MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street, NW
Suite 400W
Washington, DC 20005
Phone (202) 354-7171
Fax (202) 354-7176
www.medicaldevices.org

February 16, 2018

Via Electronic Submission – opioids@finance.senate.gov

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

RE: Comments on Opioids Misuse and Improved Pain Management

Dear Chairman Hatch, Ranking Member Wyden and Honorable Members of the Committee:

On behalf of the hundreds of innovative medical technology companies represented by the Medical Device Manufacturers Association (MDMA), I thank you for seeking comments on policy recommendations to address the root causes of the opioid abuse crisis and to improve pain management for Medicare and Medicaid beneficiaries. I am pleased to provide MDMA's perspective and recommendations on how medical technology should play a role in addressing the opioid epidemic that is crippling our nation. We believe that any successful response to the epidemic must include policies to both reduce patient exposure to potential risks of opioid therapy as well as more effectively treat pain through FDA approved, evidence-based, non-opioid treatments. Medical technology has a critical role to play in curbing opioid use, abuse and improving acute and chronic pain treatment, but many patients are being denied access to these therapies as a result of polices by the Centers for Medicare and Medicaid (CMS) and private insurance companies. The current incentive structure promotes dispensing large amounts of opioids versus utilizing proven medical technologies. We must all work together to change this dynamic.

MDMA's mission is to ensure that patients have timely access to the latest advancements in medical technology. The majority of innovations in the industry are developed by small, research-driven medical device companies, and according to the Department of Commerce, 80 percent of medical device companies have fewer than 50 employees. The innovative companies we represent are developing technologies that can help patients manage their pain more effectively than opioids. If more widely utilized, this would mitigate the risk of addiction and help patients recover more quickly from less invasive procedures obviating the need for large opioid prescriptions, and better manage the disposal of potent drugs.

The opioid crisis continues to devastate too many American families and communities. Today, drug overdose claims the lives of more Americans than HIV did at the height of the AIDS epidemic. Many times, the root cause of a dependence upon or abuse of opioids comes from pain. Pain is a debilitating problem with enormous individual and societal costs. Pain affects more Americans than heart disease, diabetes and cancer combined, and is the most

common reason Americans access the health care system as well as the number one cause of disability. Chronic pain and opioid misuse together cost the U.S. economy more than $1 trillion annually.

Despite scarce clinical data on the efficacy of long-term opioid use, health care providers continue to prescribe opioids as front or second-line therapy before referring patients to pain specialists. Polices are needed to change the broken incentives that have driven providers and payers' overreliance on opioids and revise reimbursement policies to promote coordinated and evidence-based pain care. We believe that efforts to combat the epidemic moving forward should take a more holistic view, one that considers the root cause – pain – first, and prioritize non-pharmaceutical therapies, like medical technology, that can play a role in mitigating the need to prescribe opiates to patients in the appropriate setting. As Congress investigates and legislates on this critical issue, wider adoption of medical technology solutions need to be part of the national conversation.

Healthcare leaders are recognizing the role that medical technology can play. We are encouraged by Food and Drug Administration (FDA) Commissioner Scott Gottlieb's testimony before the House Energy & Commerce Committee in which he detailed the promise of medical technology to treat chronic and acute pain. Dr. Gottlieb specifically stated:

> "So there are very interesting, very promising technologies available that could potentially treat chronic and acute pain in ways that don't lead to the same addiction. And also offer that there's a lot of medical device alternatives. We've approved about 200 different medical devices that have components to treat pain, about ten of those are very novel devices, and so we see a lot of opportunity looking across the continuum to medical devices as well to help address painful syndromes, locally rather than systemically."

The President's Commission on Combating Drug Addiction and the Opioid Crisis identified "medical technology devices" as having a role to play in efforts to combat the crisis. Specifically, the report called for encouraging research and development in new technologies and devices to assist in the opioid crisis. These included a number of traditional medical technologies as well as the emerging field of "wearables" and digital health products that can aid in the management of chronic and acute pain manifestations. Technology can also play a role in managing supply chain issues, and we are excited about the opportunities to contribute in this area as well. Specifically, the President's Commission made two recommendations, listed below, which we support and look forward to working with Congress to implement in order to combat the crisis.

