

February 20, 2018



Orrin G. Hatch, Chairman
United States Senate
Committee on Finance
Washington, DC 20510-6200

Ron Wyden, Ranking Member
United States Senate
Committee on Finance
Washington, DC 20510-6200

Dear Chairman Hatch and Ranking Member Wyden,

AdvaMed commends you for your February 2, 2018 letter seeking feedback from stakeholders regarding the need to address the opioid epidemic. As your letter notes, the opioid epidemic is devastating individuals, families and communities throughout the United States. We appreciate your focus on this critical issue and the opportunity to provide input from the perspective of medical technology innovators.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed member companies produce technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed's members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have less than \$30 million in annual sales.

Medical technologies play an important role in combatting the opioids crisis. Medical technology solutions have the potential to reduce our country's dependence on opioids in many ways, including:

- serving as alternatives to treat acute and chronic pain;
- monitoring pain and medication use;
- blocking difficult withdrawal symptoms and preventing overdose;
- improving medication management, lowering dependence and addiction, and monitoring dosage; and
- preventing diversion and inappropriate access to opioids.

The attached document details specific types of medical technologies that can help address our nation's opioid crisis. Additionally, medical technology companies are developing innovations that are minimally-invasive, enabling patients to return to routine activities in a shorter period of time, while experiencing less pain and discomfort after surgery.

There are a number of policies that can help address the opioid crisis affecting our nation. AdvaMed's recommendations largely address the first three questions in your letter.

1. Congress should mandate that HHS provide increased educational opportunities regarding technology alternatives for pain management, surgical pain minimization, addiction treatment, and proper dispensing and disposal of opioids.

While the opioid crisis is widely known and discussed, opioid-related education for physicians and our healthcare workforce is needed. This education should address medical technology alternatives to opioids for chronic and acute pain management, such as outlined in the FDA's recently issued "Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain." Some of these technologies may reduce pain (i.e., minimally invasive surgery), substitute for pharmacologic pain relievers, limit the time and dosage of opioids used, or help to manage addiction and monitor use.

Technologies are also used in the hospital setting to monitor patients undergoing opioid therapy for acute pain in order to prevent opioid induced respiratory depression (OIRD) or opioid induced ventilation impairment (OIVI). These continuous monitoring technologies provide the patient, the provider, and the institution with a safer environment for the delivery of these drugs by recognizing those patients that are at risk of overtreatment within the hospital.

There are also a wide array of technologies that help control access to opioids during dispensing, storage, and disposal. These technologies are critical to maintain, limit, and facilitate appropriate access to narcotics and safeguard against diversion. Education on proper use can improve utilization of these technologies.

2. Congress should require that CMS take appropriate steps to address the coverage, coding and payment challenges related to the use of medical technology alternatives to opioid use.

Medicare's coverage, coding, and reimbursement policies should be reviewed and amended to facilitate access to medical devices and other non-opioid pain management alternatives that can minimize reliance on opioids in treating acute, chronic, and surgical pain. This may include

- establishing appropriate reimbursement, coverage, and coding for medical devices, minimally invasive approaches, and other non-opioid options that improve pain management;

- expediting access to codes for use with medical devices used in preventing and/or managing opioid use;
- establishing and covering a distinct, separately-coded and separately-reimbursed service under Medicare's Part B physician fee schedule for physicians to educate, counsel, and discuss the full range of pain management options with their patients suffering from acute, chronic, or surgical pain;
- developing a new care management code specifically for "Chronic Pain";
- suspending co-pays for patients prescribed technology alternatives to opioids to encourage use;
- improving abstinence rates using digital therapeutics that have been clinically proven to address the underlying symptoms of opioid use disorder and improve clinical outcomes;
- establishing special coverage or coverage with evidence development opportunities for medical technology alternatives to opioid use, and/or
- carving out the cost of the use of medical technology alternatives to opioid use in alternative payment models, such as accountable care organizations and bundled payment programs, to the extent these alternatives are more expensive than use of opioids.

A number of technologies that reduce and/or treat pain and provide safe alternatives to opioids are not covered by the Medicare program. There has often been an over-reliance on randomized control trials and high evidence bars that can limit access and the collection of supporting evidence on the real-world success of medical technologies to limit or treat pain. While we want to ensure that Medicare only covers technologies that improve pain management for Medicare patients, many technologies that can help are not available to Medicare patients.

