufacturing. This migration will result in delays and in some cases barriers for American patients and their providers who need innovative technology to ensure quality care.

Senate Legislation to Repeal the Medical Device Excise Tax—S. 149

But before this happens Congress can act to repeal this onerous excise tax. We are grateful to the 35 sponsors of S. 149, a bill introduced by Senators Hatch and Klobuchar, as well as our home-state Senators Burr, Casey, Coats, Donnelly, Kirk, Tillis and Chairman Toomey, to repeal the medical device excise tax. In fact, many additional Senators serving on the Finance Committee have cosponsored this legislation or expressed support for repeal of this tax, and we are grateful for your acknowledgment that this excise tax will have serious, unintended consequences. We hope as you deliberate further about the impact of the device excise tax on jobs, innovation and patients, you will consider advancing the repeal legislation.

I should note there have been a few recent reports looking at the impact of the device tax. But I urge caution: examining stock prices to determine the impact of the device tax is a highly inaccurate measure. Companies responsible to shareholders are going to do what it takes to make their stock prices and profits healthy. Those steps include eliminating and/or moving U.S. jobs off-shore and not expanding manufacturing in the U.S. A better way to accurately measure the impact of the device tax is to hear from a statistically significant sample of companies that reflect the U.S. device industry and ask about the direct impact on jobs, medical innovation and patients.

Mr. Chairman, we are very grateful for your leadership and ongoing efforts to repeal the medical device excise tax. This issue is very important to American jobs, medical innovation, and more importantly to patients. I congratulate you and Ranking Member Stabenow for taking this important step today, but please know more work is urgently needed. The country needs your leadership to once and for all repeal this medical device excise tax before it is too late.

Respectfully submitted,

Stephen L. Ferguson
Chairman of the Board

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April 23, 2015

The Honorable Orrin G. Hatch
Chair, Senate Finance Committee

The Honorable Ron Wyden
Ranking Member

The Honorable Johnny Isakson
Committee Member, Georgia Senator

RE: Impact of the Medical Device Tax

Dear Senators Hatch, Wyden and Isakson:

In anticipation of this week's upcoming Senate Finance Committee hearing regarding "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients," I am writing, as the Chairman, President and CEO of Georgia-based CryoLife, Inc., and a long-time senior executive in the medical device industry at Medtronic, Genzyme and Deknatel/Snowden-Pencer, Inc., to respectfully request repeal of the medical device excise tax (the "Tax"). Based on my long-term experience in the medical device industry, I firmly believe that the Tax, now estimated to generate approximately $25 billion, has and will continue to adversely impact patient care, innovation and patient access to innovative medical technologies and therapies.

In January 2015, over 1,000 organizations jointly submitted a letter to Majority and Minority leaders of the Senate and House. In that letter, those organizations detailed the significant adverse impact the Tax is having on the U.S. medical device industry in terms of research and development ("R&D"), jobs, above-market wages and cutting-edge innovation leading to more and better device therapy and treatment for patients. That letter also described how the hardships associated with the Tax are not, as Congress originally anticipated when it passed the Tax, being offset by increased demand for medical devices.

To bring these adverse impacts into sharper focus for you, I would like to share our experience at CryoLife and the particularly harsh impact the Tax imposes on smaller companies, such as ours, whose annual revenues are less than $200M.

CryoLife, headquartered in Kennesaw, Georgia, is a leader in the manufacturing, processing, and distribution of implantable living tissues and medical devices used in cardiac and vascular surgical procedures. We generate approximately $150M in annual revenues, and we employ approximately 500 people in the U.S. in higher-wage, technology-driven jobs. For 2014, our average hourly wage for hourly U.S. employees was approximately $18.50, and our average annual salary for salaried U.S. employees was approximately $90,000.

CryoLife is a leader in innovation in implantable preserved human cardiac and vascular tissues and medical devices:

- Among our most significant innovations is our SynerGraft® Technology, a patented decellularization process that virtually eliminates the presence of allogenic donor cells, while maintaining the structural integrity of the tissue. This process serves as the foundation for the next generation of implantable biological tissues, which have saved or dramatically improved the quality of life for more than 12,000 patients globally since it was launched in 2000.
- We manufacture and distribute BioGlue® Surgical Adhesive, an FDA-approved protein hydrogel technology, which is indicated as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. We estimate that BioGlue has been used in more than 1,000,000 patients globally since its launch in 1998.
- We manufacture and distribute the CardioGenesis cardiac laser therapy system for the treatment of coronary artery disease in patients with severe angina and typically no other options.
- We market the Hemodialysis Reliable Outflow Graft, a solution for end-stage renal disease in certain hemodialysis patients.

In 2014, 69% of CryoLife's worldwide product revenues were from "devices," within the meaning of the Tax, and 67% of its device revenues were from U.S.-based sales subject to the Tax. As a result, CryoLife paid approximately $1.1M in Tax for 2014. Further, CryoLife estimates that its costs to date for administrative and auditor support to ensure appropriate accounting for and payment of the Tax have been approximately $27,000. We estimate that the adverse impact of the Tax on our 2014 net income was in excess of $1.1M.

In 2014, due in part to the Tax, CryoLife was able to spend only approximately 6% of its revenues (or approximately $8.7M) on R&D, and it was not able to increase the size of its workforce, which would have better enabled CryoLife to deliver more of its life-enhancing and life-saving technologies to more patients. CryoLife also had to defer significant investments in capital and start-up companies, all of which would have furthered innovation, as well as delay investment in clinical trials to support product approvals.

The Tax has not produced the primary benefit—enhanced patient access to medical device technology—which was the purported basis for its passage. To the contrary, it has largely resulted in reduced innovation, jobs, pay and access to care.

I respectfully request and thank you in advance for your timely action on legislation to repeal the Tax.

Sincerely,

J. Patrick Mackin
Chairman, President and CEO
CryoLife, Inc.

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dba Wescor, Inc.
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Tel: +1 435–512–3650
www.elitechgroup.com

21 April 2015

Senate Finance Committee
Washington, D.C.
c/o Brad Grantz
brad_grantz@toomey.senate.gov

Dear Senate Finance Committee,

I am a president of a relatively small medical device company based in Logan, Utah. Our company has about 100 employees here and another 80 employees in other states. I would like to describe the effect of the Medical Device Tax on our company.

A tax of 2.3% probably doesn't sound like a lot to the average American. But this is not a tax on how much we earn; it is on how much we sell. When our company is healthy, we allocate about 10% of our sales revenue to research and development, to improve our existing technology and to create new products that make health care safer, cheaper, and more effective. Repeal of the 2.3% device tax could increase our R&D budget by 23%! The majority of that budget is used for engineering salaries, so it represents the salary of several highly skilled professionals.

My business unit remains profitable, although at a lower level, with the device tax. But another business unit of our company has not achieved profitability in the U.S. market. It may be at risk of being shut down. With the device tax, it's not enough to reach a breakeven point—in order to justify continued operation, it has to achieve an additional 2.3% of margin.

Even the activities funded by the revenue from the device tax will eventually suffer when overall medical device development declines, followed by overall sales.

Please give the immediate repeal of this unwise and burdensome tax a very high priority.

Best regards,

Dennis R. Briscoe
President, Biomedical Systems
Division of ELITechGroup Inc.

EXACTECH®
2320 NW 66TH COURT
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April 21, 2015

The Honorable Patrick J. Toomey
Chairman
Senate Finance Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
Senate Finance Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow:

The medical device tax is damaging to our country. Forget that it is unfair to single out a single industry. Let's think back to the "Yacht" excise tax. It's cost was 50,000 lost jobs and a permanent loss of a major portion of the U.S. boat industry to Europe (mainly Italy) and to Asia. We see the beginning of the same for medical devices. This tax combined with the dysfunctionality of the FDA depresses jobs, innovation, health care breakthroughs, and business in general. In addition, it can only increase health costs. This tax never should have been enacted and needs to go.

Respectfully,

BILL PETTY, M.D.
Executive Chairman

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FLORIDA ECONOMIC DEVELOPMENT COUNCIL
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United States Senate Committee on Finance
Subcommittee on Health Care

A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients

Thursday, April 23, 2015

Amy Evancho, President & CEO
Florida Economic Development Council
3802 Spectrum Boulevard, Suite 141
Tampa, FL 33612

Dear Chairman Toomey and Ranking Member Stabenow:

I write to you on behalf of the Florida Economic Development Council in support of repeal of the medical device excise tax. This burdensome and harmful tax negatively impacts job growth, innovation, and patient care. We are pleased that the committee is holding a hearing to examine the negative impact of the tax and urge you to continue advancing this important legislative initiative.

The Florida Economic Development Council is the professional association of economic, workforce, and community developers who work in Florida's 67 counties, over 400 cities, 24 workforce regions, 28 colleges, 12 universities, as well as utilities, ports, airports, and industrial authorities. We support job-creating innovation that bolsters our states' and nation's economy. The medical device tax directly and negatively impacts our members ability to grow jobs, limits resource allocation to innovation and research and development, and stalls development of technologies that saves lives.

Across the country and in Florida, the medical technology industry is a unique American success story—both for patients and the economy. The United States is the world leader in manufacturing life-saving and life-enhancing treatments, and the industry is an important engine for economic growth. According to surveys conducted by AdvaMed, the medical technology industry employs more than 400,000 workers nationwide; generates approximately $25 billion in payroll; pays out salaries that are 40 percent more than the national average ($58,000 vs. $42,000); and invests nearly $10 billion in research and development (R&D) annually. The industry is fueled by innovative companies, many of which are small businesses with 80 percent of companies having fewer than 50 employees and 98 percent with fewer than 500 employees.

Unfortunately, the medical device tax stifles innovation and has already cost thousands of high-paying jobs. The tax resulted in employment reductions of 14,000 industry workers in 2013, with approximately 4,500 additional jobs lost in 2014, according to a January 2015 AdvaMed survey. It has caused companies large and small to reduce financial resources that could otherwise be used for R&D.

