The past several years have been very challenging for the medical technology ecosystem. However, the collective efforts of MDMA and our members have clearly gained the attention of elected officials and policy makers on how we can work together towards our common goals. Our numerous outreach efforts and grassroots activities have allowed our industry to sound the alarm bells for how misguided policies and legislation can adversely impact a proud leader in innovation.

Some of our accomplishments this year included:

- Leading continued efforts to repeal the medical device tax, MDMA built bipartisan support to include repeal in the House of Representative’s jobs plan, H.R. 4, and the Ways and Means Committee tax reform package. This was the only ACA related provision to be included.
- Working with the House Energy and Commerce Committee on their “21st Century Cures” Initiative, providing input and assisting with Congressional testimonies, while focusing on making coding, coverage and payment for medical technologies more efficient and transparent.
- Defeating unbalanced attempts to revise the patent system that would have gone beyond “patent trolls” and weakened innovators’ ability to protect their intellectual property.
- Actively engaging FDA to make the regulatory system more predictable and consistent, and taking a more risk-based approach to post-market activities. This led to the formation of an industry-FDA collaboration that is ongoing.
- Submitting numerous comments to FDA, CMS and other regulatory agencies, including on 510(k) modifications, benefit-risk factors in examining substantial equivalence, OPPS/IPPS, gainsharing and much more.
- Building out compliance and legal capabilities for our members, including expansion of our “tool kit,” as well as providing numerous opportunities for professionals to interact and meet with FDA staff.

As we all continue to adapt to a quickly changing environment—both politically and economically—it is crucial that we maintain the focus that has allowed us to achieve many of our objectives over the years. Much more work needs to be done to improve the regulatory framework, but we are well into the implementation of MDUFA III with some promising signs of positive developments. Very few thought that repeal of the medical device tax was achievable, but now leaders in both parties and in both Chambers of Congress describe it is a bipartisan objective. These and many more efforts are a direct result of the tireless work of the MDMA team and our proud medical technology community.

In addition, as the debate over the cost of care continues, CMS released updated data on common inpatient and outpatient services. MDMA directly worked with Members of Congress and key committees to share the positive role that medical technology innovation has in reducing costs and improving outcomes.

Working in the medical device industry inherently means that we take the long view of our work, recognizing there is a larger objective that makes all of the challenges and obstacles we face worth it: improving patient care. The vision and passion that drives us every day are the very qualities that have led the United States medical device industry to become the world leader in this noble field.
We all stand on the shoulders of the innovators who preceded us, and we must never forget the tremendous responsibility we all have to improve the ecosystem not just for today, but for the engineers, doctors and entrepreneurs who will follow us.

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 help guide the seminal policies that impact your ability to innovate.

The larger our voice, the more we are empowered to drive the necessary changes that will help ensure a better tomorrow for patients and innovation.

Sincerely,

Scott Huennekens
President & CEO, Volcano Corporation
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
FDA

Without a consistent, efficient and transparent FDA, U.S. patients will continue to face delays in accessing novel technologies that improve outcomes. While many member companies have seen improvements with the premarket program, more work remains. In the past year, MDMA continued working closely with FDA and policymakers to implement reforms under MDUFA III to accelerate patient access. This included working closely with Booz Allen Hamilton as they completed Phase One of the 3rd party assessment of the regulatory process. In response to this report, CDRH published its “Plan of Action” addressing their priority recommendations. This ongoing 3rd party assessment of the premarket review process will continue through 2016.

In addition, MDMA heard increasing concerns about the lack of predictability and consistency with FDA’s post-market program. To quantify the impact, MDMA surveyed our members and found that the concerns were widespread and there were a number of areas that demonstrated the need for FDA to take a more risk-based approach on post-market matters. MDMA worked with FDA and others to begin to address these concerns, and we continue to push for enhancements that will benefit patients, providers and innovators in the year ahead.

Other highlights include:

■ Continued to actively engage FDA and Congress to ensure that any changes to the 510(k) modifications process are limited and reasonable
■ Opposed attempts by the FDA to administratively change the classification process for medical technologies
■ Supported targeted efforts to incorporate benefit-risk factors for certain 510(k)s
■ Assisted with testimonies before the House Energy and Commerce Committee hearings on their “21st Century Cures” Initiative
■ Worked with member companies on the implementation of UDI, including a webinar featuring Jay Crowley, a former FDA official who led the program
■ Engaged Congress to restore collected user fees and increased funding for FDA included in the FY 2014 Omnibus Appropriations bill
DEVICE TAX REPEAL
Two years into this ill-conceived tax, companies continue to divert scarce resources from R&D and job creation to pay for it. In 2014, MDMA continued to lead efforts to repeal the medical device tax, resulting in the greatest amount of support in Congress to date. This is a result of the passionate grassroots work by MDMA members and others who continue to work on this pressing issue.

