To Our Members,

MDMA was created in 1992 by a handful of companies who believed that the innovative and entrepreneurial sector of the industry needed a strong and independent voice in the nation’s capital to ensure patients have timely access to safe and effective products. Over the past 30 years, MDMA and our member companies have passionately and effectively advocated for policies that improve patient care. MDMA has been the “eyes, ears and voice” in Washington, DC, and we are committed to helping the United States remain the global leader in this dynamic industry while you and your teams work to deliver the cures, therapies and diagnostics that patients desperately need.

As you will see throughout this year’s report, MDMA focuses on the most pressing issues facing our industry. Over the course of 2022, MDMA worked to make the regulatory processes more efficient and reasonable, including the passage of MDUFA V and other FDA reforms. MDMA also led our industry’s advocacy in the historic “CHIPS and Science Act of 2022,” which designated “medical technology” as critical to the economic and national security interests of the United States. Narrowing the gap between regulatory authorization and reimbursement continues to be a priority among our members, and we were pleased to grow bipartisan support for these efforts. In addition, we worked to help ensure a smooth transition of the European Union’s MDR, addressed supply chain challenges and served as the leading voice for our industry to maintain strong intellectual property rights.

Over the years, some of the most transformative changes for our ecosystem were achieved due to the grassroots engagement of our members. MDMA has been fortunate to lead much of this work, and we will continue to work with Congress and others on policies that will make the regulatory pathways more reasonable and transparent, as well as increase patient access to safe and effective medical technologies. MDMA and our members remain the voice of the innovative and entrepreneurial medical technology sector, and we will continue our proud tradition of passionate advocacy in Washington, DC and beyond.

If you are not an MDMA member, we encourage you to join us in helping to bolster innovation. While there will be unforeseen challenges and opportunities that await our industry over the next 30 years, we know that MDMA will remain THE voice for the innovative and entrepreneurial sector of our ecosystem. Together, we will continue to improve patient care and lead the world in developing lifesaving and lifechanging medical technologies, and MDMA looks forward to working with you on the mission we are all committed to—improving the lives of patients.

Sincerely,

Leslie Trigg
Chair & CEO, Outset Medical, Inc.

Mark Leahey
President & CEO, MDMA

2022 Annual Report
Following nearly two years of negotiations between industry, FDA and other stakeholders, a MDUFA V agreement was secured in 2022, and the reauthorization of the user fee program was signed into law. The MDUFA V agreement represents a historic increase in both overall funds and people, and it is MDMA’s expectation that this will be the last major investment needed for the MDUFA program and that moving forward, increases will be much more modest and targeted.

With these significant investments, MDUFA V establishes more transparency around the use of the funds, including ensuring that annual hiring targets are met. FDA will also conduct a HR assessment during MDUFA V to identify how many MDUFA funded vacancies exist. Beyond the financial accountability and transparency provisions that MDUFA V contains, performance goals associated with De Novos and PMA Total Time to Decision (TTD) also improve over the course of the agreement. Finally, MDUFA V also expands investments in Patient Science and Engagement to enhance the patient perspective into the medical device evaluation process.

This is a historic investment in the FDA, and it will be critical over the coming years to meet the goals and milestones within this user fee agreement to help ensure that the United States remains the global leader in medical technology development. MDMA testified before the House of Representatives and the Senate regarding the user fee agreement, and highlighted that it is critical that Congress continues its vital oversight role, and provides the necessary resources and investments to FDA for it to achieve its mission.

Beyond MDUFA V reauthorization, MDMA was actively engaged with Congress on the “Food and Drug Omnibus Reform Act of 2022” (FDORA). Specifically, MDMA was pleased with the inclusion of several provisions to enhance the premarket review process including:

- Clinical trial diversity
- Cybersecurity
- Change Protocols
- UFA Transparency

We were also pleased to see that Congress did not include expanded shortage reporting requirements for medical technology innovators, as FDA already has several existing authorities to do so.

