


# AdvaMed Advancements
# Q3 2026 Report

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# A Note from Scott

Dear AdvaMed Member,

I'm pleased to share our Q3 report, highlighting coordinated advocacy and results in Washington, D.C., with regulators, and in the states on behalf of your companies and the patients who depend on medtech innovation.

This quarter, we intensified our push to close the gap between FDA authorization and Medicare coverage for breakthrough technologies. Our medtech showcase brought 32 member companies — including 10 with FDA-designated breakthrough devices — to Capitol Hill to demonstrate their innovations to policymakers firsthand. The event anchored our broader campaign for a timely, predictable coverage pathway so Medicare beneficiaries can benefit from lifesaving innovation sooner.

Across AdvaMed, our teams made progress on several policies shaping the future of medtech. Our advocacy helped drive a significant CMS proposal to recognize certain software-based clinical technologies as separately payable medical services. We also strengthened diagnostics policy and engagement with FDA, secured important state victories protecting medical device packaging and data use, and advanced our work on tariffs, device servicing, reimbursement, and patient access.

With the Board's agreement, I entered the policy debate with the case that health care policy must reflect the full value medtech delivers. In a newspaper op-ed and later at Modern Healthcare's Leadership Summit, I pressed for investing health care dollars wisely and recognizing medtech as a cost saver, not a cost driver. This message is critical to the ongoing health spending debate, and I look forward to developing it further in the weeks ahead.

We also entered the final stretch before The MedTech Conference with strong momentum: record early registration, sponsorship pacing ahead of previous years, and exceptional exhibitor demand. These results reflect careful coordination across AdvaMed, including contributions from many of you who helped shape the conference. I'm excited to welcome our community to Boston.

These accomplishments show what we can achieve through close partnership among our members, Board, and staff. Thanks to your continued engagement and trust, we're well-positioned to build on this work in the final quarter.

Sincerely,



**Scott Whitaker**
President & CEO
AdvaMed

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# Tariffs




*The White House on September 27 issued a press release with details on the "operationalized" U.S.-China Board of Trade, with upwards of 80% of U.S. medtech exports by value included in China's list of proposed tariff cuts.*

## ADVAMED ADVOCATES FOR MEDTECH RELIEF FROM GLOBAL TARIFFS

AdvaMed continued to press for medical technologies, diagnostics, and key medical inputs to be excluded from new tariffs. In comments responding to two Section 301 investigations, one concerning forced labor practices across approximately 60 trading partners and another examining structural excess capacity in 16 economies, as well as a separate investigation into Brazil, AdvaMed emphasized that medical technologies were not identified as a sector of concern and are already subject to the ongoing Section 232 review. The submissions also highlighted the industry's highly regulated manufacturing processes, complex global supply chains, and essential role in supporting health care delivery and critical infrastructure.

In parallel, AdvaMed advanced high-level engagement with the Administration on tariffs and trade policy. During a meeting at the White House with the Chief of Staff's office, AdvaMed President and CEO Scott Whitaker reinforced the industry's case for maintaining low tariffs, preserving preferential treatment under existing trade agreements, and ensuring predictable trade policies that support U.S. medtech innovation, manufacturing, and patient care.

Following USTR's July final action in the forced labor investigation, the Global team quickly assessed the additional duties and key exemptions, including relief for certain USMCA-compliant products, Nairobi Protocol products, and UK-origin medtech.

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AdvaMed also worked with MedTech Canada and other regional partners to protect market access for medical technologies during a period of heightened U.S.-Canada trade tensions, helping secure a medtech carve-out from potential Canadian retaliatory tariffs and relief from provincial procurement restrictions.

AdvaMed also continued to explore additional tariff mitigation strategies, including the potential for domestic manufacturing credits, rebates, and analysis of other 232 programs such as onshoring agreements.

### U.S.-CHINA BOARD OF TRADE DELIVERS TARIFF CUTS FOR CHINA-BOUND MEDTECH EXPORTS

The U.S.-China Board of Trade, a mechanism for Washington and Beijing to cut tariffs on $30 billion of trade each way, became operational in late September during Xi Jinping's state visit. On a trade-weighted basis, upwards of 80% of U.S. medtech exports are included in China's list of proposed tariff cuts. The tariff reductions have yet to be implemented but are expected sometime in the coming few months when Trump and Xi meet again at the APEC and the G-20 summits. This positive development follows the Global Department's written comments to USTR on the Board and AdvaMed's broader advocacy to have medtech recognized as a strategic U.S. export category. Most U.S. medtech exported to China has been subject to an additional 10 percent tariff that Beijing first imposed in early 2025.

