

**Testimony of Mike Carusi
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**House Committee on Energy and Commerce
Subcommittee on Health**

Hearing On:

**“21st Century Cures: Examining the Role of Incentives in Advancing
Treatments and Cures for Patients”**

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Introduction

Chairman Pitts, Ranking Member Pallone, my name is Mike Carusi. I am a General Partner of Advanced Technology Ventures (ATV), based in Palo Alto, California, where I focus on investments in the biopharmaceutical and medical device sectors. I also serve as a General Partner and Team Leader for Lightstone Ventures (LSV), a recently established venture capital fund focused exclusively on healthcare investments and opportunities.

I also am a member of the National Venture Capital Association (NVCA). NVCA is the voice of the United States venture capital community, representing nearly 400 members and advocating for public policies that encourage innovation and drive entrepreneurial investment. I want to note that my testimony reflects input from the NVCA, the Medical Device Manufacturers Association (MDMA) and Advanced Medical Technology Association (AdvaMed) and generally is consistent with the views of those organizations.

I am an engineer by training who made the transition to Venture Capital in 1998. My professional career has been devoted to investing in early stage medical device and biotechnology companies. During my time in venture, ATV and LSV have funded a total of 40 companies with my having personally led 20 of these investments. As a Venture Capitalist, I provide not only capital but also guidance. My passion is helping these innovative companies develop therapies for some of the most daunting diseases and medical conditions of our time.

I have been very fortunate to be a part of numerous companies that have been at the leading edge of innovation. These include: GI Dynamics a medical device company that has developed a novel device-based approach in the treatment of Type II diabetes; Ardian, a medical device company that has pioneered the field of renal denervation in the treatment of refractory hypertension; and Plexxikon, a biopharmaceutical company that has developed a drug that has revolutionized the treatment of melanoma.

It is extremely challenging, but also extremely rewarding work. Not only do I have an opportunity to help build companies, I also have the ability to help cure disease and have an impact on people's lives. I am reminded of this every time I receive a note from a mother, a daughter, or a husband who has had a loved one who has been successfully treated by one of my companies' products.

The members of this Committee have a long history of working together to find practical bipartisan solutions to some of our nation's most pressing challenges. For example, in 2012, the Committee enacted the Food and Drug Administration Safety and Innovation Act (FDASIA), which not only reauthorized the medical device and prescription drug user fee programs but included a number of important provisions to speed the approval process at the Food and Drug Administration (FDA) so that patients would have more rapid access to life-saving treatments. I specifically want to thank you, Chairman Pitts and Ranking Member Pallone, for your continued leadership. I also want to commend Chairman Upton and Representative DeGette for recognizing that additional measures are needed to spur innovation and better coordinate activities across key government agencies to unleash the full promise of medical technology to truly benefit America's patients.

Your leadership is needed more today than ever. The medical technology industry is facing a crisis. Without changes in public policy, the U.S. will no longer lead the world in developing life-saving treatments, and American patients face a grave risk of losing opportunities for cures.

Background on the Venture Capital Community and Support for Medical Innovation

The United States has been the global leader in medical technology innovation. Our medical device innovators have pioneered novel therapies such as drug eluting stents to treat cardiovascular disease, insulin pumps to treat diabetes, endovascular coils to reduce the incidence of hemorrhagic stroke, and percutaneous heart valves to treat aortic valve disease. As noted previously, my firm and I have been very fortunate to be a part of several of these breakthroughs. These therapies clearly have improved the lives of patients. They also have benefitted a wide range of additional stakeholders within the healthcare ecosystem including physicians, payors, hospitals, foundations, and universities.

For the past 50 years, the development of innovative medical devices has been driven by small, entrepreneurial companies often fueled by venture capital. In fact, 80 percent of medical device companies have fewer than 50 employees, and 98 percent have fewer than 500.¹ Venture capitalists raise capital from institutional investors, such as pension funds, endowments, and foundations, and invest these funds in promising, young start-up companies. When we do our job well, we help create companies with high-quality jobs that provide patients and physicians access to innovative medical technologies. We also generate financial returns for our investors.

¹ "Medical Technology and Venture Capital: A Fruitful Yet Fragile Ecosystem," MDMA and NVCA, June 2009, <http://www.medicaldevices.org/node/656>.

This allows universities to educate more students, foundations to care for their constituents, and pension funds to meet the needs of their retirees. In short, the U.S. medical technology ecosystem is an incredible win-win system.

Industry Challenges

We live at a time when the promise and importance of innovation has never been greater. Our understanding of the origins of disease and human physiology are growing significantly. We are witnessing dramatic advancements in our engineering capabilities, breakthroughs in materials science, and exponential growth in the use of information technology. As the population ages and the pressure to improve the value equation of health care mounts, new and better technologies can play a critical role in helping to reduce long-term costs and improve patient care. Simply put, medical technology advances have the potential to be a central part of the solution to the many challenges facing the U.S. healthcare system over the years to come.

