April 16, 2021

VIA ELECTRONIC FILING

Ms. Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

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

Dear Acting Administrator Richter,

On behalf of our nation's venture capital investors and the entrepreneurs they support, we appreciate the opportunity to provide comments on the delayed effective date of the Medicare Coverage of Innovative Technology (MCIT), a proposed coverage pathway for FDA-designated breakthrough devices. As investors in lifesaving medical devices, venture capitalists have a unique and valuable perspective on the regulatory approach to reimbursement policies that can encourage innovation and advance our healthcare system. We strongly support the MCIT pathway and encourage CMS to move forward with implementation without further delay.

Significance of Venture Capital in the Healthcare Startup Ecosystem

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 startups 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 achieve herd immunity.

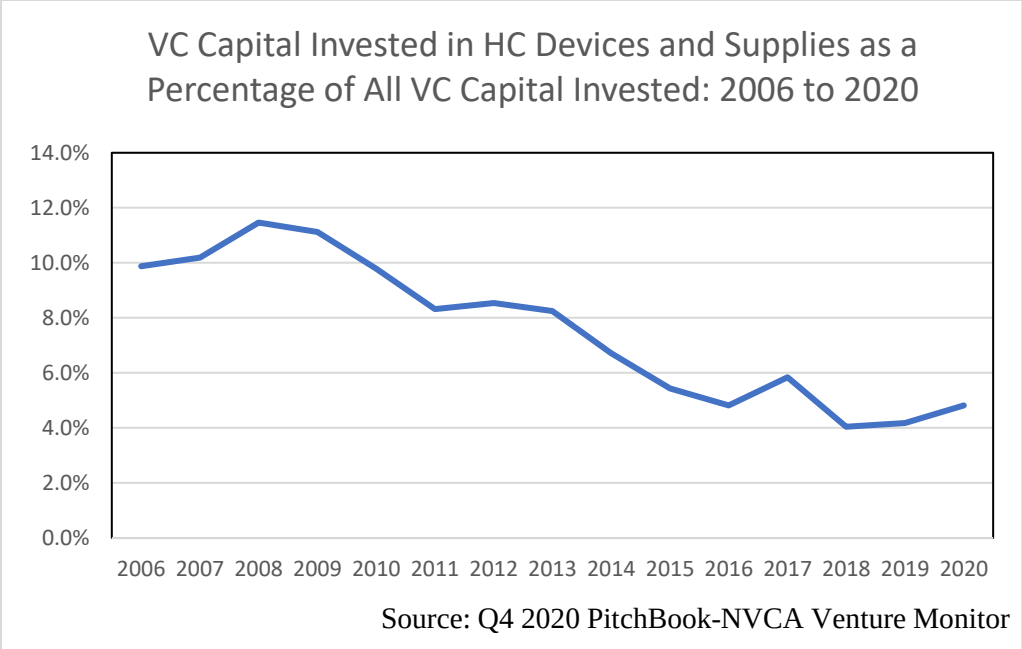
Other venture-backed companies that joined the fight against COVID-19 include A2A Pharma, which conducted research on COVID-19 viral replication and cell entry; Biomeme, which created a technology platform that allows for COVID-19 tests to be performed on a smartphone; Formlabs, which utilized 3D printing to address supply chain shortages and provide hospitals and health systems with COVID-19 testing, PPE, and medical equipment; Ovation.io, which launched an initiative to significantly expand the nation's COVID-19 testing capacity; Smart Monitor, which developed a remote patient triage solution for COVID-19 patients who are recovering at home in self-isolation; and Vapotherm, which developed a high flow nasal canula device. Venture-backed companies developed multiple COVID-19 diagnostic tests approved under Emergency Use Authorization and remote monitoring and virtual care delivery technology platforms.