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# Technology & Regulatory Affairs




*Representatives from the IMDRF Industry Group made up of Global Medical Technology Alliance (GMTA) and Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA) members gathered at the 30th International Medical Device Regulators Forum (IMDRF) Management Committee Meeting, hosted by Singapore's Health Sciences Authority (HSA).*



*During the September 2 AdvaMed/CDRH Vendor Day, AdvaMed's Khatereh Calleja joined Office of Health Technology Deputy Director Xiaolin Zheng, Associate Director for Regulatory Strategy CMDR Patricia Ellis, and participating member companies. The program connected FDA staff with medical technology innovators through hands-on product demonstrations and educational exchanges designed to enhance understanding of the technologies improving patient care.*

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# Technology and Regulatory Affairs

## ADVAMED AND IMDRF

AdvaMed coordinated GMTA industry partner associations in sharing views on the following International Medical Device Regulators Forum documents. These documents are incorporated into multiple countries' medtech regulations, so ensuring industry views are incorporated is an industry priority:

- Annual updates to adverse event codes
- Guidance on control of Products and Services Obtained from Suppliers
- Essential Principles and Content of Predetermined Change Control Plans
- Clinical Evidence for IVD Medical Devices – Definitions and Principles of Performance Evaluation

## ADVAMED AND FDA CDRH VENDOR DAYS

AdvaMed strengthened its partnership with FDA through hosting AdvaMed/CDRH Vendor Days throughout the summer. AdvaMed held four Vendor Day events, including a diagnostics-focused program, a neurological and physical medicine program, and two cardiovascular day programs focused on electrophysiology, monitoring, and interventional technologies. Collectively, these events featured participation from 55 member companies, significant engagement from Accel companies, and more than 650 FDA attendees from across the device center. CDRH attendees participated in hands-on demonstrations and educational sessions addressing device development and manufacturing, robotic advances, point-of-care diagnostics, implantable brain-computer interfaces, and other emerging technologies. Strong feedback from FDA and participating companies continues to demonstrate the value of these programs in supporting reviewer education and providing a strong foundation for continued FDA-industry engagement.

## ADVAMED ADVANCES AI AND DIGITAL HEALTH REGULATORY PRIORITIES

AdvaMed continued to advance member priorities related to artificial intelligence and digital health regulation. During a meeting with CDRH leadership and the Digital Health Tech Board, AdvaMed presented its positions on regulatory approaches for complex AI and FDA's Clinical Decision Support Software Guidance. The discussion also elevated member priorities related to improving predetermined change control plan implementation, developing AI lifecycle guidance, achieving an appropriate balance between premarket and postmarket oversight, and advancing risk-based regulatory frameworks.

AdvaMed is also currently developing comments in response to FDA's recent discussion paper on risk assessment and device performance for generative AI-enabled medical devices.

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# Technology and Regulatory Affairs

## GLOBAL REGULATORY HARMONIZATION EFFORTS EXPAND IN COSTA RICA

AdvaMed advanced international regulatory convergence through participation in the U.S. Trade and Development Agency-sponsored "Medical Innovations Forum: Aligning Regulations for Market Access" in Costa Rica. AdvaMed also participated in two additional days of capacity-building training for Costa Rica's Ministry of Health and Ministry of Foreign Trade.

The sessions addressed international best practices for medical device regulation, regulatory reliance, global harmonization initiatives, FDA premarket submission pathways, the use of publicly available FDA information, and the Medical Device Single Audit Program. AdvaMed also received Costa Rica's proposed regulation on regulatory reliance and began reviewing the draft to provide comments. These engagements reinforced AdvaMed's leadership in promoting efficient, predictable, and internationally aligned regulatory systems.

## ADVAMED ADVANCES RISK-BASED BIOCOMPATIBILITY APPROACHES

Achieving greater consistency and predictability in biocompatibility assessment remains a top AdvaMed priority. Notably, CDRH held its first biocompatibility town hall, where the Agency addressed member questions, presented device-specific examples of risk-based assessments, and discussed the practical application of ISO 10993-1:2025. Following more than two years of AdvaMed advocacy, FDA also clarified circumstances in which a well-supported material-mediated pyrogenicity assessment may be acceptable in place of rabbit pyrogen testing.

