

2020 ANNUAL REPORT

Rising to the Needs of Patients





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To Our Members

2020 was a truly unprecedented year. Many lost their lives or loved ones, while we have all lost our way of life as a result of COVID-19. The impact of this pandemic has transformed our homes, our communities, and our workplaces, and will no doubt result in changes to the delivery of health care for years to come.

Despite the overwhelming challenges that medical technology innovators faced to confront this crisis, our industry not only rose to the occasion, but also pioneered some of the most transformative diagnostics, therapies, and treatments that saved countless lives. We have never been prouder to be a part of this dynamic and caring industry, and yet we know there is much more to do.

Medical technology innovators worked closely with FDA to ensure that safe and effective therapies were delivered as quickly as possible to those who needed them most during the pandemic. Perhaps more than ever, 2020 showed how critically important it is for regulators and innovators to work closely together to address the pressing needs of patients and health care providers.

Despite all of the great work that has been done to confront this pandemic, many other hurdles remain for our industry. The MDUFA V reauthorization process has begun, and it is vitally important that we build on improvements to the regulatory pathways that have been achieved over the years. As the delivery of care becomes more complex, we must focus on enhancing what is working to clear and approve medical technologies, and avoid policies that would create unnecessary obstacles to innovation.

MDMA also continues to build upon our work to improve the reimbursement landscape for medical technology innovators. Our six-year journey to shorten the time between regulatory approval and reimbursement decisions resulted in the "Medicare Coverage of Innovative Technology (MCIT)" final rule. This is a great example where by working passionately with policy makers, we can shorten the gap between FDA and CMS decisions. The ongoing developments in the international, compliance and other arenas also highlight the need for your engagement, as we all seek to improve patient care.

If you are not a member of MDMA, now is the time to engage in our collective efforts to improve and strengthen the environment for medical technology innovation. We have all seen in the past what happens when policies are enacted that have unintended adverse consequences for our ecosystem. Working together, MDMA will continue to educate Congress, the new administration, and all stakeholders on the need for targeted policies that will boost patient care, access to new technologies, and investments in the next generation of diagnostics, therapies, and cures.

We are confident that our industry will be a leader in overcoming whatever challenges remain as the world confronts the COVID-19 pandemic, as well as so many other illnesses and conditions that cause pain and suffering. Medical technology innovators have a proud history of solving some of the biggest problems facing patient care, and 2021 will be another opportunity for the United States to lead the world in this important work.

Sincerely,



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



Mark Leahey
President & CEO, MDMA

Federal Policy Highlights

FDA

The Food and Drug Administration (FDA) and medical technology innovators worked around the clock in 2020 to address the challenges posed by the COVID-19 pandemic. Our industry mobilized in various ways to meet the demands that the health care delivery system required, while continuing to develop lifesaving and life changing medical technologies.

The FDA's use of its Emergency Use Authorization (EUA) authority enabled our industry to further confront the obstacles posed by the pandemic, while maintaining the agency's strong track record of safety. The collaboration to provide solutions and support to patients and providers is another reason why the FDA remains the gold standard in safety and efficacy.

The FDA also held a public meeting on the reauthorization of the Medical Device User Fee Amendments for fiscal years (FY) 2023 through 2027 (MDUFA V). The current legislative authority for the medical device user fee program expires on September 30, 2022, and new legislation is required for the FDA to continue to collect user fees for the medical device program in future fiscal years.

Numerous stakeholders presented at the virtual meeting, including MDMA, where we noted that the user fee collections for FY 2019 alone exceeded \$200 million, more than the entire fees collected under the first user fee agreement. We continue to highlight for policy makers that user fees should be seen as supplemental to Congressional appropriations rather than as a critical source of income for the agency's operations.

As we begin the process for reauthorizing MDUFA, MDMA is focused on making sure the commitments of the previous user fee agreement are being realized, and exploring ways to leverage the administrative efficiencies during COVID-19 beyond the current crisis. All stakeholders agree that the United States' medical technology ecosystem must retain our leadership position in innovation, and that patients get timely access to the cures and therapies this dynamic industry develops. MDMA will be focused on these objectives as negotiations move forward in 2021 and beyond.

Ethylene oxide (EtO) sterilization of medical devices continues to be an issue that MDMA is working on with various stakeholders. The EPA announced in 2020 that it would be issuing a proposed rule on EtO, and that a final rule would not be published until sometime in 2021. MDMA is working with the new administration to help ensure that any future regulations do not create hurdles for patient access to safe and effective medical technologies. Congress has also continued its interest, including introducing the "Public Health Air Quality Act" which would require the EPA to implement fence-line monitoring for targeted facilities that the agency believes cause toxic air pollutants. MDMA reiterated to 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, especially during a global pandemic.