Congress should instruct CMS, through its Coverage & Analysis Group (CAG), to study the extent to which various opioid alternatives are currently covered, not covered, have limited coverage and face payment challenges. Congress could also instruct the Center for Medicare & Medicaid Innovation (CMMI) and CAG to test models and collect evidence on the effectiveness of non-opioid alternatives for pain management/opioid addiction and to provide access to currently non-covered technologies for the purposes of determining their use as safe alternatives to opioids. These can include approaches on:

- Monitoring withdrawal and preventing overdose (including the use of several technologies and apps to manage opioid withdrawal symptoms and help caregivers and first responders administer life-saving drugs quickly and confidently to potential overdose victims).
- Incentivizing minimally invasive surgical techniques which result in reduced pain and lower opioid use following surgery.
- Treating acute pain including the reduction of opioid use following surgery.
- Managing chronic pain with medical technology alternatives that have been proven to reduce or eliminate pain altogether.

- Monitoring overdose risk through diagnostic tests to monitor pain medication use and identify high-risk patients who are abusing or diverting prescription drugs.
- Use of medication management devices and apps that:
 - Help people manage their daily medications by monitoring the medication dosage and schedule.
 - Utilize medication disposal technology across the care continuum wherever opioids are administered or dispensed by health care professionals. This technology securely captures partially administered or unused controlled substances and renders them non-retrievable and unusable.

These studies should be covered and paid (at least on a limited basis) to ensure timely access and utilize appropriately flexible methods and study design using real-world evidence of treating pain.

AdvaMed is currently fielding a survey of our members to identify medical technologies that can serve as alternative treatment to opioids and that have coverage, coding, or payment challenges under Medicare.

3. Congress should require CMS to develop new quality measurement activities and metrics for physicians and providers related to pain management and use of non-opioid alternatives, including:

- Requiring CMS to add clinical improvement activities related to the opioid crises to the improvement activity list for MIPS.
- Requiring CMS to develop quality measures (or encouraging measure stewards) in the opioid space which address utilizing non-pharmacologic alternatives.
- Requiring CMS to develop quality measures which incentivize providers to adopt minimally invasive surgical approaches that result in reduced post-surgical pain and opioid use.

4. Congress should promote appropriate dispensing and disposal of opioid products.

While coverage and payment of opioid alternatives is important, proper dispensing and disposal of unused opioids is also a key to addressing the opioid crisis. Estimates suggest that as many as 10% of healthcare workers have substance abuse disorder (including alcohol, opioids, and other substances). Other studies suggest that within the Certified Registered Nurse Anesthetists (CRNAs) profession, 1 in 10 have been involved in drug diversion, most of which results from improper dispensing or disposal of controlled substances.

Unfortunately, the legal and regulatory environment does not adequately incentivize proper disposal of unused opioids within health care facilities. Enforcement of existing disposal requirements are lax and not widely followed. In addition, there is no comprehensive data collection on compliance rates with existing disposal requirements or reporting requirements when drugs go missing or diversion is suspected or found.

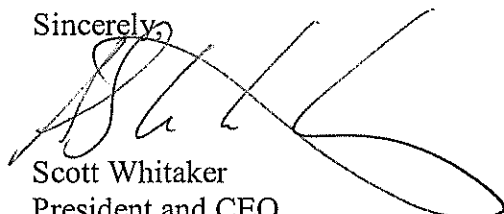
Medical technology can assist in addressing the problem of improperly disposed of opioids. HHS can play a role in developing more effective standards, trainings, or other requirements to incentivize proper disposal of opioids in a number of ways, including:

- Evaluating and modifying its requirements for dispensing and disposal of controlled substances that are included in Medicare's Conditions of Participation;
- Providing workforce training and education on proper disposal of controlled substances; and
- Requiring data collection on the extent to which hospitals are properly dispensing and disposing of controlled substances.

Congress should also request a GAO report to: (1) conduct an assessment of data available on rates of proper dispensing and disposal of controlled substances in hospitals and other health care facilities; (2) study the extent to which controlled substances are being dispensed and disposed of in hospitals consistent with current federal standards, and (3) issue recommendations for improving proper dispensing and disposal of controlled substances in hospitals.

Thank you for tackling this important issue that threatens every part of our country. We are committed to working with you to address the opioid crisis in America and to help ensure that patients have the care options they need.

Sincerely,



Scott Whitaker
President and CEO
AdvaMed

COMBATting AMERICA'S OPIOID EPIDEMIC WITH MEDICAL TECHNOLOGY

THE OPIOID CRISIS IS KILLING THOUSANDS OF AMERICANS EACH YEAR

Americans' dependence on opioids has greatly contributed to the current drug abuse epidemic in this country. The human toll of this epidemic has reached alarming proportions with more than 53,000 drug overdoses in 2016,¹ and 33,000 of those deaths were reportedly due to opioids.² As a result, the government has declared the opioid crisis a public health emergency.

