October 15, 2021

VIA ELECTRONIC FILING

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P2
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-3372-P2: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Dear Administrator Brooks-LaSure,

On behalf of our nation's venture capital investors and the entrepreneurs they support, we appreciate the opportunity to provide comments on the proposed repeal of the Medicare Coverage of Innovative Technology (MCIT) pathway and the agency's intent to conduct a future rulemaking to explore an expedited coverage pathway that provides access to innovative beneficial technologies. As investors in lifesaving medical devices, diagnostics, and digital health solutions, venture capitalists have a unique and valuable perspective on the regulatory approach to reimbursement policies that can encourage innovation and advance our healthcare system. NVCA is disappointed with the proposed repeal of MCIT and strongly encourages CMS to prioritize reforms to the reimbursement process that will expedite coverage for breakthrough medical technologies and provide faster access to new therapies and products for Medicare beneficiaries.

Significance of Venture Capital in Healthcare Innovation

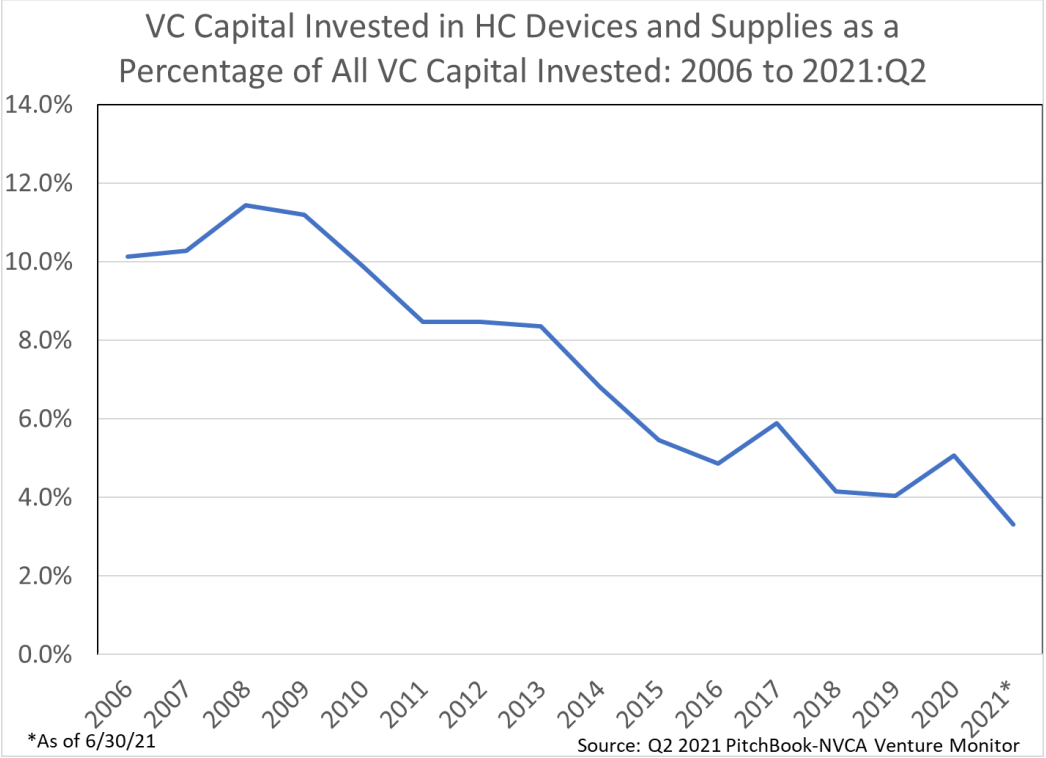
Venture capital investors are critical to healthcare innovation, working shoulder-to-shoulder with startups, scientists, universities, and entrepreneurs to develop life changing treatments and cures. Small venture-backed companies help to spur the creation of revolutionary medical discoveries aimed at diagnosing, treating, and curing the most deadly and costly diseases. The historical contribution of venture capital to medical advancement is immense, having backed 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.

