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UNITED STATES SENATE

SUBCOMMITTEE ON HEALTH CARE
FINANCE COMMITTEE

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

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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 & 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 1st 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 US 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. From kidney failure to heart surgery

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

Thank You.