PASSIONATE ADVOCACY: ENHANCING OUTCOMES

2011 ANNUAL REVIEW
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
“We all recognize the challenging times we face, but working together with one voice, we can continue to improve conditions so that today’s entrepreneurs can deliver tomorrow’s innovations.”

Eamonn P. Hobbs
President & CEO, Delcath Systems, Inc.
Chairman, MDMA
2011 was a dynamic and unique year for medical technology innovators, and it is our hope that it will also be known as a turning point for the challenges we face in the regulatory environment. Many have described today as a “perfect storm” for innovators, with the future of American patient care and ingenuity at stake. MDMA was at the forefront of engaging policy makers and elected officials to address the challenges we all face as we seek to deliver on the promises of a better tomorrow.

Some of our major efforts this year included:

• Educating elected officials on the impact current policies are having on medical technology innovation
• Leading efforts to repeal the medical device tax, organizing a powerful letter to Congressional leaders that garnered over 425 signatories
• Engaging FDA leadership, Congress and the IOM on the need for a more predictable, reasonable and transparent premarket review process
• Submitted comments on several regulations, including “Accountable Care Organizations” and FDA’s “Plan of Action for Implementation of 510(k) and Science Recommendations”
• Working with Congress to expand and make permanent the research and development tax credit
• Initiating an outreach campaign to educate policy makers and elected officials about the anti-competitive practices and impacts of GPOs
• Continuing growth of the “Medical Technology Regional Alliance” to harness the collective efforts of state and regional based groups throughout the country

There continues to be great concerns over the lack of predictability and transparency with FDA regulations, which is why MDMA continued our focus on these issues in 2011. MDMA and our members had numerous outreach and grassroots efforts throughout the country which greatly increased the awareness level for Members of Congress and their staff. These efforts also helped lead to over 220 cosponsors of legislation to repeal the medical device tax, and this year’s Annual Meeting had record attendance, with great presentations from inventor Dean Kamen, FDA Commissioner Margaret Hamburg and many other leading policy makers and elected officials.

MDMA also continued its work with federal agencies to ensure that the regulations that are a part of the Affordable Care Act will not adversely impact innovation. To that end, we are committed to ensuring that issues such as “payment sunshine” and “comparative effectiveness research” are addressed in a reasonable manner, and that they focus on maximizing patient outcomes.

If you are not a member of MDMA, we strongly encourage you to join this energetic and passionate organization. We all recognize the challenging times we face, but working together with one voice, we can continue to improve conditions so that today’s entrepreneurs can deliver tomorrow’s innovations.

Sincerely,

Eamonn P. Hobbs
President & CEO, Delcath Systems, Inc.
Chairman, MDMA

Mark Leahy
President & CEO, MDMA
“The intersection of policy and innovation has never been more evident, and having a partner like MDMA as we seek to improve the regulatory environment is crucial.”

Dan Moore
President and CEO
Cyberonics, Inc.
**FEDERAL POLICY HIGHLIGHTS**

**FOOD AND DRUG ADMINISTRATION**

**Regulatory Review**

With the increasing challenges companies faced navigating the FDA, MDMA was actively engaged in working to make the regulatory process more predictable, transparent and reasonable.

MDMA and its members continually met with senior FDA officials and Members of Congress to ensure that policy makers were aware of the impact that potential changes would have on patient care, innovation and jobs. In addition, MDMA, with the support of our member companies, conducted several hundred meetings regarding concerns over the FDA’s inability to bring new products to the market in the U.S.

MDMA’s educational efforts, coupled with engagement by patient, physician and other groups, resulted in Congress becoming much more active on FDA issues in 2011. Both the House and Senate held insightful hearings and various bipartisan FDA reform bills were introduced. In 2012, MDMA will work for passage of user-fee legislation that ensures that innovators have a predictable, transparent and reasonable FDA so patients will have timely access to innovative medical treatments.

