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April 2, 2020

Via Electronic Submission

The Honorable Steven Mnuchin
Secretary of the Treasury
U.S. Department of Treasury
1500 Pennsylvania Avenue N.W.
Washington, D.C. 20220

The Honorable Jerome Powell
Chairman of the Board of Governors
Federal Reserve System
20th Street & Constitution Avenue N.W.
Washington, D.C. 20551

**RE: Recommendations to Make the Main Street Business Lending Program
Effective and Efficient**

Dear Secretary Mnuchin and Chairman Powell,

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing hundreds of innovative and entrepreneurial companies in the field of medical technology, I want to thank you for your coordinated and decisive action to address the unprecedented economic challenges our country is facing as a result of the COVID-19 pandemic. Initiatives underway at the Department of Treasury and the Federal Reserve will serve as the financial backbone to support and help small, medium and large companies. More importantly, the programs enacted under the Coronavirus Aid, Relief, and Economic Security (CARES) Act will help their employees weather this crisis, while empowering our members to continue developing lifesaving and life-changing medical technologies, and bridging the gap with necessary liquidity that will allow our economy to thrive once again. I am writing to provide recommendations that will ensure the Main Street Business Lending Program (“Main Street”) functions in an effective and efficient manner to address the critical financial needs of companies adversely impacted by the COVID-19 pandemic.

MDMA provides educational and advocacy assistance to innovative and entrepreneurial medical technology companies, and it is our mission to ensure that patients have timely access to safe and effective medical products that improve health outcomes. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering innovative therapies to patients suffering from chronic diseases and life-threatening conditions, while lowering the cost of care. Our industry is responsible for significant advances in patient care over the years, including transcatheter heart valves, implantable cardiac defibrillators, cochlear implants and countless other innovations. Such advances have vastly improved treatments for medical conditions like heart disease, cancer and stroke – annually among the leading causes of death for Americans each year.

Small to mid-sized medical technology companies are an integral part of the medical device industry ecosystem and responsible for a majority of the truly novel and disruptive medical technology innovations that have improved the way of life for so many patients. These efforts can take many, many years and hundreds of millions of dollars before an idea can ultimately reach patients and address unmet needs. It also takes decades or more for these highly regulated and capital-intensive companies to reach profitability and even longer to reach sustainability. Given that many of our companies have not yet reached these thresholds, the current health and economic crisis requires swift and meaningful action.

As you can imagine, the road for these small to mid-sized medical technology companies includes a significant number of challenges in the best of times. However, the COVID-19 pandemic has materially increased these uncertainties. Like many other sectors of our economy, the pandemic is adversely impacting many of our members' businesses. At a White House Task Force Press Briefing on March 18th, Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma announced a federal directive recommending a deferral of all adult elective surgeries, non-essential medical, surgical, and dental procedures during the COVID-19 response. We understand the necessity of these actions and support them; however, we also believe reciprocal action is warranted to ensure that the companies MDMA represents, which also supply the products for these deferred procedures, can survive until COVID-19 countermeasures are lifted and elective procedures are allowed to resume.

The situation has created a tremendous amount of uncertainty as these innovators seek to move forward and improve patient care. Companies that were already running lean operations are now faced with the reality that absent immediate and meaningful assistance under this program, countless layoffs will result, and some will be forced to shut down. Importantly, our industry is responsible for over 2 million jobs in the United States, including some of the higher paying non-executive jobs and a significant number of high paying manufacturing jobs – all of which are at risk during this economic crisis. Companies have also been forced to pause clinical trials because they can no longer access hospital sites or track patients due to the deferral of elective and other procedures. This has led to the realization that previous timelines to commercialization and/or expansion will be extended for an uncertain amount of time, at least for the foreseeable future. Expensive clinical trials that have been delayed are creating added pressure on already finite cash burns. For companies that have commercialized, the federally directed deferrals of elective procedures have disrupted cash flows and resulted in significant drops in revenue as health providers wait for elective procedures to resume.

MDMA's small to mid-sized members are very interested in the Main Street program announced by the Federal Reserve on March 23, 2020. This commitment, coupled with Congressionally appropriated funds under the "CARES Act," will provide critical liquidity to small and mid-sized businesses adversely impacted by the COVID-19 pandemic.

In an effort to realize the full impact of the Main Street program and the Administration's desire to ensure liquidity for all small to mid-sized businesses that need it, we strongly encourage the Treasury to adopt the following elements:

- 1) Utilize banks with existing relationships to execute loans for small to mid-sized companies;

- 2) Criteria for loan amounts would be based upon the estimated amount of revenue lost as a result of COVID-19 pandemic OR the operating expenses required to keep the business sustainable during the COVID-19 pandemic;
- 3) Loan applications would be simple (1-2 pages) and processed quickly with funds available within 1 week of filing;
- 4) Loans would be unsecured and subordinate to any other loans;
- 5) Participating banks would be 1) required to provide such loans outside of any existing debt covenants and not accelerate any existing covenant provisions, and 2) prohibited from increasing interest rates on any existing loans due to perceived increased risk;
- 6) Loans would be structured as cash or paid-in-kind interest, due upon a change-in-control or after any existing credit facilities; and
- 7) Loans would not be overly restrictive, including limitation that increase the amount of debt required to stay afloat. We encourage the administration to allow companies to utilize the necessary tools to lower the amount of debt needed for liquidity and sustainability.

Thank you for the consideration of our comments and perspectives. I hope you will move quickly to implement the Main Street program to ensure that small and mid-sized medical technology companies and their employees can continue their important work to improve patient care.

Please email me at mark.leahey@medicaldevices.org with any follow up questions, concerns or clarifications.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. Leahey", with a stylized flourish at the end.

Mark B. Leahey
President & CEO, MDMA