Ironically, despite these growing needs and our scientific ability to meet them through continued innovation, the funding of medical technologies has declined substantially in recent years. Between 2007 and 2013, medical device investments fell by a total of 40 percent¹. While other sectors, such as information technology, witnessed a recovery after the financial crisis, medical device investing has continued to suffer. Of even greater concern, the decline in investment for companies at the initial phase of financing has been even more dramatic. In 2007, the Money Tree report by PricewaterhouseCoopers and the National Venture Capital Association (based on data from Thompson Reuters) showed 98 companies amassing approximately \$576 million in initial venture capital. Since then, there has been a 50 percent reduction in the number of device companies receiving initial venture capital investment and an approximate 70 percent drop in the amount of capital invested. In 2013, we witnessed the lowest level of medical device initial funding activity in more than two decades. Last year, only 44 new venture device companies raised a total of \$163 million compared to 2007's 98 companies, according to Money Tree.²

As noted earlier in my testimony, I have a very strong personal commitment to improving the lives of patients—and a long track record to back that up. This is true of many of my venture colleagues as well. However, we also have a fiduciary duty to the universities, pension funds, foundations and other institutional investors whose money we manage and invest. Over the past 10 years, the average returns for medical device investments have simply fallen short of expectations. These poor returns have resulted in institutional investors fleeing the sector. An estimated 70 percent of all medical device venture firms have or will exit the business over the next five years. Let me repeat this, 70 percent of all device investors are going away. This is an enormous problem. As venture funding falls, innovation falls.

² NVCA/PWC MoneyTree Survey, "VC Investments Q4 – MoneyTree – National Data", http://nvca.org/index.php?option=com_content&view=article&id=344&Itemid=103

Our recent fund-raising experience for Lightstone Ventures serves as a powerful reminder of the challenges our sector currently faces. Despite having outstanding returns, our fund-raising effort was extraordinarily difficult. We ultimately were successful, but it took two years and four hundred thousand miles of travel to get it done. Of note, approximately 25 percent of LSV's future investment activities will focus outside of the U.S. This is an important change from how we operated previously.

There are several reasons for this change. First, countries such as Ireland and Singapore, are offering powerful economic incentives to groups like LSV to invest outside of the U.S. Second, and more importantly, it has now become commonplace for our companies routinely to seek regulatory approval and commercialize new products in other markets ahead of the U.S. The regulatory path in these markets is simply faster and more predictable. As our companies migrate outside of the U.S., so must we. LSV, for example, just announced the opening of a Dublin office as well as a major strategic initiative in conjunction with the Irish Government. Clearly, we as venture capitalists would prefer to stay closer to home, but the U.S. path to market has become too costly and too unpredictable. This trend can be reversed, but change is needed.

Regulatory Challenges

To be clear, there is no single cause for the challenges that face medical device innovation. I believe the industry is partly responsible for its recent performance. Too many companies developed too many products that were too incremental in nature. These products were not disruptive enough to merit adoption. However, it is important to ask why the industry chose to go down this path. As the time and cost to bring a product to market increases, investor returns decrease. Investors were attempting to tweak a broken model.

In a recent survey conducted by NVCA, 42 percent of health care investors expressed that they decreased their investment in medical device companies due to the longer time frames to regulatory approval.³ Since 2005 the timeline to an approval decision has become substantially lengthier, resulting in millions of dollars of extra capital spent. A small, venture-backed company typically spends \$500,000 to \$2 million per month in operating costs as it conducts clinical trials and awaits regulatory approval. A six to twelve month delay can significantly increase the amount of money necessary to see the product through to market approval.

As we have discussed with this committee and the broader policymaking community at great length, the path to regulatory approval in the U.S. has become increasingly difficult to predict. Unexpected regulatory delays increase both the time and capital required to bring products to market. These increases, in turn, are forcing many venture capital firms, and those institutions that support them, to move away from medical device investing. Although LSV remains committed to the sector, we have had to readjust our investment strategies and tactics. I

³ "FDA Impact on US Medical Technology Innovation", Dr. Josh Makower, November 2010, <http://nvcaccess.nvca.org/index.php/topics/public-policy/155-fda-impact-on-innovation-study-out-today.html>.

personally have not invested in a new medical device company in over two years. Subsequently, we now are looking more aggressively outside of the U.S. We also are seeking ways to help limit risk. This includes running early knockout experiments, sticking to known clinical pathways, and only backing the most experienced of teams. It also means limiting our investments to those therapeutic areas where the FDA has proven to be more rational and collaborative. Given these tight filters, we likely will fund only one deal out of a hundred. These are very long odds for aspiring innovators. Perhaps most disheartening, many of the ideas that are not funded are not because of a lack of clinical importance or necessity, but because the anticipated regulatory challenges deter financing. Good ideas are being passed over, which is never a recipe for success.

