Testimony Before the Joint Economic Committee
Robert S. Kieval, VMD, PhD
June 26, 2013

Good morning. Congressman Brady, Senator Klobuchar, members of the Joint Economic Committee, it is an honor to have this opportunity to address you today and to endeavor to answer your questions. I have a deep respect for the work of this Committee, and for all of the policy makers striving to preserve and foster innovation in the United States. My name is Robert Kieval, and I am the Founder and Chief Technology Officer of CVRx, a Minneapolis-based medical device company. I have worked in the medical technology industry for over 20 years, with experience in both a large medical device company and in the entrepreneurial, start-up environment. In addition to my work at CVRx, I serve on the Board of Directors of two industry advocacy organizations, the Medical Device Manufacturers Association (MDMA) here in Washington, DC, and LifeScience Alley (LSA) in Minneapolis.

In our 11 year history, CVRx has developed an implantable medical device that is intended to treat two prevalent cardiovascular diseases: Hypertension, or high blood pressure, and chronic heart failure. Together, these diseases afflict over 80 million Americans. They are a primary cause of more than 128,000 deaths each year in the United States, and represent an annual economic burden of over $100B to CMS and private insurers in health care costs and lost productivity. They are diseases for which effective new treatments are desperately needed. Our product was approved in Europe in 2011 for the treatment of hypertension, and it is under clinical evaluation here in the US.

The medical technology industry accounts for at least 400,000 jobs in the U.S., supports nearly 2 million additional jobs in adjacent industries, and remains one of the few American industries that is a net exporter of goods and services. Small businesses like CVRx, often with fewer than 50 employees, are a vital source of innovation and comprise approximately 80% of the industry.

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Companies like ours, with a single product focus and no alternative revenue streams, depend on outside investment for our existence. Investors require assurance of a reasonable and predictable path to product approval. Ambiguous or overly burdensome approval thresholds can fatally inhibit investment and prevent development of a potentially important new therapy. This is especially critical for patients suffering from diseases that have few treatment options.

Since 2005, the time and capital required for a company to get a clear definition of its required regulatory pathway, to negotiate product testing and clinical trial requirements, and to obtain an approval or clearance decision once a completed application has been submitted have risen dramatically. Small, venture capital-backed companies typically spend $500,000 to $2 million per month to operate. A six to twelve month delay, for example in reaching agreement with the FDA about a clinical trial design issue, or in the time required to complete an overly burdensome clinical trial, could result in the loss of precious time to deliver a potentially life-saving new treatment to patients, and require a company to raise millions of dollars of additional capital in order to get through the approval process.

The regulatory approval process itself has become increasingly inefficient, inconsistent and unpredictable, and the level of clinical evidence required to obtain product approval has also continued to rise. This has led to a situation in which patients outside of the U.S. frequently gain access to American innovation and technology an average of two years before American patients do. In many cases it has also led to jobs and Research & Development moving overseas, weakening the competitiveness of our medical technology industry. Such are also the cases for CVRx. While we work through the regulatory approval process here at home, our product is being used to treat patients in Germany, Italy, the Netherlands, Hungary and Turkey. I just

returned from a trip to Europe where I heard firsthand from doctors how patients there are benefiting from our technology. As a result, the jobs that we are adding are also largely overseas. Finally, the recently enacted Medical Device Tax, a 2.3% excise tax on revenues irrespective of a company's earnings, has put additional financial pressure on companies and has compounded these difficulties. For large companies, these often represent issues of profitability. For small companies, they may be issues of survivability.

A 2011 study by the National Venture Capital Association (NVCA) found that U.S. venture capital firms have and will continue to decrease their investment in biotechnology and medical device start-ups and shift focus away from the United States toward Europe and emerging markets. In that study, FDA regulatory challenges were identified as having the highest impact on these investment decisions. The first quarter, 2013 MoneyTree report released by PriceWaterhouse Coopers and NVCA reflects a continued decline in medical technology investment. In fact, the Life Science sector experienced a dramatic drop to $98 million, the lowest quarterly amount since the third quarter of 1996. To put this in perspective, in 2007 alone, 116 early stage medical device companies raised approximately $720 million in initial venture capital. These early stage investments are the single largest indicator of future innovations and breakthroughs, and thus the current environment does not bode well for patients.

To be sure, federal regulators and policy makers have acknowledged and have been working to address these issues. Our industry appreciates the overwhelming bipartisan support for The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). This legislation reauthorized the medical device user fee program for five years and includes many reforms that, if implemented as intended, will be a real benefit for patients, innovation and our economy.

These reforms include earlier substantive interactions between FDA and industry, better manager-to-reviewer ratios to deal with capacity issues and shared outcome goals that will track performance based on calendar days.

While it is too soon to evaluate the ultimate impact of these measures, the industry is beginning to see early evidence of improvements, and CVRx has also had positive experience in this regard. In addition, the Medical Device Innovation Consortium, a public-private partnership that had its roots with LSA in Minnesota but has now become a national program, is a promising example of government and industry working collaboratively to identify and improve regulatory inefficiencies. While industry, including MDMA, AdvaMed and LSA, endeavor to work with all stakeholders to improve the regulatory environment, we will also be relying on the FDA to utilize its user fees and appropriations efficiently and effectively.

Looking forward, opportunities remain for further improvements, and we need to continue to work together so that the United States doesn't lose its leadership position in healthcare innovation. The FDA has a crucial mission to protect the public health. Clearly this means providing reasonable assurance that products are safe before they're made available to patients. However, I believe it also means that patients in need of effective treatments should not be unduly deprived of new innovations because of an inefficient or overly burdensome approval process. Successfully implementing this aspect of its mission will depend on a cultural change at the FDA as much as it will rely on processes and procedures.

As mentioned above, increasing numbers of medical technology companies are developing and evaluating their products in clinical trials outside the United States. Given the millions of dollars

of investment that this entails, we look forward to working with FDA on ways to better leverage these data domestically in a meaningful manner.

I am also encouraged by reports that the FDA is currently focusing on three highly practical priorities of 1) improving efficiency in clinical trials 2) balancing the premarket and postmarket process, and 3) identifying ways to shorten the lag between product approval by the FDA and reimbursement approval by CMS and/or private payers.

Capitalizing on many of these opportunities will require close collaboration between patients, industry and the FDA. However, Congress can play an important role as well, by ensuring that all parties continue to work in a highly constructive and productive manner.

Thank you for your attention, and I look forward to your questions.