When a handful of medical device innovators gathered in 1992 to discuss the state of the industry, they were concerned that the interests of the innovative and entrepreneurial sector of our ecosystem were not being represented before Congress and federal agencies. They agreed that in order for the United States to continue leading the world in developing and manufacturing the cures and therapies that patients and providers deserve, they needed a voice in Washington that would advocate for the right policies.
Those early conversations 25 years ago led to the creation of the Medical Device Manufacturers Association. While MDMA may have only started with a handful of companies as members, each one recognized that the same passion and perseverance that allowed them to transform patient care, if harnessed together, could also enable them to improve the innovation ecosystem. Today, MDMA is proud to have almost 300 members who work collectively to carry on this vital mission that began 25 years ago.

As we celebrate our 25 year anniversary, this milestone is a humbling reminder of the amazing role our industry has played in improving patient outcomes. Unfortunately, there still remains countless challenges and hurdles that face our nation’s and the world’s health care delivery systems. We know that med tech innovators are the answer to many of these problems, and we must remain vigilant in the face of adversity to provide the solutions that are desperately needed.

2016 saw legislative activity slow while Congress and the Administration confronted an election year, but MDMA continued to advance legislation and achieve accomplishments on behalf of the med tech ecosystem, including:

- Collecting data and touting the benefits of the 2 year suspension of the device tax, all to boost efforts for a full and permanent repeal of this policy in 2017
- Finalizing negotiations with FDA and other stakeholders on MDUFA reauthorization to build off of past progress and create more reasonable and transparent regulatory pathways
- Working with CMS to incorporate targeted reforms that will allow med tech innovators to secure reimbursement while collecting additional clinical data
- Securing regulatory and reimbursement improvements within the “21st Century Cures” legislation which was signed into law
- Strengthening the coalition to oppose provisions in the “PATENT Act” which would weaken intellectual property rights for innovators
- Expanding our members-only compliance tool-kit in light of aggressive efforts to target life science executives following the “Yates memo”
- Building out additional international opportunities with our members while strengthening relationships and communications with OUS regulators in Europe, Asia and elsewhere

Immediately following the 2016 election, MDMA and our members began outreach with the new Members of Congress and Administration officials. The 115th Congress is expected to be one of the busiest in recent memories, with several efforts underway to address Affordable Care Act reforms, a rewrite of the tax code, new incentives for health care delivery, targeted patent reforms and much more. We recognize that many of these legislative efforts will unfold quickly, and it is critical that our industry engages with policy makers to ensure that there is a positive boost for innovation.

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 activities continue to shape the countless policies that impact your ability to innovate, and together we are a stronger voice.

We are proud of the many accomplishments we’ve achieved over the past 25 years, but we are well aware of how much important work remains ahead of us. As anyone who has ever worked with MDMA knows, our passion is what drives our mission, and we are relentless in seeking improvements to the med tech ecosystem. Together, we will advance the vision of the innovators who identified the critical need to have a voice for the entrepreneurial sector of the medical device community. It has never been more important for all of us to succeed in providing better innovations today, for a brighter health care system tomorrow.

Sincerely,

Paul LaViolette
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
MDMA founded by a group of medical device manufacturers to represent the voice of entrepreneurial companies in Washington.

Testified before Congress and led efforts to convince Congress to abandon the Medical Device User Fee Act of 1994.

Played a leading role in the development and passage of the FDA Modernization Act (FDAMA).

Advocated to assure that new and innovative medical devices can be separately reimbursed through “Pass-Through” and “New Technology” vehicles in the OPPS.

Legislation passed providing mechanisms for New Technology Add-on payments
• Successfully advocated for passage of The American Jobs Creation Act

Testified before Congress on anticompetitive practices of hospital group purchasing organizations.

Passage of legislation which increased the MDUFMA small business threshold to $100M in annual revenues.

Prevented significant reimbursement cuts under IPPS, and testified before Congress calling for an end to GPO kickbacks.
2007
- Passage of the FDA Amendments Act provided greater user fee relief and created an interactive premarket review process
- Lobbied to improve Patent Reform Act provisions which would have weakened the patent
- Delayed gainsharing proposals and competitive bidding programs which would have threatened innovation.

