

2017 ANNUAL REPORT

Shaping a New Direction



TO OUR MEMBERS

As we look back on 2017, advancements in medical technology that allow patients to live longer, more productive lives continued at a rapid pace. In Washington, the MDMA team was actively working on behalf of innovators to ensure patients have timely access to these cures and therapies, and to address some of the challenges that slow their development. MDMA remains proud of our over 25 year tradition of being a member-driven organization and we are committed to ensure that our industry has the policies, resources and tools that help empower them to maintain the United States' leadership position in medical technology innovation.

2017 saw the formation of a new Administration, and new leaders in key positions that will impact our ability to succeed. President Trump brought many seasoned policy makers to lead numerous agencies, including Dr. Scott Gottlieb as FDA Commissioner, and Seema Verma as Administrator of CMS. They have already initiated aggressive agendas to reform the regulatory and payment arenas, and MDMA is working closely with these agencies, Congress and all stakeholders to help ensure that medical technology innovators can continue to lead the way in achieving our shared goal of improving patient care.

While much of the Congressional agenda in 2017 was consumed by efforts to “repeal and replace” the Affordable Care Act, the central theme of this and many other policy debates focused on the continuing priority to drive down the costs of care. With the rising costs of health care remaining the top issue to voters in an upcoming election year, we expect additional hearings in Congress in 2018 to examine the cost of care more closely. MDMA continues to work with Members sharing the positive story of the value of med tech, and its ability to drive down costs. The Congressional and media focus on this issue is a constant reminder for all of us how critically important it is to educate policy makers about the powerful impact our technologies have on patient care, and the role our industry plays in improving outcomes and the quality of life. We know we have amazing stories to share, and MDMA is here to assist with this crucial outreach.

Some of MDMA's accomplishments in 2017 included:

- Securing the inclusion of a full and permanent repeal of the medical device tax in every major legislative effort that addressed reform of the Affordable Care Act, ultimately leading to another 2-year suspension in January of 2018.
- Reauthorizing MDUFA IV following almost two years of negotiations, securing process improvements and provisions that will help ensure the regulatory pathways become more predictable and transparent.
- Working with CMS to establish a new “provisional coverage” pathway that allows med tech innovators to secure reimbursement while working to gather more clinical data.
- Establishing new MDMA Working Groups to address growing challenges facing our members and the medical technology industry including Patient Access, Cybersecurity and Pain Management.
- Hosting a Patient Access Strategy Summit that brought together leading innovators, physicians, patients and investors all committed to making the coverage and payment process more transparent, evidence based and reasonable for all stakeholders.
- Bringing together top international experts to address member needs on our international working group calls and webinars.
- Continued growth of the Medical Technology Regional Alliance to channel the collective efforts of state and regional based groups throughout the country towards protecting and improving our industry.

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. Working together, we will continue to ensure that an environment exists where patients and providers have timely access to the amazing cures and therapies our industry develops.

Sincerely,



Paul LaViolette
Executive Chairman, CardioFocus
Chairman, MDMA



Mark Leahey
President & CEO, MDMA

FEDERAL POLICY HIGHLIGHTS

“From the reauthorization of MDUFA to securing additional relief of the medical device tax, MDMA is the voice of the innovative sector of our industry, and is passionately dedicated to making sure our industry leads the 21st century in developing new cost effective diagnostics and therapies.”

Scott Huennekens
President and CEO
Verb Surgical Inc.

FDA

2017 marked a significant year for the FDA and regulatory policymaking as new leadership and talent were brought in by the Administration. MDMA worked closely with Congressional Committees and other bodies of jurisdiction as FDA Commissioner Dr. Scott Gottlieb was nominated and approved, as were numerous other presidential appointees who will have oversight of the regulatory processes.

In addition to working with the new leadership at FDA, MDMA remained laser-focused to ensure that the reauthorization of the Medical Device User Fee Act (MDUFA) that had been worked on for years was passed into law. This is the first time where reauthorization was negotiated by one Administration, and had to be signed into law by another. MDMA worked aggressively to ensure that the final agreement adhered to our members goals of prioritizing “reasonableness and consistency” as we sought out new process improvements.