Opioids are a class of drugs that include synthetic opioids such as fentanyl, and pain relievers prescribed by doctors legally, such as oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, morphine, and others. Additionally, illegal drugs like heroin are a part of this class of drugs.

In many cases, doctors have prescribed opioids to relieve acute pain related to injuries or surgery. However, a dangerous side effect is that these drugs have a high potential for abuse, and prolonged use can lead to opioid addiction and misuse. According to a 2016 survey data from the Substance Abuse and Mental Health Services Administration, 2.4 million Americans have an opioid-use disorder.³

➤ According to the U.S. Centers for Disease Control and Prevention, from 1999-2015, the amount of prescription opioids dispensed in the U.S. nearly quadrupled.⁴

or 2.8 percent of the GDP that year—six times more than any recent estimate.⁴ This figure incorporates increased health care costs related to illicit opioids and prescription opioids misuse, lost worker productivity and lost wages due to addiction and incarceration, additional criminal justice costs, and the value of lives lost to opioid overdoses.⁴

➤ More than 650,000 prescriptions for opioids are filled each day in the U.S.^{5,6} and many are consumed for non-medical, abuse related purposes.

Further, the opioid epidemic reaches deep in to the health care community, with the Substance Abuse and Mental Health Services Administration estimating that more than 100,000 health care workers struggle with abuse or addiction. Termed “drug diversion,” substance abuse among medical professionals can put patients at risk through job impairment as well as increased risk of infection.^{7,8,9,10,11} Improperly disposed, unused opioids are a significant source of drugs for this population.

➤ Tragically, 91 Americans die every day from an opioid overdose,¹² making overdoses the leading cause of death among people under the age of 50.¹³

A recent Council of Economic Advisors report found that the economic cost of the opioid crisis was \$504 billion in 2015,

1. The Altarum Institute, The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, And Substance Use Disorders Exceeds \$95 Billion Per Year, November 16, 2017.

2. The Council of Economic Advisors, The Underestimated Cost of the Opioid Crisis, November 19, 2017.

3. Substance Abuse and Mental Health Services Administration, Substance Use Disorders, October 27, 2015.

4. Centers for Disease Control and Prevention, Wide-ranging online data for epidemiologic research (WONDER), Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>.

5. Help, Resources and Information, HHS, viewed January 29, 2018: <https://www.hhs.gov/opioids/>

6. Prescribing Data, Centers for Disease Control and Prevention (CDC), viewed January 29, 2018: <https://www.cdc.gov/drugoverdose/data/prescribing.html>

7. Brummond, P.W., et al. 2017. Am J Health Syst Pharm. 74(5): 325–348.

8. Bryson, E.O. and Silverstein, J.H. 2008. Anesthesiology, 109(5): 905–917.

9. Starr, K. 2015. Nursing, 45(3): 16–17.

10. Zoltay, J. 2007. DEA, viewed 12 May, 2017, <https://www.dea.gov/pubs/states/newsrel/chicago072607.html>.

11. Baldwin, G. 2015. CDC, Division of Unintentional Injury Prevention, viewed 12 May, 2017, <https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf>.

12. Centers for Disease Control and Prevention, Drug overdose deaths in the United States continue to increase in 2015, August 2017.

13. The New York Times, Drug Deaths in America Are Rising Faster Than Ever, By Josh Katz, June 5, 2017.

MEDICAL TECHNOLOGY HAS THE POTENTIAL TO HELP FIGHT THE OPIOID EPIDEMIC

Today, there are innovative medical technology solutions available that can help play a role in combatting this national crisis. Solutions that have the potential to reduce our country's dependence on opioids include implants and other devices, as well as apps and diagnostic tests that facilitate effective pain management and help curb the misuse, abuse, and overdose of opioids. Additionally, medical technology companies are developing innovations that are minimally-invasive, enabling patients to return to routine activities in a shorter period of time while experiencing less pain and discomfort after surgery.

As the Administration and Congress investigate this critical issue, medical technology solutions should be a part of the national conversation. According to Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration (FDA), the agency has approved more than 200 different medical device alternatives that help treat pain.¹⁴ In addition, a final report issued by the President's Commission on Combating Drug Addiction and the Opioid Crisis encourages research and development of new technologies and devices to assist in the opioid crisis.¹⁵

NEW APPROACHES TO ADDICTION: MEDICAL TECHNOLOGIES AND DIAGNOSTICS

Monitoring Withdrawal & Preventing Overdose

Several technologies and apps have been developed to manage opioid withdrawal symptoms and to help caregivers and first responders administer life-saving drugs quickly and confidently to potential overdose victims. These include:

Peripheral Nerve Stimulation (PNS)

- Battery-powered chip, placed behind a patient's ear, that emits electrical pulses to stimulate branches of certain cranial nerves.
- Helps patients block difficult withdrawal symptoms when trying to quit opioids.

