December 20, 2021

The Honorable Dianna DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

On behalf of our nation's venture capital investors and the entrepreneurs they support, I write to express our support for key provisions in *Cures 2.0* that will provide greater certainty for long-term investment and accelerate medical technology innovation. As investors in lifesaving drugs, medical devices, diagnostics, and digital health solutions, venture capitalists have a valuable perspective on regulations that can encourage innovation and advance our healthcare system. We appreciate your willingness to consider the views of the venture industry.

Significance of Venture Capital to Medical Innovation and Sector Trends

Venture capital investors are critical in healthcare innovation, working shoulder-to-shoulder with startups, scientists, universities, and entrepreneurs to develop life changing therapies and cures. Small venture-backed companies help to spur the creation of revolutionary medical discoveries aimed at diagnosing, treating, and curing the most deadly and costly diseases. The historical contribution of venture capital to medical advancement is immense, having backed 42% of all FDA-approved drugs from 2009-2018[1] and impactful companies behind the development of thrombectomy for stroke, minimally invasive mitral valve repair for heart failure, minimally invasive glaucoma surgery, continuous glucose monitoring, surgical robotics, percutaneous heart valves, next generation sequencing diagnostics for early detection and management of cancer, and diabetes pumps.

Venture-backed healthcare companies had a record year in 2020 due to strong interest in vaccines, antivirals, and companies engaged in the fight against COVID-19. Numerous companies that are (or were) venture-backed in the healthcare sector continue to devote considerable resources and energy to battling the novel coronavirus. The most recognizable of these companies was Moderna, which produced a COVID-19 vaccine critical to helping the American population. In total, $36 billion in capital was invested into life sciences companies in 2020, 41% more than the previous annual record of

[1]Silicon Valley Bank, *Trends in Healthcare Investments and Exits 2019* available at https://www.svb.com/globalassets/library/managedassets/pdfs/healthcare-report-2019-midyear.pdf

$26 billion invested in 2018.[2] The pharma and biotech sector received $28 billion in investment, or 17% of total venture capital deployed in 2020. Investment in drug discovery nearly doubled from $8.8 billion in 2019 to $16.2 billion in 2020.[3]

Despite these record investments into the life science sector, medical device companies have experienced a decline in the share of overall venture activity over the last several years because of the regulatory, reimbursement and market development challenges these innovations face. In 2010, $3.2 billion was invested into medical device companies, accounting for 9.9% of all venture deals. Ten years later in 2020, $8.3 billion was invested in medical device companies but accounted for only 5% of all deals that year. Through the first three quarters of 2021, $7.8 billion was invested in medical device companies, or 3.3% of total VC investment in U.S. venture-backed startups.[4]

This decline is more apparent in measuring medical device companies receiving their first round of venture financing. Medical device companies receiving first-time financing as a percentage of total venture capital first-time funding dropped from 6.4% in 2010 to 3.2% last year, decreasing by half over a decade.[5] First-time financing is an important indicator of new company creation as it demonstrates the number of companies receiving their first round of equity financing from an institutional venture capital investor and therefore is important in assessing the future direction of a category.

Coverage and Payment for Breakthrough Devices Under the Medicare Program (Section 404)

Many venture investors cite misguided reimbursement policy and the uncertainty that follows approval of a new product as a significant challenge and reason for the decline in medical device investment. This sentiment is documented through a survey of leading venture investors in the medical device sector conducted in April 2021 by NVCA, AdvaMed, and the Medical Device Manufacturers Association (MDMA).[6]

Survey respondents cited "establishing a new reimbursement paradigm (e.g., getting payor coverage policies)" as the most challenging or intimidating hurdle that might reduce willingness to invest in medical technology companies. Further, if an early-stage company developing a novel medical technology needs to establish a new reimbursement paradigm for its product after generating clinical evidence and obtaining FDA approval, 92% would be less willing to invest or not willing to invest at all. For a startup that has received FDA approval and needs to then establish a reimbursement paradigm, respondents cited an average of an additional 4.3 years necessary to achieve an exit post-FDA approval.

Given these challenges, NVCA has been a longtime proponent of establishing a new coverage pathway for innovative medical technologies. The *Ensuring Patient Access to Critical Breakthrough Products Act*, Section 404 of *Cures 2.0*, would establish such a pathway, providing four years of national coverage for devices that are FDA-designated breakthrough devices. This approach would help

[2] NVCA 2021 Yearbook, Data Provided by PitchBook (note: life sciences is composed of pharma & biotech and healthcare devices & supplies combined).
[3] Id.
[4] Pitchbook—NVCA data.
[5] Id.
[6] Survey conducted by NVCA, AdvaMed, and MDMA from April 2 to April 9, 2021. 65 responses were received from medical device investors, available at https://nvca.org/wp-content/uploads/2021/04/NVCA-AdvaMed-MDMA-MCIT-Survey-Results_FINAL.pdf.

to address challenges obtaining reimbursement and coverage by providing needed certainty for device development and ultimately encouraging greater long-term investment and healthcare improvements for the American public. NVCA is pleased to offer support for the proposed pathway for CMS coverage in the legislation.

Advanced Research Projects Agency for Health (Section 501)

Research conducted in federal labs and research institutions provide the underlying foundation for the innovation economy in the United States. As you are well aware, federal research investment has led to groundbreaking technologies and development of lifesaving medical treatments. NVCA applauds the creation of the Advanced Research Projects Agency for Health in the *Cures 2.0* legislation, which would dedicate federal R&D efforts to the discovery and advancement of medical breakthroughs.

We appreciate the willingness of you and your staffs to consider the unique role of the venture capital industry in bridging the divide between government research and commercial demand, as well as between science and markets more broadly. In addition to equity capital investment, venture investors work alongside their portfolio companies to mentor the executive teams, offer strategic advice (often from seats on the company board), and serve as critical resources bridging the divide between the lab and market. In addition, a venture investor's participation often serves as a conduit to further growth capital opportunities and resources needed to scale, a key factor for expanding innovation opportunity and bringing next-generation medical products, therapies, and cures to the American public.

As we work together through the legislative process, we look forward to finding ways to encourage the participation of VCs in order to accomplish our shared objectives. Specifically, we recommend an increased focus on commercializing technology through prioritizing *new company formation* and explicitly including venture capital investors within the potential partnership opportunities of the program. In addition, we encourage that the interpretation of "demonstrated capabilities of the applicants" allows the agency to look through the company, which may be entirely unproven, to the capabilities of the individuals leading the company, who may be acclaimed scientists or industry veterans who have left incumbent entities.

Conclusion

Thank you for your leadership with the *Cures 2.0* legislation and addressing the current challenges of developing and bringing innovative, new medical products to market. NVCA appreciates the opportunity to share the input of the venture industry, and we stand ready to help as you move this important piece of legislation through Congress.

Sincerely,

Bobby Franklin

Bobby Franklin
President and CEO