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April 09, 2021

Ms. Elizabeth Richter/Ms. Chiquita Brooks-LaSure (Brooks-LaSure, if confirmed by April 16)
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

RE: CMS-3372-IFC - Comments on the Interim Final Rule (IFR) Proposed Delay of Medicare Coverage of Innovative Technology (MCIT) and the Definition of "Reasonable and Necessary"

Dear Acting Administrator Richter:

DuVal & Associates, P.A. respectfully submits these comments on behalf of the Minnesota Medical Device Alliance (MMDA), an unincorporated, voluntary affiliation of pre-revenue, small and mid-tier medical device companies, venture capitalists and some inventing physicians. We are responding to the public invitation of the Center for Medicare & Medicaid Services (CMS) to comment upon the proposed delay of the Interim Final Rule and requesting comments on the recent final rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary."[1] Our members are laser focused upon the unmet needs of patients where the current armamentarium of medical device technologies (including diagnostics) is not meeting those unmet needs.

Our goal is to provide overarching comments to the proposed IFR. We disagree with the delay in the MCIT, set to take effect on May 15, 2021, as it would have a deleterious impact upon our members who create these innovative technologies and who have detrimentally relied upon the commencement of this program. We do also understand that CMS must contend with and address the definition of "reasonable and necessary" under current CMS rule, but we respectfully request that those issues be decoupled for the time being. Our focus remains on being supportive of the timely commencement of the MCIT program.

Any delay in breakthrough technologies is an inherent loss for mankind and Medicare beneficiaries in particular. The intent of FDA's Breakthrough Designation was to speed access and improve availability of important technologies. The current system hampers adoption of new technologies, by failing to provide expeditious reimbursement, and MCIT will support the original aim of the program. Patients deserve the very best technologies our industry can offer. The irony is that U.S. medical device companies still invent the vast majority of medical device innovations in the world, but U.S. patients are often the very last patients in the world to enjoy the benefits of them because of our combined regulatory processes for approval and

[1] *Federal Register,* Vol. 86, No. 50, pp. 14542, et seq, March 17, 2021; *see* https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf

reimbursement. A finalized and implemented MCIT has the prospect of dramatically improving that current reality. The rule allows CMS time to evaluate a permanent decision on a treatment. This will allow patients access to lifesaving and life-sustaining breakthrough treatments to Medicare patients in need. Our view is that the number of eligible devices for the MCIT program should not delay final implementation of this rule. We must all stay focused on goal of the program, i.e., to provide increased access to safe and innovative medical technology that are a significant improvement over existing available therapy.

Our members need MCIT. Our members are the lifeblood of new medical technology which increasingly does not come from the large, publicly-held, companies known in the industry as "Strategics." Most breakthrough technologies are the product of angel and venture-backed companies that identify an unmet clinical need and invent a solution that addresses that need. As entrepreneurial companies that rely upon financing, the ecosystem in which they operate is expensive, time-consuming and difficult. Every company must contend with the FDA to obtain clearance or approval. While market access is critical and a threshold step, it is perhaps even more daunting and potentially debilitating to obtain CMS reimbursement. Without reimbursement, great medical technologies often do not come to fruition because the failure to achieve market success with adequate reimbursement disincentivizes inventors and investors whose investment of time, talent and treasure is not endlessly replenishable.

The regulatory path for new medical device technologies is daunting. Investors in these technologies are keenly aware of the regulatory gauntlet every device must run through—first the FDA and then CMS to be properly commercialized. These regulatory barriers to market entry are critical and valued but they can also create serious impediments to the successful evolution from a back-of-the-napkin invention to a real-life product helping patients and their physicians. Sometimes the regulatory processes and the people who run them can be the most difficult obstacle that stands between patients and these inventions. Delays in product clearances/approvals and reimbursement can elongate the time to develop, study, manufacture, launch and obtain reimbursement for these technologies. These delays can result in investor fatigue which signals to the capital markets that investment may be more effectively deployed to making non-medical device "widgets," rather than suffering through the regulatory processes of FDA and CMS. Well-intentioned governmental agencies often seem to lack awareness of the impact their decisions and timelines can have on the ecosystem which exists and the effort it takes to marshal these technologies through the regulatory processes to real live patients in real live settings.