Finally, MDMA continues to seek other ways to make the premarket review process more predictable and transparent. Over the past few years, our members have shared increasing concerns regarding unreasonable questions and data requests around biocompatibility and human factors that are ultimately causing delays for patient access. MDMA is working closely with FDA to address these concerns, and we are working with them to create more reasonable and efficient interactions with medical technology innovators.
Supply Chain

MDMA worked with a number of agencies and stakeholders in 2022 regarding supply chain dynamics including the FDA, HHS, the Department of Commerce and others. This work included efforts to highlight the importance of our industry in improving patient care, and working to mitigate potential shortages through enhanced regulatory flexibilities and other measures. MDMA was also involved in historic legislation - the “CHIPS and Science Act of 2022” - that will help transform our nation’s ability to develop semiconductors, boost high tech manufacturing and support the supply chain. MDMA worked closely with Congress on language that establishes “medical technology” as one of the 10 initial strategic priorities for investment under the $20 billion Directorate for Technology, Innovation, and Partnerships (TIP). This important legislation will ultimately lead to improvements in patient care, and help to strengthen the United States’ leadership position in medical technology innovation. The legislation also contains $2 billion earmarked for the production of ‘legacy’ chips that medical technology innovators rely on.
**EtO**

Ethylene oxide (EtO) sterilization of medical devices remains an issue that MDMA is working on with various stakeholders. While the EPA was expected to issue a proposed commercial sterilization rule on EtO in 2022, that has been delayed until 2023. We engaged with various agencies and stakeholders as the EPA is also looking to update registration requirements for EtO facilities via rule. If either of these rules are not issued responsibly, there are serious concerns of the impact on patient care. As FDA noted after the EPA began to look into this issue, without an adequate availability of EtO as a sterilization method, the impact to patient care could be “catastrophic.”

MDMA continues to work closely with the EPA, FDA and numerous other federal agencies to help ensure that any future regulations do not create hurdles for patient access to safe and effective medical technologies. MDMA continued to share with EPA and Members of Congress our support of the safe and effective use of EtO where no alternatives exist, and raised awareness to the severe impacts a ban on EtO would have on patient access and our country’s critical medical products supply chains.

**Reimbursement**

MDMA has a long and proud working relationship with both Congress and the Centers for Medicare and Medicaid Services (CMS) to advance policies and initiatives aimed at reducing the time between FDA market authorization and the implementation of coverage, coding and payment changes that support patient access.

In 2022, we continued our advocacy supporting the development of a Medicare Transitional Coverage for Emerging Technologies (TCET) pathway, including both improvements to the current Coverage with Evidence Development (CED) pathway and the development of a separate, more flexible TCET pathway for technologies where formal CED is unnecessary. We are engaged in ongoing work with CMS, Congress and other stakeholders as CMS works to develop a proposed rule, which is anticipated for publication in Spring 2023. In addition, we continued to work with the broad, bipartisan coalition in Congress to advance H.R. 4043 “Ensuring Patient Access to Critical Breakthrough Products Act,” a legislative proposal that is also designed to address these important issues.

In several comment letters to CMS, we reiterated our concerns about prior authorization requirements that impose unnecessary burdens on patients and providers. We also voiced concerns over Medicare Advantage (MA) plans...
denying coverage or otherwise hindering enrollee access to procedures and technologies for which coverage is generally available under Medicare fee-for-service (FFS), and highlighted the lack of transparent, evidence-based policy development processes that incorporate input from clinicians, beneficiaries and other stakeholders among MA plans. Our advocacy contributed to the publication by CMS of a proposed rule in December 2022 that would create new requirements for coverage criteria, prior authorization policies and other utilization management practices adopted by MA plans that are not explicitly included in Medicare FFS policies. We are hopeful that CMS will finalize those requirements for implementation in 2024.

We worked closely with the Regulatory Relief Coalition and a large bipartisan group of congressional legislators to advance “The Improving Seniors’ Timely Access to Care Act,” which would codify requirements for prior authorization policies by MA plans. While that legislation was left out of the year end omnibus appropriation passage enacted by Congress, we are hopeful that Congress will pass the legislation in 2023. MDMA also continued working directly with BCBS Evidence Street and other private payers to promote best practices in evidence review and policy development.

In comment letters to CMS, as well as correspondence and other advocacy with Congress, we expressed our disappointment in several payment cuts enacted by CMS, in particular cuts to office-based specialists providing technology-dependent medical care, and voiced concerns over what the cuts would mean to patient care given the decreased resources for providers as a result of the cuts.

In 2022 we also focused on enhancing the value we provide to members by expanding the scope of information communicated through our monthly Reimbursement Working Group meetings, regular updates, the annual Reimbursement and Health Policy Conference, and other educational programs.