2009
Led efforts to fight the medical device tax when first proposed as a part of the ACA.

2010
Organized industry survey detailing challenges with the FDA’s regulatory review processes.

2011
Members testified before Congress for FDA reforms and improvements to MDUFA III.

2014
Led industry efforts to protect IP rights of innovators, fighting legislation to weaken patents laws.

2015
Secured a 2-year suspension of the medical device tax.

2016
MDUFA IV Negotiations finalized.
MDMA joined with other stakeholders to negotiate the reauthorization of the Medical Device User Fee Act (MDUFA) with FDA. While our members and the industry continued to report some improved experiences with the regulatory pathways as a result of MDUFA III reforms, we recognized how important it was to hardwire process improvements and other proposals with FDA to ensure more predictability and transparency. MDMA surveyed our FDA Working Group and members to assess their top priorities in MDUFA IV negotiations, and “reasonableness and consistency” was prioritized over “speed” by a 95%-5% margin.

This guided MDMA’s approach to the negotiations, and the resulting tentative agreement represents an important step to improve patient access to safe and effective products. The provisions MDMA pushed for in the agreement will empower the input of patient communities, help ensure that regulators are asking the right questions at the right time, and strengthen the premarket review process with numerous process enhancements.

The tentative user fee agreement 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 pre-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.

MDMA will continue to work with all stakeholders so that the possibilities contained in this proposal are realized, and that America’s med tech ecosystem remains the gold standard for safety and efficacy.

MDMA also worked closely with Congress and the White House to make sure the ongoing negotiations over the “21st Century Cures Act” included provisions that would help accelerate the development and approval of new medical innovations for patients, many of whom suffer from diseases and conditions for which there is currently no treatment or cure.

95% of MDMA members preferred CONSISTENCY over SPEED as the focus in MDUFA negotiations.

“Congress and federal agencies are contemplating major changes to the regulatory pathways, the tax code and much more. MDMA’s leadership on these issues is important and provides our industry with a powerful voice as we face these challenges and opportunities.”

Eric Major
President, CEO and Co-Founder
K2M, Inc.
The legislation includes a number of critical provisions to improve the efficiency and predictability of the medical device review process, develops a new regulatory pathway for certain breakthrough devices, and empowers patients to have a greater role at the FDA to incorporate their perspectives. Combined, these policies have the potential to deliver on the bipartisan goal of increasing access to safe and effective medical technologies for patients and providers and will allow this dynamic industry to continue extending life expectancies, improving the quality of life, and reducing the costs of treating chronic conditions.

Finally, MDMA continued working with FDA to address ongoing concerns about variability and unreasonableness in post-market surveillance. While more work needs to be done, we continue to see improvements in the FDA’s approach to this challenge, including a reorganization of field offices to help ensure that the appropriate staff and expertise are working with medical technology innovators. We continue working with AAMI, FDA and other industry representatives on the development of risk-based frameworks to deal with post-market issues.

**DEVICE TAX REPEAL**

MDMA’s leadership in securing the 2 year suspension of the medical device tax laid the groundwork for putting an end to this onerous policy once and for all. The suspension was an important victory made possible by the collective efforts of MDMA’s members going back to 2009 when it was first proposed.

Following suspension, MDMA organized a massive “thank you” tour with our members and the industry to help ensure that this was simply the first step for a full and permanent repeal of the device tax. We worked with the IRS to update guidance for industry before the first suspended payment for clarity, and initiated tours and facility visits to elevate the issue during a campaign year.

MDMA spent 2016 working with Members of Congress and sharing the powerful stories of what medical technology innovators were doing with the additional resources. We organized and deployed a survey to quantify the impact device tax suspension was having in the ecosystem. The survey included over 100 responses from senior executives at some of the United States’ most innovative and entrepreneurial medical device companies. Some of the top findings included:

- 3 out of 4 innovators said that they would make additional investments in job creation and R&D if the device tax was permanently repealed, as opposed to a temporary suspension.
- **70 percent of companies** increased hiring and created new jobs as a result of the suspension
- 73 percent of pre-revenue companies noted that suspension of the device tax has improved the climate for raising capital and funding
- When asked how much respondents have increased their R&D budget, the average increase was 19 percent

MDMA conducted numerous Congressional “fly-ins” to tout the stories and anecdotes that comprised these findings, and continued to secure earned media and place Op-Eds throughout the United States.

MDMA’s consistent leadership and passion on this issue will help ensure that the medical device tax never sees the light of day again, and that this policy is fully and permanently repealed.
When MDMA led surveys in 2010 to address concerns with the regulatory pathways for medical technologies, the results led to substantive improvements for innovation. We have also been leading the charge with CMS and private payors to improve the reimbursement landscape, and we need your help to address this growing challenge. Unfortunately, there continues to be an unacceptable lag between regulatory approval and clearance for medical technologies, and securing fair and adequate reimbursement.