The medical device tax is particularly problematic for Florida—a state that is rich in medical technology manufacturers. Florida is home to one of our nation's largest medical device economies—encompassing 662 device manufacturers employing nearly 21,000 Floridians, paying an average annual wage of more than $60,000. Florida is one of the top five med-tech job producers in the country; and the vast majority of Florida medical device manufacturers (80%+) are small, entrepreneurial firms, employing fewer than 25 people. These are the companies that have been driving Florida's job creation and innovation in patient care in the medical technology sector.

This bad tax is adversely impacting innovation, R&D investment and job expansion in our state, and is disproportionately impacting small-to-midsize companies—the lifeblood of Florida's medical device industry. We respectfully request timely action on legislation to repeal this burdensome tax. Repeal will create jobs and spur economic growth in Florida and around the country by freeing up resources to pay for additional research and development and the manufacturing of new innovations.

Respectfully,

Amy Evancho,
President & CEO
Florida Economic Development Council, Inc.

FLORIDA MEDICAL MANUFACTURERS CONSORTIUM (FMMC)

United States Senate Committee on Finance
Subcommittee on Health Care
A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients
Thursday, April 23, 2015

Statement by:
John B. Ray, Executive Director
Florida Medical Manufacturers Consortium
310 W. College Ave, Suite 212
Tallahassee, FL 32301

Dear Chairman Toomey and Ranking Member Stabenow:

The Florida Medical Manufacturers Consortium (FMMC) strongly supports the immediate repeal of the medical device excise tax. Thank you for holding this important hearing to examine the negative impacts of this harmful tax—a tax on innovation and job growth that, unfortunately, has been in place for more than two years now.

By way of background, the Florida Medical Manufacturers Consortium (FMMC) is a statewide association of over 100 medical technology firms. The FMMC exists to further the interests of Florida's medical manufacturers by providing networking and education opportunities for industry members, facilitating connections with academic institutions, and promoting the interests of the industry to the general public and governmental organizations. In essence, the FMMC exists to unite, promote, and grow the Florida medical device industry, and to enhance the business success of its member companies.

Florida is a leader in the medical technology industry. Florida is home to one of our nation's largest medical device economies—encompassing 662 medical device manufacturers, employing nearly 21,000 Floridians and paying an average annual wage of more than $60,000. Florida ranks 3rd nationally in the number of FDA-registered medical device establishments. The vast majority of Florida medical device manufacturers (80%+) are small, entrepreneurial firms, employing fewer than 25 people. These are the companies driving Florida's job creation and innovation in patient care in the medical technology sector.

Contrary to some recent studies on the topic, the medical device excise tax is eroding our international dominance and competitiveness in the medical technology sector. It *is* costing our country jobs and siphoning off precious resources from research and development. Recent, competent industry surveys reveal the medical device tax resulted in national employment reductions of 14,000 industry workers in 2013, with approximately 4,500 additional jobs lost in 2014 (AdvaMed); and 72% of companies slowed or halted job creation in the United States to pay the medical device tax (MDMA).

Incredibly, this bad tax is based on sales, not profit, and is doing the most harm to small to midsize medical device companies—the lifeblood of Florida's medical device industry, responsible for the lion's share of innovation, scientific discovery and job growth in our state. The tax extracts 2.3% on every sale of medical devices, and cares not if the company is large or small, or actually making any profit at all. Medical device companies are typically not profitable for many years, even after winning FDA approval to sell a device. Removing precious resources from the top line of these innovative manufacturers is devastating their ability to develop new life-saving and life-improving devices, and create great jobs for Floridians.

America's medical device industry is one of the few where we still are the global leader, and where we actually export more than we import. We should be supporting these 21st century innovators, not punishing them. Thank you again for your dedicated efforts to repeal the medical device excise tax.

Respectfully,

John B. Ray
Executive Director

GRADIENT TECHNOLOGIES LLC

April 23, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Subject: Imposition of the Medical Device Tax

Dear Chairman Toomey and Ranking Member Stabenow,

I am a private investor who for 20 years has been engaged in scientific research and product development intended for the commercialization of an innovative transcutaneous (noninvasive) neuromodulation technology to substitute electrophysiological alternatives for opioids and nonsteroidal inflammatory drugs in managing both acute and chronic musculoskeletal pain.

In terms of the information available to members of the Senate Finance Committee regarding the consequences of this new medical device tax, I offer the following:

- The availability of startup and early-stage investment funds practically evaporated with the Lehman Brothers collapse. Risk capital was initially diverted to either existing late stage "follow on" investments or early market launch priorities. Until very recently, the medical device segment of this risk capital marketplace had been refocused to opportunities in other segments of the *technology space.*
- The U.S. regulatory regime (FDA) continues to be a remarkable challenge; FDA's new proposal for a new device classification, "wellness" (a perfunctory *exemption* from the FDA &C '76 Act medical device regulation for *low risk devices, without ascertaining efficacy*) simply devalues technology by incentivizing innovations with the vigorish of FDA regulatory avoidance. These FDA challenges transcend to both CMS and private pay for reimbursement issues. In this healthcare transition both medical device companies and healthcare professionals are being *inequitably* and *unfairly squeezed* into the economic *penalty box* as *scapegoats* in this obvious governmentally enforced transition to an eventual single-payer system.

Since the Simpson and Bowles "term paper" re the looming national financial crisis, the only strong governmental measure to resolve this now unaffordable national debt situation has been Obamacare. This stutter stepped *healthcare tsunami* continues to produce substantial uncertainty, economic turmoil, *and* as a result, significant unavoidable headwinds (in the healthcare market; 17% of GDP) for innovation. This medical device tax proposal is simply a "bridge too far."

- The *consolidation* among hospitals, the acquisition by these same major hospitals of private medical practices, the restriction of competition by expanding rulemaking in favor of group purchasing organizations, the merger trend among the major corporations in both the medical device arena as well as pharmaceuticals, all severely handicap and thus dis-incent individual (and small company) entrepreneurship and innovation.
- An investment banker, in addressing these very same (industry consolidation) marketing points to my board yesterday, offered three questions which define his life experience in financing new healthcare product investments: "Can you actually make a [commercial, functioning] product, can you sell the product, and if you can't sell the product, then why make it?" Otherwise, the new product remains simply a science project.
- With these headwinds, why *single out* medical devices which account for only 5% of the cost of U.S. healthcare system from all of the other for-profit constituents?

The only conceivable notion for this new medical device tax proposition could be that the collective majority judgment by this Congress of a likely adverse reaction to this *revenue loss* burden is that the practical repercussions would produce only a negligible political fallout. Wrong.

The stakeholders, i.e. investors, patients, healthcare practitioners, etc., all recognize the tremendous potential benefit generated by new therapies, especially given today's horrific addiction revelations associated with regular opioid and NSAID usage. Congress's proposition unfairly focuses this medical device tax exclusively on only 5% of the total healthcare cost system.

For we entrepreneurs, this medical device tax is certainly a material financial burden (i.e. reduced profitability so *critical* during the intense *cash burn* [before positive flow] in the *startup* phase). Entrepreneurs are the personal risk takers who are currently *incubating* the technological changes so fundamental to the realization of the cost reduction and quality of care improvements anticipated in the Affordable Care Act. The *forecasted* decline in NIH funding portends the significant need for additional (not less) private "risk capital."

I would be pleased to elaborate on this subject, to give my testimony, and/or to engage in personal discourse with any Member curious to learn what *it is like* to spend 20 years and $20 million *inventing* and *commercializing* a scientific concept, only to be *bombarded* by the now ever-increasing adversarial forces of this U.S. government.

Sincerely

John C. Townsend
Chairman
Gradient Technologies LLC
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HEALTHCARE LEADERSHIP COUNCIL

April 22, 2015

United States Senate
Committee on Finance Subcommittee on Health Care
219 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Statement for the Record for the Hearing, "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients"

Dear Chairman Toomey and Ranking Member Stabenow:

On behalf of the Healthcare Leadership Council (HLC), thank you for your leadership on the Senate Finance Health Care Subcommittee and for your interest in examining the impact of the medical device tax on jobs, innovation, and patients.

HLC is a not-for-profit membership organization comprised of chief executives of the nation's leading healthcare companies and organizations. HLC is committed to advancing a consumer-centered healthcare system that values innovation and provides affordable, accessible, high-quality healthcare to all Americans. As the only CEO-level organization spanning all health sectors, HLC has a unique ability to speak on the policy implications of proposals for healthcare decision-makers. As such, we write to express our concerns about the impact the medical device tax has on both patient access to treatment and vital sectors of healthcare.

Medical innovation is essential to healthcare value and progress. The U.S. has led the global medical device and pharmaceutical industries for decades and this leadership has brought hundreds of thousands of high-paying jobs to our country and life-saving, life-improving technologies to patients. However, taxes and fees imposed on these industries through the Affordable Care Act, combined with the lack of regulatory consistency, predictability and transparency, hinders innovation, hampers job growth, and adversely impacts patient access.

We believe by virtue of our high-level leadership, cross-sector collaboration, and real-world experience, HLC and its members can prove a valuable resource. We look forward to working with you on this and other critical healthcare issues.

Sincerely,

Mary R. Grealy
President

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May 13, 2015

The Honorable Patrick J. Toomey
Chairman, Senate Finance Subcommittee on Health Care
248 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
Ranking Member, Senate Finance Subcommittee on Health Care
731 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Toomey and Ranking Member Stabenow,

I am pleased to submit this statement for the record on behalf of HoverTech International.

I want to call your attention to the first article link below. I own HoverTech International, a small company that employs 23 in Bethlehem. We manufacture a product called the HoverMatt, that is used in hospitals to help nurses move patients without injuring their backs or hurting the patient. We have saved hospitals millions of dollars in workers' comp costs, including many VA facilities. Last year my small company paid more than $900,000 due to the Medical Device Tax. Part of the initial reasoning to have device companies fund the ACA was that we would have many more customers. Our product is strictly used in hospitals, and as the article states, they are reducing their number of beds due to decreased patient census. So, how is this helping HTI? I am paying $1M to reduce my potential customer pool! I would welcome testifying in front of a Senate committee, just like the CFO of B. Braun did. We have delayed building a new facility for over 2 years because of the onerous tax.

