MDMA
ANNUAL REPORT
2015

ADAPTING INNOVATION IN A
SHIFTING LANDSCAPE
THANK YOU
A MESSAGE TO MED-TECH INNOVATORS

Dating back to 2009, many thought that MDMA’s position against the device tax was untenable and foolhardy. Despite its passage as a part of the “Affordable Care Act,” we collectively never gave up fighting against this punitive policy, and suspension of the device tax is a testament to the passionate work of so many over the past six years.

On behalf of MDMA’s Board of Directors, thank you for supporting our commitment to put an end to the medical device tax, and for all the work you and your colleagues have done on behalf of this important issue. We will remain vigilant in working with you to fully repeal this tax, and will redouble our efforts to get this done.

MDMA also remains committed to making the regulatory process more reasonable and predictable, shortening the lag between the regulatory and reimbursement processes and maintaining a strong patent system. Our efforts on the device tax have shown that when innovators, patients and policy makers work together to improve the med tech ecosystem, we can make a difference.

If you are not a member of MDMA, we encourage you to visit www.medicaldevices.org and join our passionate work on behalf of innovators and patient care.

Once again, THANK YOU for all of your work and support of MDMA’s mission to improve the environment for innovative and entrepreneurial medical technology companies!

SINCERELY.

SCOTT HUENNEKENS
PRESIDENT & CEO, VERB SURGICAL, INC.
CHAIRMAN, MDMA

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
We all know that medical device innovation requires passion, tenacity, teamwork and commitment. In the face of the countless obstacles facing medical device entrepreneurs, no one can truly improve patient care and the human condition without these qualities. These same attributes are what rewarded MDMA’s steadfast opposition to the medical device tax by achieving a two-year suspension starting in 2016. We want to thank you for believing in and supporting MDMA’s advocacy on this important priority!

When MDMA first fought against the device tax in the summer of 2009, many thought it was a fool’s errand. Once this punitive policy was signed into law, even more thought it was useless to continue the battle. But just like the passion that drives our members, the MDMA team refused to give up, and steadily created a powerful coalition that, working together, suspended the tax. This advocacy is a perfect example how when industry works together and shares the powerful messages of what our technologies and advancements mean to patients, we CAN have a dramatic impact on the medical technology ecosystem. MDMA’s passion, tenacity, teamwork and commitment will continue to drive our efforts to fully repeal the medical device tax, as well as the countless other priorities we are focused on.

Some of our major accomplishments this year included:

■ Culminating six years of tireless outreach, suspension of the medical device tax was signed into law, as well as a permanent R&D tax credit and other important tax policies that will help innovative and entrepreneurial med tech companies

■ Leading up to the suspension of the device tax, MDMA led efforts in the House of Representatives to secure a veto-proof vote for a full repeal

■ Initiating MDUFA IV reauthorization negotiations with FDA, driven by our survey of MDMA member priorities

■ Working with FDA, AAMI and industry partners to make the post-market process more predictable, efficient and transparent by implementing a risk-based framework

■ Advocating policies with Congress and CMS that would narrow the gap between regulatory and reimbursement decisions

■ Working with the AMA to improve the transparency of the CPT and RUC process

■ Supporting targeted efforts in the Senate Judiciary Committee to strengthen the patent system such as the “STRONG Act,” as well as other amendments to various pieces of legislation that would support IP rights, while opposing provisions in the “PATENT Act”
MDMA’s passion, tenacity, teamwork and commitment will continue to drive our efforts to fully repeal the Medical Device Tax, as well as the countless other priorities we are focused on.

- Working with House leaders, Energy and Commerce Committee staff and CMS to push for successful adoption of ICD-10
- Building out our members-only compliance “toolkit,” while our International Working Group continues to host top experts and webinars to address our members’ needs

While suspension of the device tax and making the R&D tax credit permanent were certainly major milestones for MDMA, we also remained laser-focused on other pressing issues to our industry. Unfortunately, obtaining fair and adequate coding, coverage and payment continues to be a growing challenge for our industry, and MDMA has initiated several efforts to address these problems which will be expanded in the coming year.

We are also currently engaged in detailed negotiations with FDA over MDUFA IV reauthorization, and remain actively engaged with payors and specialty societies to improve the landscape for coding, coverage and payment. MDMA proudly engages head-on in legislative battles when they threaten the ability to innovate, and despite the House of Representatives overwhelming vote last year for legislation that would weaken the rights of patent holders, we led industry efforts in the Senate to ensure that this harmful legislation did not become law.