This progress supports AdvaMed's longstanding efforts to reduce unnecessary animal testing and promote globally harmonized, least-burdensome approaches to biocompatibility assessment.

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# Digital Health Tech




*At the AdvaMed-sponsored Consumer Technology Association Health AI+ 2026 event, Kurt Herzer (Anthropic), Ranya Habash (Sweet Medical AI), Brie Crawford (March & People Investments), Dominic King (Microsoft AI), and AdvaMed Digital Health Tech Board member Bakul Patel (Google) discussed collaboration to advance health AI and patient care.*

## ADVAMED DEEPENS FDA ENGAGEMENT ON AI REGULATION

AdvaMed strengthened its collaboration with FDA on regulatory approaches for complex artificial intelligence. At FDA's request, the Digital Health Tech Board met with CDRH Director Dr. Michelle Tarver and Digital Health Center of Excellence Director Dr. Rick Abramson to discuss complex AI, potential refinements to the Predetermined Change Control Plan process, and opportunities to develop practical use cases and illustrative examples. Seven board members participated in person, helping establish next steps for continued engagement with CDRH and the Digital Health Center of Excellence through AdvaMed's Technology and Regulatory Affairs working groups. Building on the DHT Board's engagement, our teams are collaborating with DHCoE on hypothetical examples of how the agency's Predetermined Change Control Plan policy can be leveraged to support devices that incorporate complex AI and working with regulatory subject matter experts to draft MDUFA rider concerns that could additionally support medtech innovation.

## DHT LEADERS ADVANCE DATA ACCESS AND REIMBURSEMENT PRIORITIES

Board Chair Robert Cohen of Stryker and Christian Eusemann of Siemens Healthineers participated in a Washington fly-in that included meetings with the Office of the National Coordinator for Health Information Technology and FDA. Discussions with ONC built on AdvaMed's previous engagement with the HHS chief AI officer and focused on the data access needed to support the development and use of digital health technologies. In a separate meeting, AdvaMed discussed opportunities to improve the pathway between FDA authorization of AI-enabled devices and CMS reimbursement with a special advisor in the Office of the FDA Commissioner.

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AdvaMed continued this work through a subsequent meeting involving Cohen and DHT Board members Jim Peichel of Medtronic and Karolina Wolf of ResMed. The board members presented HHS and ONC officials with examples of digital technologies and explained how limited access to necessary data can prevent those technologies from realizing their full value for patients. The discussion demonstrated the administration's growing recognition of medtech's data access needs, and the role greater regulatory clarity could play in addressing these challenges.

## ADVAMED ADVOCATES FOR DIGITAL HEALTH COVERAGE AND AI POLICY

Following years of targeted AdvaMed advocacy, in the CY 2026 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center proposed rule, CMS proposed to establish a dedicated, separate payment framework for services using software-based technologies to support clinical decision making, ("Software as a Medical Service" or "SaMS"). If finalized, this will be an important first step for innovative technologies that have faced reimbursement challenges despite their value to patients and the health care system. The Digital Health Tech team also continued member discussions regarding FDA's generative AI discussion paper and advanced broader efforts to strengthen medtech's voice in national conversations about artificial intelligence in health care.

## ADVAMED SECURES MEDICAL DEVICE PROTECTION IN CYBERSECURITY LEGISLATION

AdvaMed secured a medical device carveout in the draft Health Care Cybersecurity and Resiliency Act of 2026, helping ensure that new health-sector cybersecurity requirements appropriately recognize the existing regulatory framework governing medical devices. This is a significant win for connected devices because it recognizes the existing FDA cybersecurity framework and helps avoid the risk of overlapping or conflicting regulatory requirements for these technologies. The legislation was considered during a September 15 House Energy and Commerce Subcommittee on Health hearing focused on strengthening cybersecurity across the health care system.