Fortunately, we have made progress in recent years. NVCA applauds Congress, and the members of this Committee, for working in a bipartisan effort to make significant improvements to the FDA process. The new medical device user fee goals included as part of the 2012 FDASIA bill should help to improve this situation. FDASIA's provisions regarding breakthrough technologies also should go a long way toward reducing timelines, without compromising patient safety. Other important improvements that were included in the bipartisan FDASIA legislation include clarifications to the standards that the FDA should use in making future regulatory decisions around the risks and benefits of new products, as well as greater flexibility in the use of outside experts to help speed reviews.

Additionally, I would like to thank Commissioner Hamburg and Center for Devices and Radiological Health (CDRH) Director Shuren for listening to concerns from the venture capital community and working in a collaborative manner to help improve the regulatory process for medical devices within the U.S. The efforts to implement an "innovation pathway" and the recent guidance document outlining patient benefit vs. risk as the clear basis for PMA and de novo device approvals are specific examples of improvements that Dr. Shuren and his staff have undertaken. NVCA also applauds CDRH's 2014 Strategic Goal to provide patients in the U.S. with first in the world access to new medical technologies. These are important advancements that I truly believe will help to maintain this country's lead in medical device innovation.

With that said, we have more work to do. We need to make sure that steps are taken at the regulatory level to ensure that the goals of these new legislative provisions are fully realized. Specifically, there needs to be continued focus on management improvement and reviewer training to ensure consistency and timeliness of reviews. We need to explore opportunities for streamlining the Independent Review Board (IRB) approval process, improving the Investigational Device Exemptions (IDE) process, reducing unnecessary preclinical trial data, and improve the process for undertaking first-in-human studies here in the U.S. Lastly, there should be sustained focus on improving procedures for the evaluation and approval of combination devices. These are important additional steps that all need to be taken.

Reimbursement Challenges

Although we have made important progress in working with Congress and the FDA to help ensure a more predictable regulatory process, this is only one of the many challenges we face. In order for the promise of medical technology innovation to be fully realized, we must build on the spirit of collaboration we have developed in resolving regulatory obstacles and address what has become an even greater challenge facing medical device innovation: reimbursement.

After our companies have worked through the costly and timely process of receiving FDA approval, they then must set their sights on securing coverage and reimbursement. This is an equally complex and unpredictable process which can add another three to five years to the development of a product. This means three to five more years before patients can actually benefit from a new product and before the company can generate a meaningful revenue stream. Each phase of the reimbursement process (coding, payment and coverage) has its own unique set of challenges. As with the FDA in years past, the biggest challenge we face is the lack of transparency, predictability, and consistency of the process. Moreover, the data requirements payors impose before granting coverage are often so high and unclear that they discourage investment in and development of promising treatments. This is true of both government programs, as well as private payors—which often follow the decisions made by the Medicare program.

The overall process of obtaining coverage and reimbursement represents a classic “chicken and the egg” dilemma for the investment community. On the one hand, payors want to see more data and diffusion of a new technology until they agree to provide coverage for it. On the other, physicians and hospitals will not agree to use the product unless they get paid. Equally challenging, the data and utilization requirements are ambiguous at best.

There is increasing evidence that payors are raising the standard for coverage determinations. One study by Tufts University researchers found that the probability a therapy considered for national coverage under the Medicare program will be approved dropped by more than 60 percent between 1999 and 2007. When coverage was granted, the scope was more limited than the indications approved by the FDA in 40 percent of the cases studied.⁴ While Medicare national coverage determinations represent a relatively limited universe, we are finding that both private payors and government programs are increasing the bar for coverage and reimbursement decisions. What is most troubling is that it is often not clear where that bar lies.

I have had two experiences, recently, where a company in which ATV invested faced this very challenge. In one instance, we were told to come back time and time and again with more data. Each time we met the deliverable. Each time we were asked for more. There was seemingly no

⁴ Chambers J.D., Morris S, Neumann P, and Buxton M. (March 2012) Factors Predicting Medicare National Coverage: An Empirical Analysis. *Medical Care Journal*, 50(3).

end to the process. In another instance, we were told that utilization of our device in 5,000 patients was not enough. We came back again with 10,000 patients. Not enough. We came back again with 15,000 patients. Not enough. Once again, the process appeared to be unending. My venture colleagues and I increasingly are facing this type of situation. This is clearly an area of medical innovation where our public policy leaders can help lead the way towards a more open and transparent process.

