VENSANA CAPITAL

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April 16, 2021

Via Electronic Submission

Ms. Elizabeth Richter, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period [CMS–3372–IFC]

Dear Acting Administrator Richter:

Vensana Capital, a medical technology-focused venture capital firm based in Minneapolis and Washington, DC, is submitting this letter in response to the interim final rule delaying the effective date and requesting additional comment on the final rule establishing the MCIT coverage pathway for Food and Drug Administration (FDA)-designated breakthrough medical devices ("Notice of Delay").[1]

We urge CMS to move forward with implementation of the MCIT coverage pathway regulation starting on the delayed effective date of May 15, 2021.

MCIT is a sound strategy to improve healthcare access for Medicare beneficiaries. As we discuss in greater detail below, MCIT provides a valuable pathway to address the longstanding delays that Medicare beneficiaries continue to face in accessing critical, FDA-approved healthcare innovations that are responsive to serious unmet medical needs.

Furthermore, MCIT is an equally vital policy if CMS believes it can and should play a leadership role in fostering medical technology innovations that can improve healthcare quality at reduced costs to our system. These delayed timelines to patient access are not only unjust to Medicare beneficiaries, but the increased capital requirements necessary to support new technology innovation also impose significant burdens on a precariously strained medical technology innovation ecosystem. As some of the most experienced and active medical technology investors over the last 15 years, we can substantiate the challenges that medical technology innovators face while they develop products with the potential to impact patients' lives, and we understand why many investors – including ourselves – now balk at investing in early-stage companies due to the long timelines, substantial risk, and speculative returns afforded by these projects. We believe strongly that MCIT is an elegant solution that directly mitigates perhaps the most daunting challenge now faced by medical technology innovators and investors and that will help to ensure that there remains a robust pipeline of medical technology innovations that adhere to the highest standards of efficacy and safety in the world.

[1] 86 Fed. Reg. 4,542 (Mar. 17, 2021).

Vensana's Vantage Point

Vensana Capital is a venture capital and growth equity investment firm dedicated to partnering with entrepreneurs who seek to transform healthcare with breakthrough innovations in medical technology. Launched in 2019, our firm invests in development and commercial stage companies across the medical technology sector, including medical devices, diagnostics, drug delivery, digital health, tech-enabled services, and life science tools.

Our investment team has proudly supported dozens of entrepreneurs who have successfully developed first-in-class and best-in-class medical devices, diagnostics, and other healthcare technologies that have resulted in 17 PMA or De Novo 510(k) FDA approvals and more than 40 products introduced to the US market to date. We have led or co-led nearly every round of financing that we have participated in. We partner with our entrepreneurs as highly engaged members of their Boards of Directors and work closely with them to navigate the challenges of the medical technology innovation process. And we are strong advocates for the value of investing in rigorous clinical evidence to validate the safety, efficacy, and cost effectiveness of our companies' products. To-date, we have supported 34 multi-center randomized controlled trials to ensure that the products developed by our companies meet the highest standards of our patients and their physicians.

On a personal level, we see the technologies we invest in through the lens of our daily lives. We have experience caring for patients who died in the absence of further treatment options. We have family members who grapple with heart disease, diabetes, and cancer. And every day we celebrate our children who have thrived after premature birth thanks to modern medical technologies. Accordingly, we focus our passion on investing in breakthrough medical technologies that can impact healthcare outcomes for people as if our own family members depend on them, because sometimes they do.

MCIT Is About Ensuring Medicare Beneficiaries Have Access to the Proven Healthcare Innovations They Need

Americans, and certainly including Medicare beneficiaries, confront a seemingly endless list of serious unmet medical needs: COVID, coronary artery disease, cancer, COPD, diabetes, osteoarthritis, heart failure, end stage renal disease, atrial fibrillation, glaucoma, and so many others. For decades, we have relied on innovations in medical technology to provide solutions that save lives and restore health. Moreover, medical technology innovations can enable care delivery in safer, lower cost settings, address compliance and adherence challenges for patients, and extend care beyond the acute setting to more effectively manage chronic diseases. By their very nature, breakthrough devices that serve these unmet needs and that have met FDA's high standards are by definition "reasonable and necessary," and they should be covered for Medicare beneficiaries as soon as they are approved.

