TO OUR MEMBERS

2008 HAS BEEN AN EXTRAORDINARY YEAR FOR MDMA, OUR MEMBER COMPANIES AND THE MEDICAL TECHNOLOGY INDUSTRY.

The growing membership of MDMA joined together to promote policies that improve patient care, foster innovation and create an environment that allows entrepreneurial companies to flourish. MDMA also expanded its educational programs in 2008 to provide our Members with timely and important information to develop and grow their companies. MDMA also offered numerous national and regional opportunities for medical technology executives to interact with one another as well as senior government officials. Below are a few key highlights from the past year.

MDMA remains the true voice of innovative, entrepreneurial medical technology companies in Washington. Specifically in 2008, MDMA continued to advocate for improvements to the Patent Reform Act. MDMA also successfully advocated for nearly $300 million in additional appropriations for the FDA and testified against any additional industry user fees. The Association was active in promoting the important role that smaller companies play in the development of new technologies that improve patient care. MDMA supported efforts to reward high quality care and cautioned against initiatives that provide perverse incentives to physicians or hospitals to utilize inferior, less expensive products. Finally, MDMA continued its efforts to ensure that patients and caregivers have open access to safe and effective technologies by calling on Congress to fix the group purchasing organization (GPO) system.

In 2008, MDMA held its first Medical Technology Executive Forum in Palo Alto, California. This event was targeted toward CEOs to provide an update on recent policy discussions in Washington and how they have a direct impact on a company’s ability to develop and commercialize product. MDMA also enjoyed increased attendance for our many ongoing programs including: the Annual Meeting, the Coverage, Reimbursement and Health Policy Conference and the FDA 510(k)/PMA program.

MDMA expanded its relationship with a number of key business alliances in 2008. Based on survey results, a number of Member companies are enjoying significant savings on a variety of services and products offered at preferred rates to the Association. In 2009, MDMA will be expanding these offerings providing even greater value to our Members.

As we look ahead to 2009, the call for healthcare reform have never been greater. MDMA looks forward to working with our Members, the new Administration, Congress and other stakeholders to ensure that every American has access to high quality care. The importance of working collectively through MDMA has never been greater. We appreciate the ongoing support of our more than 200 member companies and encourage companies who are currently not members of MDMA to join us in our efforts. Together we can make a difference!

Sincerely,

Joe E. Kiani
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
working on Behalf of our Members
THE POWER OF MEMBERSHIP

MDMA is the only national trade association representing the interests of smaller, innovative medical technology companies by providing educational and advocacy assistance to its 200+ members. MDMA members all share a common goal: to provide patients with safe and effective, innovative, cost-competitive technologies as quickly as possible. Issues in Washington have never been more important to a medical technology company’s bottom line. Navigating FDA, increasing reimbursement challenges, and a changing patent landscape are just a few of the key issues being discussed and debated on Capitol Hill.

Representation in Washington
• Voice of the research-based, 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 and CMS

Advocacy
• 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 via conference call and receives additional email updates and breaking news on the following:
  ■ Medicare Coverage and Reimbursement
  ■ FDA / MDUFMA
  ■ Market Access
  ■ Gainsharing
  ■ Patent
  ■ International Issues

Information and Education
• Weekly MDMA Update, Monthly Member Service Newsletter and breaking news
• Members’ only website access — white papers, QReview, special reports written by outside experts on legal, regulatory, and international issues and other MDMA news
• Bi-monthly members only conference calls and webinars

Programs
MDMA holds a variety of programs each year which include: MDMA Annual Meeting, Coverage, Reimbursement and Health Policy Conference, Medical Technology Executive Forum and Premarket Approval (PMA) and 510(k) Premarket Notification Seminar.
• Meet industry leaders, lawmakers, and decision-makers
• Members receive special discounted rates to all programs
• Partnerships with other industry and regional organizations to offer MDMA members discounts to premier events in the United States and around the world

Business Alliances
MDMA members have exclusive access to discounts on important services through MDMA’s Business Alliances that can save companies thousands annually.
SUCCESSFUL ADVOCACY on LEGISLATIVE ISSUES
MOVING DEVICE POLICY FORWARD

MDMA continued to work with FDA and Capitol Hill to ensure that patients have timely access to safe and effective products. This included quarterly meetings with CDRH officials and monthly calls with MDMA’s FDA Working Group.

