House of Representatives Committee on Ways and Means
Subcommittee on Select Revenue Measures

Small Business and Pass-Through Entity Tax Reform Discussion Draft
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Testimony for the Record
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On behalf of
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The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide written testimony for today's hearing on simplifying the tax code in support of small businesses, as described in the Committee on Ways and Means discussion draft released March 12, 2013. AdvaMed represents approximately 400 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed members range from the smallest to the largest medical technology innovators and companies – nearly 80 percent of our members are small companies in a pre-revenue state or with annual domestic sales of less than $100 million. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and in particular, to the contribution that high quality health care technology can make toward achieving those goals. We believe that changes to the tax code are essential to support continued creation and growth of the small start-up companies that are critical to the future of our industry and to other knowledge-based, high technology industries.

About the Medical Device Industry

The medical technology industry is an American success story. The industry directly employs more than 400,000 workers nationwide. Typically, for every worker our industry directly employs, another four workers are employed by businesses supplying components and services to our industry and our employees, so that the total numbers generated by our industry nears two million.

The jobs our industry provides are good jobs—the kinds of jobs that allow employees to live the American dream. Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment. While the number of manufacturing jobs was plummeting across the larger economy, even before the recent economic downturn, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4 percent, adding 73,000 jobs. During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4 percent for manufacturing as a whole.

What the Subcommittee may not know is that the medical technology industry is heavily skewed toward small companies—the kind of companies that begin with a scientist or doctor with an idea to improve patient care. Almost two-thirds of the 7,000 medical technology firms in the U.S. have fewer than 20 employees – the majority of these companies being in pre-revenue or early revenue stages. A high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies. The long-term health of the whole industry depends on the continued success of these small firms and their access to the capital necessary to develop the breakthrough products of the future.

With this being said, these emerging and early-growth companies are facing extreme drought in terms of required capital to develop new technologies and create new jobs. In 2012, venture capital investments in the Medical Device industry fell by 13 percent in dollars and 15 percent in deals – with a total of $2.4 billion going into 313 deals. Much of

the decline occurred in first-time financings, where Medical Devices saw the lowest number of deals since 1995[i]. Prior to the financial crisis of 2008, the industry began experiencing a significant decline in the number of first-time financings, as shown in Figure 1[ii]. Total investments have also declined to levels below those present prior to the financial crisis (Figure 2).

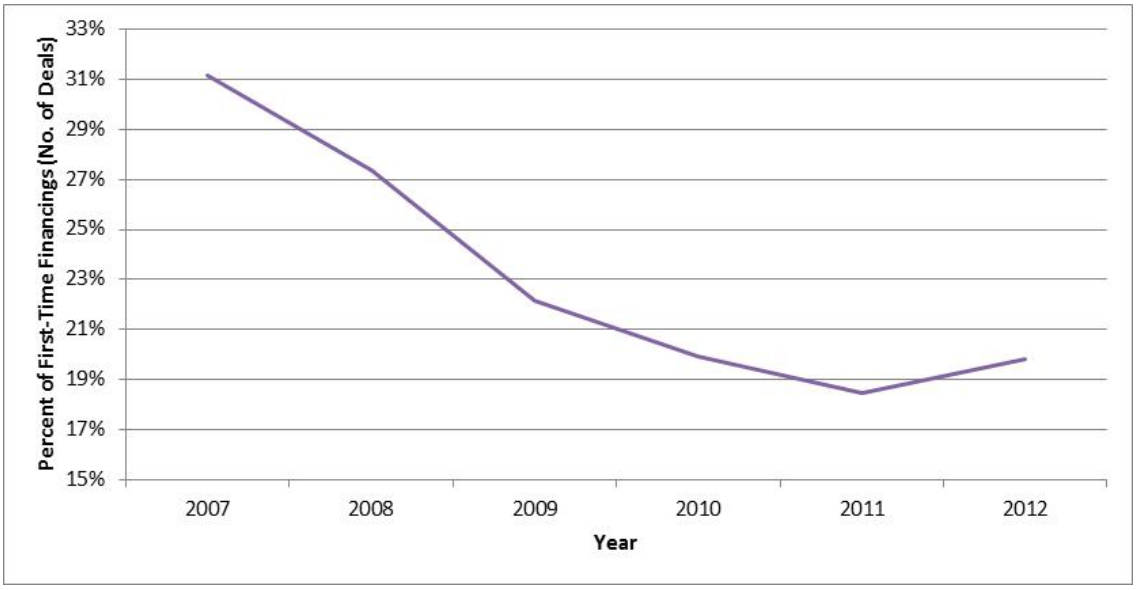

Figure 1. First-Time Investment Decline since 2007 (based on number of deals)[ii] – Medical Device Industry

