Testimony of
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Chairman Murray, Ranking Member Sessions and Members of the Committee, thank you for the opportunity to testify at today's hearing on "The Impact of Federal Investments on People, Communities, and Long-Term Care Economic Growth." I am pleased to be here representing the medical device industry.

I am testifying today as the Chairman of Cook and appreciate the opportunity to tell you a bit about our company, Cook, and about the impact we and thousands of companies like us have had on patients, communities and the economic health of our nation.

Today, my message is not just about a company, but employees, jobs, and patients. I have nearly five decades of experience in the medical device industry, so I've seen and heard a lot, but more often than I'd ever imagine, I'm told a story that stops me in my tracks. Two years ago, I was approached by an employee who said she wanted to stop and thank me. She said to me, "A second member of my family is alive today thanks to a Cook product. Your company has now saved two lives in my family." Months before, I was talking with her in the sundry store where she worked and she told me about her father who had been diagnosed with an aortic aneurysm. I contacted the Cleveland Clinic and asked them to expect a call. Her father could not survive traditional surgery but our new stent graft that had just been approved was a possible alternative. He was admitted and received the new device saving her father's life. The second involved technology that was approved in the U.S. in 2005. This time, it was a Bakri Balloon, a device that stops potentially fatal bleeding for mothers after they give birth. The doctors told her this device saved her step-daughter's life. When somebody tells you about medical technologies that save lives, it drives home just how important our mission is at Cook.

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. The company has been the first to introduce new medical devices in more than 70 procedures.

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 products 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. We also have manufacturing facilities in Ireland, Denmark and Australia. We have direct sales in most of the world where the health care system is developed. Our company employs about 10,000 people around the world with approximately 7,500 of these employees based in the United States. While more than 57 percent of our sales are outside the United States, more than 80 percent of the devices are manufactured in this country.

It has been my privilege to be associated with Cook for 45 years.

The Medical Device Industry

a) Contributing to Improved Patient Health

Over the years, improvements in medical technology have led to significant advances in the health of patients. Today, patients are living healthier, more productive and independent lives. Many of these advances are due to the development of minimally invasive medical technologies that make it easier to diagnose and treat patient problems. These advances have resulted in improved patient outcomes with fewer complications. Since 1950, the life expectancy for American men and women has increased nearly 10 years. We have also seen significant results from 1980 to 2000:

- 15 percent decline in annual mortality
- 50 percent decline in the overall mortality rate from heart attack
- 25 percent decline in disability rates
- 56 percent reduction in hospital stays.

b) Contributing to Increases in Jobs, Payroll and the Economy

In addition to patient health, the medical technology industry has been a strong and vibrant contributor to the U.S. economy. The medical technology industry is responsible directly and indirectly for two million U.S jobs. As we strive for policies that improve our economy, policymakers on both sides of the aisle have stated that a key component to turning our economy around is to invest in high technology, manufacturing, and growth industries of the future. I agree whole-heartedly and that is why we must do everything we can to ensure the U.S. maintains its leadership position in medical technology, innovation and manufacturing.

Our company is not alone when it comes to that sort of impact. According to the National American Industry Classification System (NAICS), 80 percent of the 16,424 medical device companies in the nation have fewer than 50 employees. It is an industry dominated by small companies. Cook is relatively large in the device industry, but small compared with the drug companies.

The medical device industry is one of the few U.S. industries that enjoy a net trade surplus exporting more than we import. The U.S. is the only net exporter of medical devices in the world -- the U.S. medical technology industry generates a $5.4 billion trade surplus. It is the envy of the world, and make no mistake, we hear repeatedly from countries around the world that they want to compete with the U.S. for this market share and actively recruit companies in the U.S.

c) Contributing to Advances in Medical Innovation

While the medical technology industry has helped to fuel our fragile economy in recent years, its position as a global leader may erode over the next decade. This will no doubt affect the ability of Americans to access future break-through medical advancements, and the growth of U.S. jobs. A recent study found that in the future, China, India and Brazil will experience the strongest gains in developing next-generation lifesaving products. Without changes to U.S. policies, capital, jobs and research will move away from the U.S. and toward these markets. (PwC, *"Medical Technology Innovation Scorecard; The Race for Global Leadership,"* January 2011.)

What effectively spurs medical innovation in this country is the association and talents of American doctors, engineers and innovators who are dedicated to discovering new treatments and therapies for patients. This requires an atmosphere that encourages innovation and a dynamic market that does not impede job creation but encourages it. Our company, like nearly all medical device companies, is facing road blocks to growing jobs in the U.S.

