September 10, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852


Dear Sir or Madam:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to comment regarding the July 9, 2018 public workshop on “Patient-Focused Drug Development for Chronic Pain.” AdvaMed represents manufacturers of digital health technologies, medical devices, and diagnostic products that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies. As discussed in more detail below, our membership includes manufacturers of innovative chronic pain solutions, including devices to treat pain, and medical applications and diagnostic tests that promote effective pain management.

We appreciate the Food and Drug Administration’s (“FDA” or “Agency”) organization of this public workshop to provide a forum for chronic pain patient perspectives on how chronic pain affects lives, views on treatment approaches for chronic pain, including non-pharmacologic interventions or therapies such as medical devices, and challenges or barriers to accessing treatments.

Chronic pain is a major public health problem. Chronic pain is defined as ongoing pain that lasts longer than one month beyond resolution of the underlying insult, or pain persisting beyond 3 months.1 Approximately 100 million Americans suffer from chronic pain.2 Cases of chronic pain are the leading cause of long-term disability in the United States.3 This pain also adversely

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2 National Academy of Sciences, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, 2011.
affects mental and emotional well-being, impacting a person’s ability to work, and quality of life.\textsuperscript{4} Chronic pain costs up to $635 billion each year in medical treatment and lost productivity.\textsuperscript{5}

These statistics were borne out by patient testimonials about debilitating chronic pain during the public workshop. These patients have chronic pain resulting from illnesses such as cancer, rheumatoid arthritis, sickle cell disease, fibromyalgia and arachnoiditis, in addition to accidents and other injuries. These patients testified that they are unable to work, drive, care for their family the way they wish to, or even get out of bed.

Medical devices play a vital role in the treatment and management of chronic pain. While some chronic pain may be intractable, several medical technology alternatives have been proven to reduce or eliminate pain altogether for many patients. As FDA recognized in the Opioid Analgesic REMS Education for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain, nonpharmacologic and self-management treatment options, including FDA-approved/cleared medical devices, “have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain.”\textsuperscript{6}

According to Commissioner Gottlieb, FDA has approved/cleared more than 200 different medical device alternatives that help treat pain,\textsuperscript{7} including:

\begin{itemize}
  \item Spinal cord stimulators (SCS) use electrical signals to block pain signals from reaching the brain. Use of SCS can help to manage chronic pain of the neck, back, arms and legs, often after spine surgery, or for other neuropathic conditions. These devices are minimally invasive and trialed to ensure that the device works for the individual patient before that patient receives a permanent implant.

  \item Implantable intraspinal drug infusion pumps deliver pain medication directly to the fluid surrounding the spinal cord. These devices allow significantly lower doses of an opioid to be as effective as much higher doses of orally administered opioids as the opioid is delivered locally to exactly where it is needed, instead of systemically. As a result, many patients receive effective pain relief with reduced systemic side effects.
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\textsuperscript{5} National Academy of Sciences, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, 2011.

\textsuperscript{6} U.S. Food and Drug Administration, Opioid Analgesic Risk Evaluation and Mitigation Strategy Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (January 2018), available at \url{https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm594443.htm} (last accessed August 21, 2018).

Cooled and standard radiofrequency neuroablation is a non-narcotic, minimally invasive and non-surgical outpatient procedure to target and treat nerves causing chronic pain in spinal and peripheral nerve conditions. Both cooled and standard devices use thermal radiofrequency energy to create lesions at ≥80°C at the sensory nerve level that blocks pain signals from reaching the brain for extended periods of time. This procedure can provide chronic pain relief for up to two years. Along with an indication for nerve denervation, cooled thermal radiofrequency is also indicated to treat patients with moderate to severe osteoarthritic knee pain.

Portable pain relief systems such as transcutaneous electrical nerve stimulation (TENS) reduce a patient’s perception of pain through endorphin-producing stimulation. Other medical technologies and procedures to treat chronic pain include deep transcranial magnetic stimulation (TMS) therapy and pulsed electromagnetic field (PEMF) therapy.

Also, medical technology companies have developed innovations that are minimally invasive, enabling patients to return to routine activities faster while experiencing less pain and discomfort. Examples of minimally invasive innovations include use of thoracoscopic lung surgery and laparoscopic abdominal surgery, both of which have been shown to result in significantly less post-surgical pain than the corresponding open surgical approaches. Minimally invasive surgery has been demonstrated to be associated with less long-term opioid use than the corresponding open approach. As one study concluded: “Although there is not a clear explanation as to why some patients’ opioid use was prolonged, we did find that patients who underwent minimally invasive techniques had a very low likelihood of requiring opioids beyond 30 days.”

Moreover, medical technology, including diagnostics, devices and apps, facilitate effective pain management. For instance, diagnostics can help doctors determine what medications are appropriate for the individual patient. Devices and apps help people manage their daily medications by monitoring the medication dosage and schedule.

During the public workshop, patients noted the need for a wide range of treatment options as a treatment that is effective for one chronic pain patient may not work for another chronic pain patient. In addition, many patients need a multi-faceted treatment approach. For instance, one chronic pain patient said opioids did not work for her, but a spinal cord stimulator did. As another example of the importance of a broad array of treatment options, peer-reviewed published evidence supports better and more durable pain relief and function compared to injected drugs when cooled radiofrequency neuroablation is used in chronic pain conditions such as ...
as osteoarthritis of the knee. Medical technology provides critical tools in the toolkit available to physicians treating patients suffering from chronic pain.

It is clear from the public workshop that there is unmet need surrounding chronic pain. The medical technology industry is working to continually improve existing technologies and to develop new ones. For instance, currently, instead of pain, patients using an SCS may feel a sensation of paresthesia, which is akin to the feeling of a foot falling asleep. Research is underway to explore whether the sensation of paresthesia with an SCS can be replaced with a warming sensation that may be preferred by the patient. And researchers are also working on making the existing technologies smaller, less invasive, and more effective. Members of our industry are participating in private/public partnerships intended to foster innovation, and plan to continue to do so in the future. Such private/public partnerships include the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the Stimulating Peripheral Activity to Relieve Conditions (SPARC) Program, and the recently launched Helping to End Addiction Long-Term (HEAL) Initiative.

In that vein of innovation, we are very supportive of FDA's innovation challenge to encourage development of medical technologies to combat the opioid crisis, including alternatives to opioids for safe and effective chronic pain treatment and management. AdvaMed appreciates FDA Commissioner Gottlieb and Center for Devices and Radiological Health Director Shuren’s leadership on this issue and their recognition of the importance of medical technology solutions. We encourage FDA to continue to include medical devices in efforts to respond to the issues raised by chronic pain.

Thank you again for convening the public workshop, and for the opportunity to provide our feedback on this very important issue.

Best Regards,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs

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