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]

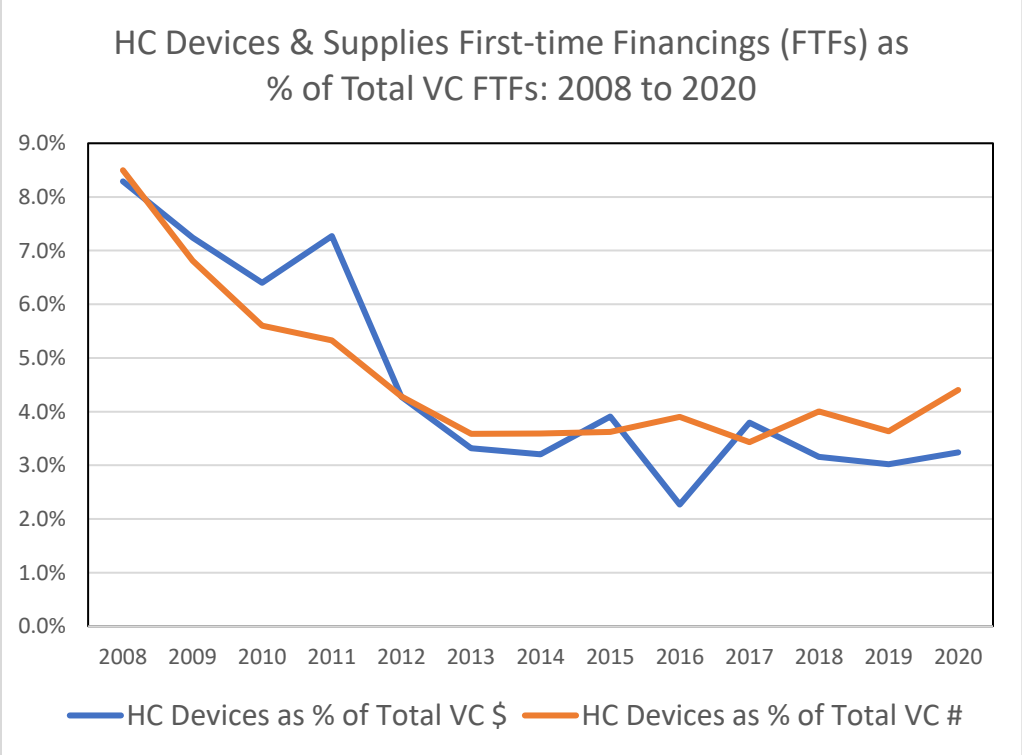
Decline of Medical Device Share of Overall Venture Activity

Despite record investments in the broader life science sector, medical device companies have experienced a decline in the share of overall venture activity over the last several years. In 2010, $3.1 billion was invested into medical device companies, accounting for 9.8% of all venture deals. Ten years later in 2020, $7.5 billion was invested in medical device companies but accounted for only 4.8% of all deals that year. This decline is even 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 almost half over a decade.[3] 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.