Policy Challenges

a) The Medical Device Excise

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 33 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 42 percent – this is more than a 25 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).

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. 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 & 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. The vast majority of companies simply cannot pass all

those costs on, let alone a 2.3 percent tax on gross sales.

Finally, we have existing contracts of 3 to 5 years with prices already negotiated. Even if we did not face other restraints in passing along the costs, we simply would be unable to do so because of existing contracts.

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 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.

Device Company Investment in the Community

Let me tell you a bit more about the vision of our late founder and my good friend, Bill Cook. Bill believed in giving back to the community and investing in America. He believed that companies should create technologies that benefit patients, but also that the companies themselves should create jobs that benefit not just individuals and families but communities as well. Bill grew up in the small town of Canton, Illinois. A few years ago, before the excise tax, Bill decided to open up a manufacturing plant in the small community of Canton. At the time, unemployment in Canton was very high and the International Harvester plant, which employed so many, had closed. Bill made the decision for Cook to invest in Canton and today we have two new factories where 140 people now work. More than 1,000 applicants applied for the initial 30 jobs at that factory, which makes catheters. The plant will employ 300 when we are at peak capacity. This growth has had a ripple effect as the local community also invested resulting in further growth. Canton is a model of what we would like to replicate in many other mid-western towns, but unfortunately this tax has forced us to shelve plans to build a similar factory every year for the next five years.

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 product lines outside of the U.S. Our previous plans to open up five new manufacturing facilities in American towns are now on hold as we use capital intended for these projects to pay the excise tax.

The impact of this tax is squarely on U.S. jobs. Cook will adjust, but those that will be most affected by the device excise tax will be the potential future employees. Make no mistake about it: we want to develop and manufacture in the U.S. but this tax is preventing our growth in this country. It is a shame that potential employees in Indiana, Illinois, Pennsylvania, California and North Carolina can compete with any place in the world based on their productivity, but are going to be denied the chance by government.

Over time, we will see an acceleration of companies manufacturing outside the U.S. to lower the costs of goods sold in an effort to offset the impact of the tax. I emphasize that this is not about labor costs. Our industry needs an educated, skilled labor force wherever we locate.

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 U.S.'s 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.

Impact of Device Tax on Other Device Companies

Cook is not alone in feeling the adverse impact of the device tax. A 25 to 30 percent increase federal taxes will dramatically change this industry. Remember that this is an industry of small companies and the industry profit margin is between 6 and 10 percent.

A good example is Orthopediatrics, a Warsaw, Indiana company whose President and CEO Mark Throdal, says his company has shelved research and mothballed developing product lines that would help disabled children walk again. He needs to devote that R&D funding to pay this medical device tax. Listen to what others say, executives who came to the Web site www.no2point3.com to urge lawmakers to repeal this tax. Dozens of founders and senior executives replied. Here are a few of their comments.

We have lower net profit margins than competitors solely due to our choice to keep prices competitive while keeping 100% of sourcing and

production domestic. For one of the products we'll be releasing for 2013 my domestic cost per unit runs in the high 40s per unit. My total cost in having it manufactured offshore, including logistics, runs about 18 per piece. That cost goes even lower if production runs become larger. By doing nothing but moving my production offshore we immediately see around a 65% savings per unit - which becomes all profit margin. There needs to be a distinction between those manufacturing domestically, paying decent wages, employment taxes, providing benefits for their workers, etc., and those who bypass our system by offshoring production. From Michael Shaffer, president of Atlanta-based Vendition Partners

Or this from Dr. Stephen R. Kerr of Pullyalup, Washington:

I am a surgeon and surgical device developer in Puyallup. I have a surgical device that I am now in the process of marketing to the major surgical device manufacturers in the US. I had the fortune...or should I say, eventual misfortune, of having dinner with the VP of sales and member of the board of directors of one of our country's major medical device manufacturers. The purpose of the dinner was for him to evaluate my new medical device. The upshot of the meeting, he loved the idea, and thought it was a significant improvement not only over what their company had available, but better than any of the other competitive devices as well. Sounds promising. He then proceeded to tell me that, unfortunately, due to the looming new medical device tax, that they would not be investing in any new medical device technology anytime soon. Regarding manufacturing of their current medical device portfolio, he informed me that their company, which does the majority of their manufacturing in the US, was now building new plants overseas and would be shifting their manufacturing there permanently. In order to offset the costs associated with the medical device tax. The president has stated that the ACA will increase the number of patients available and thereby increase their sales to make up for that. Unfortunately, as a surgeon, I can tell you with utmost certainty that this reasoning is flawed. Not once in my career did I not use, or downgrade the quality of the medical technology or devices that I use due to a lack of insurance. NEVER. I implore you to further examine the 2.3% medical device tax and its negative effects on medical innovators.