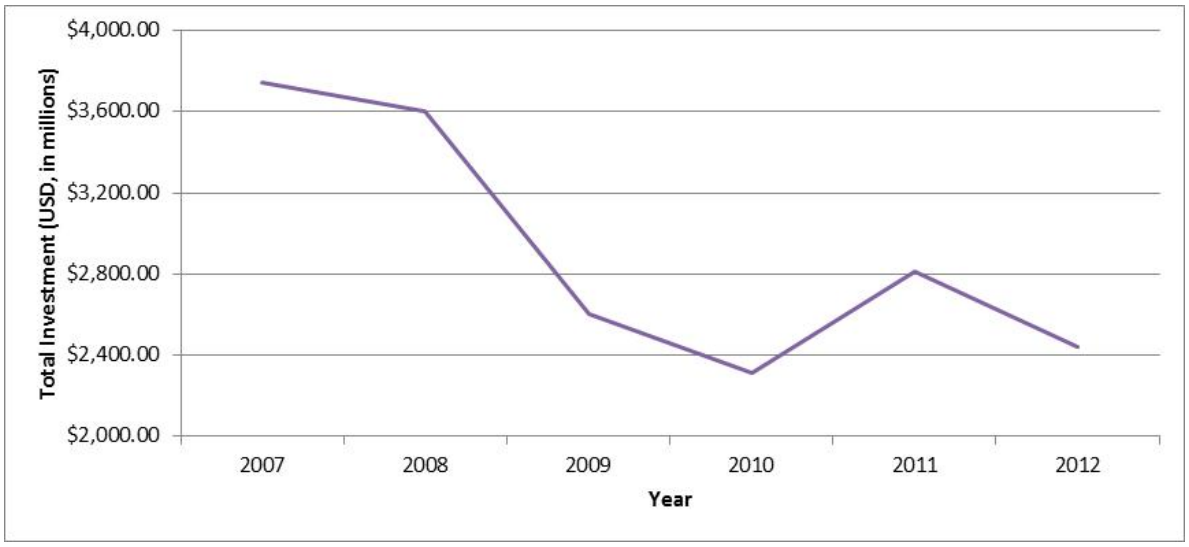

Figure 2. Total Venture Capital Investment in the Medical Device Industry[ii]

[i] Pricewaterhouse Coopers and NVCA, "MoneyTree Report," January 2013.
[ii] Thomson Reuters, MoneyTree Report Aggregate Data Q1 1995 – Q4 2012.

Whether a firm is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that extend and enhance lives. Our industry's investment in research and development is more than twice the national average. Our product life-cycle is typically only 18-24 months, so being able to invest in R&D is essential to creating the next generation of treatments and cures.

With $33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports. Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a favorable balance of trade.

While we are very proud of our contributions to the U.S. economy, we are even more proud of our contributions to improving patient care. For patients, medical progress has been remarkable. Between 1980 and 2000, medical progress added more than three years to life expectancy. The death rate from heart disease was cut in half; the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20 percent. Medical technology has been a major driver of this progress.

We have been able to make these contributions while helping to keep overall health care costs from growing. Our industry is so competitive that increases in costs for our products have averaged only one-quarter the rate of other medical goods and services and just one-half the general CPI for almost 20 years. Many of the devices produced by our companies help reduce hospital readmissions or address chronic disease, and in the long-term can provide cost-savings for the health care system through better patient outcomes.

But the continued success of our industry depends on the continued success of a vibrant and supportive environment for small companies, especially small, start-up companies that have not yet attained profitability.