Highlights include:
- The House passed the medical device tax repeal in September as part of its JOBS bill, the “Jobs for America Act,” which was the only ACA tax included in the package.
- Building on the 2013 survey of the impact of the device tax, MDMA conducted a new survey from over 100 innovators examining how repeal of the tax would improve job creation and R&D.
- MDMA staff and member companies appeared on national TV and in print media, highlighting the devastating impact the tax is having on innovation, patient care and the economy.
- Repeal of the medical device tax was included in House Ways and Means Chairman Dave Camp’s (MI) comprehensive tax reform plan. This is the only ACA related tax that was included in the Chairman’s plan.
- MDMA members testified during Congressional briefings on how to improve the ecosystem for medical technology innovation, including repeal of the device tax.

MDMA SURVEY ON DEVICE TAX
THE IMPACT OF REPEALING THE DEVICE TAX FOR INNOVATORS

- 85% Create new jobs
- 80% Increase R&D
- 14% Average R&D budget increase

Left (top): CDRH Director, Jeff Shuren addresses attendees to provide an update on MDUFA implementation and to answer questions from the audience on FDA’s priorities.

Left (bottom): Senator Kelly Ayotte (NH) receives a 2014 MDMA Chairman’s Award for her tireless work to repeal the medical device tax.

Below: Attendees gather at the MDMA 2014 Annual Meeting Opening Reception to hear from some of the nation’s leading voices in medical technology innovation.
WORKING WITH POLICY MAKERS

REIMBURSEMENT
Over the past few years, companies have faced increasing challenges related to coding, coverage and payment. MDMA has engaged a number of stakeholders including CMS, AMA, private payors and Congress to ensure that medical technologies and devices receive timely and adequate reimbursement. In addition, we continue to work with member companies to address some of the specific challenges they are facing while addressing industry-wide concerns.

As Congress sought proposals for its “21st Century Cures Initiative,” MDMA focused on ways to make the coding process more transparent, the coverage process more reasonable and the payment process sufficient.

Other highlights include:
■ Ongoing engagement with the AMA and other stakeholders to make the CPT process more transparent and predictable
■ Developed proposals to shorten the gap between regulatory approval and reimbursement
■ Made recommendations to CMS to allow for greater adoption of new tech add-on payments and pass-through payments to enhance patient access and promote innovation
■ Worked with CMS and Congress to highlight concerns with certain payment models that have the potential to penalize the use to newer technologies, including some bundled payment models and gainsharing arrangements
■ Working with member companies and others to assess trends related to coverage of technologies with Category III codes and ways to ensure coverage earlier in the process

COST OF CARE
The rising cost of health care is an area that has received significant attention over the past few years. MDMA continues to work with various stakeholders in the health care delivery ecosystem to address the growing chorus examining the increasing cost of care. As the Affordable Care Act and other policies lead to new models for accessing and delivering health care, it is more critical than ever that medical technology innovators be prepared to share their stories and data on how they are decreasing long-term costs and improving outcomes. MDMA is constantly educating policy makers on the value of medical technology, and sharing the stories of how your innovations improve patient outcomes.

Major developments in this area included:
■ Aggregated data from a variety of government and private sector sources which validate that medical devices are a very small percentage of the overall health care spend and identifies the real drivers of increased costs over the past decade
■ Participated in meetings with leading executives from hospital systems, the insurance industry, and drug and device companies to discuss ways we can work together to improve quality, reduce costs and not sacrifice patient or physician choice
■ Ongoing engagement with Members of Congress to discuss the role of medical technology in reducing overall health care costs

“MDMA’S PASSIONATE ADVOCACY IS EXACTLY WHAT OUR INDUSTRY NEEDS AT A TIME WHEN THE HEALTH CARE ECOSYSTEM IS CHANGING SO RAPIDLY. THEIR INSIGHTS AND STRATEGIC VISION ARE SECOND TO NONE.”
Mark Gilreath, Founder & CEO, EndoChoice, Inc.
Above top: Attendees listen to a panel session regarding changes to reimbursement models and clinical trial design, and what today’s executives need to know.

Middle: Patient advocates share their powerful stories how medical technologies are saving lives, and why innovators must remain resilient in this challenging environment.

Bottom: Senator Lamar Alexander (TN) receives a 2014 MEMA Chairman’s Award for his leadership on improving the FDA regulatory pathway.
PATENT LEGISLATION

Patent reform legislation remains an active area as innovators continue to look for ways to enhance existing law to promote and protect innovation. Unfortunately, some proposed changes by stakeholders not involved in medical technology innovation would have a detrimental impact on our industry. While MDMA is supportive of efforts to curb abusive practices of patent assertion entities (PAEs) or "patent trolls," we worked aggressively with other organizations representing the life science ecosystem, universities and high tech groups to ensure doing so didn’t make it more costly and burdensome for innovators to defend or assert their intellectual property rights.