Auto-Injection System

- Take-home naloxone auto-injection system with voice and visual guidance.
- Naloxone is a medication designed to rapidly reverse opioid overdose.
- Helps caregivers take fast, confident action administering naloxone in an opioid emergency.

- Can temporarily reverse the effects of opioids and help keep a patient breathing until first responders arrive.

Naloxone App

- Free mobile app designed to connect any at-risk opioid user to an enrolled naloxone carrier.
- Allows people who are alone to summon a carrier to the geolocation of the victim.
- Paired with a breathing monitor that detects when a victim's breathing rate is in a dangerous range.

Battery-Operated Chip

- Emerging intuitive device that uses naloxone to help decrease opioid overdose.
- Sends impulses to specific nerves to block pain.
- Currently in trials – almost 90 percent of patients who use the device make it through the first week of detox and into secondary therapy.

➡ Pain affects more Americans than diabetes, heart disease, and cancer combined.¹⁶ It is cited as the most common reason Americans access the health care system, and is a major contributor to health care costs.¹⁷

Treating Acute Pain

Millions suffer from acute pain that usually comes on suddenly and is caused by something specific such as surgery, broken bones, dental work, or childbirth. Acute pain typically does not last longer than six months.¹⁸

Continuous Peripheral Nerve Block (cPNB)

- Small catheter is placed at surgical site during procedure.
- Catheter allows for continuous infusion of fast acting anesthetics using an ambulatory pump, clinically proven to reduce exposure to opioids during and after surgery.
- Can be used in hospitals, home care settings, and alternative care facilities.

Cryotherapy (Cold Therapy) Treatment

- Uses the body's natural response to cold to treat peripheral nerves, immediately reducing pain.
- In some cases, delivers cold therapy through a portable, handheld delivery system.
- Reduces opioid use following surgery.

14. U.S. House Committee on Energy and Commerce, Hearing: Federal Efforts to Combat Opioid Crisis: A Status Update on CARA and Other Initiatives, October 25, 2017.

15. The President's Commission on Combating Drug Addiction and the Opioid Crisis, Final Report, November 1, 2017.

16. National Institutes of Health, Pain Management, <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=57>

17. Ibid

18. Cleveland Clinic, Acute vs. Chronic Pain. Available at <https://my.clevelandclinic.org/health/articles/acute-vs-chronic-pain>.

Peripheral Nerve Stimulation (PNS)

- Uses a small, wearable stimulator connected to a thread-like wire lead to deliver tiny electrical pulses to stimulate nerves in a manner that is intended to provide targeted pain relief.
- Delivers pain relief without drugs, implants, anesthesia or incisions.

Portable Pain Relief Systems

- Part of a multimodal pain management approach after surgery.
- Provides predictable pain relief.
- Stimulation produces endorphin release. Endorphins reduce the perception of pain.
- Reduces postoperative opioid use while achieving pain management.
- Can also be used to treat chronic pain.

Neuromuscular Electrical Stimulation

- A form of neuromodulation that uses electrical waveform and pulses to stimulate muscles, improve muscle strength, increase range of motion, increase circulation, reduce edema, and reduce weakness or atrophy.

Managing Chronic Pain

Chronic pain is defined as ongoing pain that lasts longer than one month.²¹ A study by the National Institutes of Health found that one in 10 Americans experiences pain every day for three months.²² Many people accidentally become addicted to opioids while trying to treat their debilitating pain. However, several medical technology alternatives have been proven to reduce or eliminate pain altogether.

Pain in Numbers

In the United States, 70 million patients are prescribed opioids for postsurgical pain each year. Of those patients, one in 15 will go on to experience long-term use or abuse.¹⁹

72 percent of patients would choose non-narcotic pain medication for postsurgical pain management.²⁰

Implantable Intraspinal Drug Infusion Pumps

- Neuromodulation treatment that involves administration of medications directly to the body's nervous system.
- Delivers pain medication directly to the fluid surrounding the spinal cord.
- Patients receive about one percent of the drug previously taken orally, greatly reducing the number of opioids needed to treat pain.

Deep Transcranial Magnetic Stimulation (TMS) therapy

- Performs magnetic stimulation of brain structures and networks related to chronic pain.
- Stimulates superficial cortical regions of the brain.