**HEALTHCARE LAW IMPLEMENTATION**

**Medical Device Tax Repeal**

As part of the healthcare law, Congress placed a 2.3% excise tax on medical devices sold in the U.S. The tax will be assessed on most types of medical devices and is scheduled to go into effect in 2013.

From the beginning, MDMA was the leading and most vocal opponent of the medical device tax. This tax will harm innovation, negatively impact research and development, stifle job creation, and delay patient access to new medical technologies in the U.S.

In 2011, MDMA led efforts to build support for repeal of the tax. In both the House and Senate, MDMA led the effort to secure the support of more than 250 Members of Congress to cosponsor legislation to repeal the tax. In addition, MDMA organized dozens of meetings between lawmakers and member companies to discuss the negative impact the tax will have on job creation, research, and patient care.

**Payment Reforms and Comparative Effectiveness Research**

Included in passage of the healthcare law were various payment reforms aimed at realigning incentives within the various healthcare delivery models. In 2011, MDMA provided comment on numerous aspects of payment reform including Accountable Care Organizations, value-based purchasing and payment-bundling proposals. In addition, MDMA participated in and provided meaningful comments to the new Patient-Centered Outcomes Research Institute.

In 2012, MDMA will continue to monitor and advocate for meaningful payment reforms to ensure that the value of innovative medical technologies is recognized.
FEDERAL POLICY HIGHLIGHTS

MARKET ACCESS

Group Purchasing Organizations
MDMA remained vigorous in highlighting concerns with hospital group purchasing organizations (GPOs). GPOs are entities that aggregate the collective bargaining ability of hospitals. However, the current supplier-funded model allows for the proliferation of anticompetitive market practices and potentially significant healthcare fraud.

MDMA actively worked with key Congressional committees of jurisdiction to highlight the anticompetitive nature of GPO arrangements. These educational efforts resulted in a wide-ranging, multi-committee investigation by the U.S. Senate into GPO practices. In addition, a feature film highlighting the corrupt practices of GPO’s was also released, leading to renewed interest from Members of Congress.

MDMA will continue to educate and engage Congress about the misaligned incentives of the supplier funded GPO model. In addition, MDMA will push to ensure that manufacturer payments to GPOs are included in new federal transparency laws.

REIMBURSEMENT

CMS Coding Reform
Early stage medical device companies have experienced growing difficulties in obtaining the appropriate reimbursement codes for their novel technologies. For instance, more companies seeking CPT codes have received a Category III designation, or “investigational” status, for their codes. The implications for this are significant, as many healthcare payers will choose not to cover a procedure because of this code status.

MDMA has developed a CPT Coding Initiative to determine the fundamental and inherent problems with the coding system and eventually make recommendations for change to improve the reimbursement environment for innovative medical technology companies.

Medicare Reimbursement
MDMA was active in providing comments to CMS on several issues within the domain of the inpatient prospective payment system (IPPS) and outpatient prospective payment system (OPPS). Within the IPPS, MDMA successfully advocated for CMS to address the issue of charge compression, which occurs when hospitals overvalue high-cost items and supplies and undervalue low-cost items and supplies, thereby distorting payment rates for medical technologies. CMS agreed with the recommendation of MDMA and others that hospitals further clarify their pricing schemes as it relates to charge compression, thereby reducing the level of price distortion for medical technologies. MDMA provided similar recommendations for the OPPS and CMS adopted these recommendations as well.
INNOVATION

Passage of Patent Reform

MDMA was active in ensuring that reasonable patent reform legislation moved through Congress. Building on our previous advocacy efforts, MDMA continued to meet with key members of Congress and their staffs to educate them on a reasonable approach to reforming the patent system. As a result of these efforts, the America Invents Act, passed in 2011, was considerably improved over prior iterations of the legislation. Without the efforts of MDMA, the legislation could have significantly stifled innovation in the medical technology industry by restructuring the calculation of damages in patent infringement cases and creating seemingly endless challenges to patent validity through an unnecessary enhanced post-grant system of reviews. Instead, the AIA contains a moderated approach to post-grant challenges and no longer includes language to apportion damages. MDMA will monitor implementation of the AIA in 2012.