The legislation, the “FDA Reauthorization Act of 2017 (FDARA),” was signed into law on August 18, 2017, and it contains numerous targeted investments designed to further streamline the regulatory pathways including:

- Significant process improvements that will provide more clarity, specificity, supervisory oversight and routine quality audits;
- Performance goals for De Novo submissions for the first time, with FDA committing to reach a decision on 70% of submissions by 150 days;
- Performance goals for per-submissions for the first time, with FDA committing to provide meaningful written feedback to innovators at least five days prior to a scheduled pre-submission meeting and having the meetings within 70 FDA days;
- Improved average total time to decision to 108 days for 510(k)s and to 290 days for PMAs by the end of FY2022;
- Expansion of the Independent Assessment to complete the MDUFA III review and assess MDUFA IV reforms.

In addition to the user fee agreement, FDARA included critical enhancements to FDA’s post-market inspection process requiring the agency to implement a “risk-based” approach to inspections, as well as a reinvigorated focus on “least burdensome.”

Upon passage, MDMA quickly pivoted to work with Commissioner Gottlieb and CDRH Director Jeffrey Shuren to help ensure the implementation of this critical agreement achieves the shared goals of expediting access of safe and effective medical technologies into the hands of patients and providers.

MDMA also created a Cybersecurity Working Group. This new group is working to identify priorities and to proactively provide industry solutions rather than simply responding to challenges. While there have been no reports of any harm to patients, the medical device industry is committed to making sure the United States remains the gold standard in safety and security, which includes strong safeguards in cybersecurity. Medical device innovators remain vigilant in maintaining the highest safety and security measures, and we are working closely with FDA and other stakeholders to achieve this common goal.

DEVICE TAX REPEAL/SUSPENSION

The new Administration and the Republican-controlled Congress made the “repeal and replace” of the Affordable Care Act their top priority in health care in 2017. The debate over the House and Senate efforts to accomplish their goal consumed over half the year, and while it was ultimately unsuccessful, it removed the desire of many policy makers to address any other large health-related policies.

MDMA’s leadership on repealing the device tax over the years allowed us to work with Congress to ensure that its full and permanent repeal was included in every major health care reform legislation that they worked on. MDMA initiated multiple “Action Alerts” for our members and other stakeholders to contact Congress, and continued an aggressive earned-media campaign to place op-eds and letters to the editor in targeted media markets, as well as hosted numerous company tours and town-hall meetings.

To help boost our efforts, MDMA conducted a new survey to gauge the impact of a reinstatement of the medical device tax if the two-year suspension was allowed to end. It was clear that investments in the cures and therapies of tomorrow would be drastically cut, and a major slowdown in the creation of high tech manufacturing jobs would result if the device tax is reinstated in 2018.

We communicated to Congress that medical technology innovators were making difficult decisions as a result of the uncertainty over the device tax, and that they must put a permanent end to a policy that the overwhelming majority of Congress agrees is a bad policy.

The survey included 117 responses from senior executives at some of the United States’ most innovative and entrepreneurial medical device companies. Notably, 88 percent of innovators would slow down hiring and/or have to eliminate jobs if the device tax is reinstated in 2018. A previous MDMA survey showed that as a result of the two-year device tax suspension, 70 percent of companies increased hiring and created new jobs.

Other top findings of the survey include:

- 83 percent of innovators would have to decrease investments in R&D if the device tax is reinstated
- 77 percent of respondents noted that reinstatement of the medical device tax would cause them to slow and/or stop expansion plans

All of this passionate advocacy throughout 2017 led to a continued two-year suspension that was passed in January of 2018 before medical device innovators had to send any device tax payments to the IRS. There continues to be strong bipartisan support to fully repeal the medical device tax, and MDMA’s consistent leadership since 2009 will help ensure that the medical device tax is never enacted again, and that this policy is fully and permanently repealed.