Successful FDAAA Implementation

MDMA worked with its member companies and senior CDRH officials to ensure a smooth implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including implementation of the interactive review process.

Increased FDA Appropriations

MDMA worked with multiple stakeholders to successfully lobby Congress for additional FDA appropriations. In 2008, FDA received $300M in additional appropriations beyond the previous year baseline. MDMA has long stressed that any additional resources for the FDA should come from Congressional appropriations and not additional industry user fees.

MDMA Testified Before House Energy and Commerce Committee

MDMA was actively involved with Congressional efforts to expand FDA’s inspecional capabilities. Based primarily on safety incidents in the food and drug industries, several Members of Congress proposed legislation to augment the FDA inspection process in foreign countries. The proposal would have created additional user fees for device manufactures and increased the number of pre-clearance inspections in foreign and domestic facilities. MDMA Board Member Kelvyn Cullimore, President and CEO of Dynatronics Corporation, testified before the House Energy and Commerce Committee on behalf of MDMA to express concern with the proposal. Cullimore cited that the legislation, as drafted, would compel manufacturers to pay additional and overly–burdensome user fees, despite the fact that the industry just recently agreed to double the amount of fees paid under the FDAAA. Furthermore, Cullimore argued that the legislation would also cause delays in access to innovative and life–saving medical technologies by requiring pre-clearance inspections for products regardless of the level of risk posed.

COVERAGE AND PAYMENT

MDMA successfully addressed several issues affecting the appropriate and timely reimbursement for medical technologies.

Gainsharing Exemptions Delayed

In the 2009 Medicare Physician Fee Schedule Proposed Rule, the Centers for Medicare and Medicaid Services (CMS) solicited comments on a proposed exception to self-referral laws which would permit hospitals and physicians into gainsharing agreements. On behalf of our members, MDMA urged CMS not to move forward with the proposed gainsharing exception because it could compromise care, lead to greater product standardization and would hamper innovation. MDMA was pleased that CMS chose not to move forward with its proposed gainsharing exception in its Final Rule.
MDMA Pleased with CMS Announcement to Move Toward ICD–10
MDMA was successful in its efforts to urge CMS to adopt the ICD–10 coding system. Over the years, MDMA stressed that adoption of ICD–10 by CMS is necessary to appropriately code and has recognized the numerous medical technological innovations which have occurred over the past decade. The current coding system, ICD–9, has not kept up with the pace of innovation and the adoption of ICD–10 is a necessary change.

DME Competitive Bidding Delayed
MDMA was successful in urging Congress to delay implementation of the competitive bidding program for durable medical equipment (DME). As was evidenced in the initial phases of the program, the process which CMS used to determine successful bids was structurally flawed and unfairly excluded small, innovative medical suppliers from the bidding process.

Comparative Effectiveness Debate Begins
MDMA successfully worked with key Congressional committees to educate members about the unique role of medical devices in comparative effectiveness studies. Congress is poised to move forward with the establishment of a comparative effectiveness program to further examine outcomes of clinical therapies. In 2008, MDMA formed a Comparative Effectiveness Working Group for our members.

Medicare Reimbursement Again in Focus
MDMA provided 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.

MARKET ACCESS
In order for the healthcare system to function properly, patients and clinicians must have access to the best products at the best prices. Unfortunately, many innovators face significant challenges accessing the hospital marketplace as a result of the exclusionary practices of certain group purchasing organizations (GPOs). While GPOs were established to negotiate supplies on behalf of its member hospitals, they are funded by the suppliers of products, creating an inherent conflict of interest. In addition, some hospitals are now restricting access to healthcare industry representatives unless they undergo a laborious, and often costly, credentialing process.
Reforming Group Purchasing Organizations to Protect Innovation

MDMA continued to work with Congress to highlight the access to critical markets caused by the prevalence of 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 inappropriate incentives.

MDMA testified before the House Committee on Small Business to highlight the anticompetitive problems associated with the supplier-funded GPO model and certain dominant firm conduct. Representing MDMA was Said Hilal, CEO of Applied Medical Resources Group. Mr. Hilal aptly described two critical competition issues in the medical device arena: the supplier-funded GPO model and anticompetitive practices of certain dominant firms. Both create an inability for small, innovative medical technology companies to compete in the hospital marketplace.