Having a complete reimbursement framework, including insurance coverage policies, is necessary to ensure that products and procedures are fully accessible to patients. Today, the process of obtaining new insurance coverage policies for novel medical technologies takes years after FDA approval and is fraught with risk and uncertainty. In the absence of a pre-existing coverage policy for a medical product or procedure—which, by definition, will be the case for a truly novel product—insurance companies nearly universally reject claim submissions from patients and their providers for as long as possible as a matter of business strategy. Despite some recent improvements to the Medicare coverage process, experienced medical technology investors expect that on average it will require an additional 4.3 years from FDA approval to obtain coverage and reimbursement to be developed for a novel medical product that will allow a business to be built and valued in a manner that could

support an exit.[2] This delay has forced seasoned medical technology investors to reconsider investments into novel products that won't be covered by existing policies, and more importantly, it has meant that American patients often wait many years for routine access to the diagnostics and therapies they desperately need.

MCIT provides an efficient, balanced solution for those highest value innovative breakthrough medical technologies by providing immediate coverage for four years for Medicare beneficiaries. MCIT complements alternative paths like Coverage with Evidence Development, Parallel Review, and National Coverage Determinations, which have good use cases but are infrequently used because of their unpredictability, timelines, and cost. In addition, MCIT preserves the incentives companies have to collect additional data that further validates their products as "reasonable and necessary" for Medicare beneficiaries in three important ways. First, companies will still be obligated to conduct the post-market studies that are required in conjunction with FDA approval. Second, the four years of coverage provided by MCIT is limited in duration, and companies will be motivated to convert that to permanent Medicare coverage in order to build businesses of sustaining value. And third, because Medicare patients are only part of the population that most products are intended to serve, companies are incentivized to continue to collect clinical and cost effectiveness data to convince commercial insurers that they should provide access to other patient groups.

Some have questioned whether the data gathered to support a breakthrough device's FDA approval will be sufficient to confirm the benefit/risk profile for Medicare beneficiaries when covered under MCIT. But breakthrough devices will only be covered according to the parameters of each product's label and indications for use, typically including a specified age range that FDA carefully deliberates based on evidence of benefit/risk and according to the highest standards.

While there may be operational considerations CMS must navigate with FDA and companies to ensure appropriate benefit category determinations along with specific coding and payments for products covered under the MCIT pathway, companies will be highly incentivized to collaborate with CMS in a pre-approval submission window that is generally very predictable. Similarly, CMS's expertise with benefit category determinations in the IDE approval process, as well as with coding and payment decisions for new technologies (e.g., through existing policies like the new technology add-on payment or the transitional pass-through payment), gives us confidence that these operational issues are manageable and would not justify delay in implementing MCIT.

Lastly, some people have wondered whether the growing number of breakthrough devices could somehow pose a problem. To the contrary, we should encourage and celebrate every innovation that strives to address critical unmet medical needs for patients and that does so in a manner that FDA qualifies as breakthrough and then approves. Patients need these therapies, and we should ensure that Medicare beneficiaries can access each one of them without delay. Due to the risks inherent in medical technology development, many breakthrough designated devices will ultimately fail to reach the market. Breakthrough designation can be awarded relatively early in a product's lifecycle, and significant attrition will result from product development challenges, unsuccessful clinical studies, and failure to meet FDA's high standards for approval. As a practical matter, the workload and cost of covering the select few breakthrough devices that we expect will achieve FDA approval and be relevant to Medicare beneficiaries is not only manageable, but should be a priority.