Respectfully,

David T. Davis
President/Owner
HoverTech International

http://www.modernhealthcare.com/article/20150221/MAGAZINE/302219988?utm_source=modernhealthcare&utm_medium=email&utm_content=externalURL&utm_campaign=mostreq

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LIFESCIENCE ALLEY®

April 23, 2014

Chair Toomey and Members of the Senate Finance Subcommittee on Health Care:

Thank you for your leadership in convening this hearing, titled "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients." LifeScience Alley appreciates the opportunity to be on the record in support of repealing the medical device tax.

LifeScience Alley represents the most densely concentrated medical technology cluster in the world and is home to some of history's greatest health technology and care innovations. As the birthplace of medical devices, Minnesota's economy has long benefitted from strong research-based companies such as 3M, Medtronic, Boston Scientific, St. Jude Medical and hundreds of small startups that will bring new innovation to the healthcare marketplace.

Supporting the industry's economic strength is critical to Minnesota's economy, creating high-paying, knowledge-based jobs. The medical device industry in Minnesota accounts for 38,000 direct jobs, with an additional 120,000 in indirect jobs, all of which have an average salary of $97,500 per employee. Many of these individuals are employed at companies that have fewer than 50 employees, which account for about 80% of the industry, and of these companies, roughly 95% employ 25 or fewer people. Small venture capital-backed companies typically spend $500,000 to $2 million per month to operate and need at least $100 million in investments to bring a product to market.

We thank the committee for addressing the medical device tax repeal, a critical issue for not only Minnesota, but for the entire industry. The federal medical device excise tax continues to stifle innovation in Minnesota. In fact, our state pays roughly 25% of the entire medical device tax. This is money that could be re-invested in research and development or devoted to hiring more Minnesotans into high-paying jobs. The medical device tax increases the risk of investment to investors, and it is this uncertainty that impedes our companies from bringing critical, life-saving therapies to patients worldwide.

Congress must act this year to repeal this egregious tax which is stifling innovation not only in Minnesota's Medical Alley but across the entire industry nationwide.

Thank you, Mr. Chair, for the opportunity to voice our concern.

Sincerely,

Shaye Mandle
LifeScience Alley, President & CEO

MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA)
1333 H Street, NW, Suite 400W
Washington, DC 20005
Phone (202) 354–7171
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www.medicaldevices.org

April 23, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

I write to you today on behalf of the hundreds of companies represented by the Medical Device Manufacturers Association (MDMA) offering our strong support of S. 149, the "Medical Device Access and Innovation Protection Act." The medical device excise tax has been a devastating policy for patients, innovators and providers for years, and we thank you for holding the hearing "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients" to examine how to repeal it once and for all.

MDMA represents nearly 300 medical technology companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

Since the medical device tax was first proposed in 2009, we shared our grave concerns with Congress about what this policy would mean to job creation, R&D and patient care. Sadly, much of what we predicted has come true.

We have surveyed our members since the device tax became law in 2010, and it is clear that this punitive policy has thwarted the ability of innovators to deliver on the promises of improved patient care.

In our most recent survey, we asked medical technology executives what they would do if the medical device tax was actually repealed. The message was loud and clear. The overwhelming majority of medical technology innovators would make new investments in R&D and increase hiring. The survey consisted of over 100 responses from medical technology executives, and the top findings included:

- 80% of respondents noted that they would increase R&D investments in the cures and therapies of tomorrow
- When asked how much they would increase their R&D budget, the average increase was 14%
- 72% of companies slowed or halted job creation in the United States to pay the medical device tax
- 85% of respondents said that if the device tax was repealed, they would hire newemployees in the U.S.

Since enacted in 2010, the medical device excise tax has eliminated thousands of good paying jobs, led to drastic cuts to R&D and harmed patient care in the United States. According to Ernst and Young, the 2.3% medical device tax on average increases the effective tax rate for America's medical technology innovators by 29 percent.

MDMA strongly believes that the reason for such broad, bipartisan support for repealing the medical device tax is the recognition that we need to protect and support this proud American success story. At a time where we need more high tech manufacturing and solutions to the challenges facing the health care system, it is critical that we have policies in place that will support innovation, and empower entrepreneurs. Repealing the medical device tax will do just that.

MDMA is dedicated to working with Congress and the diverse coalition of stakeholders to get repeal of the device tax across the finish line, and we thank you for your leadership on this important policy goal.

Sincerely,

Mark B. Leahey
President & CEO, MDMA

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To the Committee on Finance Subcommittee on Health Care, United States Senate

Re: A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients

April 23, 2015

On behalf of our 56 member companies, the Medical Imaging and Technology Alliance (MITA) commend the Senate Finance Committee and Health Care subcommittee for conducting today's hearing, "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients."

Across the country, the medical device industry is a unique American success story—both for patients and our economy. The United States is the world leader in manufacturing life-saving and life-enhancing treatments, and the industry is an important engine for economic growth. MITA believes the medical device tax harms job creation and the economy, cannot help but influence heath care innovation decisions, negatively impacts the medical imaging industry and therefore should be repealed.

The Device Tax Harms Jobs and the Economy

The American medical technology industry provides jobs for over 400,000 people,[1] creating a growing trade surplus, and developing the technology essential to advancing patient care in the U.S. and around the world. The industry generates approximately $25 billion in payroll; pays out salaries that are 40 percent more than the national average ($58,000 vs. $42,000); and invests nearly $10 billion in R&D annually by innovative companies, many of which are small businesses (80 percent of companies having fewer than 50 employees and 98 percent with fewer than 500 em-

[1] *http://no2point3.com/media/AdvaMed-the-New-Medical-Device-Tax-Must-Be-Repealed.pdf.*

ployees).[2] In addition many companies that in the past routinely partnered with small start-ups without adequate financial resources have slowed or stopped this type of investing. Not only does this damage economic development, but it also hinders getting innovative diagnostic and therapeutic technologies into the hands of physicians to help their patients.

Additionally, global competition has amplified the incentives to outsource research and development and move manufacturing abroad. Despite these options, many firms have largely resisted the trends seen in other manufacturing sectors and maintained successful research centers and manufacturing plants in the United States. A $29 billion tax burden on these companies amplifies these negative pressures and has already forced companies to consider finding savings in their U.S. operations to offset this cost.

This Device Tax Stifles Health Care Innovation

The medical imaging industry is in a state of constant innovation that each year brings exciting new advances in both reducing radiation dose and improving imaging fidelity. These developments have given physicians new tools to achieve accurate and early diagnoses that improves patient care by likely lessening the intensity of intervention and reducing downstream costs to the health care system. Unfortunately, this tax impacts the resource decisions that the industry makes regarding funding research and development and investing in manufacturing. Less investment in R&D slows the pace of innovation and postpones patient access to the next generation of care.

The Device Tax Negatively Affects the Medical Imaging Industry

Advocates of the device tax argued that the device tax would complement an increase in demand for medical devices due to the Affordable Care Act's insurance coverage expansions. In addition, the majority of device-intensive medical procedures are performed on older patients with existing private insurance or Medicare coverage. Added insurance coverage may enable more primary and preventive care. This is good. But when Massachusetts instituted universal insurance in 2007, sales of medical imaging equipment in the state dropped more than in any other state.[3]

Unlike other devices, imaging equipment is considered infrastructure, based in hospitals and physician offices. While many elements of health care are intended for use one time for one patient, imaging equipment is designed to be used multiple times, on many patients, for multiple years. As a result, even if a hospital or doctor's office experiences an increase in patients, they will not necessarily purchase additional equipment. Despite this key difference, firms manufacturing imaging equipment—and other multi-patient devices—are required to pay this 2.3% tax without a substantial increase in demand for their products.

This Tax Taxes Sales, Not Net Income

As a result, even companies making no profit will pay the tax, which makes it harder for entrepreneurs to attract investment required to support innovative new companies.

Conclusion

Device tax repeal has received broad bipartisan support because Democrats and Republicans both understand the deleterious impact the tax is having on job creation, innovation, and research and development. That's why a resolution supporting repeal of the tax passed the Senate with 79 votes in 2013.

Our collective opposition to the medical device tax is not a commentary on broader health reform. The reality is that increased investment in medical innovation is a national priority and imposing an excise tax on one of the most prolific medical technology industries is counter-strategic. We respectfully request timely action on legislation to repeal this burdensome tax and let us do what we do best: develop innovative cutting-edge imaging systems for the good of the millions of Americans who need them every year. We thank the committee for highlighting this important issue.

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[2] *http://advamed.org/page/44.*

[3] Sorensen, G. (2013). The Medical Device Excise Tax—Over before It Begins? *New England Journal of Medicine, 369*(10), 982–983.

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The Honorable Orrin G. Hatch
Chairman
U.S. Senate
Committee on Finance

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance

Dear Chairman Hatch, Ranking Member Wyden, and Finance Committee Members:

On April 23, 2015, you have scheduled a hearing on "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients." I write to explain the impact of the medical device excise tax on our company.

NeoTract, Inc. is a small company dedicated to developing innovative and effective devices that address unmet needs in the field of urology. Our first product the—UroLift System—addresses Benign Prostatic Hyperplasia (BPH), a condition affecting approximately 37 million men in the United States alone. Symptoms of BPH can cause depression, loss of productivity, and decreased quality of life. We employ over 70 people in California and more than 30 people in other U.S. locations and abroad.

NeoTract is at a critical inflection point in the company's life: we have recently been cleared by the FDA to sell the UroLift System commercially, and our expenses still exceed our revenue. The medical device excise tax is already having an adverse impact on our R&D investment and our ability to develop a sales force and distribution network capable of providing this device to millions of patients in need.

