



MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

ANNUAL REPORT
2018

DRIVING THE
FUTURE
OF HEALTHCARE

TO OUR MEMBERS

As our industry continues to become more diverse and complex, so does policy making in Washington, DC. If there is one takeaway from 2018, it is that we collectively as an industry and individually as innovators must remain vigilant as we passionately defend the life changing work we are engaged in, and share the powerful stories of success.

The coordinated efforts of a multinational coalition of journalists in 2018 highlighted the fact there are still many who want to undermine the regulatory framework that has guided medical technology innovation for over 40 years. During this period, we have seen simply remarkable advancements in medical care, from allowing the blind the see and deaf to hear, to extending lives and improving outcomes. Despite all of these advancements and the amazing work that you and your teams remain committed to, there are ongoing efforts to overhaul the current system. MDMA remains the voice of the innovative and entrepreneurial sector of our industry, and we will aggressively and zealously defend the medical technology ecosystem, and all of the amazing work you continue to do.

While 2018 was a year in which Congress was controlled by one political party, achieving legislative victories in any area of policy making was challenging. This is why it was so critical that the broad coalition that MDMA created in 2009 and continues to grow was able to secure an additional 2 year suspension of the medical device tax before this disastrous policy was able to inflict additional harm to patient care and investments in research and development. We will continue to work with all stakeholders for a full and permanent repeal of the device tax to provide the predictability innovators need to make long-term investments in research and development and patient care.

In addition, as challenges with reimbursement grow for medical technology innovators seeking reimbursement, MDMA accelerated its work with the AMA, private payors and CMS to improve the environment. We also

established new relationships with stakeholders who want to work on the shared goal of improving patient and physician access.

Despite all of the confusion coming out of Washington over the years, it is clear that Americans are yearning for solutions to the pressing challenges facing health care. Whether it is the ongoing debate over the cost of care, patient access to cures and therapies that are struggling to gain coverage despite regulatory success, or developing new and novel technologies to alleviate pain and reduce the use of opioids, there is no shortage of issues where MDMA and our member companies continue to lead the charge.

If you are not a member of MDMA, we strongly encourage you to join this energetic and passionate organization. MDMA's advocacy, education and outreach efforts are strengthened by your participation, your voice and your input. As Members of Congress and others expand the debates over "Medicare for All" and other novel approaches to the hurdles that remain in health care, it perhaps has never been more important to be engaged as decisions are being made that could transform our ability to succeed. As has been true since MDMA was formed over 25 years ago, our collective voice is what allows us – and most importantly, patients – to thrive.

Sincerely,



Paul LaViolette
Executive Chairman, CardioFocus
Chairman, MDMA



Mark Leahy
President & CEO, MDMA

FEDERAL POLICY HIGHLIGHTS

FOOD AND DRUG ADMINISTRATION (FDA)

2018 saw perhaps the most coordinated and direct attempt by individuals to fundamentally change the way medical devices are regulated in the United States. A large coalition of journalists and others instituted a sustained effort to undermine what has been the global gold standard reviewing medical technologies for safety and efficacy, and MDMA was at the forefront to correct the record, and defend the tremendous safety profile of the medical device industry.

As we all know, FDA, innovators, patients, physicians and all stakeholders work tirelessly to strengthen the innovation ecosystem that develops the cures and therapies addressing our nation's – and the world's – most difficult health care challenges.

The coverage of our dynamic industry was nothing more than cherry-picking a handful of adverse outcomes at the exclusion of the nearly 200,000 medical devices currently on the market improving patient

care. These efforts only served to frighten the millions of patients who benefit from medical technology innovation every day, while inaccurately portraying the rigorous regulatory pathways that are in place to ensure patient safety.

MDMA, physicians, engineers, manufacturers and all those who make-up the medical technology industry are committed to working closely with FDA and other stakeholders to ensure patients have access to technologies that improve the human condition, and that the United States remains the global leader in innovation.

DEVICE TAX

2018 began with a flurry of activity to ensure that the medical device tax did not cause additional damage to the innovation ecosystem as it did during the years when it was in place. Due to Congressional gridlock in 2017 over efforts to “repeal and replace” the Affordable Care Act, Congress did not take any action to extend the suspension of the device tax. After the device tax was

Attendees at MDMA's events gain unique insights from leading policy makers and medtech executives, while participating in numerous networking opportunities.



temporarily reinstated at the end of 2017, MDMA acted quickly and secured the second two-year suspension of the tax, passed days before the first payments were due to the IRS, and keeping the tax turned off through the end of 2019.

