To Our Members,

As the nation and the world continue to confront the COVID-19 pandemic, we remain humbled and inspired to be a part of an ecosystem that is doing so much to address the challenges facing patients and the health care delivery system. From day one, medical technology innovators answered the call to deliver diagnostics, personal protective equipment, ventilators and so much more to confront the pandemic, and our collective passion has not let up.

There certainly remains much more work ahead, but our industry’s proud tradition of developing transformative cures and therapies to address patient needs will meet the challenges to come.

As always, there is no shortage of issues that the MDMA team is engaged in on behalf of our dynamic industry. The Medical Device User Fee Authorization V negotiations continue, and it is vitally important to our industry that we build on the many improvements to regulatory pathways that have been achieved over the years and that we do so with transparency and accountability.

MDMA is also building upon our work to improve the reimbursement landscape for medical technology innovators with both public and private payors. Shortening the gap between FDA and CMS decisions will not only improve health outcomes for patients, it will provide hope for countless individuals with unmet needs who needlessly suffer.

The new administration and Congress are actively engaged in various efforts to bring reforms to the delivery of health care, and MDMA remains the voice of the innovative and entrepreneurial sector of our industry in these debates.

If you are not a member of MDMA, now is the time to get involved in our work as we seek to improve the environment for medical technology innovation. Regardless of the challenges you and your team face, whether it is regulatory, reimbursement, market access, compliance, intellectual property protections or more, MDMA will continue our proud tradition of passionate advocacy.

We are confident that the United States will remain the global leader in developing lifesaving and life-changing medical technologies in 2022 and beyond, especially with the right policies in place. We all recognize how delicate the line can be between encouraging and thwarting innovation, and MDMA is dedicated to help ensure the proper balance is struck by policymakers. Working together, the countless stakeholders committed to seeing our ecosystem thrive can deliver on the promise of a healthier, brighter tomorrow.

Sincerely,

Jeffery A. McCaulley
CEO, Avalign Technologies, Inc.
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
FDA

The Food and Drug Administration (FDA) and medical technology innovators continued their important collaboration in 2021 to rise to the ongoing challenges presented by the COVID-19 pandemic. As new variants presented themselves in the United States and throughout the world, our dynamic industry rose to meet the demands that patients, providers and the health care delivery system required.

The FDA and industry also began in earnest their negotiations for the reauthorization of the Medical Device User Fee Amendments for fiscal years (FY) 2023 through 2027 (MDUFA V). MDMA and other stakeholders focused on our principles, including the central tenant that patients get timely patient access to safe and effective medical technologies. We reiterated with FDA that user fees should be used solely for the premarket review process, and that industry and FDA should work to identify mutual goals and process improvements to achieve timely patient access.

As the nation and the world continue to turn the corner on the COVID-19 pandemic, MDMA encouraged FDA to focus on “Back to Basics” principles that have led the FDA to become the gold standard for determining safety and efficacy throughout the world. These include focusing on review processes and meeting current goals, maintaining current goal structures established in the previous MDUFA agreement, seeking targeted improvements to review processes, and building accountability into resource and hiring targets.

Lastly, we continued to encourage FDA to explore ways to leverage the administrative efficiencies during COVID-19 beyond the current crisis. MDMA remains focused on this important work to secure a negotiated agreement in 2022.

Ethylene oxide (EtO) sterilization of medical devices continues to be an issue that MDMA is working on with various stakeholders. While the EPA announced in 2020 that it would be issuing a final rule on EtO in 2021, that was delayed until 2022. MDMA continues to work closely with the agency, Biden administration and Congress to help ensure that any future regulations do not create hurdles for patient access to safe and effective medical technologies.

As the nation and the world continue to turn the corner on the COVID-19 pandemic, MDMA encouraged FDA to focus on “Back to Basics” principles that have led the FDA to become the gold standard for determining safety and efficacy throughout the world.

MDMA will continue to be the voice of the innovative and entrepreneurial medical technology companies as we work with FDA and all federal agencies who share our common goal an ensuring patients get timely access to safe and effective products.
Reimbursement

MDMA continued to work closely with CMS and Congress to advance reimbursement policies that support patient access to innovative medical technologies.