The excise tax we will pay in 2015 alone could create as many as 5 full-time jobs at NeoTract: high-quality U.S. manufacturing jobs, engineering jobs, administration jobs, and sales jobs. That is a 5% expansion in our work force that we cannot make because of just one year's worth of this tax.

Please act quickly to repeal the medical device excise tax.

Respectfully,

Dave Amerson
President and CEO
NeoTract, Inc.

OPTISCAN BIOMEDICAL CORPORATION

April 22, 2015
Members of the Finance Committee
U.S. Senate
Washington, DC

Dear Senators of the Committee:

My name is Peter Rule, and I have been an entrepreneur leading Medical Device companies since 1985. In all, I have led five such companies, which today aggregate ~$2.5 Billion in annual revenues, much of that outside of the United States, yet creating high value jobs within the U.S. These companies have all pioneered innovating, life saving, and cost effective therapies, including:

- external insulin pumps, self blood glucose monitoring, and continuous glucose monitoring systems for the treatment of diabetes,
- embolic protection devices, saving lives in those with diseased Saphenous Vein Bypass Grafts following Coronary Artery Bypass Grafting,
- Clot dissolution devices, treating occlusive clot in the leg and lungs, and
- A Real time diagnostics system for usage in hospitalized ICU patients.

My fifth company (the real time diagnostics company), which I am currently leading, is being harmed by the medical device tax, even though we are in the midst of a U.S. approval trial, and not yet generating revenues. This will likely surprise you.

Medical Device companies in today's financial climate need to achieve a minimum of $40M in a calendar year of revenues to be eligible for an Initial Public Offering. Achieving $50M in annual revenues is preferred. In general, medical device companies are not profitable until reaching $50M in annual revenues, with some needing more than $100M in yearly revenues to achieve profitability. So, the medical device tax's unintended consequence is that one has to raise more money while private, at a time when capital is the hardest to gain.

A medical device company located in the U.S. can really raise money only in the U.S., with rare exception. The reason is that investors in other countries wish to support employment in their country, and, in many cases, actually have a restriction on investing outside of their country or "circle." Thus, for a U.S. innovative medical device company, U.S. investors become the "gate keeper" for the funds necessary for innovation.

U.S. investors gauge an innovative medical device company largely on the underlying medical need, its effectiveness, nearness to U.S. approval, and the cash required to become profitable, as the assumption is that the IPO market itself is not presently available much earlier than that. They heavily discount the potential for OUS approval and revenue generation. They do not assume that a company will be acquired prior to being eligible for an IPO, as historically this is the case.

Other countries are providing incentive and subsidies for the creation of innovative medical device companies . This is common in Israel, S. Korea, and China, to name just three. If one looks at tax advantages, one easily adds several countries to the list, for example Switzerland.

So, today's U.S. innovative medical device companies are at a strategic cross road. We face competitors who have in effect a lower cost of capital thru government intervention at a time when we face higher costs of innovation through such actions as the medical device tax. It is awfully hard to compete under such circumstances.

We need relief from this tax in order to even approach a "level playing field" for the creation of innovative medical device companies.

Thank you for your time and consideration.

Peter Rule
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Submitted to the United States Senate Committee on Finance Subcommittee on Health Care

Hearing on "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients"

April 23, 2015

The Pennsylvania Biotechnology Association (Pennsylvania Bio), the statewide trade association for the biotechnology, pharmaceutical, medical device and diagnostic manufacturers in Pennsylvania is pleased to have this opportunity to share its views on the repeal of the medical device excise tax. The life sciences community of Pennsylvania includes more than 2,300 individual businesses with $7.2 billion in annual wages in the Commonwealth.

Pennsylvania Bio has been on record opposing this excise tax since its implementation in January of 2013. This misguided tax, on an industry that employs more than 31,000 in Pennsylvania, stifles innovation and prohibits further investment in research and development. At a time when Congress is working on a bi-partisan, bicameral effort to speed the development of therapies and medical devices for patients, this tax continues to undermine the effort. We thank the 14 Members of Congress and both Senators from the Pennsylvania delegation for co-sponsoring legislation that would repeal this tax and put job growth back on track in Pennsylvania.

A January 2015 nationwide survey of medical device manufacturers by the Advanced Medical Technology Association (AdvaMed) found a substantial negative impact on jobs and R&D, and identified companies that deferred or canceled capital investments, deferred or canceled plans to open new facilities, and a reduction in investment in start-up companies. The tax resulted in employment reductions of 14,000 industry workers in 2013, with approximately an additional 4,500 jobs lost in 2014. Furthermore, the industry will forgo the hiring of more than 20,000 employees over the next five years. Considering both jobs lost and jobs not created, the tax will result in 39,000 fewer industry jobs.

Pennsylvania Bio appreciates the attention the subcommittee on Health Care is bringing to this important issue under the leadership of Chairman Pat Toomey and Ranking Member Debbie Stabenow. We are pleased with the bi-partisan work in both chambers of Congress and remain hopeful this job killing tax policy will be repealed for good. Thank you for this opportunity to present our views.

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April 21, 2015

To the Senate Finance Committee,

RE: Hearing 4/23/2015 on Medical Device Tax on Jobs, Innovations, and Patients

This letter supports repeal of the medical device tax to avoid unintended consequences for innovators of non-invasive therapies that promote healing and relief from disorders having no current solution.

The confiscatory ACA tax extracts its toll from pre-profit companies by requiring additional borrowed or invested funds and up to 100% of profit in addition to accounting costs.

Why you should care about success for small companies

Do you, your loved ones, or your constituents endure chronic pain or impairment of the central or peripheral nervous system? With typical maintenance costs to ACA payers of $20K to $50K+ per year for life!

For example, **PhotoMed Technologies** (currently 5 part-time employees) has developed a non-invasive solution for disorders and impairments, such as diabetic neuropathy, complex regional pain syndrome (CRPS or RSD), stroke or spinal cord spasm or paralysis, an non-healing wounds. Specifically, **solutions for disorders having NO current solution.**

Healing effects are easily documented because relief persists or improves after therapy ends. Interventions that must be present to maintain effect do not heal.

Since 2000, I personally funded the technical risks for PhotoMed's discoveries. Now, our experimental therapy is sufficiently robust for the next steps toward commercialization.

Unfortunately, the ACA tax, billing code acquisition, and escalating regulatory risks add challenges to fund the next steps. **Outside funders are considering entirely skipping America.** That saddens me because I took on this project especially to help my friends and military people having NO solution for their pain.

I hope that you and your family never suffer disorders resolved by our experimental therapy.

Please end or revise the ACA tax to reduce challenges to the success of small stakeholders who offer the hope of healing for future generations.

Sincerely,

Allan Gardiner

STATEMENT OF MARY WOOLLEY, PRESIDENT AND CEO, RESEARCH!AMERICA

1101 King Street, Suite 520, Alexandria, VA 22314

Before the United States Senate Committee on Finance
Subcommittee on Health Care

A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients

April 23, 2015

Chairman Hatch, Ranking Member Wyden, and distinguished members of the Senate Finance Committee:

On behalf of Research!America, the nation's largest non-profit alliance committed to making medical progress a top national priority, I appreciate this opportunity to comment on the medical device excise tax.

The more than 350 members of the Research!America alliance include patient advocacy organizations, foundations, research universities, academic medical centers, independent research institutes, scientific societies, and large and small businesses within the bioscience industry. What brings this diversity of organizations together is the conviction that faster medical progress should be treated as a national strategic imperative. Whether the objective is to advance the longevity, productivity, independence and well-being of individual Americans, protect our nation from pandemics, bioterrorism and other destabilizing population health threats, or foster a strong, globally competitive economy, medical progress is pivotal to America's progress.

We believe it is in the nation's best interests to assure that federal policies are aligned with the objective of speeding medical progress. By dis-incentivizing investment in medical device research and development, the medical device excise tax contravenes this basic principle. We hope Congress will take bipartisan action as soon as possible this year to repeal the medical device tax.

The Role of Medical Devices in Advancing the Health and Well-Being of Americans

The term "medical device" refers to technologies engineered to advance and restore health. From stents to wheelchairs to artificial organs, devices save lives and work to mitigate the effects of physical disabilities. While far from exhaustive, the following examples help convey the significance of past—and future—research and development in the medical device arena.

- According to a study initiated by the Christopher & Dana Reeve Foundation, nearly 1 in 50 people live with paralysis—approximately 6 million people. That's the same number of people as the combined populations of Los Angeles, Philadelphia, and Washington, D.C. Medical devices are the tools used to provide mobility, restore the ability to communicate, and in other fundamental ways enhance autonomy and quality of life for these men, women and children.[1]
- Between 1993 and 2009, 2.9 million patients received permanent pacemakers in the United States. These implanted medical devices, which have been refined significantly over time to dramatically increase safety, efficacy, and patient satisfaction, address disabling and sometimes life threatening irregularities in heart rhythm.[2]

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[1] Christopher & Dana Reeve Foundation, Paralysis Resource Center, Paralysis Facts & Figures *http://www.christopherreeve.org/site/c.mtKZKgMWKwG/b.5184189/k.5587/Paralysis_Facts__Figures.htm.*

[2] Arnold J. Greenspon, et al, Trends in Permanent Pacemaker Implantation in the United States from 1993 to 2009: Increasing Complexity of Patients and Procedures, Journal of the American College of Cardiology, Vol. 60, Issue 16 (2012) *http://www.sciencedirect.com/science/article/pii/S0735109712028100.*

- A total of 30 million blood transfusions occur each year in the U.S. Transfusion devices enable these life-saving procedures.[3]
- As of March, 2012, nearly 1,300 service members lost a limb as a result of combat in Operation Enduring Freedom, Operation Iraqi Freedom, or Operation New Dawn; of that number, 359 lost more than one limb. Increasingly sophisticated prosthetic devices play a crucial role in enabling wounded warriors to achieve their personal and professional goals, as do devices that aid in breathing, communication and external mobility. According to a 2014 survey conducted by The Wounded Warrior Project, 7% of wounded warriors are permanently housebound as a result of their injuries. Our nation must continue to research and deploy advanced medical technologies to reduce this alarming and tragic statistic.[4]

The Economic Impact

According to the Advanced Medical Technology Association, the medical device industry generates approximately $25 billion in payroll, with median salaries 40 percent above the national average, and invests nearly $10 billion in R&D annually.[5] But that is only part of the story. As the global economy evolves, export potential in the medical device arena will grow. And as the examples above illustrate, medical devices play a particularly important role in helping individuals overcome physical disabilities that rob them of independence and compromise productive capacity. Medical devices can reduce the need for caregiver support and empower Americans to return to, or stay in, the workforce and maintain healthy, active lifestyles. These tangible and intangible economic benefits convey to individuals and society as a whole, empowering wounded warriors to provide for their young families and older Americans to choose when to retire from the workforce instead of being forced by physical limitations to do so.