Pulsed Electromagnetic Field (PEMF) Therapy

- Uses dual-field electric and magnetic energy to effect a more natural expression of genes and proteins.
- Pain pathways are affected in two ways: Increasing the body's naturally-occurring pain-relief mechanisms, and reduction of inflammation and swelling.
- Treatment is non-invasive and typically sensation-free.
- Patients can be treated in the outpatient setting or at home.

Radiofrequency Neuroablation

- Uses a minimally invasive procedure to heat up a small area of a nerve or tissue, blocking pain signals traveling from the pain area to the brain.
- Performed as an outpatient procedure and usually does not require general anesthesia.
- Useful for the management of chronic back pain, neck pain, and pain associated with arthritis of the knee and hip.

Spinal Cord Stimulation (SCS)

- Neuromodulation treatment that involves stimulation of the body's nervous system.
- Uses electrical signals to block pain signals from reaching the brain.
- Can help to manage chronic pain of the neck, back, arms and legs, often after spine surgery, or for other neuropathic conditions.
- Minimally invasive and is trialed for efficacy before a patient receives a permanent implant.

19. Becker's Spine Review: Mary Rechtors Nov 3, 2015 Reducing Opioid Dependence: Available From: <http://www.beckersspine.com/spine/item/27948-reducing-opioid-dependence-the-multimodal-approach-to-pain-management.html>

20. Apfelbaum JL, Chen C, Mehta SS, Gan TJ. Postoperative pain experience: results from a national survey suggest postoperative pain continues to be undermanaged. *Anesth Analg*.

2003 Aug;97(2):534-540

21. Guidance for Industry Analgesic Indications: Developing Drug and Biological Products: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384691.pdf>

22. The Good Body. Chronic Pain Statistics: Facts, Figures and Research, 2017.

Draining the Health Care System

Cases of chronic pain are the leading cause of long-term disability in the United States. This pain also adversely affects mental and emotional well-being, impacting a person's ability to work, and their quality of life.²³

Chronic pain alone costs up to \$635 billion each year in medical treatment and lost productivity.²⁴

Monitoring Overdose Risk through Diagnostic Tests

Diagnostic tests are a critical tool to monitor pain medication use and are essential to reducing the number of people addicted to opioids. These tests also help identify high-risk patients who are abusing or diverting prescription drugs, and help doctors determine what medications are appropriate for the individual patient.

Diagnostic Tests

- Monitor pain medication use, helping ensure the appropriate treatment for patients who can be helped by medications.
- Identify high-risk patients who are abusing or diverting prescription drugs.

Pain Medication DNA Insight

- Provides genetic testing to help physicians determine appropriate medication.
- Explains how patients metabolize certain drugs, which medications may cause adverse side effects, and which medications may require higher or lower dosages.

Blood Testing

- Administered to chronic pain patients receiving daily opioids.
- Helps opioid prescribers document and assess patient tolerance, monitor patient safety, and evaluate patient compliance.

Medication Management Devices and Apps

There are devices and apps that help people manage their daily medications by monitoring the medication dosage and schedule to encourage responsible stewardship. Additionally, medication delivery, dispensing, and disposal technology can help to prevent and detect drug diversion in health care facilities, while also promoting patient safety.

Medication Management/Dispensing Technology

- Technology that stores and dispenses medications of the correct dose, at the appropriate time.
- Can be used in a hospital setting or at home.
- Technologies can be paired with software that can monitor and track pain levels as well as alert patients if they are late for a dose or don't receive their dose.

Medication Disposal Technology

- Technology that securely captures partially administered or unused controlled substances and renders them non-retrievable and unusable.
- Used across the care continuum wherever opioids are administered or dispensed by health care professionals, from EMS vehicles to ORs to pharmacies.

Medicine Management App

- App captures the color and shape of a patient's medications along with dosages and schedules.
- Sends patients push notifications when it's time to take their medications, and notifies a friend or family member if the patient forgets.

Less Invasive

Millions of U.S. patients per year undergo surgery resulting in acute post-operative pain. Medical technology enables minimally invasive surgery (inclusive of laparoscopic surgery, video-assisted thoracoscopic surgery, and robotic surgery) which delivers safe and effective treatment while reducing the size of the surgical incision, resulting in less operative trauma versus open surgical approaches.



AdvaMed.org

701 Pennsylvania Ave, N.W., Suite 800
Washington, D.C. 20004

23. American Chronic Pain Association, ACPA Resource Guide to Chronic Pain Medication & Treatment, 2015.

24. American Pain Society, Chronic Pain Costs U.S. Up to \$635 Billion, Study Shows, 2012.