“The future of medical technology innovation is also being shaped in Washington, and MDMA is the eyes and ears ensuring our industry can remain the global leader. Their advocacy and outreach efforts are second to none.”

Mark Deem
Partner
The Foundry, LLC
1. Senator Scott Brown (MA) accepts the 2011 MDMA Legislator of the Year award.

2. Attendees mingle at the Opening Reception at MDMA’s Annual Meeting.

3. Congressman Erik Paulsen (MN), Co-Chair of the Med Tech Caucus, discusses efforts in the House of Representatives to support innovation.

4. World renowned med tech innovator and inventor Dean Kamen delivers the Keynote Address on the future of medical technology innovation and the role of entrepreneurs in America today.

5. Senator Amy Klobuchar (MN) talks with Vascular Solutions, Inc. CEO and MDMA Board member Howard Root.

6. FDA Commissioner Margaret Hamburg addresses attendees on the plans and initiatives being undertaken by the agency.

7. Senator Orrin Hatch (UT) discusses efforts on the Finance Committee, where he is the ranking Member, to support med tech innovators.
8. Attendees enjoy another interesting panel providing unique insights and trends.

9. David Kappos, Director of the U.S. Patent and Trademark Office, provides an update on how changes in his office are impacting business development.

10. Serial entrepreneur Dr. Thomas Fogarty asks CDRH Director Jeff Shuren questions about the 510(k) reform plan.

11. NuVasive, Inc. CEO and MDMA Board Member Alex Lukianov and ExploraMed Development CEO Dr. Josh Makower participate in a panel discussing industry insights on FDA reforms.
MEMBERSHIP

As the consistent national trade association representing the interests on behalf of innovative and entrepreneurial medical technology companies, MDMA is YOUR voice in Washington. MDMA and our members ensure an environment exists where patient care and innovation thrive.

REPRESENTATION IN WASHINGTON
- Voice of the innovative, entrepreneurial sector of the medical technology industry
- Shape policies that impact your company
- Maintain relationships with key Members of Congress and high-level staff at FDA, CMS and other regulatory agencies
- Access to top medical technology lawyers and lobbyists

ADVOCACY
- MDMA works with members to coordinate visits and tours with their respective Members of Congress to their Facilities
  - This grassroots effort is to show elected officials first-hand how the decisions and policies made in Washington affect the employees and companies that drive innovation and improve patient care
- Members are actively involved in developing and implementing MDMA’s public policy agenda
- MDMA’s Legislative Action Center—quickly and easily contact Members of Congress regarding important issues and legislation
- MDMA Working Groups address the many challenges facing innovative medical device companies. Each working group meets monthly via conference call and receives additional e-mail updates and breaking news.
  - Public Affairs/Communications
  - Healthcare Reform Implementation
  - International Issues (quarterly)

BREAKING NEWS AND EDUCATION
- Weekly MDMA Update, Monthly Member Service Newsletter and breaking news
- Members-only conference calls and webinars
  - Webinars include topics of interest outside our normally scheduled working group calls
- Special discounted rates to MDMA events
- Members’ only website access—white papers, special reports written by outside experts on legal, regulatory, and international issues and other MDMA news

MDMA BUSINESS ALLIANCES
- MDMA members have exclusive access to discounts on important services through MDMA’s Business Alliances that can save companies thousands of dollars annually, some include:
  - The Gray Sheet, medtech insight, IN VIVO and START-UP: Members may be eligible for 25% discount (first year only)
  - Chubb Group of Insurance Companies: Members save 10%
  - Medical Device Daily: Members save 30%
  - PR Newswire: Member product package valued at more than $2,000
  - ReadyTalk Conferencing: Discounted Audio and Web Conferencing
  - RegLink Associates, Global Update: Members receive a 30-day Free Trial and discount
  - VWR International: Members save up to 75%

Members have access to all of these benefits as well as regular interaction with MDMA staff and industry leaders to share ideas and learn best practices.
MDMA hosts 4 major conferences each year. In 2012, MDMA plans to add additional Regional CEO events, a Compliance conference, multiple webinars and expand our PMA/510(k) seminar to include a specialized one-day session on “What is needed to submit a successful PMA/510(k).” Please visit our website at www.medicaldevices.org/events to view our 2012 events.