The Case for Repealing the Medical Device Excise Tax

The reasoning that underlies our support for repealing the excise tax is straightforward: Because the excise tax reduces the return on investment in new medical devices, it decreases the capital available for medical device R&D and tilts investment decisions within the device arena toward lower risk, higher return R&D. Given the enduring value of breakthrough medical devices, neither outcome is a desirable one.

Concerns have been raised that repealing the medical device tax would jeopardize continued implementation of the Affordable Care Act (ACA). However, revenues generated from the medical device tax are not earmarked for a specific purpose; they flow into the federal treasury and are fungible. The future of the ACA is a critically important issue, but it should be de-linked from decisions regarding the future of the medical device tax.

Conclusion

Medical device R&D drives medical progress in profoundly important ways. By increasing the attractiveness of investment in medical devices, repealing the medical device excise tax is a pragmatic means of putting more medical innovation to work for Americans. Research!America is grateful to the Committee for holding today's hearing, and hope that your deliberations help lay the groundwork for bipartisan action to repeal the tax as soon as possible this year.

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April 21, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate

[3] American Red Cross, Blood Facts and Statistics *http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics.*

[4] Wounded Warrior Project, 2014 Wounded Warrior Project Survey *http://www.woundedwarriorproject.org/media/691673/2014-wwp-alumni-survey-report.pdf.*

[5] Advanced Medical Technology Association (AdvaMed), *http://advamed.org/*.

Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

The medical device tax is having a series of unintended consequences on small to medium-sized medical device companies. A 2.3% tax on revenue is devastating for a number of reasons. First off, it can mean an effective tax rate for smaller companies of well over 50% when one considers federal, state and device taxes. This increase of "cash out" to pay taxes is costing our industry and our country jobs and innovation. The jobs issue is obvious, as we have begun to move real "over minimum wage" jobs out of Waltham Mass. to the Dominican Republic. The cost is a fraction of the U.S. costs and the labor force is more than adequate. We have also added a new plant in Juarez, Mexico taking jobs from northern California just to give you two real life examples affecting almost 500 U.S. jobs. This is being done in large part to cover the increased costs the tax has created. If we don't stay competitive, there won't be any jobs for our company, regardless of the location.

Let me briefly speak about innovation. A large portion of true medical device innovation comes from the small companies that ultimately sell or license their new technology to big medical companies. This incremental tax many times equates to the cost of an engineer, researcher, or lab tech which would have to be let go or simply not hired to pay for this tax. Many people think of the large multi-national companies when they think of the medical device industry. They do play a significant role but the real bread and butter of the industry are the thousands of small device companies that have been the heart and soul of our industry for decades. This tax is disproportionally affecting the small to medium sized companies struggling to stay afloat in this time of increased regulation and taxation.

I still want to believe that all branches of our government want to do the "right" thing for our country as a whole, but it is past time to admit a mistake, fix it and move on. We do this in our company frequently, it is not a sign of weakness to acknowledge that something didn't work out as originally planned, but rather it is a sign of strength to do something about it in a timely manner.

It is time to REPEAL the medical device tax regardless if there is a corresponding offset or not. Congress (both parties) and the President need to stand up do the right thing for the right reason not just what is politically expedient and fix this problem NOW. Obviously this is a great industry in an even greater country, let's not let there be any more governmental incentives to move jobs or innovation dollars off of our shores.

Respectfully submitted,

Joseph F. Damico
Founding Partner and Co-Chairman

SUBMITTED BY SIEMENS HEALTHCARE

From the *New England Journal of Medicine,* September 5, 2013

THE MEDICAL DEVICE EXCISE TAX—OVER BEFORE IT BEGINS?

TO THE EDITOR: The Perspective article by Kramer and Kesselheim (May 9 issue)[1] contains factual errors about the medical device tax that could lead to critical policy blunders.

[1] Kramer DB, Kesselheim AS. The medical device excise tax—over before it begins? N Engl J Med 2013;368:1767–1769.

First, the claim that "purchases by government agencies and nonprofit institutions" are exempted from the tax is incorrect. Section 2 of the law specifically excludes some typical exemptions (e.g., sales to governmental and nonprofit agencies) from the tax. Therefore, those sales are taxable.

Second, the claim that broadening insurance coverage, "including appropriate use of medical imaging and other diagnostic tools, would translate to enhanced sales for many device companies," is incorrect. The opposite is true: added coverage should enable more primary and preventive care, leading to reductions in utilization of imaging. The implementation of "Romneycare" in Massachusetts in 2007 has shown this to be the case. Sales of medical-imaging equipment in that state have dropped more than they have in the rest of the country and have not recovered (Fig. 1). Medical device manufacturers will already be paying dearly for the Affordable Care Act (ACA) through reduced sales, even without the tax.

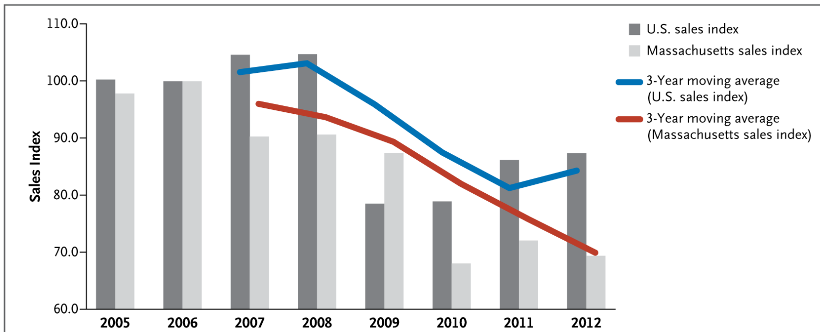

Figure 1. Sales of Medical-Imaging Equipment in Massachusetts and the United States, 2005–2012.
Data are from the National Electrical Manufacturers Association. The sales index is calculated from the sales volume as measured in both number of devices sold and total dollars for all equipment sold. Where only unit volume was available (Massachusetts state data through 2009), the data points represent unit volume. The 3-year moving average is the mean of the sales indexes of the current year and the previous 2 years.

Third, the claim that job reductions cannot be traced to this tax is incorrect. As an executive responsible for such decisions, I can assure readers that this tax has led to a decrease of hundreds of research-and-development jobs at my company. I have already been forced to lay off workers as a result of the tax. Furthermore, the math that is laid out by the authors belies their assertion: If 7 to 8% of sales are spent on research and development, as the article states, then the 2.3% tax on sales represents more than a quarter of research-and-development budgets.

Fourth, claims that repealing the medical device tax would have an effect on the health insurance provisions of the ACA are incorrect. The added revenue merely helped offset the cost of the bill, very much as occurred with the Community Living Assistance Services and Supports (CLASS) Act, an original provision of the ACA that was repealed earlier this year after it was determined to be unworkable. Repeal of the device tax would not impede the ACA, and 79 senators, including staunch supporters of the ACA, recently voted for repeal.

And finally, recent data highlight that diagnostic errors are the most common, most deadly, and most costly of medical errors.[2,3] Yet, the tax discourages accurate diagnosis. In some ways, taxing the very devices that can facilitate discovery is similar to establishing a tax on supercomputers while attempting to sequence the human genome. Policies should be aimed at encouraging, not discouraging, society to put resources into improved diagnosis.

[2] Saber Tehrani AS, Lee H, Mathews SC, et al. 25-Year summary of U.S. malpractice claims for diagnostic errors 1986–2010: an analysis from the National Practitioner Data Bank. BMJ Qual Saf 2013;22:672–680.

[3] Misdiagnosis is more common than drug errors or wrong-site surgery. Washington Post. May 3, 2013
(*http://www.washingtonpost.com/national/health-science/misdiagnosis-is-more-common-than-drug-errors-or-wrong-site-surgery/2013/05/03/5d71a374-9af4-11e2-a941-a19bce7af755_story_2.html*).

A. Gregory Sorensen, M.D.

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TO THE EDITOR: Regarding the Perspective article on the medical device excise tax, three additional points deserve attention. First, since the expanded coverage in the ACA is skewed toward younger patients who are less likely to require medical devices for their care, the promise of enhanced device sales may be overstated.[1] For example, similar legislation that was passed in Massachusetts in 2006 has not resulted in a convincing spike in device sales.[2] Second, since the tax is levied on sales rather than profits, it could have a disproportionate effect on startup companies that are trying to bring new products to the market, which could affect treatment options for patients.[3, 4] Third, the cost of medical devices to hospitals is based on negotiated contracts; companies will probably not be able to completely pass on the tax to consumers. Funding the ACA is vital, but arbitrary approaches to revenue generation could have unintended consequences. Therefore, the true costs of the medical device excise tax to device companies and patients remain uncertain.

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H. Benjamin Harvey, M.D., J.D.
Rahmi Oklu, M.D., Ph.D.

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No potential conflict of interest relevant to this letter was reported.