We continued to share our commitment to working in good faith with regulators to find and validate alternatives over appropriate timelines, focused on encouraging collaboration between FDA and EPA.

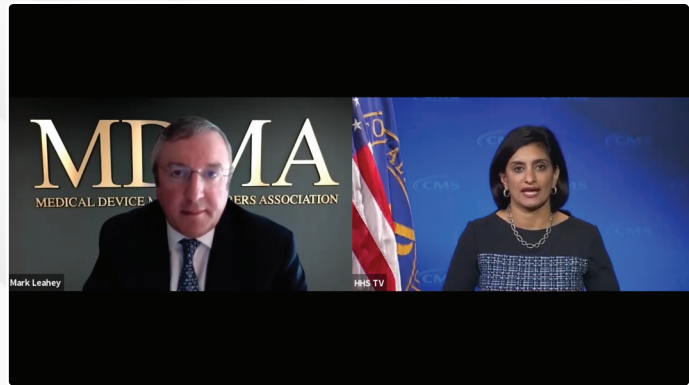


CDRH Director Jeff Shuren

Reimbursement

Over the course of 2020, MDMA worked with CMS and Congress to achieve significant progress on initiatives aimed at reducing the time between FDA market authorization and implementation of coverage, coding and payment changes that support patient access.

After many years of work by MDMA and our members, CMS moved forward with the establishment of a new coverage pathway providing a four-year period of automatic national coverage for FDA-designated breakthrough devices (MCIT). CMS Director of Coverage and Analysis Tamara Syrek Jensen discussed the proposal and other agency priorities with members at our annual MDMA Reimbursement Conference in November. The final rule was issued in the closing weeks of the Trump Administration, and MDMA continues working with the Biden Administration and Congress to secure its implementation in early 2021. While limited to FDA-designated breakthrough devices, we believe creation of the new pathway will provide a foundation to accelerated coverage for other novel technologies in the future.



CMS Administrator Seema Verma shares the agency's policy priorities and reforms with MDMA members

Establishing patient access can involve a combination of coverage, coverage and payment decisions, and MDMA has long advocated for greater coordination between the different organizations that control or contribute to those decisions, both inside and outside of CMS. We supported the establishment, announced in August 2020, of a new “one-stop-shop” within CMS to assist innovators with navigating the coverage, coding and payments processes to accelerate beneficiary access to innovative new technologies.

MDMA also remained engaged in discussions with the AMA regarding numerous issues relating to the CPT coding process, reaching agreement on the use of data from outside the U.S. We continue to make progress on clarifying criteria for satisfying the requirement for widespread use and eliminating the conversion of applications for Category I codes to Category III without the applicant’s consent.

MDMA took a strong stand against unnecessary use of prior authorization in Medicare in reaction to the agency’s plan to impose pre-approval requirements for additional procedures. We are prioritizing these efforts in 2021, working with Congress and other stakeholders to ensure that prior authorization is required only when necessary to address actual excess utilization, and that the process does not delay patient access to care or impose excessive burden on providers.

Finally, MDMA responded to a proposal by CMS to use commercial payer policies to define Medicare coverage criteria with comments highlighting the lack of transparency, predictability and stakeholder input in coverage decision-making by private payers. CMS ultimately declined to move forward with the proposal, and in 2021 we will be engaging with CMS on developing guidance on the use of commercial coverage policies in Medicare coverage evaluations. MDMA also continued working directly with BCBS Evidence Street and other private payers to promote best practices in evidence review and policy development.

We are committed to building on all of these efforts in the coming year, and to strengthening our relationships with Congress and the new administration in support of timely access to innovative medical devices.

"Liquidity" Activities

As the nation and the world paused "elective procedures" to help confront the COVID-19 pandemic, MDMA created a new Working Group to explore policy proposals that provide access for medical technology companies to necessary liquidity during these challenging times. Since numerous medtech companies operate on a pre-revenue basis, or with revenue and no profits, the impact of the shutdowns across the world had the potential to close their doors. MDMA engaged with Members of Congress to ensure that the various "CARES" relief packages permitted innovative and entrepreneurial medtech companies to access the loan programs. We also engaged policymakers on ways to improve the employee retention tax credit which was ultimately enacted into law. We continue to explore ways to spur further investments in innovation by leveraging "Net Operating Losses" (NOL) and R&D Tax Credits into refundable and advanceable tax credits to provide critical liquidity.

MDMA developed numerous surveys and grassroots activities to include provisions in federal legislation that would support medical technology innovators. MDMA continues to work closely with Congress and the Administration as they are developing additional relief legislation for the economy.