MDMA directly communicated with Members of Congress and the Administration that the lack of predictability caused by this timeline prevents innovators from fully investing in the cures and therapies of tomorrow, especially with the knowledge that temporary suspensions do not lead to long-term expenditures.

Despite Congress remaining bitterly divided over partisan debates over health care, MDMA led numerous grassroots and earned-media activities to generate a historic level of support to fully and permanently repeal the device tax.

As a testament to MDMA's passionate advocacy against the medical device tax since it was first proposed in 2009, these activities culminated in passage of H.R.184 in the House of Representatives with 283 votes – the largest and most bipartisan vote for repeal ever.

In addition, MDMA worked with Congressional leaders to include a five-year additional suspension of the device tax in year-end efforts to fund the government. While the larger bill was not signed into law, this inclusion represented the longest relief of any ACA tax, and is yet another example of growing support to once and for all repeal the medical device tax.

REIMBURSEMENT

Narrowing the gap between the regulatory and reimbursement decisions remains a top priority for MDMA, and in 2018 we focused on working directly with Congressional Committees, CMS, private payors and more to expedite much-needed changes to the process. In addition to our ongoing work with the American Medical Association (AMA) to improve the CPT process and with CMS and private payors to ensure coverage decisions are timely and reasonable, MDMA initiated productive relationships with some payors who share the goal of examining how to improve physician and patient access to medical technologies that improve outcomes and drive down costs.

With the selection of Adam Boehler as Health and Human Services (HHS) Secretary Alex Azar's Senior Advisor for Value-Based Transformation and Innovation, administrative efforts to address the cost of care gained new attention. Director Boehler has a strong track record of developing innovative solutions to the pressing needs facing patient care and addressing complex disease states. Director Boehler's first public remarks were at MDMA's Annual Meeting, and he expressed his desire that outcomes and costs are measured over the appropriate time horizons when assessing payment models.

CDRH Director Jeff Shuren answers questions from attendees of MDMA's Annual Meeting during an interactive "Town Hall" session.



FEDERAL POLICY HIGHLIGHTS

In addition to working with CMS and others on novel approaches to improving coverage of medical technologies, MDMA also supported policies that advanced in Congress. Legislation such as H.R. 3635, the “Local Coverage Determination Clarification Act,” recognize that medical technology innovators work tirelessly as they develop the cures and therapies of tomorrow, and it is critical that patients and providers have access to them. It builds upon past efforts to establish a more reasonable and transparent environment for making coverage decisions within Medicare, including the establishment of a formal CMS appeals process for a local coverage denial.

MDMA remains committed to working with Congress to help improve the reimbursement landscape so that patients throughout the United States get timely access to medical technology innovation.

PAIN MANAGEMENT

Medical technology has long played an important role in helping patients manage their chronic and acute pain. With the ongoing crisis caused by opioids, FDA Commissioner Dr. Scott Gottlieb testified before Congress that there are over 200 evidence based, FDA cleared or approved medical devices with components to treat chronic and acute pain. In 2018 MDMA re-doubled our efforts to raise awareness on the appropriate role for medical devices as pain management treatment options and worked with a number of stakeholders to develop policies intended to drive greater adoption of medical device treatment options throughout the pain care continuum.

Some of these highlights include:

- Working with Members of both the House and Senate and the various committees of jurisdiction to support the ultimate passage and signing into law by the President of H.R. 6, the SUPPORT for Patients and Communities Act, resulting in 15 important medical device and pain management provisions.
- Providing comments to the HHS Pain Management Best Practices Inter-Agency Task Force. The Task Force spent the majority of 2018 working to identify gaps or inconsistencies in pain management, and their work culminated at the end of the year with a Draft Report identifying gaps or inconsistencies and proposed updates to best practices and recommendations for pain management, including chronic and acute pain as required by the Comprehensive Addiction and Recovery Act of 2016 (CARA). The report will be finalized in the second quarter of 2019, upon which it will be sent to Congress.
- Working directly with National Institutes of Health (NIH) Director Dr. Francis Collins and his team on the Helping to End Addiction Long-Term (HEAL) Initiative, providing perspectives from the medical technology industry and connecting researchers directly with members of the MDMA Pain Working Group.
- Engaging leadership at FDA on the Innovation Challenge, intended to spur the development of medical devices to help combat the opioid crisis and achieve the goal of preventing and treating opioid use disorder.
- Participating in meetings with leaders from the Centers for Medicare and Medicaid Services (CMS) as a part of the CMS Roadmap to Address the Opioid Epidemic, highlighting reimbursement policies that currently inhibit greater adoption of medical device alternatives.