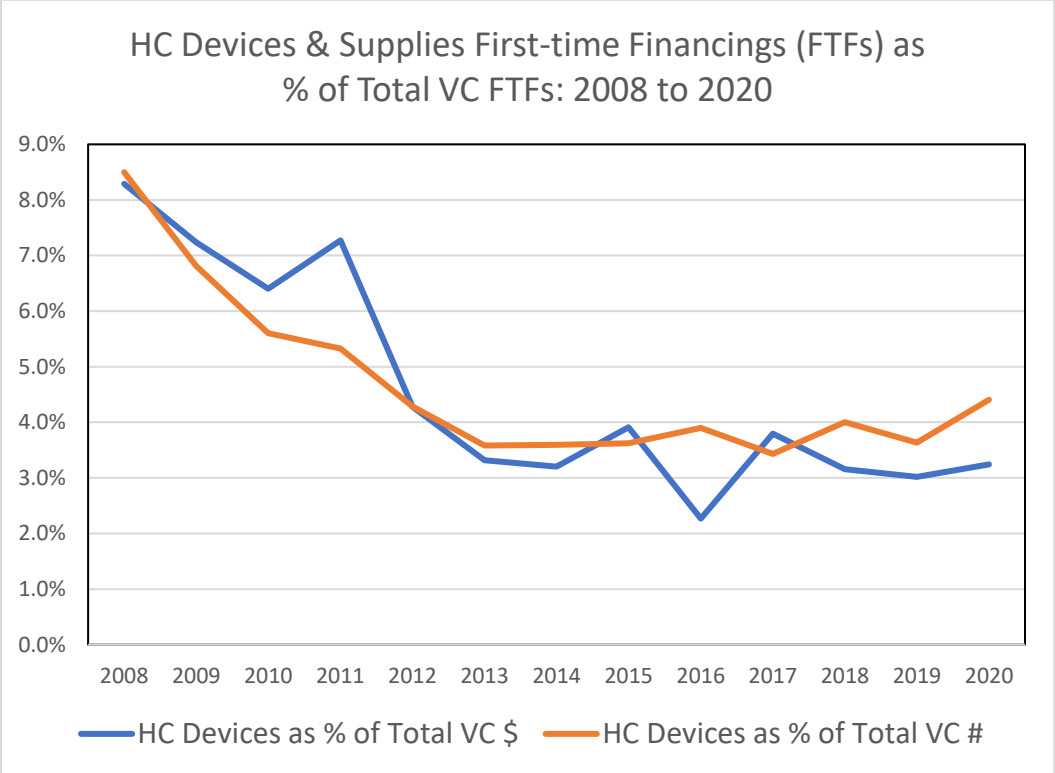
Venture-backed healthcare companies had a record year in 2020 due to strong interest in vaccines, antivirals, and companies engaged in the fight against COVID-19. Numerous companies that are (or were) venture-backed in the healthcare sector devoted considerable resources and energy to battling the novel coronavirus in 2020. 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, 41% more than the previous annual record of $26 billion invested in 2018.[1] 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.[2]

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, $3.1 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 5.1% of all deals that year. In the first half of 2021, $5 billion was invested in medical device companies, or 3.3% of total VC investment in U.S. venture-backed startups.[3]

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.[4] 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.

[1] NVCA 2021 Yearbook, Data Provided by PitchBook (note: life sciences is composed of pharma & biotech and healthcare devices & supplies combined).
[2] Id.
[3] Pitchbook—NVCA data.
[4] Id.





Source: Pitchbook-NVCA data

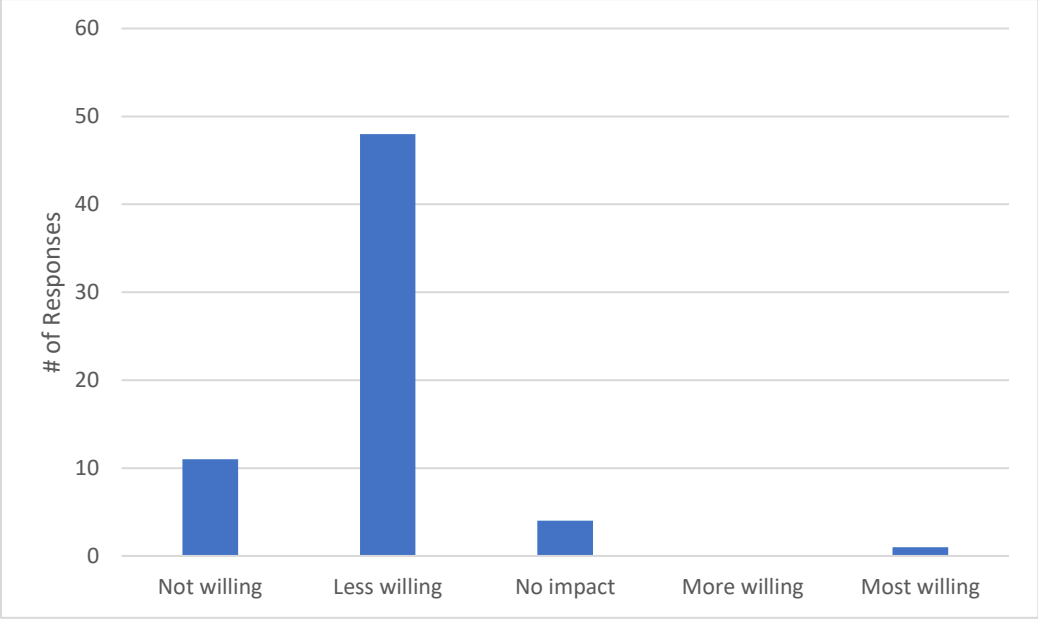
Impact of Reimbursement Framework for Investment into New Products

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).[5]

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.