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# Global Affairs




*AdvaMed's Aileen Nandi led a delegation of member company leaders in India, with India Executive Committee Chair Mandeep Singh Kumar of Medtronic, who met with U.S. Ambassador to India Sergio Gor to discuss AdvaMed's priorities in India for market access and regulatory issues, and opportunities to strengthen U.S.-India collaboration.*

## ADVAMED ELEVATES MEMORY CHIP SUPPLY CONCERNS WITH FEDERAL OFFICIALS

AdvaMed expanded its advocacy on memory chip constraints and their potential implications for medical device manufacturing and patient care. The team briefed the White House National Economic Council and a broad group of officials from HHS, ASPR, FDA, USTR, the International Trade Administration, the Department of Veterans Affairs, and other agencies on growing concerns related to memory chip availability, lead times, and pricing. AdvaMed also recommended strategies to help ensure a reliable supply of memory chips for medtech manufacturers, particularly as the sector faces additional pressures from tariffs and geopolitical instability.

In parallel, AdvaMed engaged the major memory suppliers, Micron, Samsung, and SK Hynix, to highlight the health care implications of supply constraints and advocate for prioritization of the medtech sector. Finally, AdvaMed engaged with The New York Times, helping shape coverage that highlighted the medtech industry's specialized memory chip requirements and amplified industry concerns to a broader audience.

## SUSTAINED ADVOCACY ON PROCUREMENT AND VALUE-BASED PURCHASING IN CHINA

AdvaMed's China Office provided substantive feedback on this year's national volume-based (VBP) tender for gastrointestinal and endoscopy products, which introduced novel mechanisms to ensure more reasonable pricing that are consistent with our asks. The Global Department also submitted detailed comments on proposed revisions to China's *Government Procurement Law*, emphasizing the need for greater clarity on the law's scope and raising concerns about any further expansion of domestic product preferences.

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The Global Department also convened a roundtable in Washington, D.C., with Professor Xuan Jianwei, a leading Chinese health economist, to discuss opportunities and strategies for incorporating value metrics into China's procurement system. The discussion offered useful insights as AdvaMed sharpens its value proposals for the Chinese government, which has shown an increased openness to exploring outcomes-based criteria.

## REGULATORY RELIANCE EFFORTS ADVANCE IN THE UNITED KINGDOM AND COSTA RICA

AdvaMed made significant progress toward more efficient, internationally aligned regulatory pathways in Costa Rica. The Global team designed and delivered in-person training for Costa Rica's Ministries of Health and Foreign Trade on implementing a medtech reliance policy. AdvaMed also organized a delegation of regulatory leaders from member companies and the Costa Rica MedTech Cluster to participate in a U.S. Trade and Development Agency regional program for Latin American regulatory authorities. The delegation highlighted industry priorities for reducing non-tariff barriers and improving patient access.

Building on this engagement, Costa Rica's Ministry of Health hosted a three-hour workshop with AdvaMed and its members to review regulatory challenges and potential solutions as part of the country's ongoing regulatory reform. Member companies presented detailed case studies, and the Ministry agreed to additional sessions addressing administrative issues and proposed improvements to its online submission system.

In the United Kingdom, AdvaMed briefed senior U.S. Commerce Department and Embassy officials on priorities including the full implementation of agreed tariff relief and increased UK reliance on FDA regulatory decisions. AdvaMed also encouraged FDA engagement with UK regulators and industry partners. Subsequent meetings among senior FDA, MHRA, and UK medtech leaders reflected growing support for continued progress toward FDA reliance.

## ADVAMED FURTHER STRENGTHENS REGULATORY PARTNERSHIPS IN JAPAN AND BRAZIL

Approximately 60 members participated in an AdvaMed-hosted regulatory workshop with Japan's Pharmaceuticals and Medical Devices Agency. The program provided an overview of Japan's regulatory framework and consultation pathways, while member companies shared lessons from entering and expanding in the Japanese market. PMDA's willingness to conduct this specialized outreach demonstrated the trust developed through AdvaMed's engagement in Tokyo and Washington and reinforced AdvaMed's role as a leading convener between the agency and the U.S. medtech community.

In Brazil, AdvaMed's partner organization ABIIS continued engagement with ANVISA as the agency reported progress in reducing market authorization timelines. Actions aligned with AdvaMed and ABIIS priorities have increased the number of dossiers reviewed while bringing review times for certain product categories to historic lows.

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### INDIA ENGAGEMENT ELEVATES MEMBER PRIORITIES

AdvaMed led a delegation of member company leaders in India for a roundtable with the U.S. Ambassador in New Delhi. Members highlighted the medtech industry's contributions to the U.S. economy and discussed persistent challenges involving pricing, refurbished equipment, Quality Control Orders, and procurement policies. The Ambassador committed to raising these concerns with the Government of India and requested additional information to support upcoming discussions with senior U.S. trade officials. The engagement created an important new channel for advancing medtech priorities at the highest levels of the U.S.-India relationship.