In 2019, MDMA will continue our efforts to raise awareness of medical devices for pain management and advocate for policies that increase patient access to these innovations.

INTERNATIONAL

MDMA continued to provide comprehensive analysis and advocacy on international issues to keep our members up to date on the latest trends, especially with the ongoing confusion related to “Brexit” and other activities taking place that would impact access to medical technology. MDMA does so through numerous means including newsletters, calls with international experts, trips to strategic markets and much more.

2018 was certainly a busy year in numerous markets, and 2019 looks to be just as active. Some of these events included:

“Brexit”

MDMA closely tracked the latest developments and the very significant impact on the medical device industry and the healthcare supply system, working closely with partners in Europe. The lack of a deal in early 2019 would affect contracts with UK-based suppliers, create supply-chain issues and affect medtech firms that currently

use a UK-based Notified Body to CE-mark their products for sale in the EU and/or medtech firms that currently use a UK-based authorized representative as their legal entity for the EU.

EU-MDR (Medical Device Regulation)

The transition period to the new MDR from the existing MDD (Medical Device Directive) ends in May 2020. Despite the potential for disruption this process can have, the first Notified Bodies that would be able to certify products to the new MDR have yet to be named. The first such certifications are not expected to happen until the middle of 2019, meaning the medtech firms will have barely over a year to align and be reviewed and certified to the new MDR prior to the end of the transition period.

USMCA

The proposed new US-Mexico-Canada Agreement that was negotiated in late 2018 is scheduled to be reviewed, debated and voted on by Congress starting in 2019. The agreement contains improvements for the medtech sector

FDA Commissioner Scott Gottlieb updates attendees on his reform efforts at the agency, and how he envisions medical technology innovation in the 21st century.



FEDERAL POLICY HIGHLIGHTS

including greater regulatory transparency, mutual recognition and harmonization of regulations and a consultative mechanism that can be used if there are problems or disputes over access or treatment of U.S. medtech firms. MDMA has been working with the Administration and Congress to help ensure any final agreement does not inadvertently harm medical technology innovators.

US-China Trade

In 2018 the US and China imposed substantial tariffs on a significant amount of trade between the two countries, including on most medical device products. The Trump Administration called a temporary truce in that trade war until a trade agreement can be worked out. While China is prepared to open its markets to US goods and to reduce tariffs and other barriers, fundamental differences separate the two trading partners.

US-India Trade

While trade with India is very healthy, the growing US trade deficit is becoming a bigger irritant between the countries including in the

area of medical devices. India launched in 2018 a National Healthcare Protection Scheme which is pouring tremendous resources into India's healthcare system. Hospitals are being upgraded, many clinics are being built and patients have access to the health system at a much higher level than in the past. India is actively seeking to promote its own medical device industry which is creating some protectionist overtones in the area of regulation and pricing.

PATENTS

MDMA has long recognized how important it is for our members and the industry to have a strong system in place that protects patent rights, enabling innovators to attract investments to fund new cures and therapies, while fighting against any infringement in the United States or abroad. Unfortunately, recent changes to patent laws and court decisions have created uncertainty in the patent system, and this is a major reason that the US fell from 1st in patent system strength to 12th in the U.S. Chamber of Commerce's Global IP Index.

CMMI Director Adam Boehler shares his priorities in updating reimbursement models for patient care, and how CMS is looking to reform coverage policies.



In 2018, MDMA continued its close work with PhRMA, BIO, the National Venture Capital Association and others to raise awareness with Members of Congress about the importance of patents for innovation. This broad coalition of innovators have come together to support the “Stronger Patents Act” to address many of the problems currently facing the patent system.

While Congress did not take any votes on substantive patent legislation in 2018, USPTO Director Andre Inaucu did incorporate many of the most important provisions of the “Stronger Patents Act” through rule-making, restoring much needed predictability in the patent system.

MDMA will continue to be the lead voice for medical technology innovators in securing and strengthening intellectual property rights.

CYBERSECURITY

As digital technologies and traditional medtech continue to become more intertwined and connected, MDMA created a Cybersecurity Working Group within our membership focused on the dissemination of timely and relevant cybersecurity related information. The working group has become an environment for collaboration among medical device cybersecurity professionals from small, mid-sized and large companies. We also continued to advocate to policy makers about the need for a balanced approach to any potential cybersecurity legislation or guidance(s), and warned against overly-prescriptive policies that, while well-intended, would have unintended consequences thwarting innovation.