While disappointed that CMS reversed course and repealed the “Medicare Coverage of Innovative Technology” (MCIT) pathway prior to its implementation, MDMA worked with Congress and other stakeholders to secure a commitment from the agency to move quickly on the development of a replacement proposal in 2022. We believe a dedicated transitional coverage pathway for emerging technologies will help reduce the time that can elapse between FDA marketing authorization of an innovative medical device or diagnostic test and the issuance of coverage policies providing access for Medicare beneficiaries—an especially important step forward for Medicare beneficiaries whose medical needs are unmet by currently available technologies.

Following the swearing in of CMS Administrator Chiquita Brooks-LaSure, MDMA congratulated her and encouraged her to support several of the priorities that the medical technology industry has been working on to improve patient access to care. In addition to expediting coverage for important new technologies, we reiterated our concerns about prior authorization requirements that impose unnecessary burdens on Medicare beneficiaries, providers, and beneficiaries. We worked closely with the Regulatory Relief Coalition and bipartisan Members of Congress and Senators to introduce legislation addressing the use of prior authorization by Medicare Advantage plans. MDMA also organized a letter to CMS from 40 patient advocacy, physician and life science associations, including the American Medical Association, the Federation of American Hospitals and the American College of Surgeons, objecting to recent expansion of prior authorization requirements in the Medicare fee-for-service program.

MDMA remained engaged in discussions with the AMA regarding numerous issues relating to the CPT coding process, including eliminating the conversion of applications for Category I codes to Category III without the applicant’s consent. In 2021 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 e-mail updates, the annual Reimbursement and Health Policy Conference, and other educational programs.

As the Biden administration continues to establish its priorities within CMS, and with ongoing challenges with private payor policies, MDMA remains laser-focused on improving the environment for timely access to innovative medical devices.
Legal and Compliance

DMA also continued to work closely with our members to understand their compliance priorities and keep them up to date on enforcement trends and regulatory developments, as well as industry “best practices” to help companies maintain a robust compliance program.

Legal and Compliance activities in 2021 included:

- Hosting regular calls and webinars to keep members up-to-date on important legal and compliance developments
- Developing and sharing compliance tools and resources as well as benchmarks on priorities and policies
- Conducting three virtual roundtables to discuss emerging trends and share best practices on topics identified as priorities by Compliance Working Group participants
- Hosting a Q&A Session with OIG Counsel to better understand OIG’s Special Fraud Alert on Speaker Programs
- Developing a Code of Conduct Guidance on Speaker Programs to guide member companies as they evaluate their compliance programs in light of the OIG Special Fraud Alert

“RETURN TO OFFICE”

The ongoing pandemic continued to present challenges to MDMA companies navigating evolving public health guidance and a patchwork of federal, state and local laws and orders while trying to keep their workforce safe and productive. To help member companies navigate these challenges, our “Return to Office” activities included:

- Hosting monthly calls to help keep members up to date on evolving guidance and mandates and to provide a forum for members to ask questions and share advice
- Sharing “return to office” resources including sample policies and procedures as well as relevant guidance and regulations
- Periodic benchmarking surveys regarding return-to-office plans, workplace policies and protocols, and vaccine mandates

Congresswoman Anna Eshoo (CA) shares her priorities for medical technology innovation as the Chairwoman of the House Energy and Commerce Subcommittee on Health.
Medical Device Manufacturers Association focused on a handful of international issues and discussions in 2021 with many of them affected by the COVID-19 efforts of other countries. MDMA continued to gather information and to advocate on a targeted set of international issues of great importance to our innovative and entrepreneurial members.

The range of issues and challenges included:

- Seeking a delay in the May 2022 implementation date for the EU IVDR;
- Expanding the number and capacity of EU Notified Bodies for both the MDR and IVDR;
- Encouraging input and understanding of the UKCA mark requirements in the UK;
- Supporting EU use of COVID-19 related measures such as virtual audits;
- Assessing the new Biden’s Administration trade priorities and impact for our industry;
- Promoting the continuation of 100 medtech exemptions from the China trade tariffs;
- Explaining the Administration decision to coordinate pressure with allies on China; and
- Monitoring and communicating other key overseas regulatory and reimbursement developments, such as in Germany.