The past can inform the future. When Congress passed the Food and Drug Administration and Modernization Act of 1997 (FDAMA), it was concerned with FDA's regulatory performance and impact upon innovative new therapies and American jobs. The 1997 Senate Report stated the following (emphasis added):

> These increases in the time, complexity, and cost of bringing new products to market are borne directly by the public, in delayed access to important new products--including life-saving medical therapies--and in higher costs. ***They are a growing disincentive to continued investment in the development of innovative new products and a growing***

> ***incentive for American companies to move research, development, and production abroad, threatening our Nation's continued world leadership in new product development, costing American jobs, and further delaying the public's access to important new products.***

While these comments were targeted to FDA, the same can be said about the 21st Century Cures Act and CMS. Over the past 25 years, a bipartisan consensus has emerged on the need for reforms of the FDA and CMS to strike a better balance between the need to ensure that products are safe and effective, on the one hand, and to facilitate the timely availability of and payment for new products, on the other. The MCIT rule falls into that category of needed regulatory improvement of the kind that feeds, not starves or kills, innovation and investment in innovation so critical to improving patients' lives. It is notable these things were predicted in 1997 and they are, unfortunately, coming to fruition today despite the best intentions of the FDAMA and the 21st Century Cures Act legislation. Industry has clearly lost ground to a burgeoning and increasingly difficult bureaucracy. Patients often wait for years before gaining access to potential lifesaving or quality of life improving treatments, resulting in a considerable gap in coverage.

Our members were buoyed by the enactment of the 21st Century Cures Act in 2016 under the Obama/Biden Administration, which among other things, advanced medical device innovation by creating a new FDA program to expedite the approval of diagnostics and devices that represent breakthrough technologies and to promote their use in health care delivery. We also appreciated that AdvaMed and the Medical Device Manufacturers Association (MDMA) supported the inclusion of provisions that would have created a streamlined approach to coverage, coding and payment for those innovations, but Congress did not include such language in the statute at that time. CMS began creating new pathways, such as the new technology add-on payment (NTAP) pathway, to ensure breakthrough products would receive faster and enhanced reimbursement.

This culminated in the MCIT rule that was finalized on January 14, 2021 under the Trump Administration. This was a bold initiative which demonstrated CMS's support for new innovation and the companies that invent breakthrough products.

We also note that the positive benefit of MCIT in the investment community. When our members were able to tell prospective or current investors that they were able to achieve FDA Breakthrough Designation it made funding of technologies that much easier. The FDA's imprimatur on a technology through the Breakthrough Designation clearly carries weight in the investment community. When you couple that designation with the MCIT program, CMS had clearly provided an enormous saleable bonus to potential investors to know that, upon clearance or approval, a medical technology would automatically be given reimbursement for four years. This added benefit cannot be under-estimated.

The MCIT has already been open for public comment, it need not be delayed. The MCIT program has already been publicly vetted. It enjoys widespread support. The process was

deliberative and thorough and took into consideration a wide variety of opinions leading into the final rule.

In conclusion, we greatly appreciate the opportunity to comment on the MCIT IFR. We ask that CMS not abandon its previously expressed commitment to ensuring access to innovative new technologies that will improve the lives of patients with debilitating conditions. We defer any discussion of the proposal to codify the definition of "reasonable and necessary" at this time except to propose it be decoupled from the discussion surrounding the MCIT provisions of the IFR. If you have questions regarding these comments or if you require additional information, please contact me at duval@duvalfdalaw.com or 612.338.7170 x102, or Bryan Feldhaus, Senior Associate, at feldhaus@duvalfdalaw.com or 612.338.7170 x103.

Respectfully submitted,

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