Highlights:

- Supported targeted efforts in the Senate Judiciary Committee to strengthen the patent system like Senator Dianne Feinstein’s proposal to permanently repeal the practice of “fee diversion” at the U.S. Patent & Trademark Office (USPTO)
- Worked with a broad coalition of stakeholders from across the American innovation ecosystem who opposed certain provisions in the Senate Judiciary Committee to alter the patent system due to concerns over the broad scope of the legislation and its potential to negatively impact future med tech innovation
- Endorsed legislation introduced in the House Judiciary Committee that appropriately targeted abusive demand letters sent by patent trolls but protected the constitutionally guaranteed rights of legitimate patent holders
- Helped lead efforts to support the “Trade Secrets Protection Act” that would create a harmonized, uniform standard and system for companies to protect their trade secrets

“MDMA recognizes the importance of sharing the incredible stories of medical technology, and they are a strong partner in working with all stakeholders to empower this dynamic industry to help reduce the cost of care.”

April Giles, President & CEO, Colorado BioScience Association
COMPLIANCE

Recognizing the growing complexities that compliance issues present to medical technology innovators, MDMA added Jackie Huber as our new Vice President of Compliance.

MDMA hosts monthly Compliance Working Group calls, and works with regulators and industry professionals on improving practices. Building off of our compliance “toolkit” that includes sample governance, training and auditing documents, MDMA organized several activities to educate members and improve processes including:

■ Hosted a 2-day Compliance Conference with the American Bar Association with industry peers and experts to discuss key topics and to exchange best practices
■ Led Sunshine Act webinar to answer questions on the “nuts and bolts” of report submission and compliance readiness
■ Conducted a post-market inspection survey to aggregate member experiences and establish proposals to improve the process
■ Expanded MDMA’s Compliance tool kit with a variety of domestic and international documents

INTERNATIONAL

Beyond our efforts to improve the US environment for medical technology, MDMA continued its proud tradition of providing an array of services and opportunities on international issues, and what the global markets offer for medical technology innovators.

This year’s efforts included:

■ Coordinated with members for participation in a U.S. Department of Commerce trade mission to South Korea and Japan
■ Ongoing work with the European medical device association, Eucomed, to limit any potential changes to the Medical Device Directive
■ Held numerous webinars detailing the latest global changes to the regulatory environment, including the China Food and Drug Administration revised regulations on labeling, registration and distribution
■ Analyzed and detailed new Japanese medical device regulations, including its impact on Class 2 and Class 3 devices and software

Left (top): Senator Joe Donnelly (IN) provides an update on efforts in the U.S. Senate to repeal the medical device tax and to support adequate reimbursement for innovations.
Left (bottom): Over 150 senior executives attended this year’s Annual Meeting, here networking at the Chairman’s Reception and discussing the day’s unique panels.
Below: Senator Bob Casey (PA) discusses the role medical technology can play in reducing healthcare costs and preventing errors in the delivery of care.
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

VALUE OF MDMA MEMBERSHIP

“MDMA’S RESOURCES AND PROGRAMS ARE AN INVALUABLE ASSET TO MY TEAM AS WE SEEK TO ADDRESS TODAY’S CHALLENGES IN THE MARKETPLACE. THE VALUE PROPOSITION SIMPLY CAN’T BE BEAT.”

Doug Godshall, President & CEO, HeartWare, Inc.

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
2014 WEBINARS

MDMA members benefit from multiple webinars that are archived and added to the members-only section of our website for later viewing. In 2014, we had 12 webinars addressing a wide range of topics impacting our members and medical technology innovation, ranging from regulatory and international issues, to post-election analysis and more. Some of our most popular webinars included:

**Sunshine Act Compliance: Countdown to Disclosure**
This session focused on the “nuts and bolts” of report submission and compliance readiness. Topics addressed were: Latest CMS developments, data remediation pointers, appropriately classifying spend items, physician outreach, pre-disclosure and dispute processing.

**The Realities of UDI Implementation**
Jay Crowley, author of the UDI rule and former CDRH Senior Advisory for Patient Safety, presented a review of FDA’s UDI final regulation and addressed some of the implementation challenges that have started to arise.

**21st Century Cures: Accelerating the Discovery, Development and Delivery of Medical Technology**
Congressional leadership outlined their “21st Century Cures” initiative, a bipartisan examination of federal policy aimed at accelerating the pace of cures and medical breakthroughs in the U.S. Participants were given the opportunity to directly engage with Congressional staff as they began drafting comprehensive legislation to address many of the top regulatory challenges facing the device industry.
MDMA OFFERS UNIQUE EVENTS

2014 PROGRAMS

2014 FDA Forum:  
March 5-6, 2014 – Palo Alto, CA  
MDMA’s 2014 FDA Forum focused on unique insights and strategies to govern the 510(k) and PMA regulatory pathways. FDA Officials, Christy Foreman, Director, CDRH’s Office of Device Evaluation and Barbara Zimmerman, Deputy Director, CDRH’s Office of Device Evaluation addressed attendees on: Recent trends in Device Regulations, navigating the 510(k) program, clinical trials & PMA review considerations, and MDUFA III. Our expert panels also provided an interactive session with open dialogue and “real life” situations.