IF THE MEDICAL DEVICE TAX IS REINSTATED



83% of innovators
would have to decrease
R&D investments.



77% noted
reinstatement would
cause a slowing and/or
stop to expansion
plans.

FEDERAL POLICY HIGHLIGHTS

REIMBURSEMENT



Catherine Ross, a K2M, Inc. employee and beneficiary of medical technology innovation, shares her powerful story on how the industry changed her life, and why she has dedicated her career to help develop the cures of tomorrow.



MDMA filed comments with CMMI to make coverage and payment for medical technologies more timely.

Similar to FDA, the Centers for Medicare and Medicaid Services (CMS) had new leadership in 2017 when Seema Verma was sworn in as the new Administrator. MDMA has been working aggressively to improve the coverage landscape for medical technologies with both private and public payors. Based upon feedback from our Reimbursement Working Group, we devised a survey to assess our members' experiences in the coverage environment. We conducted the survey to gather data similar to the Makower study that MDMA helped lead in 2010 regarding the regulatory pathways. That report helped spur the legislative activities that helped improve the regulatory environment for med tech innovators, and we plan to do the same in this arena.

MDMA has been sharing the concerns identified by our members with senior policy makers as we work together to improve the environment for innovation. We also heard from many members that there has been an increasing trend in private insurers denying coverage of novel and breakthrough technologies for patients across the United States. MDMA created a new **Patient Access Working Group** to catalog these stories and what the trends were in these negative coverage decisions, and to develop a prioritized list of solutions that we can advocate with policy makers and other stakeholders. To boost these efforts, we also hosted a Patient Access Summit in Washington, D.C. that gathered innovators, patients, physicians, venture capitalists and other stakeholders to share their respective experiences in the current environment, and to identify what shared-goals the larger group should work on. This ongoing work will help drive MDMA's advocacy in 2018 and beyond.

Finally, Members of Congress and others continue to advocate a UDI field to insurance claims for medical devices, and MDMA remained the leading voice advocating against a policy that would block innovative technologies from entering the market place.

Other highlights include:

- ✓ Ongoing discussions with CMS, FDA and payors to shorten the gap between regulatory approval and coding, coverage and payment, including provisional coverage for new technologies
- ✓ Filed comments with CMMI to make coverage and payment for medical technologies more timely
- ✓ Worked to ensure proper implementation of provisions in the "21st Century Cures Act" that require local MACs to be more transparent related to coverage decisions, as well as the nomination of a CMS Ombudsman
- ✓ Ongoing efforts with CMS and other stakeholders to provide more transparency and clarity to the HCPCS process
- ✓ Submitted various comments to CMS including proposed changes to the hospital inpatient prospective payment system (IPPS), the outpatient prospective payment system (OPPS) and physician fee schedule (PFS) and more
- ✓ Ongoing work to make the CPT process more transparent and fair

PAIN MANAGEMENT

The White House released a report in 2017 on how to combat drug addiction and opioid misuse, highlighting how important it is for all of us to work together to address the crisis plaguing families and communities across the United States. The President's Commission recognized that medical devices should play an important part in our collective efforts to address the challenge of addiction and it is critical that medical technology innovation plays a central role in this campaign. While various therapies are already on the market, awareness is low and countless others face unreasonable regulatory burdens and coverage denials by public and private payers. This is impeding patient and provider access to the very cures and therapies they desperately need.

MDMA initiated a **Pain Management Working Group** for our members to gather our collective resources to address this crisis, and to identify policies and regulations that can expedite getting safe and effective therapies into the hands of patients. MDMA has organized numerous meetings and briefings with Members of Congress and the Administration to share the powerful role our industry plays in alleviating suffering.

Medical technology innovation is already playing a central role in addressing this epidemic, but there is so much more this innovative industry can provide if the proper policies are in place. Working with Congress, FDA, CMS, patient groups and other stakeholders, MDMA and our members will continue to lead efforts to provide med tech solutions to the suffering and pain that is felt by too many.