Lastly, the growing media and Congressional attention to the cost of care is a further reminder of how important it is that we educate policy makers about the powerful impact our technologies have on patient care. We know we have amazing stories to share, and MDMA is here to assist with this crucial outreach.

If you are not a member of MDMA, we strongly encourage you to join this energetic and passionate organization. While MDMA’s advocacy, education and outreach efforts help guide the seminal policies that impact your ability to innovate, it is YOUR voice and YOUR input that determine our priorities, and ultimately our success.

Again, we cannot thank you enough for your support and trust which enable MDMA to fight on behalf of our industry. The past few years have certainly been trying for medical technology innovators, but we have never lost sight that patients are the ultimate beneficiaries of our cumulative efforts. This will always be our guiding principle, and we will continue to passionately work on your behalf so that the promises of a better tomorrow are fulfilled.

Sincerely,

Scott Huennekens
President & CEO, Verb Surgical, Inc.
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
MDMA’s Annual Meeting includes insights from leaders in industry, Congress, federal agencies, academia and more. Clockwise from top-left: Paul LaViolette, Managing Partner & Chief Operating Officer, SV Life Sciences, Angela Sykes, Director, Technology Center, US PTO Office, Prof. James Chambers, Tufts Medical Center, Senator Amy Klobuchar (MN). Center: Sean Tunnis, Founder and CEO, Center for Medical Technology Policy.
FEDERAL POLICY HIGHLIGHTS

FOOD AND DRUG ADMINISTRATION (FDA)

A reasonable, efficient and consistent premarket and post-market regulatory system remains a top priority for MDMA. MDMA and our members have been actively engaged with the Association for the Advancement of Medical Instrumentation (AAMI), FDA and other stakeholders to bring a risk-based approach to post-market activities, and we advanced numerous policies and ideas to enhance the premarket process. In addition, MDMA initiated MDUFA IV negotiations seeking process improvements to reduce unnecessary delays, provide more accountability and accelerate patient access to new technologies.

MDMA participated in the public stakeholders meeting with FDA, patient groups and more to discuss priorities for MDUFA IV, and what the goals should be as we work together to improve the innovation ecosystem.

The House of Representatives also overwhelmingly passed the “21st Century Cures Act” by a vote of 344-77. The legislation includes several provisions designed to increase access to the treatments and therapies of tomorrow for patients, but also contains some provisions that would stifle patient access. MDMA will continue to work with the House and Senate as this legislation moves forward, and increase activity with the MDUFA IV negotiations, driven by the priorities identified by our members.

Other highlights included:

- MDMA worked with FDA, AAMI and industry partners to make the post-market process more predictable, efficient and transparent by implementing a risk-based framework
- Coordinating visits with Members of Congress and MDMA members to help assess FDA experiences and how legislation could address current challenges
- Providing ongoing legislative suggestions and feedback to Congressional Committees as the “21st Century Cures Act” was drafted
- Ongoing work with Booz Allen Hamilton on their Independent Assessment
- Hosting a webinar focusing on “Best Practices in Risk Reduction for Medical Device Manufacturers”
- Continued quarterly meetings with FDA and other stakeholders to examine how the agency is meeting the metrics and goals established in MDUFA III
- Participated in a workshop with FDA and others to examine the post-market risk management of medical devices
- Submitted comments to FDA on “Clinical Trials Registration and Results Submission”

95% of MDMA members preferred PREDICTABILITY over SPEED as the focus in MDUFA negotiations.
DEVICE TAX

Following more than six years of leadership and passionate advocacy, MDMA secured a two-year suspension of the medical device, to include sales for 2016 and 2017. While this milestone was the culmination of work that began when the device tax was first proposed in the summer of 2009, a major catalyst this year was the historic vote in the House of Representatives in June. The 280-140 final tally was largely a result of the passionate outreach by MDMA members leading up to the vote.

The Senate held hearings as well on the medical device tax where MDMA members testified, all which built up towards this victory for innovation. MDMA remains committed to a full repeal of this onerous legislation, and will be working towards this goal in 2016 and beyond.

MDMA expanded the coalition of innovators, regional organizations and stakeholders to maximize the voice for device tax repeal, leading to countless outreach, points of contact, letters to Congress, earned media and more.

Additionally, MDMA has long worked with Congress to ensure that the R&D tax credit was continued as a part of “tax extenders” legislation, while urging lawmakers to make this critical policy permanent. Congress finally agreed and also made the R&D tax credit a permanent tax policy which will provide predictability for med tech innovators.