> Recommendation # 54: The Commission recommends further research of Technology-Assisted Monitoring and Treatment for high-risk patients and substance use disorders (SUD) patients. CMS, FDA, and the United States Preventative Services Task Force (USPSTF) should implement a fast-track review process for any new evidence-based technology supporting SUD prevention and treatments.
>
> Recommendation #55: The Commission recommends that commercial insurers and CMS fast-track creation of Healthcare Common Procedure Coding System (HCPCS) codes for FDA-approved technology-based treatments, digital interventions, and biomarker-based interventions. NIH should develop a means to evaluate behavior modification apps for effectiveness.

MDMA recently established a pain management working group within our membership tasked with identifying therapies that could serve as an alternative to opioids to treat pain as well as obstacles to greater adoption of those technologies.

While not an exhaustive list of all the technologies currently in the marketplace or being developed, below are just a few technologies that treat chronic and acute pain and serve as, in certain instances, an alternative to opioids.

Cryoablation:

- Temporary freezing of nerves at incision site during surgery for post-operative pain management;
- The procedure adds up to 15 minutes per surgery;
- Potential benefits include reduction in the need for post-surgery opiate pain medication, less patient pain, reduced length of stay, and quicker recovery.

Continuous Peripheral Nerve Block (cPNB):

- Uses an infusion catheter to pump anesthetics during a procedure, which reduces pain during and after a surgery.

Implantable Drug Pumps:

- Delivers pain medication directly to the fluid surrounding the spinal cord;
- Greatly reduces the amount of opioids needed to relieve pain.

Less Invasive Surgical Procedures:

- Patients who are in chronic pain can often be treated effectively using minimally invasive surgical procedures. Many of these can be performed in an hour or less. For example, 31 million people in the United States suffer from lower back pain each year. Many peer-reviewed technologies can address this problem, but they are not covered by payers, denying patients access to life-changing therapies. Studies show less invasive procedures lead patients to having an 11-times less likelihood of reliance on opioids.

Peripheral Nerve Stimulation (PNS):

- Using a chip emitting electrical pulses to stimulate cranial nerves to block withdrawal symptoms.

Radio Frequency Ablation (RFA):

- A special needle is inserted into the area of pain and a radiofrequency current is created and delivered to the pain nerve providing 6 – 12 months of ongoing pain relief.

Spinal Cord Stimulators (SCS):

- Minimally invasive neuromodulation treatment that uses electrical signals to block pain signals from reaching the brain;
- The system is minimally invasive and is trialed for efficacy before a patient receives a permanent implant;
- SCS has helped 500,000+ patients who have reported a 50 percent or greater reduction in pain and use of pain medication, improving quality of life and reducing disability.

Several federal agencies have now recognized the urgent need to address chronic pain as a part of the comprehensive strategy to curb the opioid epidemic, and we have been encouraged by bipartisan efforts in Congress as well as the President's recent budget request to find solutions to the crisis, including calls for additional funding to the National Institutes of Health (NIH) to develop alternative treatments and empower FDA to fast track these technologies. We believe the Committee should improve upon the policy frame work of the Comprehensive Addiction and Recovery Act (CARA) to include proposals contained in the NIH's National Pain Strategy, HHS' Opioid Strategy to advance the practice of pain management and FDA's Opioid Initiative to promote non-opioid pain therapies. These policies would improve models of pain care, modify reimbursement strategies and promote patient and provider awareness about evidence-based opioid treatment alternatives. We encourage the Committee to hold a pain specific hearing to examine these federal initiatives, pain management best practices, and break down barriers to non-opioid treatments to improve pain management. The medical device industry is also hopeful that a robust pain title advancing the practice of pain management to enable access to high-quality, evidence based medical technology will be included in any follow-up legislation to CARA.

As we have detailed, there are many medical technologies currently cleared or approved by the FDA with clinical data to support the ability to treat chronic or acute pain. Unfortunately, greater adoption of and patient access to these technologies is impeded due to 1) prescribing practices and reimbursement incentives that prioritize lower cost therapies on the front end, like opioids, but ultimately cost the healthcare system more to manage the dependence and/or addiction of the patient vs. a non-pharmaceutical treatment like medical technology and 2) coverage, coding and payment policies that create barriers to access by public and private payers. To aid in the Committee's efforts, we will focus on barriers at the Centers for Medicare and Medicaid Services (CMS) and not private payers but want to acknowledge that there are private entities with overly restrictive, opaque and inconsistent coverage policies that block access to innovative technologies for patients who are in pain.