The sentiment captured in this survey question helps explain the decline in venture investment in new medical device companies, as described above. This is a challenge for policymakers as a lack of early-stage investment ultimately means fewer innovative companies to tackle our healthcare challenges and reduce cost throughout the system.

Survey question:
If an early stage (seed or product development) company developing a novel medical technology will need to establish a new reimbursement paradigm (e.g., getting new payor coverage policies) for its product/procedure after generating clinical evidence and obtaining FDA approval, which of the following statements best describes your willingness to invest in that company today?



[5] 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.

Support for Implementation of an Expedited Coverage Pathway for Medical Devices

Given the challenges with existing paths available for innovative technologies to achieve Medicare coverage, NVCA has been a longtime supporter of establishing an expedited coverage pathway at CMS. The decline in device investment share of overall venture investment and survey data illustrate the substantial challenges and uncertainties faced during the development of new products and devices, particularly in the earliest stages. The proposed rule to repeal the MCIT pathway for breakthrough products was disappointing as it would have provided significant benefits while requiring rigorous clinical evidence. We encourage CMS to prioritize establishing a revised framework for innovative technologies, an effort supported by a wide range of industry stakeholders and policymakers on both sides of the aisle. Representative Suzan DelBene (D-WA) recently introduced the bipartisan *Ensuring Patient Access to Critical Breakthrough Products Act,* which would expedite the coverage process to improve availability of breakthrough products for patients. This proposal was also included in the bipartisan *Cures 2.0* framework championed by Representatives Diana DeGette (D-CO) and Fred Upton (R-MI).

The proposed rule states CMS's intent to conduct a future rulemaking to explore an expedited coverage pathway that provides access to innovative beneficial technologies, including breakthrough designated devices and beyond. NVCA and the medical device investment community are very interested in working with CMS on this framework and creating solutions for the areas described in the proposed rule. We know that our member investors and their portfolio companies are highly incentivized to generate high quality clinical evidence supporting clinical validity and appropriateness for Medicare beneficiaries, both prior to and after FDA approval. These companies are also willing to engage with CMS directly to inform evidence generation plans, and NVCA would support additional efforts to further resource CMS so that engagement can be substantive, predictable, and timely. CMS action in this space has the potential to bring major improvements to the U.S. healthcare system, including encouraging greater long-term investment and providing immediate benefits for the Medicare population through delivery of transformative new products. As you consider a coverage framework, we offer recommendations to maximize impact and provide meaningful improvements for the medical device development and advancement process.

Expand the breakthrough designation

NVCA encourages CMS to explore an expanded pathway beyond the FDA breakthrough designation. To achieve this, we recommend a mechanism to apply the pathway to circumstances in which medical device products have been approved and meet the spirit of a breakthrough pathway but are not designated and currently do not have existing coverage in place. One example of this scenario could occur if an approved product pre-dated creation of a coverage program. Alternatively, real world experience with the FDA has shown that the breakthrough designation thus far has been utilized primarily only for the first technology in a new indication. Second generation products with the same indication are usually denied breakthrough designation by the FDA because the agency believes there is already a device available that treats that indication and/or the second-generation product does not offer significant advantages. We believe this view is mistaken.

CMS should provide coverage for a non-breakthrough designated device with potential to offer compelling clinical benefits that are different from or in addition to those offered by existing therapies.

This approach would generate a higher degree of marketplace competition for medical device products and ultimately lead to product improvements, lower costs, and innovation for the Medicare population.

Extend 2-year 'look-back' period and start 4-year coverage period when a device is accepted into pathway

Additionally, we propose applying the "look-back" to devices approved more than 2 years before the program. The path to broad coverage can take five or more years and so limiting the coverage pathway to only recently approved devices will leave many companies stuck in limbo, which undercuts the aim of a program. As a solution, we recommend starting the clock on 4 years of coverage when a device receives marketing authorization/marketing availability or the effective date of coverage under a final rule, whichever is later. This approach would ensure all devices, including existing devices, would receive adequate opportunity and a full 4 years of coverage, providing the time needed to generate necessary data collection and a clinical evidence base.

Conclusion

The entrepreneurial ecosystem thanks you for the opportunity to comment and further illustrate the need to reform the complex process of bringing innovative, new medical products to market. Advancement of medical innovation is a priority to improve the lives of patients and overall healthcare opportunities. NVCA appreciates the opportunity to share the input of the venture industry, and we urge CMS to move forward on establishing an impactful new pathway.

Sincerely,

Bobby Franklin
President and CEO