MDMA remains committed to continue working with the Biden Administration, Congress, CMS and other stakeholders to improve patient access to American medical technology innovations and medically necessary procedures.
Cybersecurity

MDMA’s cybersecurity working group serves as a key channel to disseminate timely and relevant information to medical technology innovators as they institute and strengthen their cybersecurity functions. With input from the cyber and other MDMA working groups in 2022, we successfully advocated for cybersecurity policies in the MDUFA V agreement that balanced cybersecurity robustness and clinical impact for medical technologies. We also worked with Congress to help ensure that legislative efforts to improve cybersecurity that were included in the “Food and Drug Omnibus Reform Act of 2022” (FDORA) acknowledged the unique circumstances of “legacy” devices.

MDMA also maintains a partnership with the Healthcare & Public Health Sector Coordinating Council (HSCC) Cyber Working Group (CWG). This public-private partnership develops outputs for risk mitigation, recommendations, best practices and guidance for health sector cybersecurity improvements, as well as advice to government partners about policy and regulatory solutions.

Compliance

MDMA shared the latest enforcement trends and regulatory developments with our members, as well as industry best practices to help companies maintain a robust compliance program and to learn about their compliance priorities.

Legal and Compliance activities in 2022 included:

- Hosting regular calls to keep members up-to-date on important legal and compliance developments
- Conducting webinars and virtual roundtable meetings on topics identified as priorities by our members
- Finalizing and publishing speaker program guidance based on the MDMA Code of Conduct
- Conducting benchmarking surveys on compliance policies and best practices for meal guidelines
- Hosting an in-person roundtable meeting in Washington D.C. to discuss best practices for compliance program, structure operations and best practices
International

MDMA focused on a handful of international issues and discussions in 2022, specifically the European Union (EU) medical device regulation (MDR) reform legislation and United Kingdom’s regulatory system changes. MDMA’s main international focus, actions and challenges included:

European Union

- Seeking an extension of the EU transition period so that changes could be made to the MDR
- Requesting improvements to the proposed MDR rules and legislation to better address market access, innovation pathways and SME challenges
- Surveying MDMA members on their experiences with the backlog of MDR applications and other challenges given the shortage of Notified Bodies (NB)
- Sharing the MDMA member survey results about the scope and size of these challenges with the EU
- Promoting MDMA member-supported solutions to address and correct the backlog and market access issues in the EU
- Meeting with EU regulators and other stakeholders to find common and agreed solutions to the challenges
- Focusing EU regulators and other decisionmakers on the real-life patient access problems being created as a result of the huge approval backlog
- Supporting the proposed administrative and legislative actions of the EU to address the backlog and related problems

United Kingdom

- Developing information and holding discussions with members and UK experts about of the UKCA (Conformity Assessment) mark requirements and the transition period issues in the UK
- Meeting with UK officials and other stakeholders to collect information and provide member feedback on ways to address our concerns about the tight deadlines and lack of guidance

Germany

- Communicating to MDMA members about other key trade and reimbursement developments such as where hybrid inpatient/outpatient DRGs are being developed

MDMA was very encouraged by the developments and actions taken by overseas policymakers in 2022 regarding our top issues and concerns. The EU transition period for the MDR was pushed back significantly to December 2027 or 2028 depending on the risk classification of the device. Relief was granted for medical device makers holding expiring or recently expired certificates as long as they have been working with a NB on their new MDR approval. Those holding a Medical Device Directive (MDD) certificate that was still valid as of May 2021 will also be made part of the extended transition period process. In addition to keeping “legacy” devices on the EU market, steps were also being taken to improve the market access pathways for orphan and novel/innovative devices as well as for SMEs.

In the UK, the Life Sciences Council which is comprised of government leaders, regulators and industry proposed three workstreams (Innovation, International and Capacity) to ensure market access and a streamlined regulatory process for
medical devices in the UK. With regard to the Innovation workstream, the UK is working on a program called the Innovative Devices Access Pathway (IDAP) to ensure that novel devices have a clear pathway to the market in the UK including for SMEs. The International workstream is exploring the use or acceptance of overseas conformity assessment modules such as from the US and EU. High on that list is UK integration into MEDSAP (Medical Device Single Audit Program). The Capacity workstream is focused on ensuring that UK Conformity Assessment Bodies (CABs) are able to handle the workload now that the end of the UK regulatory transition period has been pushed back until July 2024.

Finally, MDMA has and continues to regularly host international speakers to address member concerns about important overseas regulatory, reimbursement and trade developments and issues.