Perhaps John Micek of Buford, Georgia, has the most sobering perspective: *"I have lost my job due to this tax. So have 50 to 60 other people at Remington Medical, Inc. My past employer is moving to the Dominican Republic."*

<u>Senate Legislation to Repeal the Medical Device Excise Tax – S. 232</u>

But before this happens Congress can act to repeal this onerous excise tax. We are grateful to the 29 sponsors of S. 232, a bill introduced by

Senators Hatch and Klobuchar, as well as our home-state Senators Burr, Casey, Coats, Donnelly and Toomey, to repeal the medical device excise tax. In fact, many Senators serving on this committee have cosponsored this legislation or expressed support for either a delay or 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 ways to encourage medical innovation and investment in long-term economic growth you will consider advancing the repeal legislation.

b) Other Important Steps to Maintain Leadership in the Development and Manufacture of Medical Devices.

It is important to note that the medical technology industry faces other challenges from the federal government. The U.S. has been able to put a man on the moon and ought to be able to have the best system for the approval of safe and effective medical devices. Today, we have good people working hard at the FDA, but Americans access to the latest technology is behind those outside the U.S. **Congress needs to support changes in the system (not lower standards) to give American patients access to the latest technology. Cook historically has introduced all of its devices in the U.S. Now, almost 100 percent are first introduced outside the U.S.**

I also would like to mention the broader issue of taxation. The U.S. medical device industry conducts most of its manufacturing and invests the majority of its research and development dollars within the U.S. but as mentioned previously this trend is changing. Both Congress and the Administration recognize the importance of creating a climate to retain and expand these jobs. **Passing legislation to enact a manufacturing tax credit and a permanent research and development tax credit are two steps toward making this happen.** The current manufacturing deduction should be replaced with a manufacturing tax credit that results in qualifying manufacturing income being taxed at 20 percent. The research and development tax credit should be made permanent because a credit that continually expires and is reinstated does not provide the necessary predictability when companies are planning to conduct research and development in 3, 5 or 10 years.

Not many years ago, 75 percent of Cook device sales were in the U.S. Now, 57 percent of Cook sales are outside the U.S. while more than 80 percent of Cook devices are manufactured in the U.S. International markets are growing much faster than domestic markets. Thus, for U.S. companies to grow and prosper, their products must be sold internationally. This requires having operations outside the U.S. to cultivate these markets. In the medical device industry, it is necessary to have employees close to our customers to demonstrate products to health care professionals and to be able to deliver products for next day procedures. With the current U.S. tax system, companies are effectively locked out from repatriating earnings from these

operations located outside the United States due to the incremental U.S. tax cost. Thus, **a repatriation incentive should be created to allow these funds to be returned to the U.S. at a minimal incremental cost with appropriate safeguards to ensure the funds create jobs.** During the prior repatriation holiday in 2004-2005, Cook invested repatriated funds in 2 start-up companies that currently employ a total of 500 people – up from a total of 73 prior to the repatriation. Another example of the use of repatriated funds at Cook was to allow for expansion at another of its subsidiaries by purchasing and renovating a larger building. This allowed the company to increase employment from 104 to 224 employees.

Closing

I come to you today as the Chairman of the Board of a multi-national medical device company. I shared with you quotes from other device companies to demonstrate the breadth of concern in the industry and am happy to assist you in reaching out to these companies if helpful to you. But today, I also sit here and speak to you not jut as a Chairman of Cook, but as a husband, father, grandfather, patient, and, finally, as an employee myself.

I spoke earlier of our catheter plant and what we've done in Canton, Illinois, and in closing I want to tell you a story about the first person hired at the new plant which opened two years. I heard this story on a tour given to a new Congresswoman representing our district: "When I was hired I was a single mother on welfare and lived in a small, subsidized apartment in Canton. I could not afford to get married and lose my benefits. Now, I have health care, I am married, and I just purchased a home because I got the job at Cook." Like more than 1,000 others from her town, she applied for a job at Cook and she got that job, she has a 401(k), she has profit-sharing, along with health insurance and steady income. Getting off welfare enabled her to finally get married to her boyfriend. She no longer needed access to government care. She just bought a house. This job, she will willingly tell you, has changed her life - brought her and her young family self-reliance and hope for a better future.

The country needs your leadership on this issue – your statesmanship – and we need it now. I urge every Member of this Committee and beyond to put partisanship aside and do what's right: protect families and patients. Repeal this medical device excise tax. Future generations are counting on it.

Thank you.