MCIT Provides CMS a Valuable Opportunity to Foster Medical Technology Innovation

CMS plays an essential role in the US healthcare system and has the opportunity with MCIT to provide leadership in fostering medical technology innovations that can improve healthcare outcomes at reduced costs to

[2] 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.

our system. For reasons we explain below, the early-stage medical technology ecosystem is in a precarious position, threatening the future pipeline of breakthrough device innovations that American patients and providers rely on.

We know the long road that a medical technology innovation must travel if it should ever be successful: defining the problem, ideation and invention of the solution, iterative product development and validation, rigorous clinical evidence generation, FDA regulatory approval, new reimbursement framework development with codes, payment, and insurance coverage policies to ensure patients have access to care, and market development with healthcare providers referring patients to well-trained specialists that can appropriately utilize innovative technologies.

We recognized a decade ago that burdensome FDA regulatory processes for studying, reviewing, and approving innovative medical devices and healthcare technologies were leading to a significant lag in Americans receiving timely access to life-saving innovations compared to patients in other countries. For example, in 2011 FDA approved the use of the first percutaneous aortic heart valve—the Edwards Sapien heart valve—more than four years after that product was first available in Europe.[3] The PARTNER trial of Edwards' Sapien device showed that for our most fragile elderly patients who were not candidates for an open surgical procedure for aortic valve replacement, the one-year all-cause mortality rate for patients receiving standard of care medical therapy was 50.7% compared to 30.7% for patients receiving minimally invasive, catheter-based valve replacement.[4] In other words, if the catheter-based valve replacement option had been available to everyone in need, 40% more lives could have been saved in each of the four years that Americans waited for approval. A remarkable success story, transcatheter aortic valve replacement has been performed in the US over 275,000 times since the Sapien valve was approved by FDA.

The Sapien story is not unique to novel medical devices and diagnostics. Frequently, and especially for our most novel and potentially transformative innovative healthcare solutions, the path from starting a company to getting an FDA approval can take many, many years. The chart below illustrates a number of examples of innovative medical technologies like Sapien that have proven their clinical value. It is important to note that each of these companies was a venture-backed start-up company, and many of their products took 10 years or more to reach FDA approval.

Product	Use	Venture Backed Company	Year Company Founded	FDA Approval Year	Years to Approval
CardioMEMS HF System	Chronic implantable heart failure monitor	CardioMEMS	2001	2014	13
FoundationOne	Genomic cancer test	Foundation Medicine	2010	2017	7
HF10	Spinal cord stimulator for chronic pain	Nevro	2006	2015	9
iStent	Minimally invasive glaucoma shunt	Glaukos	1998	2012	12
MitraClip	Mitral valve repair	Evalve	1999	2013	13
Sapien Valve	Aortic valve replacement	PVT Technologies	1999	2011	12
tSlim Pump	Diabetes	Tandem Diabetes	2006	2019	15

[3] Scott Gottlieb, *How the FDA Could Cost You Your Life*. The Wall Street Journal, October 3, 2011.

[4] Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. The New England Journal of Medicine, 2010; 363:1597-1607.