MDMA also established a partnership with the Healthcare Sector Coordinating Council (HSCC), a public-private organization focused on the development and dissemination of sector-wide recommendations and guidance to help facilitate sector-wide mitigation, response and resilience to cybersecurity threats. MDMA members received the opportunity to participate directly through various HSCC Cyber Working Group (CWG) initiatives or indirectly through opportunities to comment on certain work products.

Significant work products from MDMA’s activities in this sector include:

- The Medical Device & Health IT Joint Security Plan (JSP)
- Health Industry Cybersecurity Practices (HICP): Managing Threats and Protecting Patients four part publication
- 2018 Annual Report for the Healthcare Sector Coordinating Council

Additionally, MDMA members received the opportunity to participate in webinars hosted by industry experts focused on medical device security, coordinated vulnerability disclosure (CVD) and other issues. For companies small and large, the MDMA Cybersecurity Working Group offers the resources, contacts and channels needed to stay up to date on policies and news impacting medical device cybersecurity and development.

LEGAL AND COMPLIANCE

MDMA continued to increase our offerings to members in the legal and compliance fields. We worked closely with our members to understand their compliance priorities and keep them up to date on enforcement trends and legislative developments, as well as industry “best practices” to help companies maintain a robust compliance program.

Legal and Compliance activities in 2018 include:

- Hosting regular calls to keep members up-to-date on important legal and compliance developments
- Providing regular and timely updates to members on important enforcement and compliance developments
- Conducting three in-person Compliance Working Group roundtables to discuss emerging trends and share best practices
- Ongoing expansion of MDMA’s Compliance Toolkit

MDMA provides numerous programs, events, webinars, working groups and more where medical technology innovators learn the latest insights and strategies, share best-practices and network with leaders from across the country.





2018 WEBINARS

MDMA members benefit from multiple webinars that are archived and added to the members-only section of our website for later viewing. In 2018, we had 8 webinars addressing a wide range of topics impacting our members and medical technology innovation, ranging from “Next Steps in Repealing the Medical Device Tax” to “Post Election Update”:

Medical Device Tax Update – Next Steps

The MDMA Team hosted a webinar to discuss the latest on our efforts to repeal/suspend the medical device tax and next steps.

Key Developments for Medical Device Inspections in the U.S. and Around the Globe: Are You Prepared?

Nathan Brown and Howard Sklamberg, partners at Akin Gump Strauss Hauer & Feld LLP and co-authors of *World of Change Coming for Device Manufacturers: Developments in FDA and International Inspections*, discussed important developments for medical device inspections and the implications for device manufacturers.

Nate and Howard highlighted three recent and important initiatives: FDA’s Program Alignment, the FDA Reauthorization Act of 2017, and the Medical Device Single Audit Program, all recently implemented by FDA and Congress to improve regulatory efficiency and predictability in the inspection of medical device facilities. Members learned how their companies can constructively engage with these new programs and effectively reap the benefits of each, how these changes can offer medical device-makers opportunities to streamline and enhance their compliance and quality programs, and how to leverage these programs as FDA explores ways to collaborate with other regulators around the world as a result of the rapid growth of globalization of medical device production.

Compliance AND Competitive Advantage – the Intelligent QMS

E.M.M.A. International Consulting Group hosted a webinar on Compliance and Competitive Advantage. The ongoing changes in the international regulatory landscape will have a direct impact on quality management systems (QMS) design and implementation. Thus, this is an appropriate time to reveal a new approach to QMS thinking and analysis that will undoubtedly pave the way to the future of QMS architecture. The purpose of this webinar is to introduce some new and innovative concepts that are aimed at taking our current thinking into the future. And yes, this includes incorporating Artificial Intelligence into the design and architecture of a QMS.

2018 Election Results – Impact on the MedTech Industry

The purpose of this webinar was to introduce the MDMA team to share some of the possible Congressional Committee assignments that have jurisdiction over med tech issues and policies for 2019, as well as a discussion about what the “lame duck” Congress might address for the rest of 2018.

2018 PROGRAMS



2018 FDA Forum

March 12-13, 2018 / Palo Alto, CA

MDMA hosted over 160 attendees and heard from more than a dozen FDA officials at our 2018 FDA Forum in Palo Alto. This incredible turnout made for an exceptional event which allowed industry leaders to discuss critical issues affecting the medical technology industry. Topics included navigating the 510k program, explaining the De Novo program, PMA review considerations, key issues impacting IVD's, digital health and much more! Attendees had numerous opportunities to pose questions directly to FDA officials and expert panels which led to insightful and interactive sessions.