TO THE EDITOR: Contrary to the views of Kramer and Kesselheim, repeal of the medical device excise tax has nothing to do with health policy, and the negative effects of the tax are not merely "unproven assumptions." When enacted, the tax was used in a bookkeeping sense to offset some of the costs of the ACA, but it is now simply part of U.S. general revenue.[1] Repealing it will have zero effect on programs authorized by the ACA. The tax makes the already uncompetitive U.S. tax system even more uncompetitive by raising the industry's tax burden by 29%.[2] Thousands of workers have already been laid off because of the tax, and two separate studies have estimated potential job losses of 40,000 or more.[3, 4] Moreover, the tax will cut research-and-development investment by an estimated $2 billion per year, meaning less medical progress for patients.[5] The bottom line is that repeal of the tax is not a retreat from health reform but is essential to America's continued leadership in medical technology.

Stephen J. Ubl
Advanced Medical Technology Association (AdvaMed), Washington, DC

Mr. Ubl reports being an employee of Advanced Medical Technology Association. No other potential conflict of interest relevant to this letter was reported.

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[1] Dolan M. Innovation 101—technology and innovation in the medical device industry. Newport Beach, CA: ROTH Capital Partners, September 13, 2012 (*http://www.roth.com/files/marketing/email_blasts/Roth%20Capital%20CONNECT.pdf*).

[2] Torres C. U.S. health reform burden falls on medical devices. Nat Med 2010;16:500–500.

[3] Medical device tax would mostly hit the biggest firms. MedCity News. March 24, 2010 (*http://medcitynews.com/2010/03/medical-device-tax-would-mostly-target-the-biggest-companies*).

[4] Weaver C. Excise tax remains for medical device makers. Wall Street Journal. June 28, 2012 (*http://online.wsj.com/article/SB10001424052702304441404577480972664688712.html).*

[1] Health Care and Education Reconciliation Act of 2010 § 1405, 26 U.S.C. § 4191 (2010).

[2] Effect of the medical device excise tax on the federal tax liability of the medical device industry. Ernst & Young, November 2012 (*http://advamed.org/res/14/effect-of-the-medical-device-excise-tax-on-the-federal-tax-liability-of-the-medical-device-industry*).

[3] Furchtgott-Roth D, Furchtgott-Roth H. Employment effects of the new excise tax on the medical device industry. California Healthcare Institute, September 2011 (*http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf*).

[4] The economic impact of the U.S. advanced medical technology industry. Battelle Technology Partnership Practice, March 2012 (*http://www.chi.org/uploadedFiles/Industry_at_a_glance/BattelleFinalAdvaMedEconomicImpactReportMarch2012.pdf*).

[5] Zycher B. ObamaCare's tax on medical devices: cuts R&D by $2 billion a year. Pacific Research Institute, May 2012.

THE AUTHORS REPLY: Sorensen and Ubl repeat common rhetoric surrounding the medical device excise tax. Despite their references to anecdotal claims and industry reports, we remain skeptical that this tax will have the effects they claim on personnel decisions, the international competitiveness of the U.S. device industry, or innovation. Indeed, we agree with Prabhakar and colleagues that the true effects of the medical device excise tax on patients and industry remain to be seen, and we look forward to independent, rigorous research in this area.

Sorensen's points regarding the use of imaging in Massachusetts do not support his conclusions. First, imaging is only one component of the entire medical device sector. Second, other changes in the health care market in Massachusetts and elsewhere during recent years may have influenced the utilization of imaging, including payment reform [1] and uptake of strict conflict-of-interest policies at Massachusetts academic medical centers, which insulate physicians from industry-related marketing of services,[2] both of which are unrelated either to excise taxes or insurance coverage. Third, regional differences in health care utilization in general and in utilization of high-cost elements in particular challenge extrapolations from Massachusetts alone.[3] Sorensen's prediction about the effects of the ACA is also undermined by evidence from an ongoing randomized natural experiment in Oregon, which showed that expanding insurance coverage led to enhanced utilization of at least one type of imaging, since the use of mammography in women who were 50 years of age or older increased by nearly 30%.[4]

We appreciate Sorensen's clarification that sales to government and nonprofit entities, which ordinarily are exempt from taxation, are not exempt from this specific excise tax. This point has been clarified in the online version of our article.

Daniel B. Kramer, M.D.
Beth Israel Deaconess Medical Center
Boston, MA

Aaron S. Kesselheim, M.D., J.D.
Brigham and Women's Hospital
Boston, MA

Since publication of their article, the authors report no further potential conflict of interest.

THE SPECTRANETICS® CORPORATION

April 23, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow:

The Medical Device Tax is much larger than a "profits bill" before Congress—it's about realizing our potential as a world power, economically and through medical advancement. The debate is grounded in fierce conversations that impact jobs, innovation, education, health care and building on America's leadership position globally.

Spectranetics, a Colorado-based clinical solutions company, is committed to saving lives and limbs by developing, manufacturing and marketing medical devices that

[1] Ginsburg PB. Achieving health care cost containment through provider payment reform that engages patients and providers. Health Aff (Millwood) 2013;32:929–934.
[2] Kesselheim AS, Robertson CT, Siri K, Batra P, Franklin JM. Distributions of industry payments to Massachusetts physicians. N Engl J Med 2013;368:2049–2052.
[3] Report to the Congress: regional variation in Medicare service use. Washington, DC: Medicare Payment Advisory Commission, 2011 (*http://www.medpac.gov/documents/Jan11K_RegionalVariationK_report.pdf*).
[4] Baicker K, Taubman SL, Allen HL, et al. The Oregon experiment—effects of Medicaid on clinical outcomes. N Engl J Med 2013;368:1713–1722.

address the most challenging cardiovascular conditions of our time. We employ 830 globally and serve 65 countries worldwide. In the last 2 years, we received 140 regulatory approvals in 18 countries across four continents. We live for the next discovery and the next life saved.

We, our industry and our health care system, share a common goal—better care, lower costs and improved access.

I applaud the Senate Finance Committee for hosting a hearing on the impact of the Medical Device Tax on patients, innovation and jobs. We understand that the Committee is currently reviewing the repeal of the Medical Device Tax, a part of the Affordable Care Act, which levies a 2.3% tax on gross sales of all medical equipment sold in the United States. On behalf of Spectranetics, I urge you to take direct action and vote for the repeal.

In Colorado alone, the medical technology sector employs roughly 10,000 individuals. The average yearly wage of medical technology sector employees is $74,000 with an annual payroll impact of $732 million. Bioscience products, Colorado's leading export, accounted for 17% of 2013 exports. Bottom line, the industry is vital to Colorado's economy.

I want to thank Colorado Senators Michael Bennet and Cory Gardner, who have expressed support for the repeal. At a time when it seems as if no one agrees on anything, I'm pleased to speak on behalf of a state that is working together to maintain the United States' global foothold as a leader in biosciences and medical technology.

Increasingly, bioscience companies are shipping manufacturing and clinical jobs overseas. It is imperative that the United States preserve and enhance an industry that is clean, sustainable and leads to better and longer lives for millions of patients. It exemplifies what American health care reform is all about and is, indeed, critical to maintaining our leadership position as a country and our commitment to accessible, affordable care for all.

The Medical Device Tax is levied on gross sales, not on profits. This means a business can actually owe taxes before ever earning a dollar in profit. The tax will effectively consume 65% of the average device maker's already-narrow 3.4% average profit margin. Over the next decade, the cost to manufacturers is estimated at $20 billion.

At Spectranetics, we anticipate that the Medical Device Tax will result in a payment of about $4 million in 2015. Ironically, we will be forced to redirect funds destined to reduce the cost of health care through research and development, clinical trials and business expansion to pay the tax. The tax, as well as other roadblocks to innovation within the Colorado bioscience community, was highlighted by the *Denver Business Journal* recently and noted as a threat to our regional and national economy.

According to the Medical Device Manufacturers Association (MDMA), there are no data or studies to suggest that the cost of this "innovation tax" will be offset by a larger pool of insured people receiving treatment, particularly for companies producing acute care products.

The medical device ecosystem is noteworthy for the volume of start-up activity it produces. Eighty percent of medical device makers have fewer than 50 employees—they are the entrepreneurs and innovators responsible for the lion's share of the health care breakthroughs that keep America on the leading edge of the medical device field. The results of the tax are devastating to small business and patient care; a decrease in dollars going to venture capital-backed medical device companies, the lifeblood of innovation, is more severe than any time in the last 30 years. Now is not the time to stifle the industry with misplaced tax burden.

The medical device industry is a unique American success story—both for patients and our economy. The United States is the world leader in manufacturing lifesaving and life-enhancing health care solutions, and the industry is an important engine for economic growth. It is critical that we work together to fuel its future.

Sincerely,

Scott Drake
President & CEO
The Spectranetics Corporation

3D Medical Manufacturing, Inc.

April 21, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow

Re: Repeal of Medical Device Tax

Please communicate to the committee that I support the repeal of the medical device tax. Here is what the device tax does for America:

- It motivates device companies to purchase their products in China and LCC as opposed to being manufacturing in America, so they can save or recoup the money they are paying out in additional device taxes; this puts small companies out of business.
- It motivates them to move corporate headquarters out of America to save on other taxes.
- We need American manufacturing jobs, additional taxes kill American jobs.
- With more manufacturing jobs we are not so dependent on a consumer economy.
- If you need to pay for healthcare put the tax on fast food, alcohol, and tobacco companies that sell the products that make people unhealthy.
- We need to preserve the few manufacturing sectors we have left in America.

It baffles me why this logic is hard for some educated people in government to understand.

Thank you for your support to repeal this tax.

Joe Davis
3D Medical Manufacturing, Inc.
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Riviera Beach, FL 33404

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U.S. Chamber of Commerce

ON: A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients

TO: U.S. Senate Committee on Finance Health Care Subcommittee

DATE: May 1, 2015

1615 H Street, NW, Washington DC 20062

The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

The U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than three million businesses and organizations of every size, sector, and region, appreciates this opportunity to provide a statement for the record as part of the Committee on Finance Health Care Subcommittee's April 23, 2015, hearing titled "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients." The Chamber and its members continue to strongly support repeal of the medical device tax and we have summarized our concerns, and the concerns of the employer community, below for the record.