Source: Q4 2020 PitchBook-NVCA Venture Monitor



Source: Pitchbook-NVCA data

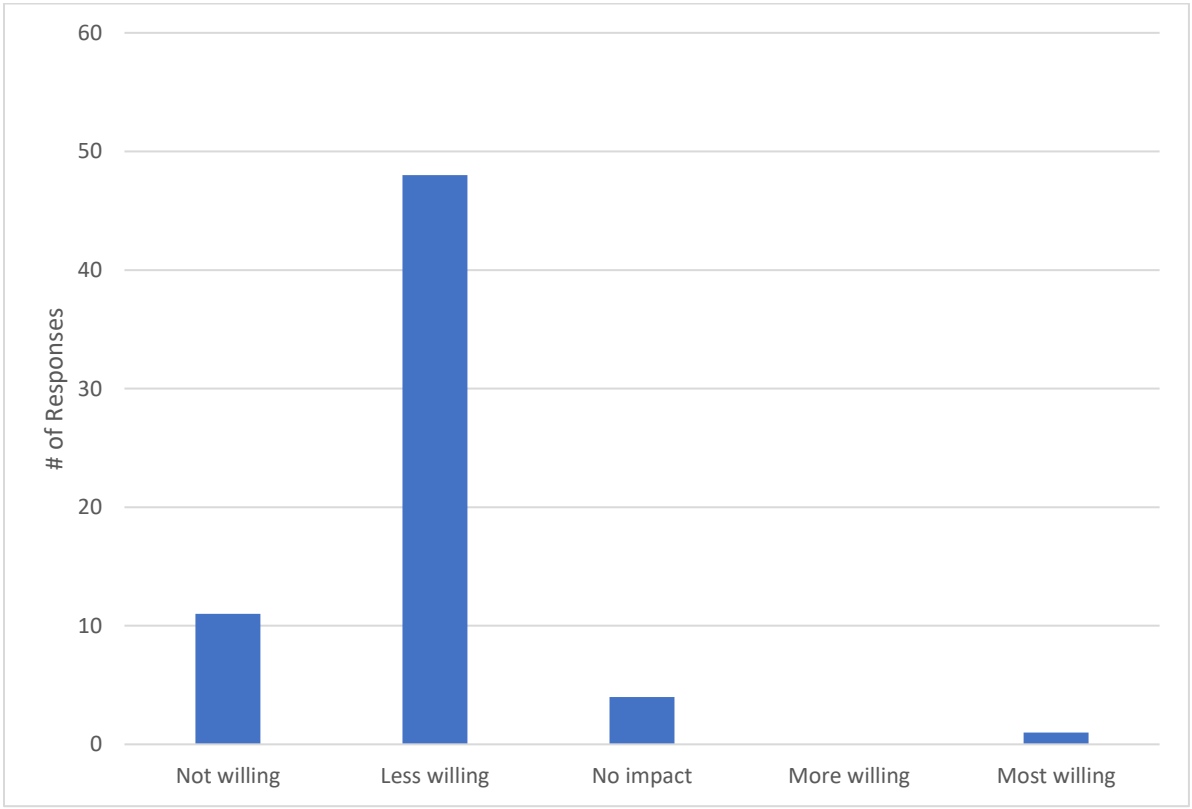
Impact of Reimbursement Framework for Investment into New Products

Many venture investors cite misguided reimbursement policy and the uncertainty that follows approval of a new product as a significant challenge to investment in medical devices.

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).[4]

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.

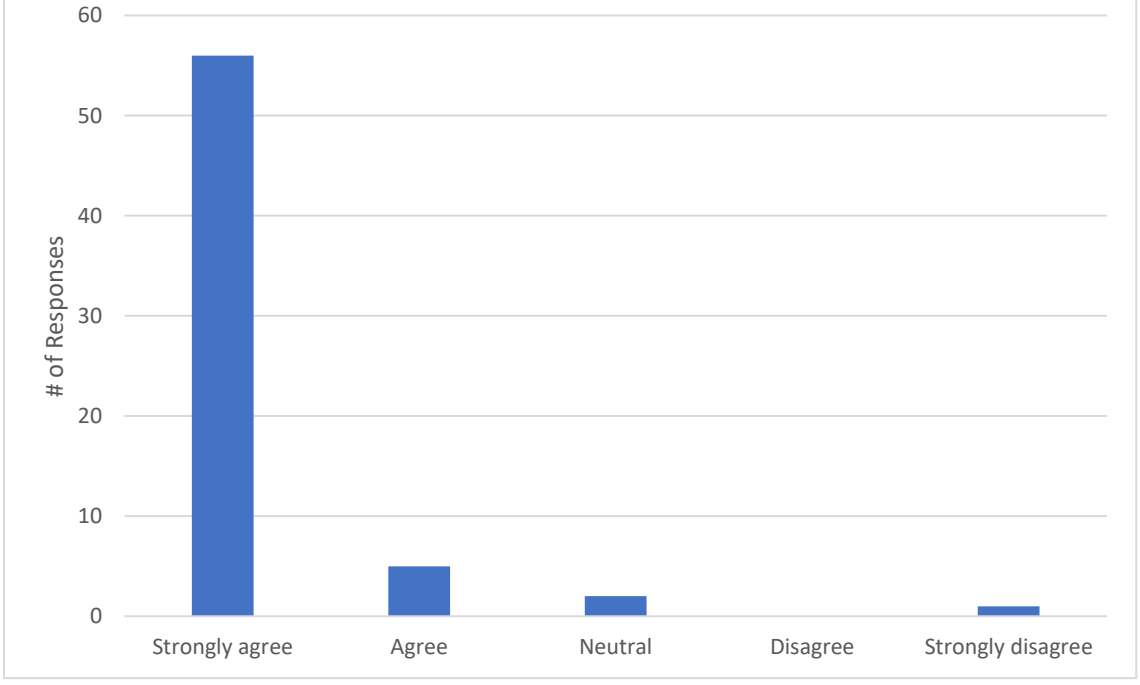
Survey question:
If an early stage (seed or product development) company developing a novel medical technology will need to establish a new reimbursement paradigm (e.g., getting new payor coverage policies) for its product/procedure after generating clinical evidence and obtaining FDA approval, which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



