November 2, 2020

VIA ELECTRONIC FILING

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

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

Dear Administrator Verma,

On behalf of our nation's venture capital investors and the entrepreneurs they support, we greatly appreciate the opportunity to provide comments on the administration's efforts to create a new 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. The entrepreneurial ecosystem thanks you for your efforts to create a more effective coverage pathway for innovative medical devices and appreciates the opportunity to share the views and recommendations of the venture capital industry. We strongly support the establishment of the Medicare Coverage of Innovative Technology (MCIT) and offer refinements that will strengthen its effectiveness.

Introduction to venture capital and its economic contribution

The venture capital industry raises capital from a broad range of limited partners (LPs), such as endowments, foundations, pension plans, family offices, and fund-of-funds. That capital is then invested in great entrepreneurs with breakthrough ideas. Venture capitalists invest anywhere from the very early stage, where the startup has little more than an idea and a couple of people, to growth-stage startups, where there is some revenue coming in and the focus is on effectively scaling the business. Generally, a company leaves the venture ecosystem via an initial public offering (IPO), a merger or acquisition, or bankruptcy. There is often a misconception that venture capitalists are like other investment fund managers in that they find promising investments and write checks. But writing the check is simply the beginning of venture engagement; the hard work begins when a venture capitalist works closely with startups to help entrepreneurs turn their ideas into successful companies. The reality is that successful venture capitalists—whether in healthcare or other areas of the economy—do not just pick winners. They work actively with startups to help them throughout the company-building lifecycle over a long period of time.

Venture investors often support a portfolio company with multiple investment rounds generally spanning five to ten years, or longer as is frequently the case in healthcare. Venture capitalists commonly serve on the boards of portfolio companies, provide strategic advice, open contact lists, and generally do whatever needs to be done to help a company succeed. The hope of a venture capitalist is that all their startups succeed against huge risks and grow into successful companies, but the reality is that the majority fail.

Entrepreneurship is inherently a risky endeavor, but it is absolutely essential to the American economy. Successful venture-backed companies have had an outsized positive impact on the U.S. economy. According to a 2015 study by Ilya Strebulaev of Stanford University and Will Gornall of the University of British Columbia, 42 percent of all U.S. company IPOs since 1974 were venture-backed.[1] Collectively, those venture-backed companies have invested $115 billion in research and development (R&D), accounting for 85 percent of all R&D spending, and created $4.3 trillion dollars in market capitalization, 63 percent of the total market capitalization of public companies formed since 1974.[2] Specific to the impact on the American workforce, a 2010 study from the Kauffman Foundation found that young startups, most venture-backed, were responsible for *almost all* the 25 million net jobs created since 1977.[3]

It is quite clear that the American economy is dependent on the economic activity that comes from young firms scaling into successful companies. The rapid hiring, innovative product development, increasing sales and distribution needs, and the downstream effects all serve to push the U.S. economy forward. The American economy needs more of this activity to help deal with many of the challenges we see today. Historically, the United States has done an excellent job encouraging risk-taking and entrepreneurship, but it is imperative that policymakers, entrepreneurs, and venture capitalists work together to encourage entrepreneurship in our country.

Significance of venture capital in the healthcare startup ecosystem

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,

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[1] "The Economic Impact of Venture Capital: Evidence from Public Companies," Stanford University Graduate School of Business Research Paper No. 15-55, *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2681841.

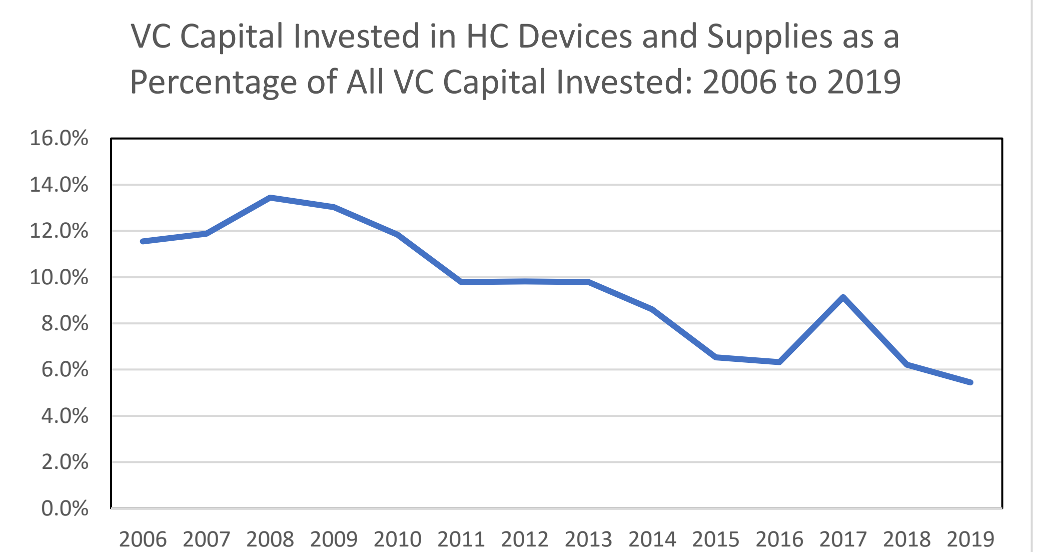
[2] Id.