Ensuring Hospital Access

An increasing number of hospitals have been requiring healthcare industry representatives to become “credentialed” before gaining access to a hospital. While MDMA supports efforts to ensure that certain industry representatives have appropriate training, and immunizations, the current system is overly burdensome and costly for innovative manufacturers. MDMA supports a national credential, similar to a passport; it would permit access to all hospitals upon verification. MDMA is concerned that the credentialing process may be used by some to prohibit industry representatives from accessing hospitals and healthcare professionals.

PROMOTING INNOVATION

MDMA successfully advocated on several innovation-related proposals that affect the medical technology industry. Efforts to modify the patent system received widespread attention as well as efforts focused on bringing greater transparency to financial relationships in the industry. In addition, Congress looked at several proposals specifically affecting small businesses, including reauthorization of the Small Business Innovation Research (SBIR) program and renewal of the research and development tax credit (R&D tax credit).

Advocating for a Strong Patent System

Building upon our advocacy efforts from 2007, MDMA continued to meet with key members of Congress and their staffs to prevent passage of the Patent Reform Act (PRA). The PRA, as crafted, would significantly stifle innovation in the medical technology industry by restructuring the calculation of damages in patent infringement cases. While MDMA believes that patent reform is necessary to update the patent system and reduce the backlog of pending patent submissions, the apportionment of damages language and other provisions, including a never ending post grant review process, would significantly harm and stifle innovation in the medical technology industry. Due to the efforts of MDMA and others, the PRA was withdrawn from debate in the Senate.
Improving the Physician Payment Sunshine Act: Congress Addresses Industry Transparency

The financial relationships between drug and device manufacturers and physicians received continued scrutiny in 2008. In response to this issue, Senator Charles Grassley (R-IA), Ranking Member of the Senate Committee on Finance, and Herb Kohl (D-WI), Chairman of the Senate Special Committee on Aging, proposed legislation to require the disclosure of most payments, and other transfers of value between manufacturers and physicians. MDMA supports efforts to move toward greater transparency. However, MDMA also believes that legislation to address relationships must be structured in a manner that does not adversely harm the vital developmental relationship that exists between physicians and device manufacturers. To this end, MDMA continued its efforts to educate lawmakers about the unique nature of this relationship. Specifically, MDMA advocated that any disclosure legislation includes delayed disclosure provisions so competition remains unharmed and sensitive information is kept confidential. In addition, MDMA also advocated that the legislation contain a Federal preemption provision to reduce the administrative burden of small, start-up companies who may otherwise be compelled to adhere to Federal disclosure requirements and potentially numerous state disclosure requirements.

A History of Action on Behalf of the Medical Technology Industry

1992
MDMA founded by a group of medical device manufacturers who realized the interests of small companies were not represented in Washington.

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

1997
Played a leading role in the development and passage of the FDA Modernization Act (FDAMA).
MDMA hosts First Annual Coverage and Reimbursement Conference

1999
MDMA lobbied to assure that new and innovative medical devices can be separately reimbursed through “Pass-Through” and “New Technology” vehicles in the OPPS.

2002
Successfully lobbied for small business discounts and greater oversight of reused single use devices under The Medical Device User Fee and Modernization Act.
Testified before Congress on anticompetitive practices of hospital group purchasing organizations.

2003
Passage of the Medicare Prescription Drug, Improvement, and Modernization Act which provided a mechanism for New Technology Add-on payments for innovative technologies under IPPS.
MDMA Testified on the Importance of SBIR Grants in Device Innovation

In 2003, the Small Business Administration (SBA) implemented a rule which would limit the ability of small businesses with a majority ownership by venture capital firms to participate in the SBIR grant program. Since its inception, the SBIR has been a conduit for small, innovative medical technology firms to acquire invaluable Federal funds for research, development and eventual commercialization. However, since the implementation of the 2003 SBA rule, the number of medical technology companies applying for and receiving SBIR grants from the National Institutes of Health has significantly dwindled.

MDMA was active in urging Congress to overturn the SBA rule as part of the SBIR reauthorization. In addition to meeting with the relevant Congressional committee staffs, MDMA also testified before Congress on the program’s reauthorization, stressing the impact on innovation in the medical technology industry. MDMA’s testimony focused on the importance the program has provided in the development of medical technologies. MDMA also recommended that the reauthorization legislation include changes to current law and regulations including an increase in Phase I and Phase II grant levels and refining the small business ownership definition to include businesses with a majority ownership by venture capital investors.