PATENT REFORM

MDMA was tireless in working with the broad coalition that has united to protect the intellectual property rights of patent holders in 2017 as policy makers continued the debate over patent reform. MDMA continues to support efforts to curb abusive practices of patent assertion entities (PAEs) or "patent trolls," but we maintained our passionate advocacy with the diverse coalition of innovators to make sure this goal is not accomplished with adverse consequences to product development.

MDMA continued to work with champions of strong intellectual property rights in Congress, including Senator Chris Coons who introduced the "STRONG Act," as well as opposing provisions in the "PATENT Act" that would harm medical technology innovation.

MDMA is working with the new Administration and Congressional leaders on targeted solutions to frivolous and illegitimate patent lawsuits, and to strengthen the intellectual property rights of med tech innovators.

"When you are trying to take a new medical invention to market, there are many possible hurdles. For 25 years, MDMA has helped medical innovators navigate through this challenging territory—helping lifesaving technologies make their way to clinicians and patients."

Joe Kiani
Chairman and CEO
Masimo Corporation

1. U.S. Senator Amy Klobuchar (MN) addresses attendees at MDMA's 2017 Annual Meeting on Congressional efforts to repeal the medical device tax and to improve the regulatory pathways.

2. MDMA is a proud supporter of the Code of Support and MVPvets programs that support America's veterans in transferring their skills into the med tech industry, as well as provide the support they deserve as loved ones serve our nation.

3. MDMA Board Chairman and Executive Chairman of CardioFocus Paul LaViolette gives the opening address detailing his vision for the medical technology ecosystem in the 21st century.



3

1

4

2



5



6

4. CDRH Director Jeff Shuren shares his vision for implementation of the MDUFA IV reauthorization, as well as other reforms that the FDA is working on.

5. U.S. Senator Todd Young (IN) accepts the 2017 Chairman's Award for his leadership in repealing the medical device tax and supporting policies that boost innovation.

6. Chairman of the House Energy and Commerce Committee Greg Walden (OR) describes the recently enacted "CURES" legislation, as well as what his committee is working on that would impact medical technology development.

FEDERAL POLICY HIGHLIGHTS

“Having MDMA as a partner not only benefits our members and the industry, but more importantly the patients and providers across the United States who are relying on the next generation of medical technology innovation to address the challenges facing the health care ecosystem.”

John Lewis
President and CEO
BioOhio



Caps on Indian stents, orthopedics and other medical devices resulted in a 60% price drop.

INTERNATIONAL

MDMA continued to provide unique insight, analysis and advocacy on numerous international issues and trends by working with some of the most seasoned and influential sources around the world. Our focus in the international arena is to inform our members on the most important and ever-changing reimbursement and regulatory trends in the major and emerging medical device markets. From the United Kingdom, Germany and Japan, as well as from China, India and Brazil, MDMA was there gathering information and sharing insights with our members. From Germany’s planned cut in reimbursement because of the “perceived” over-payment of medical technology to India and China’s bolstered and expanded regulatory regimes, there is no shortage of challenges facing med tech innovators.

One of the most important issues of concern and consternation to MDMA members has been the new medical device regulation that was worked on in 2016 and was enacted in the spring of 2017. There will be a 3-year transition period whereby companies can use, for the most part, the EU’s existing medical device regulations or choose to submit applications under the new regulatory rules being enacted this year. Key issues to watch and to deal with under new EU medical device regulations include: the re-certification of Notified Bodies that can work with medical device firms going forward, additional “scrutiny” for higher risk Class III and Class IIb products, the new requirement placed on medical device firms for maintaining an “authorized representative” in the EU and a host of other transition issues to consider and make decisions on.