### GLOBAL TEAM MOBILIZES SUPPORT FOLLOWING VENEZUELA EARTHQUAKES

Following earthquakes in Venezuela, AdvaMed launched a centralized resource page to help member companies support relief and recovery efforts. The resource consolidated information on urgently needed medical supplies and equipment, donation channels, and trusted response organizations. The initiative gave members an actionable way to assist health care recovery efforts while demonstrating AdvaMed's ability to mobilize industry support during humanitarian crises.

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# Legal




*Alex Abbott, Chief People & Compliance Officer at Arthrex, Ida Nassar, Vice President, Assistant General Counsel, Head of Global Ethics & Compliance Policy at AdvaMed, Mark Geraci, Corporate Counsel, Global Ethics & Compliance at CooperSurgical, Terri C. Segura, VP, Compliance Officer - Americas at Zimmer Biomet, and Kathryn Stager, VP, Quality, Regulatory, and Corporate Compliance at SPR Therapeutics, at the 2026 AdvaMed Compliance Bootcamp providing a Legal and Compliance Industry Perspectives Panel.*

## DATA STEWARDSHIP & PRIVACY

The Legal Committee approved revised draft best practices for responsible data access and use, building on work by the Data Stewardship & Privacy Working Group and DHT Board feedback. The framework provides practical guidance on data access, transparency, privacy, governance, and the responsible use of de-identified data, AI, and advanced analytics. It positions the medtech industry as a trusted data partner and is designed to reduce barriers to data-sharing agreements with health systems.

Next steps: DHT Board review approval at its Q3 Board meeting, where they will also decide on the next steps and broader action plan to advance the underlying policy objectives.

## ADVANCING ETHICS AND COMPLIANCE PRIORITIES

Following the Q2 Board meetings, AdvaMed launched three working groups to advance key Ethics and Legal Committee priorities. The groups are updating the AdvaMed Code of Ethics to expressly incorporate durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers; developing model state legislation to expand formal recognition of the AdvaMed Code; and developing comments on HHS Office of Inspector General (OIG) Compliance Program Guidance documents.

These initiatives reinforce AdvaMed's commitment to maintaining the Code as the medtech industry's gold standard and demonstrating industry leadership in ethical business practices and compliance excellence.

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AdvaMed also convened a members-only webinar with Reed Smith examining evolving OIG Anti-Kickback Statute guidance. With more than 150 registrants, the program addressed recent advisory opinions, emerging enforcement themes, and changing interpretations relevant to the medtech industry.

## MODERNIZING CLINICAL TRIAL COMPLIANCE RULES

AdvaMed convened a joint Device and Diagnostics Compliance Group and Technical and Regulatory Clinical Trials Working Group meeting to evaluate OIG's Request for Information on remuneration provided to clinical trial participants. The meeting brought together more than 110 member company representatives and featured legal analysis from Reed Smith on potential new or modified Anti-Kickback Statute safe harbors and beneficiary-inducement exceptions.

Building on that engagement, AdvaMed submitted comments to OIG on August 24 urging the government to modernize fraud and abuse rules to better support clinical trial participation. AdvaMed recommended establishing a new clinical trial safe harbor protecting reasonable participant-support programs while maintaining transparency, Institutional Review Board oversight, and safeguards against patient steering and improper inducements.

## ADVOCACY PROTECTS LEGITIMATE DMEPOS SUPPLIERS AND PATIENT ACCESS

CMS allowed its six-month moratorium on new Medicare DMEPOS supplier enrollments to expire, restoring enrollment opportunities for legitimate suppliers and preserving patient access to innovative medical technologies. The outcome followed coordinated advocacy by AdvaMed's Rapid Response, Payment, and Legal Policy teams, including sustained engagement with CMS on approaches that combat fraud, waste, and abuse without creating unnecessary barriers for responsible medtech suppliers.

AdvaMed further advanced its long-term DMEPOS policy priorities through comments on CMS's proposed CY 2027 Home Health rule. AdvaMed supported stronger program-integrity protections while urging CMS to ensure that expanded enrollment, affiliation, and revocation authorities do not inadvertently penalize legitimate suppliers or disrupt beneficiary access to medically necessary technologies. The comments recommended objective criteria, notice and an opportunity to correct deficiencies, and recognition of established safeguards such as FDA oversight.