[4] 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.

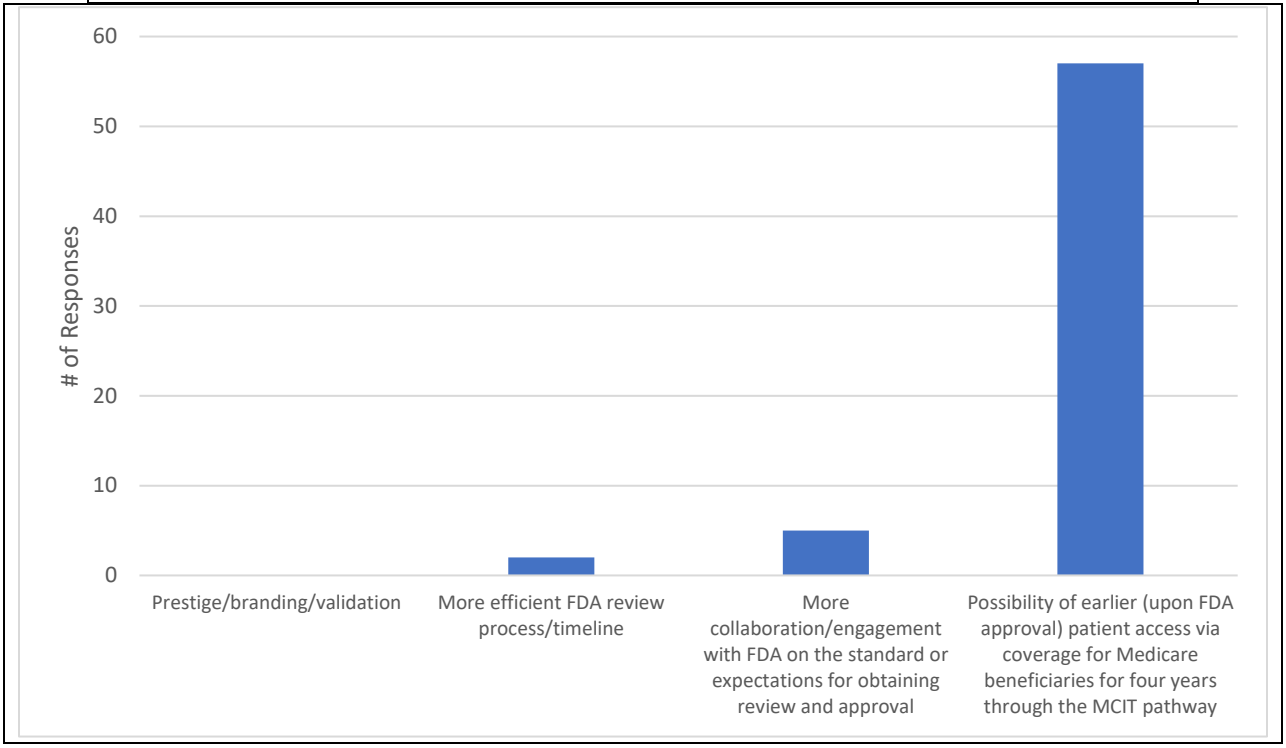
Contemplating implementation of the proposed MCIT pathway, investors were asked if they would be *more* willing to invest at earlier stages of medical technology product development than done so today if breakthrough products could receive four years of immediate Medicare coverage upon FDA approval. 95% of respondents agreed with the statement, with 88% saying they strongly agreed with the statement. With respect to FDA breakthrough device designation and MCIT implementation, 89% said that the possibility of earlier patient access via coverage for Medicare beneficiaries for four years through the MCIT pathway would be the most important potential benefit of receiving breakthrough designation.[5]