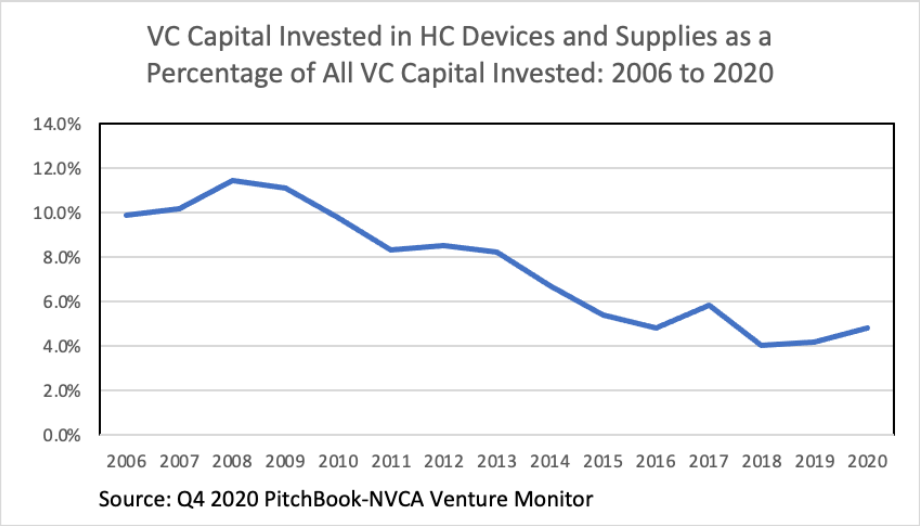
When the average duration of a venture capital partnership is 10 years, but development timelines and regulatory reviews can consume 12-15 years for innovative products, the economics necessary for entrepreneurs to start companies and for venture capitalists to support early-stage investment in novel medical technologies break down.

For private, venture-backed medical device start-up companies, the average value for a company that successfully exited via acquisition was $210 million in 2020.[5] Those exits could come at any point in a company's life, but in general, they happen after clinical evidence has validated the product and procedure, and typically after a company's product has received FDA approval. But for truly novel technologies that do not fit within an existing reimbursement framework with insurance coverage policies, a business cannot be built or valued adequately until a supportive reimbursement framework is created and patients and physicians can access the technologies they need. As described above, this additional work consumes significant time and money. In a recent survey of active medical device venture capital investors, respondents estimated that an additional $60.9M in investment capital will be required to support venture backed companies once they have received FDA approval through the reimbursement development process and to an exit.[6] In many cases, this total timeline—from founding the company through FDA approval and then through the process of establishing coverage policies for patients like Medicare beneficiaries—can exceed 15 years and $200M in total required capital.

When the average venture fund is only 10 years in duration, and when 3-4 of those years are consumed trying to identify attractive investment candidates, not to mention accounting for development timeline delays that inevitably occur with these projects, investors can only reasonably consider investing in the last 5-6 years of this journey. As the total projected capital requirement of $200M for a novel innovation without access to an existing reimbursement framework approaches the average exit value for *successful* companies, one can quickly see why it is arguably irrational to initiate a venture investment in the early stages of product development in this sector. It is for this very reason that our investment strategy at Vensana is currently biased toward mid and late-stage opportunities. When asked about the earliest stage at which they would be willing to invest in a start-up company that needs to navigate this entire path, our peers agree: 76% of active medical device investors indicated they would not typically invest until after product development and clinical evidence generation was complete and a company is at least prepared to submit for FDA approval.[7]

This chart shows the result at a macro level: a 50% decline in venture capital dollars allocated to medical devices and supplies relative to the total dollars invested by venture capital investors over the last 15 years.

[5] Silicon Valley Bank, Healthcare Investments and Exits: Annual Report 2021.
[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.
[7] Id.



As capital will flow towards the opportunities with the most attractive risk/reward potential, this data reflects the declining relative attractiveness of investing in the early stages of novel medical device development compared to other things like Bitcoin, Fortnite, and cat GIFs. And this dearth of capital for early-stage medical technology companies is not just a challenge for medical device entrepreneurs and investors—it is a problem for our healthcare system and our society at-large.

Fortunately, there are solutions. Recognizing the potential cost of extended timelines to market for innovative technologies like the Sapien transcatheter aortic valve, FDA has made significant efforts to streamline its processes and improve its transparency and responsiveness with patients, physicians, and innovators. Multiple initiatives, including the Breakthrough Devices Program created with bipartisan support by the Obama Administration under the 21st Century Cures Act, have shortened the timeline for life-saving medical technology innovations to navigate the road from invention to FDA approval while not lowering the bar for the highest FDA standards for assurances of safety and efficacy. These policies have at least helped stop the declining relative allocations of venture capital dollars to medical devices and supplies to a 4-5% level since 2018.