AdvaMed also urged CMS to recognize adherence to the AdvaMed Code of Ethics — including AdvaMed Code Certification — as a potential "Gold Standard" indicator of supplier legitimacy and compliance.

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## DMCA RULEMAKING

On September 28, AdvaMed filed comments with the U.S. Copyright Office opposing streamlined renewal of the medical device repair exemption in the tenth triennial rulemaking under section 1201 of the Digital Millennium Copyright Act (Docket No. 2026-4). The exemption permits circumventing access controls on software "contained in and controlling the functioning of" a medical device for purposes of diagnosis, maintenance, or repair. An exemption drafted for operating software embedded in a machine is being applied to a separate servicing software suite licensed in a separate market. The Copyright Office has not previously examined that distinction. The D.C. Circuit's September 1 opinion in our suit to vacate the exemption made the classification of the protected work decisive to the fair-use analysis. It set our distinction aside for want of evidence, not for want of merit. That gap is now filled in this rulemaking by first-hand sworn declarations from member companies describing how these access controls, license terms, and markets actually work.

## ADVANCING GLOBAL COMPLIANCE ENGAGEMENT

AdvaMed advanced a key China Board priority under its China Compliance Strategic Plan, securing strong support from the China Board, Chief Compliance Officers Committee, and China Code and Compliance Working Group for its position statement on the NHSA Medical Pricing and Procurement Credit Evaluation System. Working closely with members and outside counsel, the position statement reinforces industry commitment to strong compliance standards while advocating for greater transparency and predictability in implementation of the System as well as stronger due process, company responsibility aligned with conduct within its control, and proportionate corrective measures. AdvaMed anticipates submitting the position statement to NHSA and other relevant government agencies in October, followed by stakeholder meetings in November.

AdvaMed hosted the 2026 MedTech Compliance Workshop on September 16-17, at its headquarters in Washington, D.C., bringing together compliance, legal, and business leaders from across the medtech sector to discuss emerging enforcement trends, evolving compliance expectations, global policy developments, AI and data-related compliance considerations, and best practices for ethical business conduct. The event drew 60+ attendees and featured an AdvaMed policy update from our legal and government affairs teams, covering key U.S. and global policy priorities impacting industry.

AdvaMed also hosted a members-only webinar with Reed Smith examining the European Union's new Product Liability Directive. The session addressed expanded product definitions, new evidence-disclosure requirements, rebuttable presumptions favoring claimants, and resulting litigation, compliance, and business risks. Members received practical guidance for preparing for the Directive's December 2026 applicability date.

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## LITIGATION REFORM

AdvaMed secured two significant litigation reform victories in Q3. In New York, A. 804-C / S. 1104 – Consumer Litigation Funding Act officially took effect, creating the state's first comprehensive rules for the consumer legal funding industry. It protects plaintiffs from predatory lending practices while keeping legal funding available. In North Carolina, H.B. 315 – Prohibit Litigation Investments Act, having been signed into law and immediately taking effect, makes the state the first in the nation to enact an outright ban on third-party litigation financing rather than just regulating or requiring disclosure of it.

AdvaMed continued to strengthen engagement across the broader medical technology risk management and insurance ecosystem through participation in Medmarc's annual Broker meeting. AdvaMed used the forum to highlight growing concerns related to Third-Party Litigation Funding (TPLF) and other emerging litigation trends that can increase costs, create uncertainty, and divert resources from patient care and medical innovation. The engagement reinforced collaboration across the medtech ecosystem on shared priorities related to risk mitigation, litigation transparency, and maintaining an environment that supports continued investment in life-saving technologies.

*Amicus Brief Program*

AdvaMed filed an amicus brief asking the full U.S. Court of Appeals for the Federal Circuit to rehear the Insulet v. EOFlow trade-secret case. AdvaMed argued that the panel's decision would start the Defend Trade Secrets Act's three-year limitations period when a competitor merely introduces a similar-looking product — even before a sale and before the trade-secret owner could reasonably discover misappropriation.

AdvaMed warned that the decision could force companies either to sue based on speculation or wait for evidence and risk being time-barred, weakening protections for valuable trade secrets and discouraging investment in medical innovation.