Shortening this lag remains a top priority for MDMA, and to boost our advocacy efforts, we surveyed our members to ascertain what the most pressing challenges were in the marketplace impacting reimbursement. Some of the top takeaways were:

- When asked which area of the reimbursement ecosystem is in the most need of reform, Coding, Coverage or Payment, Coverage was the top priority by a 2-1 margin
- 57% of respondents felt that narrowing the gap between a regulatory decision and coverage WITH a requirement to collect additional data would improve innovation, while 28% felt it wouldn’t make a difference.
- When asked “Have your experiences with the RUC provided properly valued physician payments?,” 73% of respondents said NO.
- 78% stated that the environment for coverage has gotten worse over the past 2 years.

MDMA prides itself for being a member-driven organization, and these results were shared with senior policy makers as we work together to improve the environment for innovation. We also heard from many members that there has been increasing variables in coverage decisions, and a trend in insurers not taking into account the voice of the patient community. To assess this problem, MDMA commissioned a study to examine the largest commercial payers’ coverage policies for medical technologies. The study concluded that the coverage of medical interventions varies widely across US private payers. Payers often reported reviewing different evidence when formulating coverage policies, and none reported considering input directly from patients in evidence assessments. MDMA met with CMS, FDA, provider groups and payors to discuss this challenge, and to push for more transparency on coverage criteria.
Finally, when Members of Congress and others begin advocating a UDI field to insurance claims for Medical Devices, MDMA was the leading and only voice advocating against a policy that would block innovative technologies from entering the market.

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
- Secured provisions in the “21st Century Cures Act” that require local MACs to be more transparent related to coverage decisions and establish a CMS Ombudsman
- Submitted comments and worked with CMS to establish more reasonable and fair assessment models for their ongoing bundled payments initiatives
- Urged CMS for greater clarity in the development of ICD-10 codes to properly value medical technology
- Worked with Congress on creation of bipartisan legislation (H.R. 5009) to provide immediate coding and coverage for “breakthrough” technologies
- Pushed back on insurers increasing attempts to rely on sole-source contracts for medical technology, thereby limiting patient and provider access
- 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

“As the marketplace gets more complex, so do the hurdles confronting us as we develop medical technologies. MDMA’s working groups and programs are an excellent source of insights and analysis for my team as we seek to grow our organization.”

Michael Carrel
President and
Chief Executive Officer
AtriCure
PATENT REFORM

While momentum to adversely change the nation’s patent laws slowed in 2016 due to the coming elections, MDMA was tireless in working with the broad coalition that has united to protect the intellectual property rights of patent holders. 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 is the sponsor of the “STRONG Act,” as well as opposing provisions in the “PATENT Act” that would harm medical technology innovation.

MDMA will work 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.

LEGAL AND COMPLIANCE

MDMA continued to increase our offerings to members in the legal and compliance fields. Carolyn Bruguera joined MDMA as Vice President and General Counsel in April 2016 and undertook legal and policy initiatives while continuing our outreach to our Compliance Working Group on program best practices. Some of 2016’s top Legal and Compliance activities include:

• Gathered member feedback and submitted responses to CMS regarding proposed Open Payments rule making
• Hosted webinars to address recent legislative and regulatory developments affecting interactions with health care professionals
• Provided periodic updates to members on important enforcement and compliance topics
• Conducted in-person roundtable meetings to share and discuss best practices and emerging trends
• Surveyed members on compliance priorities to guide program development
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 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 will be 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.

Other highlights included:

• 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

Left: CMS Director of Clinical Standards Dr. Katie Goodrich talks about the latest reforms to reimbursement.

Right: Founding Partner and Co-Chairman of RoundTable Healthcare Partners and MDMA Board Member Joe Damico (center) networks with attendees at the Annual Meeting.
MDMA members benefit from multiple webinars that are archived and added to the members-only section of our website for later viewing. In 2016, we had 14 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:

**Top International Trade Issues for Medical Devices**

Over 50% of all medical devices used in the U.S. are imported and companies that export devices are increasingly exposed to risks as a result of international collaboration efforts through partnerships, acquisitions, and other types of transactions. This session provided an overview of the key issues and compliance risks relating to the international trade of medical devices. While trade issues can often cause unexpected challenges to device sales and research and development, many of these issues can be avoided with planning. Topics included FDA import alerts, obtaining export certificates (Certificates to Foreign Governments) from FDA, implications of ACE integration, trade controls due diligence, export and sanitations licensing, U.S. Customs importer responsibilities, and much more.

**Navigating the Coverage Policy Landscape**

This webinar focused on identifying and utilizing resources in the marketplace that are available to stay abreast of coverage policy changes, both by commercial and government payers. MDMA members learned how medical policies are developed and what is changing as a result of recent provider and insurer mergers, Medicare demonstration projects and new payment methodologies. The webinar also detailed how the transition to ICD-10 may impact coverage policies, and what manufacturers need to know to expand access to their technologies.