Highlights:
- A two year suspension of the medical device tax was included in legislation overwhelmingly approved by Congress, and signed into law by the President
- Organized an intricate outreach and grassroots campaign for both the House vote on device tax repeal as well as during Congressional year-end negotiations, incorporating traditional and social media tools
- The House of Representatives voted to repeal the medical device tax 280-140, greatly increasing Congressional support from the last effort with a veto-proof majority
- MDMA conducted a survey of innovators to show policy makers how repealing the medical device tax would increase investments in R&D and job creation
- MDMA organized and led a coalition letter to Congressional leadership urging them to act quickly on device tax repeal with over 900 signatories
- Worked with various groups within Congress to show the broad support for repealing the tax, including the incoming Freshman class, as well as Democratic leaders
- Continued to work with innovators and industry leaders to drive attention to the negative impact this misguided tax is having on local economies and patient care
- MDMA members continuously went before Congress to share the harmful impact of the tax, and urging them to act quickly

Left: Cook Group Chairman Steve Ferguson awards Senator Dan Coats (IN) with MDMA’s “Legislator of the Year” award for 2015.

Right: CMS Deputy Administrator and Director Sean Cavanaugh engages with attendees about the agency’s latest payment reforms for medical technologies.
In 2015, MDMA continued working with Congressional Committees, CMS and others to ensure that medical technologies and devices receive timely and appropriate reimbursement.

**REIMBURSEMENT**

Narrowing the gap between the regulatory and reimbursement decisions is a top priority for MDMA. In 2015, MDMA continued working with Congressional Committees, CMS and others to ensure that medical technologies and devices receive timely and appropriate reimbursement.

We recognize how critical it is for companies to have a fair coding, coverage and payment process. As a result, we continue to 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.

Highlights:
- Ongoing discussions with CMS, FDA and payors to shorten the gap between regulatory approval and coding, coverage and payment
- Worked with House leaders, Energy and Commerce Committee staff and CMS to push for successful adoption of ICD-10
- Working to include language in the “21st Century Cures Act” that would require local MACs to be more transparent related to coverage decisions and establish a CMS Ombudsman
- Submitted comments on CMS’ Winter 2015 Advisory Panel on Hospital Outpatient Payment (HOP)
- Submitted comments on CMS’ proposed changes to the hospital inpatient prospective payment system (IPPS), focusing on add-on payments, bundled payment initiatives, ICD-10 and more
- Submitted comments on the outpatient prospective payment system (OPPS) and physician fee schedule (PFS)
- Submitted comments to CMS on its “Medicare Shared Savings Program: Accountable Care Organizations” proposed rule
- Shared concerns with CMS over its OPPS pass-through process
- Ongoing work to make the CPT process more transparent and fair

**MAINTAINING A STRONG PATENT SYSTEM**

Despite increasing momentum to drastically change the nation’s patent laws, MDMA worked with a diverse coalition of life science stakeholders to prevent an overhaul of the system that would have penalized medical technology patent holders. MDMA continues to support efforts to curb abusive practices of patent assertion entities (PAEs) or “patent trolls,” but we worked with a growing coalition of innovators to ensure this is not done at the expense of innovation.

MDMA members worked with a coalition of life science industries to develop a documentary that highlights just how precious the innovation ecosystem is, and hosted events that brought in leading policy makers to address the threats in patent reform proposals.

- MDMA supported targeted efforts in the Senate Judiciary Committee to strengthen the patent system such as Senator Chris Coons’ STRONG Act, as well as other amendments to various pieces of legislation that would support IP rights, while opposing provisions in the PATENT Act
MAINTAINING A STRONG PATENT SYSTEM continued

- MDMA and a broad coalition of stakeholders from across the American innovation ecosystem opposed certain provisions in the House Judiciary Committee this spring to alter the patent system due to concerns over the broad scope of the legislation.

- MDMA worked with House leaders to gather support for the “Targeting Rogue and Opaque Letters Act (TROL Act)” which would allow law enforcement agencies to go straight to civil penalties for bad faith demand letters.

MDMA will work with the House and Senate Judiciary Committees to find targeted solutions to frivolous and illegitimate patent lawsuits, while also pushing back on proposals that would weaken the intellectual property rights of med tech innovators.

COMPLIANCE

MDMA continued to increase our offerings to members in the compliance field. This included adding to our “compliance toolkit” for our members and gathering industry best practices as we all seek to address the shifting landscapes and heightened scrutiny by government agencies corporate activities.