The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system. More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large. Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented.

The Medical Device Tax Undermines Health Care Reform

Since the legislative debates before the passage of the Affordable Care Act (ACA), the Chamber has testified [1] on the myriad of challenges the ACA poses to the business community through its mandated benefits, the imposition of taxes and penalties, and other burdensome requirements. Instead of controlling costs, the law decreases the flexibility employers and their workers have to access affordable and quality coverage. As the Chamber has reiterated in both testimony and letters to Congress, this new 2.3 percent tax on the sale of almost all medical devices will harm the ability of American companies to compete.[2] The tax will undermine America's global leadership position in product innovation, clinical research, and patient care. This tax weakens the medical device industry's ability to create and maintain well-paying jobs in the United States and hinders the development of breakthrough treatments.

The Medical Device Tax is Already Costing Jobs and Stifling Innovation

The medical device industry, which adds over $23 billion to the American economy annually, has already felt the impact of the medical device tax on jobs and innovation since its January 1, 2013, implementation.[3] According to a recent survey by the Advanced Medical Technology Association (AdvaMed), two-thirds of the companies surveyed reported that they have had to "slow or halt U.S. job creation as a result of the tax." [4] A recent survey by the Medical Device Manufacturers Association (MDMA) of 100 industry executives found that 72 percent "slowed or halted job creation" to pay for the tax, and 85 percent would hire more workers if the tax were repealed.[5] The AdvaMed survey also found that the medical device tax has resulted in:

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[1] *See* "Health Reform in the 21st Century: Proposals to Reform the Health System," The House Committee on Ways and Means, June 24, 2009; "Roundtable Discussion—Health Care Reform Legislative Options," The Senate Health, Education, Labor and Pensions Committee, June 11, 2009.

[2] *See, e.g.,* "The Challenges Facing America's Businesses under the Patient Protection and Affordable Care Act," The House Energy and Commerce Committee Subcommittee on Oversight and Investigation, June 26, 2013, *available at:https://www.uschamber.com/sites/default/files/documents/files/Katie%2520Mahoney%2520Testimony%25206%252026%252013%2520Challenges%2520Facing%2520America%2527s%2520Businesses%2520under%2520the%2520PPACA.pdf;* Josten, R. Bruce (Letter to Representatives Erik Paulsen and Ron Kind), "H.R. 523—Protect Medical Innovation Act," Feb. 8, 2013, *available at:*
https://www.uschamber.com/sites/default/files/documents/files/130208_HR523_ProtectMedicalInnovationAct_Paulsen_Kind.pdf.

[3] Mary Kate Hays, *Medical Technology Adds $23.6 Billion Annually to Economy,* U.S. CHAMBER OF COMMERCE BLOG, July 18, 2014,
https://www.uschamber.com/blog/medical-technology-adds-236-billion-annually-economy.

[4] AdvaMed, Impact of the Medical Device Tax: A Status Report from AdvaMed (Jan. 2015), *available at http://advamed.org/res.download/835.*

[5] Sean Hackbarth, *New York Times Avoids Mentioning the Damage Caused by the Medical Device Tax,* U.S. CHAMBER OF COMMERCE BLOG, Feb. 2, 2015,
https://www.uschamber.com/blog/new-york-times-avoids-mentioning-damage-caused-medical-device-tax.

- Employment reductions of 14,000 industry workers in 2013 and years prior to implementation of the tax;
- An estimated 4,500 jobs lost in 2014;
- Almost 20,500 employees that will not be hired over the next five years;
- About 39,000 fewer industry jobs (considering both jobs lost and jobs not created); and
- Up to 156,000 jobs lost in indirect employment, leading to a total job loss of 195,000 jobs.[6]

Similarly, the effect of the medical device tax on current and future innovation has been equally as alarming. The AdvaMed survey found that 53 percent of respondents have reduced research and development as a result of the tax and 75 percent said they have:

- Deferred or cancelled capital investments and plans to open new facilities;
- Reduced investment in start-up companies;
- Found it more difficult to raise capital (among start-up companies); and
- Reduced or deferred increases in employee compensation.[7]

While studies and survey results have shown the aggregate effects of the medical device tax, many companies have voiced the unique challenges they have dealt with because of this onerous tax. As Dr. Gregory Sorensen, President and CEO of Siemens Healthcare North America, recently explained, businesses often have no choice but to lay off employees and reduce research and development when dealing with such a heavy tax:[8]

> *I personally have had to let people go as we have had to eliminate jobs. For example, we have a factory in Walpole, Mass., where we make point-of-care devices, such as those to manage conditions like diabetes. . . . In Walpole, when this tax hit, we had to cancel projects, and we laid people off. And that's just one factory. At dozens of our other factories around the world we have similar stories, whether it is MRI scanner advances that are delayed, or new types of diagnostic devices for testing, or developments to reduce X-ray dose. When this heavy of a tax hits us, we have very little recourse other than to reduce our spending. Some of that involves cutting back on research and development, and some of that is reducing employees. It's a very painful process for us and is something that our country neither needs nor wants.*

In his statement for the record, Christopher Cerone, Vice President of Global Government Affairs for Zimmer, an orthopedic medical device company based in Indiana, described how the medical device tax is affecting Zimmer's operations worldwide:

> *Medical device companies, such as Zimmer, continue to take significant steps to offset the bottom-line impact of the tax, including restructuring global operations and diverting capital away from key projects and investments. For instance, as a recent AdvaMed survey noted, many medical device companies are scaling back R&D initiatives. Passing on the cost of the tax is simply not an option, given the tight reimbursement environment for our consumers.*

Cook Group, Inc., the largest family-owned medical device manufacturer in the world, detailed in its written testimony for the record similar challenges as they deal with how to continue product innovation in this tax environment:

> *Cook has made the difficult decision that without repeal, we will move important new, device-related product lines outside of the U.S. Our previous plans to open up five new device manufacturing facilities in American towns continue to be on hold as we use capital intended for these projects to pay the excise tax. The direct impact of this tax is squarely on U.S. jobs and because device manufacturing is performed mainly by a female workforce in many sectors, it will hit these workers the hardest.*

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[6] AdvaMed, *supra* note 4.

[7] *Id.*

[8] Michael Bassett, *Siemens' Sorensen describes impact of the medical device tax,* RADIOLOGYBUSINESS.COM, Feb. 10, 2015, *http://www.radiologybusiness.com/topics/policy/siemens-sorensen-describes-impact-medical-device-tax?page=0%2C0.*

OrthoPediatrics, the world's only company specializing in making orthopedic equipment for children, has had to slow hiring and development as a result of the medical device tax. As CEO Mark Throdahl explained:[9]

> *We are a company that is not yet profitable. We've only been in the market for 5 years. This is a very burdensome tax because it is based on sales, not profits, and the only way we can pay a tax like this is to cut expenses. . . . In terms of magnitude, [the tax] is about the size of our entire product development budget. We have had to reduce our development budget. We're developing less products than we otherwise would. It has cut into our development expenses. The only way we can trump up the money to pay this tax is to reduce expenses.*

According to M&S Technologies Inc., a company that develops and manufactures computerized vision testing products, the medical device tax has even hurt their ability to donate resources to children in need of specialized care:

> *Prior to the medical device tax, M&S Technologies actively participated in donating technology and other resources to assist in vision screening for children who may not have access to vision care. Our sponsorship of the Special Olympics, Children's Calendar fundraisers and other events have all been eliminated due to the medical device tax of which we paid over $100,000 in 2014. The tragedy of all of this is that those kids who were at least getting some form vision testing are no longer receiving that service due to our cuts in our philanthropic activities due to the medical device tax, especially knowing that 80 percent of all eye problems in children are solvable before the age of 8–10.*

The Medical Device Tax Needs to be Repealed

As we continue to see the destructive effects of the medical device tax hit employers, employees, and the U.S. economy at large, the Chamber urges swift bipartisan and bicameral action to repeal this tax before further damage is done. Legislation in both the House and the Senate has been introduced to repeal the medical device tax[10] and we encourage you and your colleagues to support these bills. The Chamber thanks you for taking the time to hold this important hearing on the ongoing impacts of the medical device tax on jobs, innovation, and patients. We look forward to working with you as you continue to examine this important issue. Please do not hesitate to contact us if we may be of assistance in this matter.

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April 22, 2015

To Whom It May Concern:

Our Company, based in Exeter, NH, manufactures an advanced respiratory support technology that offers substantial clinical and economic benefits to patients, caregivers and payors. To achieve our guiding principle of Total Customer and Patient Focus, we must invest in attracting, developing and retaining the Very Best People in the Medical Device Industry. We make investments in our People through the development programs that are accessible to them, the projects they work on to advance their experiences and careers and the product they develop, assemble and sell to improve the care and quality of life for patients across the country. We currently employ 122 people, up from 46 people 3 years ago and have grown our revenues by 28% over the past 2 years.

We are a privately held, venture backed Company poised for rapid growth. Our latest fundraising round was completed last month. Not yet being profitable means accessibility to capital is critical to our success. Once we become profitable, which will now take longer due to the medical device excise tax, we will reinvest back into our business to fund innovation thereby leading to job creation and an expanded portfolio of products to serve patients in respiratory distress. Since the adoption of the

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[9] Patrick Howley, *Company that makes medical equipment for kids hit hard by Obamacare,* THE DAILY CALLER, Feb. 25, 2014, *available at http://dailycaller.com/2014/02/25/company-that-makes-medical-equipment-for-kids-hit-hard-by-obamacare/.*

[10] Protect Medical Innovation Act of 2015, H.R. 160, 114th Cong. (2015); Medical Device Access and Innovation Protection Act, S. 149, 114th Cong. (2015).

medical device tax, we have seen a reduction in the number of venture capital firms investing in the medical device space as the excise tax has squeezed the industry's profit margins and hence better returns can be found elsewhere, including overseas. Reduced access to capital will severely limit medical device innovation in this country.