Survey question:
Please indicate your level of agreement with the following statement:
"If the proposed MCIT rule for Breakthrough Designated Devices is implemented and those products could receive four years of immediate Medicare coverage upon FDA approval, on average, I would be willing to invest at earlier stages of medical technology product development than I do today."



[5] Id.

Survey question:
With respect to FDA Breakthrough Device designation pathway, and if MCIT is implemented, what do you perceive is the most important potential benefit of receiving Breakthrough Designation?



NVCA Supports Implementation of the MCIT Pathway

NVCA was greatly encouraged by and supported the efforts of CMS to propose the MCIT pathway to provide four years of national coverage for FDA-designated breakthrough devices, a longstanding priority for the device community. The MCIT pathway seeks to resolve the significant challenges and uncertainties faced during the development of new products and devices, particularly in the earliest stages as described above. MCIT has the potential to bring major improvements to the U.S. healthcare system, including by encouraging greater long-term investment. In fact, MCIT and breakthrough products have been cited as considerations for investors assessing recent investment opportunities, ultimately resulting in commitments to companies that have received FDA breakthrough designation.[6] Implementing MCIT will provide immediate benefits for the Medicare population through delivery of transformative new products and make significant progress towards increased healthcare innovation.

[6] Justin Klein, Kirk Nielsen (NVCA Blog), *VC Policy Pulse: Medical Device Coverage Reform with Vensana's Justin Klein & Kirk Nielsen*, available at https://nvca.org/vc-policy-pulse-medical-device-coverage-reform-with-vensanas-justin-klein-kirk-nielsen/ ("In fact, we - like other investors – have already been proactively considering breakthrough products and MCIT as part of our assessment of new opportunities, and we recently made commitments to three companies that have received FDA breakthrough designation [].").

The decision to delay the March 15 implementation date is disappointing, particularly considering the agency has already taken adequate steps to undergo a sufficient notice and comment rulemaking, which generated a wide range of stakeholder comment submissions and engagement. The reforms that comprise the MCIT proposal are the result of a multi-year effort among multiple agencies, policymakers, and industry stakeholders who recognized the need to provide a path forward in solving the challenges in the reimbursement process. While the investor community appreciates this opportunity to reiterate strong support of the MCIT pathway, NVCA encourages the agency to implement MCIT and not further delay the May 15 effective date.

NVCA believes that the MCIT program will not impose a significant additional administrative burden on CMS, since the number of final approvals/clearances of breakthrough products will be only a fraction of products receiving breakthrough designation initially. First, we recognize the Technology, Coding and Pricing group at CMS (newly established last year to harmonize coding, coverage and payment processes for innovative technologies, such as Breakthrough Devices) will have the expertise to resolve operational challenges collaboratively with FDA and with sponsors by adapting current processes or developing new ones where warranted in sub-regulatory work. If resource availability is a concern, NVCA and its members would be pleased to work with CMS to find workable solutions that both protect the integrity of CMS's ability to appropriately code and assign payment to those breakthrough technologies using the MCIT pathway and ensure that those technologies are subsequently held to the same high standards our healthcare system expects for potential permanent Medicare coverage. Regardless, NVCA does not believe that these operational considerations should delay the availability of breakthrough therapies through implementation of the MCIT rule now as these therapies are urgently needed by patients.

Conclusion

The entrepreneurial ecosystem thanks you for the opportunity to comment on the MCIT pathway to further recognize 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 the timely implementation of these impactful changes.

Sincerely,

Bobby Franklin

Bobby Franklin
President and CEO