MDMA Worked to Successfully Extend R&D Tax Credit

At the end of 2007, Congress failed to renew the R&D tax credit. The tax provision has been essential to the development of many new, innovative medical technologies throughout the past decades. The expiration of the credit would have had serious implications for the companies as they looked to expand their businesses and product lines within a frail economy. Due to MDMA and others’ efforts, Congress renewed the tax credit as part of a larger, financial recovery package in 2008.
creating Alliances for our Members
NETWORKING

MDMA understands the value and importance of our member company executives interacting with one another. In addition to our formal programs, MDMA hosts a series of regional events that engage executives in discussions on key policy issues and seeks their feedback. These events provide the perfect setting for entrepreneurial executives to catch up with local colleagues.

Wilson Sonsini Goodrich & Rosati Dinner
November 20, 2008  /  Palo Alto, California

Current and new MDMA members gathered in Palo Alto for a dinner hosted by MDMA Board Member Casey McGlynn, Chairman of the Life Sciences Group at WSGR.

Orange County CEO Dinner
December 11, 2008  /  Newport Beach, California

MDMA partnered with BIOCOM to host a dinner in Irvine, CA that featured MDMA Board Chairman, Joe Kiani, Chairman and CEO of Masimo Corporation.

MDMA Breakfast for Minnesota Medical Technology Executives
December 9, 2008  /  Minneapolis, Minnesota

Minnesota medical technology executives heard from MDMA’s President and CEO and Board Members Howard Root, CEO of Vascular Solutions and Rob Kieval, Executive VP and Chief Technology Officer of CVRx, Inc.

PROGRAMS

MDMA Annual Meeting: Looking Forward Leading the Way
June 11–13, 2008  /  Washington, DC

With a record turnout of more than 150 medical technology executives and professionals, the 2008 MDMA Annual Meeting was a huge success. Speakers included Mr. Tommy Thompson, Former HHS Secretary; Dr. Steve Phurrough with CMS; Kate Cook, Dr. Diane Mitchell and Donna Bea Tillman of CDRH; as well as the other representatives from Congress, FDA, CMS, and industry.

Medical Technology Executive Forum: Key Commercialization Issues Impacting the Medical Technology Industry
October 15, 2008  /  Palo Alto, California

This one day interactive forum provided CEOs and senior medical technology executives of entrepreneurial companies with a practical perspective on managing the key issues that directly impact successful product commercialization. Industry experts addressed attracting and securing funding, recent developments at FDA, navigating reimbursement challenges, protecting and licensing IP and much more. In addition, speakers discussed managing these key elements as a company plans for the successful launch of new products and technologies. Dr. Dan Schultz, Director of the Center of Devices and Radiological Health (CDRH) provided the keynote presentation at the conference.
Premarket Approval (PMA) and 510(k) Premarket Notification Seminar  
*October 16, 2008 / Palo Alto, California*

This seminar helped companies understand the requirements of submissions, provide practical advice on how to prepare them, help manage and maximize communications with FDA, avoid fraud and abuse in clinical trials, and understand compliance issues. The program provided valuable insight from a variety of perspectives and gave companies considering submitting a 510(k) or PMA in the future the tools they need to prepare successful submissions. Heather Rosecrans, Director of 510(k) Staff, Office of Device Evaluation, Center for Devices and Radiological Health (CDRH) provided an insider’s look into the 510(k) process from the FDA perspective.

11th Annual Coverage, Reimbursement, and Health Policy Conference  
*November 11–12 / Washington, DC*

The Conference presented a unique opportunity for attendees to interact with leading stakeholders and decision makers in the reimbursement arena. Participants were treated to in-depth presentations on basic Medicare reimbursement concepts, the international reimbursement landscape, the role of private investment and venture capital in developing reimbursement strategies, coding concerns, and the role of private payers of medical devices.

**MDMA BUSINESS ALLIANCES**

MDMA members have exclusive access to discounts on important services through MDMA’s Business Alliances that can save companies thousands annually.

*The Gray Sheet*
Medical Device Daily
Medtech Insight
Chubb Insurance Group *(2009)*
Office Depot
PR Newswire
Underwriters Laboratories Inc
R-Squared
Linguistics Systems, Inc.
Freightquote.com
Location Management Services
Arkadin Global Conferencing
Hertz
VWR International *(2009)*
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