Unfortunately, FDA approval is not the last hurdle that breakthrough therapies like percutaneous heart valves must overcome to reach the patients in need on a widespread basis. For those of us on the frontlines shepherding medical technology innovation to market, we know that coverage and reimbursement can be the most challenging and least predictable of all obstacles to overcome. In a 2021 survey of the most active medical technology venture capital investors, 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.[8] Specifically, 92% of these investors say that they would be less willing or unwilling to invest in an early-stage company if the novel product it is developing requires a new reimbursement paradigm.

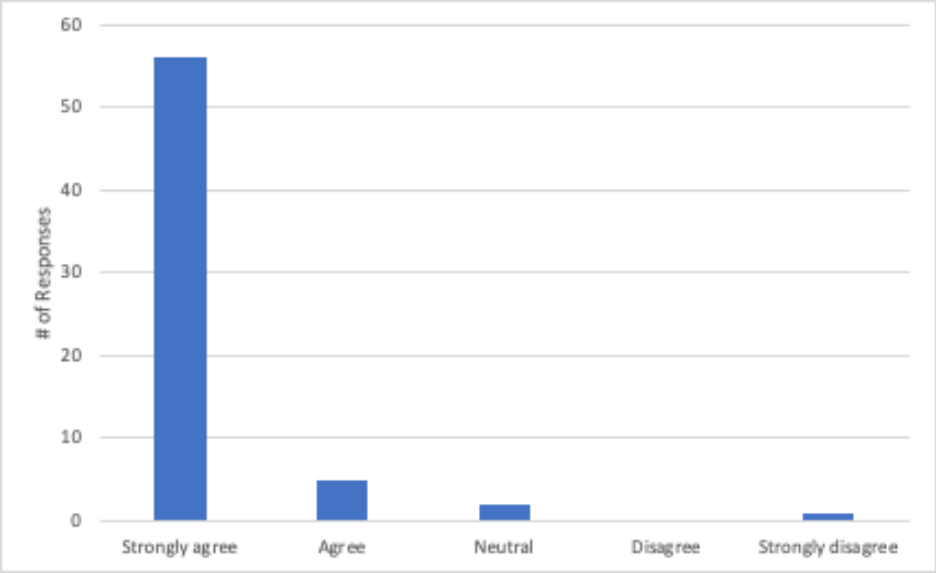
CMS has an opportunity to support the innovation ecosystem, and MCIT is directly responsive to these concerns in a balance, efficient way. MCIT creates incentives that align with patient needs to ensure that entrepreneurs and investors will pursue development of novel innovations that can be the most time and capital intensive, but also the most clinically impactful. This premise has been endorsed by active medical device investors: when asked if they would be *more* willing to invest at earlier stages of medical technology product development than done so today if breakthrough devices could receive four years of immediate Medicare coverage upon FDA

[8] 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.

approval, 95% of respondents agreed with the statement, with 88% saying they strongly agreed with the statement.[9]

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."



MCIT is a necessary companion solution to FDA regulatory reforms that help the 21st Century Cures Act achieve its intended mission: ensuring that Medicare beneficiaries aren't denied or delayed in receiving access to important, clinically validated technologies once they have been approved by FDA. When FDA designates an innovative medical technology as breakthrough, they are affirming that this innovation has the potential to serve as a more effective diagnosis or treatment of life-threatening or irreversibly debilitating diseases or conditions. And once approved or cleared by FDA—meeting the highest standards for a medical product's assurance of safety and effectiveness—we believe patients have a right to insist on access to these technologies.

Sincerely,

Justin Klein, MD, JD
Co-Founder and Managing Partner
Vensana Capital

Kirk Nielsen
Co-Founder and Managing Partner
Vensana Capital

[9] Id.