Tax Reform: An Opportunity to Promote Innovation and Stimulate Investment in Emerging Companies

AdvaMed applauds Ways and Means Committee Chairman Camp and Chairman Tiberi, Ranking Member Neal, and the Select Revenue Measures Subcommittee for their consideration of small businesses as the tax code is reformed. Lowering the overall tax rate can make a vital contribution to the health and competitiveness of a small business. Simplifying the tax code to allow these small businesses to better leverage their capital in investment and job creation rather than tax preparation is also commendable. For the start-up small businesses that are so important to our industry, however, access to capital in the pre-profit stage is also crucial. Development of a new breakthrough product to point of FDA approval and marketing typically requires years and close to $100 million in investment, and companies generally do not reach profitability until they achieve annual revenues exceeding $100 million. We urge you to consider ways of adjusting the tax code to address the needs of these small, innovative, research-intensive businesses through incentives that encourage investments from other companies, individuals, and funds. Providing additional incentives for investment in these pre-profit companies is

critical to encouraging their ultimate success and their ability to create new jobs and commercialize life-changing technologies.

"Broadening the base and lowering the rate," while desirable, is not by itself sufficient to support the establishment, survival, and growth of these companies, especially those not yet realizing a revenue stream. We commend Chairman Camp for his proposal to increase the threshold for the deductibility of start-up expenses. While this will be helpful to some small companies, the need to raise capital in a very challenging regulatory and economic environment and to compete globally will require the enactment of some of the proposals that are set out in this testimony.

We also commend the Chairman for his commitment to simplify the tax system; start-ups should focus as much as they can on the challenges of developing and marketing new products instead of dealing with a confusing and over-complex federal tax system. In addition to simplifying the tax code, comprehensive tax reform should also encourage current – and new – investors to finance companies sooner. With the new challenges posed by an increasingly demanding regulatory and payment environment, incentives in the tax code to encourage availability of capital for companies developing the life changing innovation and great products of the future are essential. To achieve this objective, AdvaMed believes that the following policies should be part of tax reform:

Device Tax Repeal

The 2.3% Medical Device Excise Tax poses an enormous burden for small companies – in terms of capital and compliance. From their first sale, these companies are subject to the tax, even with millions of dollars in net operating losses incurred over years of development. AdvaMed continues to advocate for full repeal of this detrimental tax burden.

Section 469 R&D Partnership Structures (Attachment 1)

AdvaMed, along with the Coalition of Small Business Innovators (CSBI), supports a limited exception from the passive activity loss (PAL) rules for R&D-focused pass-through entities. Relaxing the PAL rules will incentivize investors to finance companies at an earlier stage when capital is most needed – and where current investments in the Medical Device industry have dried up most since 2007.

Section 382 Net Operating Loss (NOL) Reform (Attachment 1)

AdvaMed, along with CSBI, supports the exemption of NOLs generated by qualifying research and development conducted by a small business from Section 382. Currently, the usage of NOLs by companies who have undergone an "ownership change" is restricted. Such reform would encourage additional outside financing and help make such businesses more attractive to investors.

Section 1202 Capital Gains Reform (Attachment 1)

AdvaMed, along with CSBI, supports changing the qualified small business (QSB) definition to include companies with gross assets up to $150 million (from $50 million), with that cap indexed to inflation. This change would also include S-Corps and LLCs in

the definition of a QSB. Furthermore, AdvaMed and CSBI support excluding the value of a company's IP when calculating gross assets. These changes would also encourage investment into emerging and early-growth medical device companies.

Permanent Extension of Section 179 Depreciation Deduction

AdvaMed also supports the permanent extension of the Section 179 expense, which allows qualifying small business owners to deduct the cost of depreciating business assets on their tax returns at a limit of $500,000. Furthermore, AdvaMed supports the permanent extension of bonus depreciation in Year 1 (50% of cost) of a qualified business asset purchase. Such incentives allow companies to invest more heavily in their businesses and encourage job creation and growth. We commend Chairman Camp for including a permanent extension of Section 179 in his small business discussion draft. We believe, however, that the higher $500,000 limit we are proposing is needed given the high cost of equipment needed to start a new business in today's economy, especially in the capital-intensive medical device and diagnostic industries.

