

Welcome Ladies and Gentlemen the Senate Finance Subcommittee on Healthcare 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 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'll 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. 300,000 people die every year in our country from heart failure. It took five 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 five 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 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 Costa 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 five 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 five 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 they make. 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. four to five 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.