[3] "The Importance of Startups in Job Creation and Job Destruction," Kauffmann Foundation Research Series: Firm Foundation and Economic Growth, (July 2010), *available at* http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2010/07/firm_formation_importance_of_startups.pdf.

having backed 42% of all FDA-approved drugs from 2009-2018 and impactful companies like Moderna, Intuitive Surgical, Amgen, Genentech, and many more.

In 2019, 1,487 life science companies nationwide attracted over $22 billion in venture investment, accounting for 17% of total capital invested and 14% of total deal count last year. On a relative basis, both of these metrics are a decline compared with 2010. However, on an absolute basis, 2019 life science dollars invested and deal count were 2.9x and 1.7x higher, respectively, than 2010.[4]

More recently, venture capital investment in healthcare innovation has come under pressure due to escalating time, cost, and uncertainty of new product development. Many venture investors cite misguided reimbursement policy as challenging the economics of medical device investing, resulting in a tremendous decline in investment and promising startups unable to raise the capital needed to grow and prosper. In 2009, $3.55 billion was invested in medical device companies which accounted for 13% of all venture deals that year. Ten years later in 2019, $7.22 billion was invested in medical device companies but only accounted for 5.45% of all venture deals that year.



Source: PitchBook-NVCA data

Furthermore, the below charts demonstrate the gradual decline in medical device companies receiving their first round of venture funding. Notably, medical device companies receiving first-time funding as percentage of total venture capital first time funding dropped from 8.4% in 2008 to 3.6% last year.[5] First-time funding is an important indicator of new company creation as it demonstrates the amount of companies receiving their first round of equity financing from an institutional venture capital investor.