2014 Annual Meeting:  
May 14-16, 2014 – Washington, DC  
Attendees at this year’s conference heard from innovators, patient advocates, Members of Congress, regulators and more. Senators Kelly Ayotte (NH), Bob Casey (PA), Al Franken (MN), Joe Donnelly (IN) and Lamar Alexander (TN) addressed meeting attendees and inspiring patient panels reiterated how our industry is helping people live longer, more fulfilling lives. Senators discussed the broad, bipartisan support for repeal of the medical device tax and how they continue to work together to get this accomplished, as well as the need to continue making the regulatory environment more reasonable and predictable.

More than 150 industry professionals were in attendance for this year’s conference and dozens of executives participated in over 50 meetings on Capitol Hill with Members of Congress and their staffs as a part of the Congressional fly-in.

7th Annual Medical Technology Executive Forum:  
September 25, 2014 – Palo Alto, CA  
Nearly 150 CEOs and senior medical technology executives gathered at the Crowne Plaza Cabana Hotel in Palo Alto for MDMA’s 7th Annual Medical Technology Executive Forum. Attendees heard from a broad range of speakers representing the entire spectrum of the medical technology industry for intimate discussions on the current trends and challenges impacting patient care and the industry today.

17th Annual Coverage, Reimbursement and Health Policy Conference:  
November 12-13, 2014 – Baltimore, MD  
Med tech reimbursement professionals and decision makers gathered in Baltimore, Maryland for MDMA’s 17th Annual Coverage, Reimbursement & Health Policy Conference. Participants interacted with a number of experts from CMS, industry and more on a wide ranging list of issues impacting the coverage, coding and reimbursement of medical technologies.

MDMA & ABA Compliance Roundtable: December 11-12, 2014 – Washington, D.C.  
Medical Device and Legal Professionals: A Collaborative Exchange was held December 11-12, 2014 in Washington, D.C. hosted by MDMA and American Bar Association. This program brought together general counsel, private practice lawyers and medical device executives to discuss effective compliance programs, best practices and emerging trends in such areas as off-label marketing and mHealth, among others. The program dedicated a full day to practical demonstrations based on hypothetical internal investigations that covers identifying the compliance issues, to strategies for settling with the government, which involved an actual medical device CEO acting as the responsible corporate officer.
Above top: Attendees take full advantage of the interactive component of MDMA’s events, engaging with some of the nation’s top elected officials and policy makers.

Second: Highlights of the 2014 meeting included a presentation of cutting-edge exoskeletons that allow the paralyzed to walk.

Third: Attendees gather at the Closing Reception on Day 3 of another successful MDMA Annual Meeting.

Fourth: Outgoing MDMA Chairman and President and CEO of Cyberonics Inc. Dan Moore addresses attendees on some of the associations top priorities and outreach activities on behalf of our members.
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
  Volcano Corporation

- **Daniel Moore**
  Immediate Past MDMA Chairman
  President & CEO
  Cyberonics, Inc.

- **Wil Boren**
  President
  Biomet SET

- **Joseph Damico**
  Founding Partner & Co-Chairman
  RoundTable Healthcare Partners

- **Scott Drake**
  General Partner
  Spectranetics Corporation

- **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 & CTO
  CVRx, Inc.

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

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

- **Jeff McCaulley**
  President & CEO
  Smiths Medical

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

- **Eric Meier**
  President & CEO
  Cervel Neurotech

- **Steve Meyer**
  President & CEO
  Welch Allyn

- **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
Thomas “Tommy” Thompson served as the Founding Chairman and longtime Board Member of the Medical Device Manufacturers Association (MDMA).

Tommy was a passionate leader and a tireless mentor whose central focus was to improve the human condition and support America’s medical technology ecosystem.

Tommy was the leader of several medical technology start-ups including Vicra, which was acquired by Baxter, Quest Medical, a public company that designed, developed, manufactured and marketed proprietary medical products, and most recently the Neuro Resource Group, Inc. (NRG).

Tommy joined with a group of innovators in 1992 to establish MDMA with the belief that the innovative and entrepreneurial sector of the industry needed a strong and independent voice in the nation’s capital. What started as a handful of medical technology companies has grown to nearly 300 members across the United States.

We have all lost a selfless advocate who dedicated his life to ensure that America would be better able to address the challenges in health care with innovative medical technologies.