MDMA was encouraged by some of the developments and actions taken by overseas policymakers in 2021 regarding our top issues and concerns. The EU IVDR was delayed with its transition period pushed back to 2025, 2026, 2027 or even beyond for some “in-house” IVDs. The number of Notified Bodies able to review products for a CE mark under the MDR doubled to 25. While much more work needs to be done, the number of NBs continued to rise quickly in early 2022 and other “easing” measures such as acceptance of virtual audits remained in place in many cases. While the Biden Administration agreed to extend the medtech-related trade tariff exemptions with China, the Administration also made good on their promise to circle the wagons with our Western trading partners on recalcitrant Chinese trade practices such as its support for State-owned companies, government subsidies and IP-related concerns. Lastly, MDMA hosted numerous international speakers that could address member concerns with trade issues and developments.
Pain Management & Non-Opioid Alternatives

MDMA’s Pain Management Working Group provides a forum for companies with non-opioid products to treat pain or address issues associated with substance use disorder, and to coordinate advocacy efforts and other activities. This group advocates for policies that increase access to opioid sparing medical technologies before the U.S. Congress and other agencies including the FDA, CMS, CDC, AHRQ and others. This group works in a collaborative fashion with other MDMA working groups including our FDA and Reimbursement committees. Highlights from 2021 included:

- Advocacy efforts to oppose burdensome prior authorization requirements that restrict patient access
- Provided comments to CDC’s National Center for Injury Prevention and Control (NCIPC) on their update to the 2016 Guideline for Prescribing Opioids for Chronic Pain
- Engaged policy makers to disseminate best practices for pain management via annual appropriations process
- Submission of various comments and letters to federal agencies and Congress, as well as teleconferences that allowed for benchmarking and “best practices” sharing

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. In 2021, working with federal partners, MDMA helped members navigate vulnerability disclosures, threats and ransomware activity targeting the health care and public health sector. 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 enterprise cybersecurity improvements, as well as advice to government partners about policy and regulatory solutions that facilitate mitigation of cybersecurity threats to the sector.

Patents

MDMA has long recognized how important it is for our members and the industry to have a strong system in place that protects patent rights, enabling innovators to attract investments to fund new cures and therapies, while fighting against any infringement in the United States or abroad.

In 2021, 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. As with every new session of Congress, new Members joined the Judiciary Committee, as well as a freshman class that was new to this important issue. Working with the broad coalition that has assembled to confront this issue, 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.

MDMA will continue to be the lead voice for medical technology innovators in securing and strengthening intellectual property rights.
2021 Programs & Webinars

As the United States and the world continued to confront the challenges posed by the COVID-19 pandemic, MDMA hosted all of its events virtually in 2021. We 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.

2021 FDA Forum – March 10-11, 2021 – VIRTUAL

MDMA hosted another successful FDA Forum with 185 participants, learning first-hand from top FDA officials and other 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.

2021 Annual Meeting – April 29, 2021 – VIRTUAL

MDMA hosted a successful Virtual Annual Meeting with nearly 200 participants. Attendees heard firsthand from several Members of Congress on their perspectives on health care priorities, and what legislative proposals the Senate and House of Representatives were working on that would impact medical technology innovation. Additionally, participants were able to ask CDRH Director Jeff Shuren questions on the agency’s priorities and goals, and top CMS officials led a discussion focusing on our members’ concerns. Other key issues covered during the sessions included insights on “Return to Work” challenges, as well as a compliance update.
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 industry, Members of Congress, FDA, CMS and more on challenges and opportunities facing our industry. Speakers included CDRH Director Jeff Shuren, CMS Principal Deputy Administrator & Chief Operating Officer Jonathan Blum, HHS Chief of Staff Sean McCluskie, Congresswoman Diana DeGette, Congressman Fred Upton and others.

24th Annual Reimbursement & Health Policy Conference
– November 9-10, 2021 – VIRTUAL

MDMA hosted over 135 attendees at our virtual Reimbursement & Health Policy Conference. Participants had the unique opportunity to ask questions from some of the leading experts from the Centers for Medicare and Medicaid Services (CMS).

The JD Lymon Group provided the first day session on Practical Reimbursement Strategy. Day two included a CMS Update from the Deputy Administrator, Meena Seshamani; a CMS Town Hall with the CMS Ombudsman, TCPG Group Administrator and Director of Coverage & Analysis Group.
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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Avalign Technologies, Inc.
MDMA Chairman

Paul LaViolette
Managing Partner & COO
SV Health Investors
Immediate Past MDMA Chairman

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Randel Woodgrift
Senior Vice President, Cardiac Rhythm Management
Abbott Laboratories