Patents

MDMA continued as the leading voice for protecting the intellectual property rights of medical technology innovators. In 2022, MDMA continued its close work with PhRMA, BIO, the National Venture Capital Association and others to raise awareness with Members of Congress about the importance of patents for innovation and shared our concerns over the recent erosion of patent rights. MDMA continued to build support for the “Stronger Patents Act” and legislation to reform Section 101 of the Patent Act to strengthen the patent system.

In addition, MDMA and a coalition of stakeholders sent a letter to Congress expressing our opposition to S. 2774, the “Pride in Patent Ownership Act.” In the letter, we noted that the legislation unfairly and excessively punishes inventors and patent holders for record-keeping errors and ultimately rewards willful infringers by reducing the amount of damages a patent holder can recover. In addition, the bill would adversely place a spotlight on inventors and patent holders, by requiring a registry of all patent transactions that could serve in practice as a ledger of potential targets for infringers, and assist them to attack innovators through frivolous challenges at the U.S. Patent and Trademark Office.

Congresswoman Suzan DelBene is awarded the 2022 Champion of Innovation award during the MDMA Annual Meeting.
2022 Programs & Webinars

MDMA continued our proud tradition of bringing together the leading voices in government, Congress, industry and more to share their insights on how to improve patient care and the innovation ecosystem, and how to strengthen the collaboration that has resulted in the United States being the world leader in developing safe and effective medical technologies.

2022 Webinars included:

- Medical Device Industry Enforcement Priorities in 2022
- Changes to the HCPCS Application Process & Impact on AI Coding and Reimbursement
- Quality Management System Regulation (QMSR) – the Road Ahead
- NTAP & TPT: Key Elements of Successful Applications
- Protecting and Managing Trade Secrets in the Medical Device Industry
- Post Election Analysis
- Navigating the Evolving Regulatory Framework for New Patient Digital Health

2022 FDA Forum – March 9-10, 2022 - Virtual

MDMA hosted our FDA Forum in Palo Alto, CA on March 9-10, 2022 where attendees were able to learn first-hand from regulatory officials and experts on the latest strategies and reforms to the regulatory processes. The virtual conference consisted of 2 days of productive and interactive discussions covering various topics and provided numerous opportunities for attendees to have their questions addressed.

2022 Annual Meeting – April 27-29, 2022

MDMA hosted a successful in person Annual Meeting in Washington, DC! The meeting was highlighted by a Keynote Address by HHS Secretary Xavier Becerra who shared with attendees the agency’s priorities for FDA and CMS, as well as his vision for innovation in patient care. Attendees also heard firsthand from several Members of Congress on their health care priorities, and were able to ask top CMS officials including Dr. Lee Fleisher, Tamara Syrek Jensen, Jason Bennett and Carol Blackford questions directly during several CMS presentations.

The meeting included a Congressional fly-in as Congress returned from their district work period to begin several weeks of legislative business prior to the Memorial Day recess.
15th Annual Medical Technology Executive Forum – September 23, 2022 – Virtual

MDMA hosted another successful virtual Medical Technology Executive Forum with over 100 CEOs and senior executives participating. Participants heard from a compelling lineup of speakers from FDA, CMS and more on challenges and opportunities facing our industry. Dr. William Maisel, Office Director, Office of Product Evaluation and Quality and CDRH Chief Medical Officer, and Jonathan Blum, CMS Principal Deputy Administrator & Chief Operating Officer, were among the lineup of many dynamic speakers.

24th Annual Reimbursement & Health Policy Conference – November 9-10, 2022

MDMA hosted a SOLD OUT Reimbursement & Health Policy Conference in Washington, DC. Participants had the unique opportunity to ask questions to some of the leading officials from the Centers for Medicare and Medicaid Services (CMS), as well as to learn the latest insights from industry experts on securing reimbursement for their innovations.
MDMA Board of Directors

The MDMA Board of Directors represents a broad cross section of our membership and the medical device industry. Voting members include:

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Chief Executive Officer
Outset Medical
MDMA Chair

Jeff McCaulley
Chief Executive Officer
Avalign Technologies
Immediate Past MDMA Chairman

Veronica Acurio
President, Medical Solution Division
Health Care Business Group
3M Health Care

James Allen
Sr VP & Chief Financial Officer
B. Braun Medical, Inc.

Laurent Attias
SVP, Head of Corporate Strategy,
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Alcon Laboratories

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Victoria Carr-Brendel
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Group Vice President, Cochlear
Implants
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