MDMA’s Vice President of Compliance Jackie Huber increased the scope and interaction of the Compliance Working Group, and we hosted several opportunities—both in-person, online and via teleconference—for compliance professionals to discuss the latest trends and share insights, including:

- Hosting a webinar to address anti-corruption and anti-bribery efforts that various national and international government entities are undertaking.

- MDMA’s Annual Meeting hosted a special session analyzing topics including cybersecurity, sunshine challenges, vendor credentialing, UDI and more.

- Hosting a webinar focusing on “Cybersecurity: Risks and Best Practices for Medical Device Makers”

- Sharing best practices and addressed challenges with CMS’ Open Payments system

“Whether fighting against the device tax or stopping legislation that would weaken patent rights, MDMA’s passionate, unwavering and effective advocacy allows our team to continue innovating and growing. As the health care delivery system evolves, it is also a tremendous asset to have access to MDMA’s resources and educational tools.”

Robert Kieval
Founder & Chief Development Officer
CVRx Inc.
2015 MDMA Annual Meeting attendees enjoying insightful panels and networking events.
INTERNATIONAL

MDMA continued to provide comprehensive analysis and advocacy on international issues to keep our members up to date on the latest trends. We worked with international partners and others as the European Union (EU) sought to take steps to tighten regulations on medical devices throughout the continent. The EU continues to take steps that will increase scrutiny through notified bodies, post-market surveillance and clinical investigations. Device manufacturers will now be required to form a postmarket surveillance system “proportionate to the risk class and appropriate for the type of device.” Further, companies must demonstrate that their products have an acceptable benefit-to-risk ratio.

MDMA provided insights on China’s regulatory agency of medical devices, the China Food and Drug Administration (CFDA), as it planned to collect fees from foreign medical device manufacturers. We also updated members on India’s new monitoring program of medical devices, and analyzed India’s Ministry of Health and Family Welfare activity on changes to their Drugs and Cosmetics Act of 1940, which includes a definition of medical devices that covers in vitro diagnostic (IVD) products, as well as expanded requirements for manufacturing, importing and marketing medical devices.

Other highlights included:

- Monthly calls on hot industry issues, with insights from top international experts including Jean Marie Vlassembrouk, Former Chairman of Eucomed, Gerry Zapiain, Senior International Trade Specialist at the US Department of Commerce, Amy Hariani, Director and Legal Policy Counsel for the US-India Business Council and more
- Monthly newsletters that take a look back and a look ahead at current issues on the international scene
- Webinars on the latest international best-practices, including “Opportunities in the Asian Medical Device Markets”

MDMA’s International Working Group can help you and your company navigate the challenging international issues and opportunities confronting med tech innovators today.

COST OF CARE

Insurers and hospitals continued a rapid pace of consolidation, and pricing pressures impacted medical technology innovators more and more. Congressional and presidential campaigns are also increasingly highlighting this issue, and 2017 will surely result in some form of legislative activity. This is why it is critical to share the value of innovation, and why it is important to have a fair and adequate reimbursement system that rewards investments in patient care.

MDMA remains vigilant in highlighting the critical importance of patient access and long-term value vs. short-term price cuts.

Major developments in this area included:

- CMS updated its data on medical services physicians provide and how much they are paid under Medicare Part B Fee-For-Service
- Private payors and federal investigators continue to question the wide variety of health care costs in similar regions, as well as the role of stakeholders in determining costs
- Medicare released a detailed look at prescription drug prices, and is examining other areas in the healthcare ecosystem to do similar transparency efforts
- Patient, consumer, employer, physician and insurer organizations continued to join together to form coalitions demanding more pricing transparency from innovators and others
- CMS expanded its bundled payments models for knee and hip replacements, and is looking at other procedures and regions where it will further study the reform method

“As the health care ecosystem becomes more complex, it is critical that the medical device industry works together to improve the environment for innovation. MDMA is a dynamic partner with their state and regional allies as we all advocate on behalf of innovators.”

Kelly Slone
President & CEO
BioUtah
MDMA is the leading voice representing the interests of innovative and entrepreneurial medical technology companies. We provide education and advocacy assistance to hundreds of member companies. MDMA members all share a common goal: to ensure that patients and clinicians have timely access to safe and effective medical technologies that improve our quality of life.

Washington has never played a more direct role in a medical technology company’s ability to succeed. Changes with the regulatory process at FDA, implementation of the healthcare reform law, increasing reimbursement challenges and the medical device tax are just a few of the key issues being discussed and debated on Capitol Hill.