Top issues that MDMA worked on and addressed in 2017 included:

- The new EU Medical Device Regulation (MDR) which was passed into law in May 2017 with a transition period until May 2020
- New price caps in India causing price cuts of greater than 60% places on drug eluting stents, orthopedics and other medical devices
- Evolving Chinese medical device price controls and regulations which require more clinical trials, regulations and scrutiny of manufacturers
- Annual bundled payment (DRG) adjustments and expanding HTA (Health Technology Assessment) evaluations in major overseas markets including Germany, Japan, Australia and the UK
- International working group calls covering potential impacts of TPP agreement on industry and market access
- Continuing to monitor ongoing discussions on potential changes to the EU’s MDD
- Ongoing webinars and conference sessions on international issues to convey the latest intelligence and to answer MDMA member questions
- Monitoring latest regulatory developments in emerging markets such as India and South Africa
- Keeping MDMA members updated on new regulation and registration issues in China and Japan



LEGAL AND COMPLIANCE

MDMA continued to increase our offerings to members in the legal and compliance fields. We continued to work closely with our members to make sure they were kept up to date with the latest news in enforcement, as well as industry “best practices” to help companies maintain a robust compliance program.

Some of 2017’s top Legal and Compliance activities include:

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

Top left: Congresswoman Elise Stefanik (NY) receives the 2017 Chairman’s Award from MDMA Board Member and Executive Vice President, External Affairs of NuVasive, Inc. Carol Cox.

Top right: Chairman & Chief Executive Officer of Masimo Corporation Joe Kiani joins former Senator and HELP Committee Chairman Tom Harkin (IA) to discuss but how med tech innovators address unmet challenges that impact patient populations and demographics throughout the world.

Bottom: Attendees at MDMA’s programs get unique insights and experiences from leading policy makers and CEOs, and interact and network with executives from across the industry.



2017 WEBINARS

“MDMA’s educational programs and webinars provide instructional opportunities to hear the latest thinking and learn best practices in our rapidly changing industry.”

Jennifer Kerr
President
Cook Research, Inc.
Cook Medical

MDMA members benefit from multiple webinars that are archived and added to the members-only section of our website for later viewing. In 2017, we had 13 webinars addressing a wide range of topics impacting our members and medical technology innovation, ranging from patient assistance programs to the Supplier Quality and more. We also had 3 webinars hosted by FDA Staff:

Case for Quality

Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance and Francisco Vicenty, Program Manager–Case for Quality (acting), Office of Compliance presented the Case for Quality and how CDRH supports that vision. CDRH also provided details on their current quality-focused pilots and engaged on how this may provide benefit to small manufacturers or what potential barriers need to be considered.

CDRH 510(k) Review Template: A Demo of the 510(k) Smart Template Used by CDRH Reviewers to Review 510(k)’s

Patrick Axtell, Program Operations Staff, Office of Device Evaluation, Food & Drug Administration provided a demo that began with a brief description on how the Smart Templates were developed and are presently maintained, followed by a demo of the main characteristics and parts of the 510(k) Smart Template. The demo also included a brief look inside the automated guides used by reviewers to review cross-cutting disciplines (e.g., Biocompatibility, Sterilization, Cybersecurity). By the end of the demo attendees were able to understand how the template is used, how a single template can be used to review multiple device types, and what the components of the template are.

Role of the CDRH Ombudsman

Abiy Desta (CDRH Ombudsman) and Melissa Sage (CDRH Deputy Ombudsman) presented a webinar to explain the role of the CDRH Ombudsman. The CDRH Ombudsman’s office is an independent entity within CDRH that can facilitate in the resolution of scientific and regulatory disputes between companies and the Center, assuring fair and even-handed application of FDA regulations, policies, and procedures. The presentation walked MDMA members through the process of contacting the Office—beginning with what members can expect during an initial phone conversation to specific case studies and examples of the various methods used by the Ombudsman’s Office for resolving disputes and complaints. The presentation concluded with a discussion of the formal 21 CFR 10.75 Appeals Process and expectations for appeal meetings.