2018 Annual Meeting

May 2-4, 2018 / Washington, DC

MDMA hosted another successful Annual Meeting in Washington, DC where nearly 200 attendees were able to network and mingle with top policy makers, as well as to get the latest insights from some of the most dynamic executives in our industry. Keynotes included a roundtable discussion with FDA Commissioner Dr. Scott Gottlieb, an interactive "Town Hall Meeting" with CDRH Director Jeff Shuren, a CMS Update from Adam Boehler, Director of the Centers for Medicare and Medicaid Innovation (CMMI) and an update from Tamara Syrek Jensen, the Director of the Coverage and Analysis Group at CMS.

Other popular panels included a Political Panel and Election Preview, a discussion of EU Medical Device Regulation, Leveraging Real World Evidence for the Purpose of Regulatory and Reimbursement, and much more. Additionally, we examined the impact of medical

technology on patient care and heard powerful stories of how the industry is rising to the challenges that patients and providers face today. Attendees also heard from a panel of medtech CEOs about key industry issues, motivating their workforce, and what they are considering as they look to the future of innovation.



11th Annual Medical Technology Executive Forum

September 21, 2018 / Palo Alto, CA

Over 100 CEOs and senior executives joined us at our 11th Annual Medical Technology Executive Forum. Participants gathered to hear from a compelling lineup of speakers from industry, FDA, and more on challenges and opportunities facing our industry.



21st Annual Coverage, Reimbursement & Health Policy Conference

November 7-8, 2018 / Washington, DC

MDMA held another successful Coverage, Reimbursement & Health Policy Conference in Washington, DC. Attendees had the unique opportunity to ask questions from some of the leading experts from the Centers for Medicare and Medicaid Services (CMS). CMS is currently examining numerous initiatives to improve outcomes and promote value-based health care, and the Centers for Medicare and Medicaid Innovation (CMMI) Deputy Director, Amy Bassano, shared how the agency is working to improve the delivery of health care and payment systems. Additionally, the former Director of the CPT at the American Medical Association and the current CMS Ombudsman presented about the latest strategies to successfully secure coverage from CMS and how to navigate the CPT process.

2018 BOARD OF DIRECTORS

The MDMA Board of Directors represents a broad cross section of our membership and the medical device industry. Voting members include:

Paul LaViolette

*Executive Chairman
SV Health Investors
MDMA Chairman*

Scott Huennekens

*President & CEO
Verb Surgical, Inc.
Immedicate Past MDMA Chairman*

Wil Boren

*President
Advanced Surgery
Baxter International*

Michael Carrel

*President & CEO
Atricure*

Joe Damico

*Founding Partner
RoundTable Healthcare Partners*

Ryan Drant

*General Partner
Questa Capital*

Thomas Frinzi

*Worldwide President
Surgical
Johnson & Johnson Vision*

Doug Godshall

*CEO
Shockwave Medical*

Chris Holmes

*President & CEO
Smiths Medical*

Walt Humann

*President & CEO
OsteoMed, LLC*

Jennifer Kerr

*President
Cook Research, Inc.
Cook Medical*

Joe Kiani

*Chairman & CEO
Masimo Corporation*

George Leondis

*President & CEO
Argon Medical Devices, Inc.*

Matt Link

*President
NuVasive, Inc.*

Pat Mackin

*President
CEO & Chairman
CryoLife, Inc.*

James Mazzo

*Global President
Ophthalmic Devices
Carl Zeiss Meditec Inc.
ZEISS Group*

Jeff McCaulley

*Global President
DJO Surgical
DJO Global*

J. Casey McGlynn

*Partner
Wilson Sonsini Goodrich & Rosati*

James Momtazee

*Head of Health Care Industry Team
Kohlberg, Kravis Roberts (KKR)*

Michael Onuscheck

*President
Global Business & Innovation
Alcon Laboratories, Inc.*

Rick Packer

*Chairman
ZOLL Medical Corp.*

Robert Perry

*Senior Vice President
Device R&D
Allergan, Inc.*

David Pierce

*SVP & President
Urology
Boston Scientific Corporation*

Jason Richey

*Interim CEO
Cutera, Inc.*

Walt Rosebrough

*President & CEO
STERIS Corporation*

Benson Smith

*Chairman
Teleflex Incorporated*

Spencer Stiles

*Group President
Stryker Instruments*

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street NW, Suite 400 West, Washington, DC 20005
medicaldevices.org