**Managing Cybersecurity Challenges for Medical Devices**

Medical device manufacturers are increasingly coming under scrutiny for cybersecurity concerns. Experts from the law firm of Hogan Lovells examined the most critical aspects of cybersecurity preparedness and how to respond to potential threats. From conducting a comprehensive risk analysis to managing vulnerabilities and planning for breach response, this webinar addressed FDA's expectations and recent guidances, as well as best practices and industry standards.

**Patent Marking in the World of Medical Devices and The New Standard on Willful Infringement**

Patent owners can mark their products with their patent numbers to gain additional rights. In the world of medical devices, questions arise regarding whether to mark the products, how to mark them, and the effects of doing or not doing so. By marking their products, patent owners can get additional money damages in an infringement lawsuit that they might not get absent the marking. A court may also increase damages if it finds the infringement was “willful”—a subject recently addressed by the U.S. Supreme Court. The speakers discussed what MDMA members need to know about patent marking, how marking may relate to the topic of willful infringement, and the effect the new guidance by the Supreme Court on willful infringement may have on medical device companies.
2016 PROGRAMS

2016 FDA FORUM
March 16-17, 2016: Palo Alto, CA
MDMA held our annual FDA Forum in Palo Alto, CA. This year’s successful forum was our largest, most attended FDA Forum to date! Over 150 attendees gathered to hear from a wide array of policy makers and industry experts.

Speakers included CDRH officials such as Dr. William Maisel, Marjorie Shulman, John Weiner and more, who shared their unique insights and strategies to navigate the 510(k) and PMA regulatory pathways, as well as what to expect regarding the implementation of the user fee reauthorization and FDA reforms.

FDA Commissioner Robert Califf also gave an intriguing address on his priorities fresh on the heels of his confirmation to lead the agency. He answered several questions from the audience, and shared suggestions on how innovators and FDA staff can work better together as we strive to improve the regulatory process.

In addition, one of the overarching themes discussed by attendees and panelists was the ongoing and increasing debate over the cost of care, and how it will dictate legislation and policy in 2017. Price transparency continues to build as a possible solution to the rising costs of care, and CMS is continuing its efforts to disclose what Medicare pays providers for their services.

2016 ANNUAL MEETING
May 4-6, 2016: Washington, DC
Over 180 medical technology executives gathered in Washington, DC for MDMA’s 2016 Annual Meeting, focusing on the needs and challenges for innovative and entrepreneurial medical technology companies.

Participants heard from a wide range of speakers including senior officials from FDA, CMS, the White House and more. Topics covered included the latest insights on reimbursement, compliance, the patent landscape and lessons learned from device tax suspension.

One of the highlights of the meeting was an interactive panel led by Dean Kamen with CDRH Director Jeff Shuren and CMS’ Director of the Center for Clinical Standards and Quality Kate Goodrich. It was a great discussion between innovators and regulators about how the various agencies can work better together to speed up access to medical technologies for patients and providers.

MEDICAL TECHNOLOGY EXECUTIVE FORUM
September 29, 2016: Palo Alto, CA
MDMA hosted over 120 CEOs and senior executives in Palo Alto for our 9th Annual Medical Technology Executive Forum. Participants gathered to hear from a compelling lineup of speakers from industry, FDA and more on the critical issues, challenges and opportunities facing our industry.

REIMBURSEMENT CONFERENCE
November 16-17, 2016: Baltimore, MD
MDMA hosted another successful and interactive Coverage, Reimbursement and 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.
The MDMA Board of Directors represents a broad cross section of our membership and the medical device industry. Voting members include:

Paul LaViolette  
MDMA Chairman  
Executive Chairman  
CardioFocus

Scott Huennekens  
Immediate Past MDMA Chairman  
President and CEO  
Verb Surgical, Inc.

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

Joe Damico  
Founding Partner and Co-Chairman  
RoundTable Healthcare Partners

Scott Drake  
Chief Executive Officer  
Spectranetics Corporation

Walt Humann  
President and CEO  
OsteoMed, LLC

Joe Kiani  
Chairman and CEO  
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Robert Kieval  
Founder, Chief Development Officer  
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Pat Mackin  
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Eric Major  
President, CEO and Co-Founder  
K2M, Inc.

James Mazzo  
Global President Ophthalmic Devices  
Carl Zeiss Meditec Inc.  
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Jeff McCaulley  
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Jane Rady  
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Jason Richey  
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Walt Rosebrough  
President and CEO  
STERIS Corporation

Benson Smith  
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Teleflex Incorporated