2017 PROGRAMS



2017 FDA FORUM

March 8-9, 2017: Palo Alto, CA

MDMA hosted another successful FDA Forum in Palo Alto, CA where several senior FDA officials joined with industry leaders to discuss critical issues affecting the medical technology industry. Topics included detailing the specifics of the user fee agreement, narrowing the gap between the regulatory process and securing reimbursement, and much more. Attendees had numerous opportunities to pose questions directly to FDA officials and expert panels which led to insightful and interactive sessions.



2017 ANNUAL MEETING

April 26-28, 2017: Washington, DC

Nearly 200 attendees were able to network and mingle with top policy makers and Members of Congress, as well as to get the latest insights from some of the most dynamic executives in our industry. Keynotes included an interactive "Town Hall Meeting" with CDRH Director Jeff Shuren, an address from the Chairman of the House Energy and Commerce Committee Greg Walden (OR) as well as Senator Amy Klobuchar (MN), and a Congressional Fly-In where attendees met with their Members of Congress, and much more.

Other popular panels included a celebration of MDMA's 25th Anniversary and discussing the importance of passionate advocacy, as well as a "Giving Back" discussion detailing what med tech innovators are doing to improve their communities. As a part of this panel, MDMA announced its support of a pilot program dedicated to supporting veterans and their families. To learn more about this program and to join this important work, contact Sheri DeVinney at sdevinney@medicaldevices.org.

Five leading Members of Congress also addressed attendees on the latest developments related to health care and tax reform and more.



10TH ANNUAL MEDICAL TECHNOLOGY EXECUTIVE FORUM

September 15, 2017: Palo Alto, CA

150 CEOs and senior executives joined us at our 10th 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.



20TH ANNUAL COVERAGE, REIMBURSEMENT & HEALTH POLICY CONFERENCE

November 8-9, 2017: Baltimore, MD

MDMA hosted another successful and interactive Coverage, Reimbursement & Health Policy Conference in Baltimore, MD. Attendees heard from a range of policy experts, leaders, industry executives and CMS officials on the current and future reimbursement trends and healthcare landscape.

Below: Chairman, President & CEO of Teleflex, Inc. Benson Smith shares best practices and techniques on how to strengthen teams and optimize growth with Annual Meeting attendees.



MDMA 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 and CEO
Verb Surgical, Inc.
Immedicate Past MDMA Chairman

Wil Boren

President
Advanced Surgery
Baxter Healthcare Corporation

Michael Carrel

President and CEO
Atricure

Kevin Conroy

Chairman
President and CEO
Exact Sciences

Carol Cox

Executive Vice President
External Affairs and Corporate
Marketing
NuVasive, Inc.

Joe Damico

Founding Partner and Co-Chairman
RoundTable Healthcare Partners

Ryan Drant

Founder and Managing Director
Questa Capital

Thomas Frinzi

Worldwide President
Surgical
Johnson and Johnson Vision

Doug Godshall

CEO
Shockwave Medical

John Groetelaars

Group President
CR Bard

Chris Holmes

President and CEO
Smiths Medical

Walt Humann

President and CEO
OsteoMed, LLC

Jennifer Kerr

President
Cook Research, Inc.
Cook Medical

Joe Kiani

Chairman and CEO
Masimo Corporation

George Leondis

President and CEO
Argon Medical Devices, Inc.

Pat Mackin

President
CEO and Chairman
CryoLife, Inc.

Eric Major

President
CEO and Co-Founder
K2M, Inc.

James Mazzo

Global President Ophthalmic Devices
Carl Zeiss Meditec Inc.
ZEISS Group

J. Casey McGlynn

Partner
Wilson Sonsini Goodrich & Rosati

James Momtazee

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

Rick Packer

Chairman
ZOLL Medical Corp.

Robert Perry

Vice President
Device Research and Development
Allergan, Inc.

David Pierce

SVP and President
Urology
Boston Scientific Corporation

Jason Richey

President
North America
LivaNova PLC

Walt Rosebrough

President and CEO
STERIS Corporation

Benson Smith

Chairman and CEO
Teleflex Incorporated

Spencer Stiles

President
Stryker Instruments

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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