In short, we need to make the coverage process in both the public and private payor context more open and transparent. We need to take steps to expedite coverage and reimbursement decisions. We need to foster improved collaboration among the innovator, payor and patient communities. And we need to ensure that our government programs are more receptive to rapid coding and coverage of new technologies. Below, we include several areas where we believe progress could be made and which would help to improve the process of medical device innovation in the U.S.

Policy Recommendations To Improve the Coverage and Reimbursement Climate

As I indicated previously, just as there is no silver bullet to revitalizing U.S. investment in innovative medical devices, there is no simple solution to improving the reimbursement climate in the United States. NVCA recognizes that we must balance our nation's need to better address the growth in overall health care costs while at the same time ensuring that patients have access to life saving technologies. These two goals, however, do not need to be mutually exclusive.

We believe that several important steps can, and should, be taken to improve the coverage and reimbursement climate for medical technologies. As mentioned earlier, progress can be made if we begin by encouraging our public payor programs to take a page from the collaborative and more transparent environment we have begun to create in the regulatory approval process. First, in building on the work of this Committee with the FDA, we believe that the Medicare program should be required to take into account patient perspectives on risk and benefit in making coverage and reimbursement decisions. In addition, we believe that Medicare should be encouraged to expand opportunities for participation by patients, providers, innovators and investors in meaningful dialogue about coverage determinations beyond the existing MedCAC advisory role in which some patient representatives are now allowed to participate.

Second, Congress should consider expanding the Medicare program's overall mission to encourage the program to help promote and adopt improved treatments for beneficiaries. This would be similar to the FDA mission statement providing that the agency should advance public health by "helping to speed innovations that make medicines more effective, safer, and more affordable." Broadening the focus of the Centers for Medicare and Medicaid Services may help to achieve a more appropriate balance that could truly benefit the patients Medicare serves.

There are some additional concrete steps we urge the Committee to consider. These include streamlining the requirements of the Coverage with Evidence Development (CED) program to better align with FDA post-market data collection and study standards. The administration of the CED program should also be re-oriented toward expanding and speeding coverage of promising treatments, rather than posing an additional barrier. Too often, in practice, CED requirements simply add to the burden of data collection and, as a result, delay patient access to new therapies.

In addition, we believe Medicare's process for assigning billing codes to new technologies can be streamlined. As you know, obtaining codes is often a prerequisite to coverage and reimbursement and, often, the process of obtaining codes can take up to 18 months or more following FDA approval. This is simply too long for patients to wait for new cures and imposes yet another unnecessary roadblock to investment in medical technologies.

Finally, we too believe that there are opportunities to improve overall value in the Medicare program by utilizing new provider risk-sharing arrangements and value-based payment models. We know that the Centers for Medicare and Medicaid Innovation (CMMI) is experimenting with a range of alternative payment models (APM) and that there is considerable interest among policymakers in evolving the Medicare program from a fee-for-service system that compensates providers based largely on volume to one that reimburses for value. At the same time, new forms of APMs and provider risk-sharing arrangements can create strong, often overpowering, incentives for cost reduction at the expense of patient access to treatments and cures. In part, this is because there are significant gaps in the current measures used to reward system quality. Therefore, we urge greater oversight over these innovative payment models in Medicare. We also believe it is important to provide greater transparency around measures upon which payments will be based and to ensure that payment models are flexible enough to accommodate new, improved and innovative treatments, even when those treatments may come at a higher cost than outdated therapies. Again, none of these steps alone will ensure that our nation's medical technology innovation engine is again working at full speed. But, a renewed focus on drastically improving the coverage and reimbursement situation at least in our nation's major public programs can help repair the medical device research and development ecosystem.

Medical Device Tax Repeal

On a related note, while I know that this Committee has been focused on regulatory and reimbursement challenges facing the medical community, I also want to mention just briefly the importance of repealing the medical device tax, which has overwhelming bipartisan support in the House of Representatives. This flawed policy adds yet another burden to medical device innovators and is a major deterrent to developing the cures and technologies of tomorrow.

Conclusion

Again, thank you for the opportunity to testify today. We greatly appreciate the work that the Energy and Commerce Committee has done to improve the innovation ecosystem and we welcome the 21st Century Cures initiative. With that said, more work is needed. We need to continue to build upon the progress we have made with improvements at the FDA and the regulatory approval process. Equally important, we need to greatly improve the reimbursement climate within this country. Lastly, we need to repeal the medical device tax. With these improvements, we can continue to ensure that the U.S. remains a global leader in the development of life saving medical device therapies. Without them, I fear medical device innovation will continue to leave our shores. The choice is ours.