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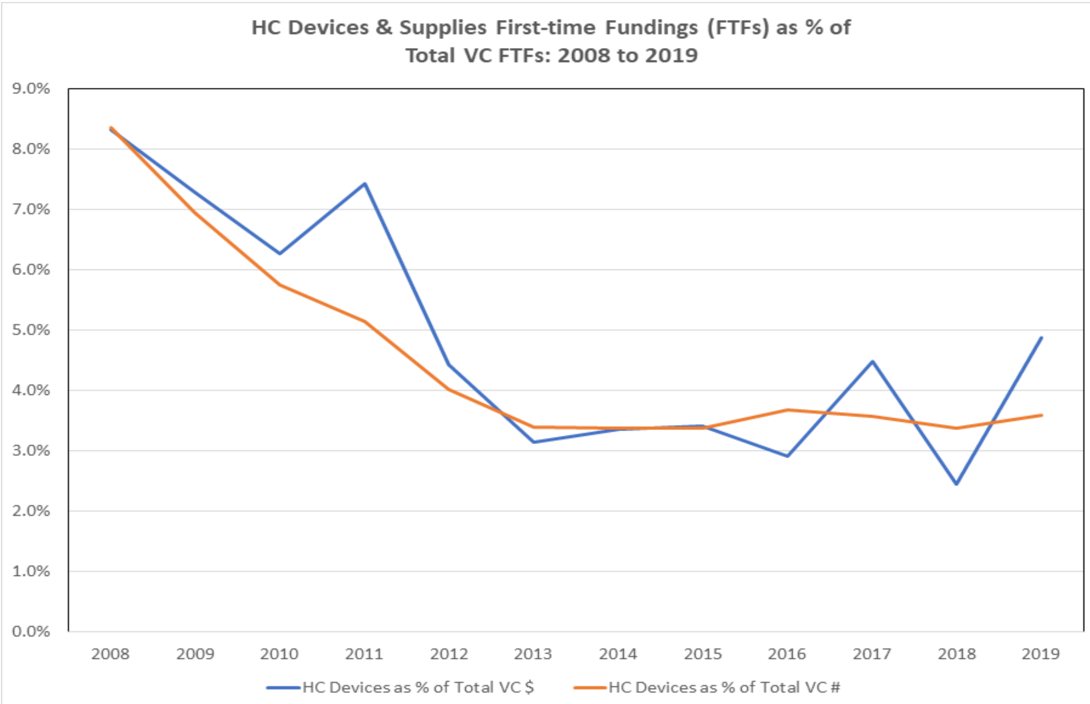
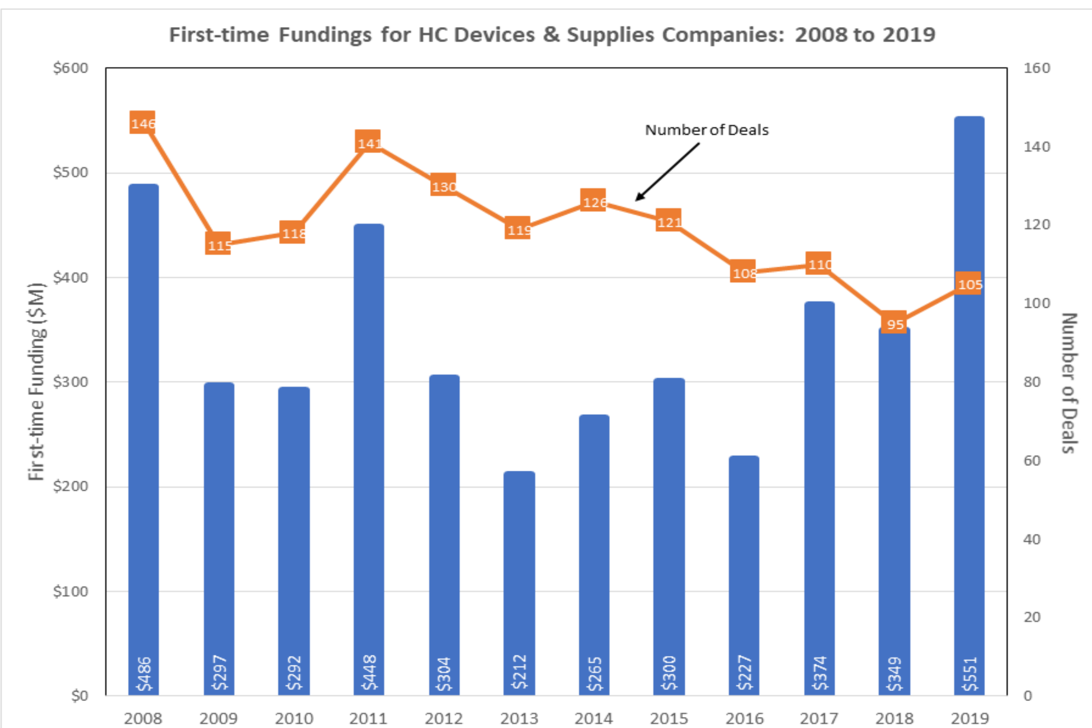
[4] Pitchbook – NVCA data.
[5] Pitchbook – NVCA data.



Source: Pitchbook-NVCA data



Source: Pitchbook-NVCA data

Medicare Coverage of Innovative Technology Pathway Proposal

NVCA appreciates the opportunity to provide feedback on the proposed coverage pathway for innovative medical devices. As proposed, the Medicare Coverage of Innovative Technology (MCIT) would provide four years of national coverage for devices that are FDA-designated breakthrough devices and are FDA market authorized. The coverage provided under this pathway would be voluntary and require the manufacturer to affirmatively opt-in to coverage, which would begin on the date of FDA market authorization.

NVCA commends the efforts of CMS to define a better coverage pathway for new technologies, an area in need of reform to address the unfortunate decline in investment in medical devices over recent years. The MCIT pathway approach would help 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 of the proposed MCIT pathway and respond to specific elements of the proposal. Below we offer recommendations to maximize the impact of MCIT and provide meaningful improvements for the medical device development and advancement process.

Expand the breakthrough designation requirement

NVCA encourages CMS to expand the MCIT pathway beyond the breakthrough designation requirement. To achieve this, we recommend a mechanism to apply the MCIT 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 the 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 have flexibility to provide coverage for a non-breakthrough designated device pursuing the MCIT pathway 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 and innovation for the Medicare population.

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

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 MCIT pathway to only recently approved devices will leave many companies stuck in limbo, which undercuts the aim of the 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 the 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, a time period proposed given the time needed to generate necessary data collection and a clinical evidence base.

Conclusion

The entrepreneurial ecosystem thanks you for recognizing the need to reform the complex process of bringing innovative, new medical products to market. Advancement of medical innovation is a priority we share to improve the lives of patients and overall healthcare opportunities. NVCA appreciates the opportunity to share input, and we look forward to working with you to implement these impactful changes.

Sincerely,

Bobby Franklin

Bobby Franklin
President & CEO