Statement of
David Groll, CEO
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Subcommittee on Agriculture, Energy and Trade
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Mr. Chairman, and members of the subcommittee, good morning and thank you for your invitation to speak before you today.

I would like to applaud this committee's efforts regarding free trade agreements with Columbia, Korea and Panama. I urge continued efforts to reduce barriers to market access in Asia and Latin America, in particular, Brazil.

My name is David Groll and I am CEO of Circadiance. Circadiance designs, manufactures and sells facemasks for the treatment of Obstructive Sleep Apnea, a condition that affects an estimated 30 million Americans and 100 million people worldwide. Although we do sell in over 30 countries, currently less than 10% of our revenue is from sales outside the US. This committee's effort to remove trade barriers supports our goal of growing our export business faster than our overall business.

There are two main issues facing the medical device industry – the medical device levy tax and competitive bidding.

As an American medical device manufacturer, I am staunchly opposed to the medical device levy tax. This job killing provision was included in the Patient Protection & Affordable Care Act, signed into law in 2010. According to the act, a 2.3% excise tax will be imposed on the total revenues of all US medical device companies, regardless of whether the company generates a profit. This tax will impact countless small manufacturing businesses throughout the country. For instance, our company 2012 budget calls for us to spend 10% of our revenue on research and development. Should the medical device levy go into effect at the beginning of 2013, as called for in the Affordable Care Act, we will have no choice but to cut our research and development spending by an offsetting amount. This will result in a 23% reduction in our rate of research and development investment. Companies throughout our industry face the same challenge. The result will be devastating to innovation, impede job creation and weaken the position of the United States as the global leader in medical technology innovation. Should the Affordable Care Act survive the current Supreme Court challenge, I urge you to support the efforts of Representative Erik Paulsen (R – MN) to have this provision of the Affordable Care Act repealed before it becomes law at the end of this year.

Circadiance sells primarily to Home Medical Equipment providers who provide our products to their patients and then bill their insurance providers, including Medicare. The Home Medical Equipment industry represents a cost-effective alternative to hospital-based care, for example:

- Home Medical Equipment represents only 1.6 percent of the total Medicare budget.
- Home Medical Equipment and services represent the slowest-growing portion of Medicare spending, increasing only 0.75 percent per year, compared to more than 6 percent annual growth for Medicare spending overall.

The Medicare Modernization Act of 2003 established requirements for a Competitive Bidding program for certain Home Medical equipment and supplies. Under the program, the Centers for Medicare & Medicaid Services (CMS) awards contracts to suppliers to meet beneficiary demand for the bid items. Competitive bidding was rolled out to 9 metropolitan areas in 2010 and is currently being extended to an additional 97 areas this year.

Medicare Competitive Bidding is deeply flawed.

- It is anti-competitive, as it reduces the number of suppliers in a market, forcing many of these small businesses to close.
- It reduces access to care, patient choice and quality of care.
- It forces patients, most of whom are senior citizens or disabled, to switch away from local providers they rely on and trust.

We have already seen the results of competitive bidding in the initial 9 competitive bidding areas.

- There has been a drop in submitted claims in these areas reflecting the more restricted access to approved Medicare suppliers for seniors.
- At the same time, there has been a rise in the same beneficiary group in emergency room admissions, reflecting the inevitable shifting of care from the low-cost home based model to the much higher cost hospital based model, which is still paid for by Medicare.

Competitive bidding is causing the cost of Medicare to go up, in direct conflict with the goals of the program. I urge members of this committee to support H.R. 1041, the bipartisan bill to repeal the competitive bidding program. In turn, I urge committee members to support the alternative known as the Market Pricing Program which, like competitive bidding, is based on an auction process, but addresses the flaws of the competitive bid program. The Market Pricing Program will meet the goal of lowering prices for medical equipment, without restricting access to the system for seniors and those with disabilities. Currently the Market Pricing Program is pending a score from the Congressional Budget Office (CBO). I urge committee members to pressure the CBO to present this score as quickly as possible so that the Market Pricing Program has a chance to replace the flawed competitive bidding system before the end of the year.

My goal today is to seek fair treatment for my company and the industry that I have worked in for over 25 years. I urge you to continue providing access to international markets, to seek a simple and fair tax code that treats all companies equally, and to support efforts to replace the flawed Medicare competitive bidding program.

I have included additional comments, which are in my written testimony for the public and committee record. Thank you for the opportunity to speak today.

Global Harmonization of Device Regulation: I support H.R. 3230: Keeping America Competitive Through Harmonization Act of 2011, which is currently in the House Energy and Commerce Committee. This bill amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS) to enter into agreements with many countries regarding methods and approaches to harmonizing regulatory requirements for premarket review, inspections, and common international labeling symbols for medical devices. I recommend that this harmonization be extended to require the Federal Drug Administration to recognize valid clinical data generated in other countries and used as part of FDA pre-market submissions.

Vendor credentialing: Vendor credentialing is a process to certify the sales representatives that enter hospitals are properly registered and have all of their inoculations and other health records in order. The process of vendor credentialing is run by a number of independent vendor credentialing services that compete to act as the gatekeepers between the sales representatives and the doctors. The justification for this system is that it promotes patient safety even though there is no clinical evidence showing that sales representatives pose a health risk to patients. This fragmented system causes an individual sales representative to register with perhaps half a dozen vendor-credentialing services or individual hospital systems, each with their own fees and documentary requirements. The burden of this system falls disproportionately on smaller manufacturers and their sales representatives who tend to have a smaller product lines and who service more hospitals than representatives of larger organizations. We support a single vendor-credentialing standard for all hospitals, in which the credentials established through one service receive mutual recognition by all other services. This would allow private companies to continue serving this market, promoting competition among the various credentialing services, but requiring a sales representative to register with only one such service to be recognized by all hospitals.

David Groll Biography

Founder and CEO of Circadiance, David Groll has developed, manufactured and sold medical devices for more than 25 years. He worked for Respironics from 1986 – 1997. He was the Project Manager for the Patient Interface Group where he was responsible for the development of Respironics CPAP masks. Subsequently, he was General Manager of Respironics Hong Kong Ltd, where he was responsible for running the factories in Asia that manufactured Respironics masks.

In 1997, he founded and was the CEO of Vincent Medical, a company that does contract manufacturing of medical devices in China. He sold that business in 2002. He has held senior management positions in several other medical device companies. Mr. Groll holds a Bachelor of Science Degree in Biomedical Engineering from the University of Texas at Austin and a Masters Degree in Manufacturing Systems Engineering for the University of Pittsburgh.