More and more, our members are experiencing an unacceptable lag time between regulatory approval and clearance for their technologies, and securing fair and adequate reimbursement. This growing challenge refers to when medical technologies have been approved by the FDA, but can take 2 – 5 years to be adequately reimbursed and accessible to patients and providers. In fact, we recently conducted a survey of our members, in which 78 percent of respondents indicated that coverage policies have worsened over the past two years. Sadly many of the technologies that are inaccessible to patients and providers due to reimbursement challenges, have clinical data to support and fit a benefit category of being able to treat chronic and acute pain. In addition to continuing to raise awareness of medical technologies as an alternative to opioids, prioritizing devices in legislative efforts to combat the crisis, and holding a pain specific hearing, we believe addressing this reimbursement challenge is perhaps the most critical issue the committee can address to spur greater adoption and patient access to medical technologies to treat chronic and acute pain. We are aware of specific examples of patients being denied access to technologies with clinical data to support indications to treat chronic and acute pain and are happy to share those with the committee; however, in response to your letter, we

will focus on more general recommendations to the questions that you are seeking feedback on below.

1. **How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?**

   Medical devices and medical technology therapies have a demonstrated ability of being able to treat chronic and acute pain. FDA Commissioner Dr. Scott Gottlieb has stated that over 200 different medical technologies with components to treat pain have been approved. FDA approval requires a rigorous and time consuming regulatory process to determine if a device is safe and effective. Unfortunately, much of the evidence data required for regulatory approval does not translate into evidence needed for Medicare or Medicaid coverage. For many small companies that rely on an increasingly finite pool of venture capital money, the inability to gain coverage with CMS and establish a revenue stream to fund additional evidence generation can keep a promising technology from benefitting patients. Increasingly, private payers are following the lead of CMS and automatically deny coverage without a coverage determination from CMS. For small companies trying to bring a new technology to the market, this has become a tremendous barrier to patient access. CMS has policies in place in an attempt to bridge this gap; however, for small companies the cost and risk associated with participating is prohibitive. CMS should reform processes to allow for provisional coverage of medical technology after FDA approval or clearance in order to allow companies to gather additional evidence needed for a permanent coverage while improving patient access to technologies to treat chronic and acute pain.

   CMS should also prioritize technologies that can treat pain as a part of ongoing efforts to improve quality. This is something that the Center for Medicare & Medicaid Innovation (CMMI) could look into as a part of ongoing efforts and initiatives to develop innovative payment programs and should reward those that utilize non-opioid pain management solutions like medical technology.

2. **What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?**

   In addition to the reimbursement concerns that we mentioned in our general comments and in response to question #1, our members have identified specific barriers as it relates to coding and payment incentives that currently drive physicians away from non-pharmaceutical alternatives, like medical devices.

   For example, CMS could administratively update codes that would immediately drive more utilization of non-pharmaceutical therapies while others have provided recommendations on how hospital Medicare Severity Diagnosis Related Group (MS-DRG) payment bundles could be split into separate payments, prioritizing those that utilize non-pharmaceutical therapies and technologies during procedures for pain

management. In addition, CMS could create a new Current Procedure Terminology (CPT) code for non-pharmaceutical technologies like medical devices to treat pain that would drive greater patient and provider access.

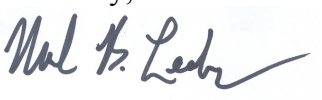
Also, as mentioned in our general comments, the President's Commission on Combating Drug Addiction and the Opioid Crisis report recommended that CMS fast-track creation of Healthcare Common Procedure Coding System (HCPCS) codes for FDA-approved technology based treatments, digital interventions, and biomarker-based interventions.

3. **How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?**

   In addition to our responses in questions #1 & #2, which call for narrowing the gap that many companies experience between regulatory clearance or approval and establishing adequate reimbursement, updates to MS-DRG, CPT, HCPCS and other codes that incentivize non-pharmaceutical pain management alternatives, like medical devices, we believe the U.S. Department of Health and Human Services (HHS) and CMS should continue to highlight the positive stories and role that medical technology can play as an alternative to opioids for chronic and acute pain management.

Thank you for the opportunity to provide our perspective. We appreciate the Committee's commitment to finding a solution to this terrible crisis and look forward to working together to leverage the expertise and technologies of our collective membership to support efforts to address this important issue and improve the environment for treating patients suffering from pain.

Sincerely,



Mark B. Leahey
President & CEO, MDMA