**PREMARKET APPROVAL (PMA) AND 510(K) PREMARKET NOTIFICATION SEMINAR**
**MARCH 24, 2011 – WALTHAM, MA**

Over 75 med-tech leaders and executives participated in MDMA’s PMA/510(k) Seminar. The highlight of the event was a presentation by Lawrence “Jake” Romanell, Deputy Ombudsman for CDRH, on how to resolve problems and challenges with the FDA. The event also had several panels and roundtables to discuss best practices and share ideas on how to improve interaction with regulatory pathways.

**2011 MDMA ANNUAL MEETING**
**JUNE 8-10, 2011 – WASHINGTON, DC**

The 17th Annual Meeting hosted over 225 medical technology executives, policy makers and innovators. Attendees gained first-hand insights from multiple Members of Congress, including Senator Orrin Hatch (UT) and Senator Amy Klobuchar (MN). We also had a successful Congressional fly-in that included over 50 meetings with Members and Capitol Hill staff. This year’s meeting included interactive sessions with senior Administration leaders, including FDA Commissioner Margaret Hamburg and CDRH Director Jeff Shuren, along with a rousing presentation from world-renowned inventor Dean Kamen.

**MEDICAL TECHNOLOGY EXECUTIVE FORUM: TRANSFORMING INNOVATION AND POLICY**
**SEPTEMBER 16, 2011 – PALO ALTO, CA**

This 4th Annual Executive Forum provided a one-day interactive forum of over 150 CEO’s and senior executives to discuss critical issues that impact medical technology development and commercialization. Speakers included Congresswoman Anna Eshoo (CA), Dr. William Maisel, Deputy CDRH Director and other industry experts who discussed topics on funding and how to launch overseas.

**14TH ANNUAL COVERAGE, REIMBURSEMENT AND HEALTH POLICY CONFERENCE**
**OCTOBER 24-25, 2011 – PALO ALTO, CA**

Over 70 executives and specialists heard from some of the leading officials in government and industry on the changing landscape of med-tech reimbursement. One of the hottest topics of discussion was the recent Accountable Care Organizations (ACO’s) rule that was issued by CMS, and what impact it could have for medical device innovators.
THE POWER OF PARTNERSHIPS

MDMA MEDICAL TECHNOLOGY REGIONAL ALLIANCE

MDMA continues our proud tradition of working with various groups to achieve the common interests of the medical technology industry. The MDMA Medical Technology Regional Alliance (MTRA) has continued to grow with over 20 state and regional organizations coming together to fight for innovators and patients, speaking with one voice.

MTRA was instrumental in helping gather over 400 signatories on a powerful letter to Congressional leaders urging for a vote to repeal the medical device excise tax. The alliance also strengthened its voice with powerful new studies conducted in 2011 by CHI, LifeScience Alley and others.

FDA continues its internal reform efforts, and over 20 bills have been introduced in Congress to address concerns of the medical technology industry. As MDUFA negotiations continue, this alliance will play a central role in supporting the bipartisan efforts to restore predictability to the regulatory process, and securing an environment that allows innovation and patient care to thrive. The group continues to work together on outreach and advocacy efforts, and this unique partnership has added a powerful voice in Washington, DC and across the country.
“MDMA is a tremendous partner for the regional associations as we work towards improving patient care and innovation. This unique group delivers a powerful voice for the companies that are transforming health care.”

Geary A. Havran
President, Florida Medical Manufacturers’ Consortium, Inc.
President, NDH Medical, Inc.
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