MDMA provides members with the opportunity to learn about and engage on the key issues facing the medical technology industry. Some of the benefits of membership include:

- Leveraging the experiences and insights of 300 member companies
- Breaking news alerts, weekly MDMA Updates and more
- The chance to network with peers and leading industry experts
- Member discounts to a variety of services and events

**Monthly Working Group Calls**
MDMA members are actively involved in developing and implementing MDMA’s public policy agenda. Our monthly working groups address the many challenges facing innovative medical device companies. Each working group meets monthly via conference call and receives additional email updates and breaking news.

- FDA
- Coverage and Reimbursement
- Device Tax
- Patent
- International
- Compliance
- Market Access
- Public Affairs

“**There’s no shortage of challenges confronting medical technology innovators. We need a strong ally in Washington to help educate lawmakers and overcome these challenges. MDMA is a powerful voice with a strong reputation that ensures our industry is being heard loud and clear.”**

Jeff McCaulley
President & CEO
Smiths Medical
2015 WEBINARS

In 2015, we had 10 webinars addressing a wide range of topics impacting our members and medical technology innovation, ranging from regulatory and international issues, to reimbursement and more. Some of our most popular webinars included:

**Cybersecurity: Risks and Best Practices for Medical Device Makers**

Beyond data breaches, security risks can lead to patient harm by interfering with the proper functioning of medical devices. This webinar described FDA’s current expectations for cyber-security protections, and offered strategic cyber-security considerations for product clearance and life cycle management. Akin Gump’s attorneys recommended best practices for preventing and responding to breaches, and addressed the latest policy developments concerning cybersecurity.

**Best Practices in Risk Reduction for Medical Device Manufacturers**

The webinar addressed the following topics:
- Life Science Product Liability/Human Clinical Trial Litigation Drivers
- Product Liability Insurance Considerations
- Life Science Property and Business Interruption Exposures and Controls

**Where in the World? Global Location Frontiers for Medical Device Manufacturers**

As the world markets evolve and the economic tides shift, opportunities and challenges for global growth and competitive advantage are becoming more dynamic. Performance driven companies require global perspective, experience and knowledge to navigate the process of global location selection successfully. But where do you start? Where are the Global Location Frontiers that will provide maximum value for your expanding business?

**Opportunities in the Japanese and Chinese Medical Device Markets**

This webinar focused on:
- Best market entry strategies for Japan and China
- New regulations and registration issues in Japan and China
- Pitfalls to avoid and best ways to succeed in Japan and China

**Supply Chain Chemical Regulation Update**

Managing regulatory compliance and associated risk includes assimilating changes in chemicals regulation. Substances in the supply chain are newly added to regulatory “lists” and others are moved to different levels of regulation—impacting supply chain operations and presenting challenges and opportunities for product manufacturers.
The MDMA Board of Directors represents a broad cross section of our membership and the medical device industry. Voting members include:

**Scott Huennekens**  
MDMA Chairman  
President & CEO  
Verb Surgical, Inc.

**Daniel Moore**  
Immediate Past MDMA Chairman  
Chairman  
LivaNova

**Carol Cox**  
Executive Vice President,  
External Affairs &  
Corporate Marketing  
NuVasive, Inc.

**Joseph Damico**  
Founding Partner & Operating Partner  
RoundTable Healthcare Partners

**Scott Drake**  
Chief Executive Officer  
Spectranetics Corporation

**Ryan Drant**  
Founder  
Cuesta Capital

**Mark Gilreath**  
Founder, President & CEO  
EndoChoice, Inc.

**Doug Godshall**  
President & CEO  
HeartWare, Inc.

**Walt Humann**  
President & CEO  
OsteoMed, LLC

**Joe Kiani**  
Founder, Chairman & CEO  
Masimo Corporation

**Robert Kieval**  
Founder & Chief Development Officer  
CVRx, Inc.

**Paul LaViolette**  
Managing Partner & COO  
SV Life Sciences Advisors

**Pat Mackin**  
President & CEO  
CryoLife, Inc.

**Eric Major**  
President & CEO  
K2M, Inc.

**James Mazzo**  
Chairman & CEO  
AcuFocus, Inc.

**Jeff McCaulley**  
President & CEO  
Smiths Medical

**J. Casey McGlynn**  
Partner  
Wilson Sonsini Goodrich & Rosati

**Rick Packer**  
Chief Executive Officer  
ZOLL Medical Corporation

**David Pierce**  
SVP & President, Endoscopy  
Boston Scientific Corporation

**Jane Rady**  
Divisional Vice President,  
Business Development  
Abbott Medical Optics, Inc.

**Benson Smith**  
Chairman, President & CEO  
Teleflex Incorporated