Since adoption of the tax, we've made medical device excise tax payments amounting to $514,555, excluding compliance related costs. That money would have been used to accelerate new product development to stay ahead of foreign based competition, expand our sales presence and augment the benefits package we offer to our employees. I consistently share with our team that they do "work that matters" and I share this brief background to express how the Medical Device Tax has hindered the growth that is so critical to our people and the work that they do.

As part of the medical device community, we work diligently to improve the lives of others, and to do so within our great country is an honor. We are proud of the work we do, the Company we are building and the country we are doing it within. We hope to see the medical device excise tax repealed to allow us to innovate, enterprise and compete on a global playing field.

Great People + Total Customer Focus + Great Technology = Success

Sincerely,

Joseph F. Army
President & CEO

WELCH ALLYN INC.

Senate Finance Committee Subcommittee on Health
"A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, andPatients"

Thursday, April 23, 2015

Welch Allyn applauds the Senate Finance Committee for taking a renewed look at the impact of the medical device excise tax on device manufacturers, innovation, and patients. Repeal of the medical device tax remains a top priority for Welch Allyn, a privately-held manufacturer of innovative medical devices, products and solutions used by caregivers in doctors' offices, hospitals, and emergency response settings around the world. Headquartered in Skaneateles Falls, New York, Welch Allyn celebrates 100 years of family ownership in 2015 with over 2,400 employees working in 17 different countries.

The tax—on revenues, not profits—raises the total amount of federal taxes paid by medical device manufacturers by almost 30 percent. The industry is fueled by innovative companies, the majority of which are small businesses, with 80 percent of medical device companies having fewer than 50 employees and 98 percent having fewer than 500 employees. Industry growth—once expansive—has slowed considerably. The tax unequivocally hinders job expansion, economic growth, innovation, and global competiveness for American medical devices sold at home and abroad.

As an Upstate, New York company for our entire 100 year existence, we note the special threat the device tax poses to the New York State economy. New York State's vibrant med-tech industry is the eighth largest medical device presence in the nation, employing over 13,000 people with a net economic impact of $4.6 billion. The medical device industry plays a vital role particularly in the struggling Upstate New York economy, employing over 8,400 individuals. Already in decline since 2001, the tax places significant additional burdens on device makers statewide.

Proponents of the device tax claim that any burden it creates for companies will be offset by an increase in sales due to the growth of the insured population under the Affordable Care Act (ACA), or that device makers can and will pass the cost of the tax on to their customers. However, in reality, this premise is erroneous. No such offsetting or positive factors or windfall has arisen, or is expected to; moreover, not only have the average sales prices for many medical devices not increased, they have eroded. Most Americans who need the most expensive medical devices already were covered under Medicare, so the ACA has had no impact, other than a negative one.

It should be clear that strong bipartisan Congressional support exists for repeal of the device tax. Currently, the House Bill, *The Protect Medical Innovation Act* (H.R. 160) has garnered 277 co-sponsors, including 36 Democrats. The Senate companion legislation has 35 cosponsors. Both the House and Senate have shown support since enactment of the ACA for repeal of the medical device tax. Welch Allyn urges Congress to act now and repeal this tax for good. Again, we thank the Senate Finance Committee for your willingness to address such an important issue, and we urge you to move beyond this hearing to a timely full Committee markup and passage of the device tax repeal legislation.

WENZEL SPINE, INC.
Simple. Dependable. Proven.
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April 21, 2015

U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

RE: IMPACT OF THE MEDICAL DEVICE TAX

Senate Finance Committee Members,

I am writing on behalf of our team at Wenzel Spine to relay the real world impact the Medical Device Tax, imposed by the Affordable Care Act, has had on our company in the last 16 months, since the tax was implemented in January 2014.

Wenzel Spine is an early stage medical device company. We are currently bringing to market a unique minimally invasive implant for use in spine procedures. This device shortens surgery time, shortens patient recovery time, and reduces overall cost of implant and use of healthcare services by patients. The exact technology desperately needed in our current system of high costs, and overutilization of services.

We operate in one of the most regulated industries in the world. In addition to normal business start-up costs, we content with enormous regulatory costs associated with the FDA, and reimbursement costs to gain approval from HHS all while prices are declining in the marketplace. The Medical Device tax is an incredibly regressive tax on an industry that is already under tremendous cost and pricing pressure—especially to small, start-up companies with limited resources.

The following are several examples of the direct impact the Medical Device Tax has had on our company:

- We have delayed the hiring of 3 management positions, each with over $100,000+ basecompensation.
- We have downsized our engineering team, eliminating two $100,000 engineering positions.
- Our headcount budget for 2015 will remain neutral (i.e. we will not increase our total number of employees).
- We have delayed the launch of a new product.

The Medical Device Tax has a real negative impact on job creation, innovation of new products, and ability for new ventures (the engine of U.S. job growth) to gain new funding and launch new products.

Even though we are an early stage, pre-profit company, we are subject to the same 2.3% excise tax on gross revenue that billion dollar multi-national corporations are subject to. No other industry in the U.S. has to contend with the costs that the Medical Device Industry now faces.

While I support the immediate repeal of this tax for the entire industry, if that is not possible, surely they is across the board support to eliminate the tax for small Medical Device Companies who are in early stages and cannot execute on their growth plans with this onerous tax.

I appreciate your continued attention and leadership on this matter.

Thank you.

Chad G. Neely
CEO
Wenzel Spine, Inc.
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direct: (512) 501–4016

ZIMMER

April 22, 2015

The Honorable Patrick J. Toomey
Chairman
Subcommittee on Health Care
Committee on Finance
U.S. Senate
Washington, D.C. 20510

Dear Senator Toomey:

On behalf of Zimmer and its approximately 150 employees in Pennsylvania and over 5,000 employees in the United States, I am writing in support of your efforts in the U.S. Senate to examine the impact of the medical device excise tax. The Health Care Subcommittee's hearing, titled "A Fresh Look at the Impact of the Medical Device Tax on Jobs, Innovation, and Patients," is important and timely.

Zimmer is a leading orthopaedic medical device company based in Warsaw, Indiana. The Company has opposed the medical device tax from the start and continues to work with AdvaMed and other stakeholders to repeal the tax. As AdvaMed notes in its testimony submitted for the record as part of this Subcommittee hearing, the device tax continues to impose a significant cost burden on a vibrant medical device industry that contributes positively to the U.S. economy through advanced R&D and manufacturing, high-paying jobs and exports.

Medical device companies, such as Zimmer, continue to take significant steps to offset the bottom-line impact of the tax, including restructuring global operations and diverting capital away from key projects and investments. For instance, as a recent AdvaMed survey noted, many medical device companies are scaling back R&D initiatives. Passing on the cost of the tax is simply not an option, given the tight reimbursement environment for our customers.

The device tax also worsens a corporate tax code that is already globally uncompetitive, thus undermining the competitiveness of a U.S.-led medical device industry, which supports hundreds of thousands of jobs in this country. Most importantly, the device tax will continue to adversely impact the development and introduction of new and improved medical devices, a natural consequence of tough decisions being made to offset the cost of the tax through reduced spending on R&D. This will ultimately jeopardize patient access to medical innovation and harm health care quality.

Zimmer appreciates the opportunity to provide input into the Subcommittee hearing. The Company joins AdvaMed and its other member companies in commending you and your Subcommittee colleagues for holding this hearing on the medical device tax. Zimmer looks forward to working with its industry colleagues, other stakeholders and a growing number of members of Congress who support repealing the device tax. Thank you.

Sincerely,

Christopher A. Cerone
Vice President
Global Government Affairs

ZOLL® LIFEVEST®

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www.zoll.com

May 6, 2015

The Honorable Patrick J. Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Senators Toomey and Stabenow,

Western Pennsylvania is fortunate to be a leader in one of the most innovative and dynamic industries in the world: medical device manufacturing. The local companies that participate in this high-tech industry provide the good paying jobs that our nation needs and enable health care providers to give the best possible patient care.

As the leader of a rapidly growing local medical technology company based in Pittsburgh, I know firsthand the ingenuity and skills of western Pennsylvania's workforce. Every day, some of the brightest entrepreneurs, engineers and physician-inventors are developing and improving cutting-edge medical devices. We have a superior skilled manufacturing base that produces them and provides the best possible service and support.

I strongly believe that the medical device tax has inhibited innovation, slowed job creation and harmed patient care. It takes years of substantial investment to introduce a new or improved device, and I know firsthand that companies are often not profitable while growing and creating jobs. Amazingly, the tax is applied to the sales, not profits, of medical device companies. This means that these companies would actually still owe the government a hefty tax bill, despite not having a penny in profits. Advocates of the tax argue that the cost of the tax can simply be absorbed by medical device companies or passed along to the customer; however, it is far more complicated than that. Passing along cost as a price increase to the health care system directly contradicts many of the goals of health care legislation, and, in a system with fixed reimbursement, additional costs directly impact the ability to create jobs. In response to the tax, companies have been forced to lay off employees, cut back on research and development, or both. If the medical device tax is not repealed soon, the impact of the necessary operational and executional decisions companies are being forced to make in response to the tax will permanently harm the leadership position of the United States in the medical device industry.

The medical device industry is responsible for more than 400,000 American jobs—and is indirectly responsible for almost 2 million jobs that supply and support this highly-skilled workforce. Here in Pennsylvania, it is responsible for over 22,000 jobs, and the medical device manufacturing job pays 25% more than the average manufacturing position. In fact, Pennsylvania has the highest job-multiplier in the country, meaning that for every medical device job, 3½ jobs were created to support and supply this vibrant industry. While congressional leaders urge us to increase exports, the medical device industry is one of the only net-trade exporters in the United States, with a trade surplus of $5.4 billion in 2007.

America's medical device industry is widely recognized as the global leader in this field, though a recent PwC report stated that we could lose this leadership position in the next decade if we do not continue to grow and innovate. We simply can't let this happen—we need to repeal the medical device tax to allow America's medical device innovators to drive leadership in the future.

Sincerely,

Marshal Linder
President and COO
ZOLL LifeVest

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