Legal and Compliance

The COVID-19 pandemic led to numerous challenges for innovators as they sought to continue developing cures and therapies for patients. MDMA worked with various federal and state entities early in the pandemic to ensure that medical device employees were deemed "essential employees." In addition, MDMA worked with Congress and numerous state governments to determine appropriate "return to work" protocols. MDMA will continue to advocate for liability protections for medical device manufacturers who abide by federal, state and local COVID-19 safety guidelines.

While much of our attention focused on responding to the COVID-19 pandemic, MDMA 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.

Other Legal and Compliance activities in 2020 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 Compliance Working Group roundtables to discuss emerging trends and share best practices
- ◆ Implementing the Revised MDMA Code of Conduct on Interactions with Healthcare Providers.

International

MDMA participated in a range of targeted international activities, trade policy discussions and trade agreements in 2020. MDMA stayed engaged in direct discussions with U.S. and foreign policymakers and industry representatives during various negotiations, and sought our members' feedback and input via monthly international conference calls and more. While the COVID-19 pandemic was the central issue impacting health care policy around the world, numerous international regulatory and trade activities continued.

MDMA remained focused on advocating for our innovative and entrepreneurial members on various issues, including:

- ◆ EU medical device regulations;
- ◆ BREXIT;
- ◆ New United Kingdom (UK) trade and regulatory policies for medical devices;
- ◆ Finalization of the USMCA;
- ◆ China trade policies and related tariff issues involving USTR; and,
- ◆ India's regulatory and trade developments.

MDMA was pleased to receive positive communications back from European Union (EU) authorities about our concerns of their regulatory proposals and deadlines on innovative medical device companies. MDMA was also integral in helping to secure the creation of new regulatory safeguards and opportunities for medical device makers in the USMCA. MDMA worked with the UK to take into account and develop ways to reduce the potential disruptions of "BREXIT" as it moves to implement its own regulatory scheme over the next 3 years. While many international challenges remain, including trade policies with China and the EU's implementation of the IVDR, MDMA will continue to vigilantly monitor and address the most significant international challenges facing the industry.

Pain Management

MDMA continued to develop and grow our Pain Management Working Group that is dedicated to providing greater access for patients to opioid sparing medical technologies that can alleviate acute and chronic pain. While many of the issues discussed intersect with other MDMA regulatory and reimbursement work streams, this dedicated working group provides an opportunity for companies in this space to share information and organize outreach activities.

Some of the highlights from this group's work in 2020 included:

- ◆ Advocacy efforts to oppose burdensome prior authorization requirements that restrict patient access.
- ◆ Successful lobbying efforts highlighting the need for better data on pain, provider educational materials and reimbursement policies for FDA cleared/approved devices.
- ◆ Engagement with HHS, CMS, CDC, FDA, Congress and other policy makers.
- ◆ 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. Working with federal partners, MDMA helped members navigate a number of vulnerabilities, threats and ransomware activity targeting the health care and public health sector in 2020.

MDMA also maintains a partnership with the Healthcare & Public Health Sector Coordinating Council (HSCC), which is focused on the development and dissemination of sector-wide recommendations and guidance to help facilitate sector-wide mitigation, response and resilience to cybersecurity threats. FDA launched a Digital Health Center of Excellence in 2020 and released a long-awaited "Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan." In collaboration with MDMA's FDA working group, members have an opportunity to shape cybersecurity, digital health, AI, ML and other cutting-edge issues that promote patient access, safety and innovation.

MDMA continues to provide our members with opportunities to participate in teleconferences and webinars with various industry experts to receive updates on legislative, legal and commercial activities that could impact their companies.

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 2020, 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. This broad coalition of innovators advocated support for the "Stronger Patents Act" and legislation to reform Section 101 of the Patent Act to strengthen the patent system.

Additionally, MDMA supported reforms undertaken by the US Patent and Trademark Office to address inequities in the review of patent claims between the federal courts and administrative reviews at USPTO.

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

2020 Programs & Webinars

From the start of the COVID-19 pandemic, the medical device industry has been on the front lines developing diagnostics for patients, and providing the necessary tools to protect our nation's critical healthcare workers.

MDMA established a COVID-19 Working Group within our membership where we provided **26 COVID-19 Update Webinars**, a dedicated **COVID-19 Resource Center** and additional work streams including:

- ◆ Liquidity Working Group
- ◆ Return to Office Best Practices
- ◆ Med Tech Representatives Access
- ◆ Supply Chain Issues

With this in mind, MDMA also hosted our 2020 conferences virtually.



MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

2020 FDA Forum: PMA/510(k) Workshop

MARCH 12-13, 2020 | CROWNE PLAZA CABANA HOTEL | PALO ALTO, CA

2020 FDA Forum – March 12-13, 2020 – VIRTUAL

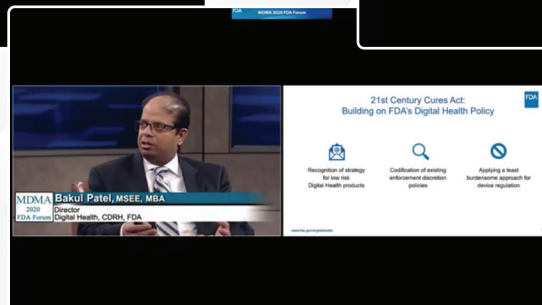
MDMA hosted 12 top FDA officials to address over 130 attendees and answer their questions during this popular two day event. MDMA was able to provide a unique and effective opportunity to share best practices and common challenges as top policy makers, industry executives, regulators and others confronted the growing COVID-19 pandemic.



FDA and MDMA Staff Answering Attendees' Virtual Questions



Deputy CDRH Director and CMO
William Maisel



Director of CDRH Digital Health Center of Excellence
Bakul Patel



2020 Annual Meeting – April 30, 2020 – VIRTUAL

MDMA hosted our “virtual” Annual Meeting with over 150 attendees. During the meeting we heard from CDRH Director Jeff Shuren, three Members of Congress, Adam Boehler, the White House COVID-19 Task Force Advisor, and FDA Commissioner Stephen Hahn. Commissioner Hahn and Director Shuren updated attendees on what FDA is doing at this time to address the COVID-19 crisis while still continuing to approve life-changing medical devices.

The Annual Meeting consisted of 4 hours of productive and interactive conversation with top policy makers who answered our members’ questions directly. Speakers provided clarity on the path going forward for the health care system, our economy and the nation. Dr. Shuren provided an overview of the tremendous collaboration between innovators and regulators to enhance patient care. With each Member of Congress, MDMA addressed the need to accelerate patient access to deferred procedures, provide liquidity to companies impacted and urged them to continue working in a bipartisan manner to address the pandemic. Policy makers praised our industry for powering through and ramping up production of many supplies needed to attack COVID-19.



FDA Commissioner Stephen Hahn



U.S. Senator Todd Young (IN)

MDMA 2020 MEDICAL TECHNOLOGY EXECUTIVE FORUM
SEPTEMBER 25, 2020 **VIRTUAL EVENT**

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

13th Annual Medical Technology Executive Forum –

September 25, 2020 – VIRTUAL

MDMA hosted over 150 CEOs and senior executives at our virtual Medical Technology Executive Forum. Participants heard from a compelling lineup of speakers from industry, FDA, CMS and more on challenges and opportunities facing our industry.

CMS Administrator Seema Verma presented a fireside chat discussing the agency's key priorities and Tamara Syrek-Jensen, Director of CMS' Coverage and Analysis Group, joined us to provide a CMS update.

Participants also heard from CDRH Director Jeff Shuren on the latest policies and strategies the FDA is developing to confront the COVID-19 pandemic, as well as from Leslie Trigg, CEO of Outset Medical on confronting challenges as a CEO during COVID-19 and how businesses can thrive despite the challenging times.



*CMS' Director of Coverage and Analysis Group
Tamara Syrek-Jensen*



*MDMA President and CEO Mark Leahey
and Outset Medical CEO Leslie Trigg*



MDMA's 2020 Reimbursement & Health Policy Conference Thursday, November 12, 2020

A VIRTUAL EVENT

23rd Annual Reimbursement & Health Policy Conference –

November 12, 2020 – VIRTUAL

MDMA hosted over 150 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). CMS is currently examining numerous initiatives to improve outcomes and promote value-based health care, and the CMS Director of the Coverage and Analysis Group, Tamara Syrek Jensen, shared how the agency is working to improve patient and provider access to medical technologies. Kimberly Brandt, CMS' Principal Deputy Administrator for Policy & Operations, also detailed the numerous initiatives and policies that the agency is implementing to help confront COVID-19.

Jason Bennett, Acting Director of the new Office of Technology, Coding and Pricing Group (TCPG) at CMS and James Bailey of the TCPG Navigator Team provided an update from the new group. In addition, Jay Alman, Vice President of CPT Coding and Reimbursement Strategy for the American Medical Association shared some of the reforms to the process and tips to navigate CPT.



CMS officials answering attendees questions



Interactive panels of policy makers and industry experts discuss the latest medtech developments

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
MDMA Chairman
Avalign Technologies

Paul LaViolette
Immediate Past MDMA Chairman
SV Health Investors

Chris Barry
Chief Executive Officer
NuVasive, Inc.

Wil Boren
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Baxter Healthcare Corporation

Paul Buckman
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Glaukos

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AtriCure

Joe Damico
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Jason Richey
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Leslie Trigg
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Outset Medical

Ramakrishna Venugopalan
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Randel Woodgrift
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1333 H Street NW, Suite 400 West, Washington, DC 20005

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