Permanent Extension of Sections 992-996 IC-DISC Status

AdvaMed supports the permanent extension of IC-DISC status for qualified small companies exporting to other countries. Many medical device companies are forced to commercialize their products first overseas. The tax rate reduction to 15% provides these companies with capital to fuel organic growth, finance clinical studies and regulatory approvals in the United States, and develop new technologies.

Conclusion

In closing, we would like to thank Chairman Tiberi and Ranking Member Neal for their interest in the tax code's impact on small businesses and consideration of the proposals contained herein to support research and development-intensive firms. Our industry stands ready to work with the Ways and Means Committee and Subcommittee on Select Revenue Measures as you continue your efforts to reform the tax code, which will help provide the medical device and diagnostics industry the opportunity to continue be the world leader in the development of new technologies that allow patients to lead longer, healthier, and more productive lives.

Attachment 1. Promoting Innovation Through Tax Reform

The Coalition of Small Business Innovators (CSBI) supports a U.S. tax code that recognizes innovation as a crucial part of the 21st century American economy. By itself, a lower corporate tax rate will not support growth and innovation in America's small businesses, many of which are pre-revenue. Comprehensive tax reform should go further than "broadening the base and lowering the rate." Instead, policymakers should specifically promote innovative research-intensive businesses through incentives for other companies, individuals, and funds to invest in small companies and support their research.

Section 469 R&D Partnership Structures

Background: Prior to 1986 tax reform, many growing companies attracted investors by using R&D Limited Partnerships, in which individual investors would finance R&D projects and then utilize the operating losses and tax credits generated during the research process. These structures gave investors a tax incentive to support high tech research, which is entirely dependent on outside investors but often too risky or expensive to attract sufficient investment capital. The enactment of the passive activity loss (PAL) rules in 1986 prevented investors from using a company's losses to offset their other income, thus removing the incentive to support vital research.

Proposal: CSBI supports a limited exception from the PAL rules for R&D-focused pass-thru entities. Under this proposal, small companies would be able to enter into a joint venture with an R&D project's investors. The losses and credits generated by the project would then flow through to the company and investors, who would be able to use the tax assets to offset other income. Relaxing the PAL rules to allow investors to enjoy a more immediate return on their investment, despite the long and risky timeline usually associated with groundbreaking research, would incentivize them to invest at an earlier stage, when the capital is most needed.

Section 382 Net Operating Loss (NOL) Reform

Background: Innovative companies often have a long, capital-intensive development period, meaning that they can undergo a decade of research and development without any product revenue prior to commercialization. During this time period, companies generate significant losses, which can be used to offset future gains if the company becomes profitable. However, Section 382 restricts the usage of NOLs by companies which have undergone an "ownership change." The law was enacted to prevent NOL trafficking, but small high tech companies are caught in its scope – their reliance on outside financing and deals triggers the ownership change restrictions and their NOLs are rendered useless.

Proposal: CSBI supports reform of Section 382 to exempt NOLs generated by qualifying research and development conducted by a small business from Section 382. This change would allow small companies the freedom to raise capital for innovative research without fear of losing their valuable NOLs. Additionally, the ability of a small business to maintain its NOLs makes it more attractive to investors and purchasers looking to take its research to the next level.

Section 1202 Capital Gains Reform

Background: Section 1202 allows investors to exclude from taxation a portion of their gain, temporarily set at 100%, from the sale of a qualified small business (QSB) stock if they hold the stock for five years. This provision was designed to promote investment in growing businesses, but its overly restrictive size requirements prohibit innovative companies from accessing valuable investment capital. Currently, QSBs must have gross assets below $50 million. The high costs of research, coupled with valuable intellectual property and successive rounds of venture financing, often push growing innovators over the $50 million gross assets limit and out of the QSB definition.

Proposal: In addition to making the 100% capital gains exclusion permanent, CSBI supports changing the QSB definition to include companies with gross assets up to $150 million, with that cap indexed to inflation. CSBI also supports excluding the value of a company's IP when calculating its gross assets. These changes would allow more growing innovators to attract investors to fund their vital research. Providing incentives to invest in high tech research will increase the innovation capital available to research-intensive businesses and speed the development of groundbreaking technologies.