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# AdvaMed Accel



*JC Scott, who joined AdvaMed Accel as Executive Director in August, joins Patrick Brennan and Jamila Mitchell in advancing the priorities of small and emerging medtech companies.*

## JC SCOTT NAMED HEAD OF ADVAMED ACCEL

JC Scott joined AdvaMed Accel as Executive Director at the end of August. JC previously served as AdvaMed's Chief Advocacy Officer and for the last seven years served as Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA). Under his leadership, Accel has already begun advancing initiatives to strengthen member engagement, increase industry and policymaker awareness of AdvaMed's work on behalf of small and emerging medtech companies, reinvigorate Accel board operations and elevate the policy priorities of early-stage innovators. JC joins a team, including Patrick Brennan and Jamila Mitchell, dedicated to our small company members.

## ACCEL ADVOCATES FOR SMALL COMPANY FUNDING

AdvaMed Accel continued to advocate for federal policies that support small medtech companies and early-stage innovation. In July, Accel submitted comments to the Office of Management and Budget on proposed regulations governing federal financial assistance, calling for an open and transparent system for grant review that is guided by scientific merit and accountability.

Following the reauthorization of the SBIR / STTR programs, Accel continued to educate and share information with member companies on how to navigate an evolving funding environment, impacted by a shortened application cycle, the rollout of new programs (i.e., strategic breakthrough awards), and implementation of foreign risk assessment, which continues to present critical challenges to medtech companies seeking federal R&D support.

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After members and prospective members reported receiving NIH funding denials without explanation, Accel began coordinating with AdvaMed Government Affairs and coalition partners to elevate these concerns. The Accel team has renewed engagement with Congress — including the Small Business Committees — as well as outreach to other parts of the Administration.

## CREATING NEW OPPORTUNITIES FOR ACCEL MEMBERS

Accel, with support from across the AdvaMed team, continued to expand new opportunities for our member companies.

Accel partnered with Medical Mondays, a national syndicate of angel Investors, to host the first in a series of pitch opportunities exclusive to AdvaMed members. Three Accel companies participated in the first round.

In the last quarter, Accel members were major contributors to the FDA Vendor Days, where companies meet directly with FDA leadership and review teams, demo their products first-hand, and discuss common issues in the technical and regulatory review process.

Accel members also featured strongly in AdvaMed's annual MedTech Showcase on Capitol Hill, demonstrating breakthrough medtech products to Members of Congress and Hill staff.

AdvaMed also celebrated member companies, Epitel and Prapela, as they were named among the initial participants in FDA's READI-Home Innovation Challenge. Part of FDA's Home as a Health Care Hub initiative which has been championed by Dr. Tarver to bring home-based care into the health care delivery system, the challenge is designed to accelerate patient access to medical device technologies that can help reduce hospital readmissions.

## ACCEL LAUNCHES BRAND AWARENESS INITIATIVE

Accel launched an initiative with AdvaMed's Public Affairs, Marketing and Membership teams to develop a coordinated strategy and newly aligned messaging designed to raise its profile among industry and policymaker audiences, and position AdvaMed as the home for small medtech companies.

The initiative is intended to support membership recruitment, bring more of the small-company community to the AdvaMed table and strengthen industry advocacy by improving policymakers' understanding of the breadth of who AdvaMed represents through Accel. We aim to launch the messaging campaign by year-end.

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# Medical Imaging




*At Siemens Healthineers' servicing headquarters in Cary, North Carolina, AdvaMed Imaging staff toured the training facility and learned how servicing practices support quality care and patient safety; pictured are Gonçalo Arnaut (Siemens Healthineers), Alexa Garcia (Siemens Healthineers), Ana Loloei (AdvaMed), Sarah Gianni (Siemens Healthineers), Jennifer Tomasello (AdvaMed), Julianne Weiss (Siemens Healthineers), Zach Rothstein (AdvaMed), Peter Weems (AdvaMed), Amanda Koivuranta (Siemens Healthineers), Leah Kegler (Siemens Healthineers), Beth Wheeler (Siemens Healthineers), and Amanda Smith (Siemens Healthineers).*

## ADVOCATING FOR SAFE AND EFFECTIVE MEDICAL DEVICE SERVICING

AdvaMed has engaged for months with key lawmakers to sound the alarm on unintended but significant negative impacts for patient safety, cybersecurity, and innovation that could result from "right to repair" language in the House-passed National Defense Authorization Act (NDAA). AdvaMed's advocacy helped to achieve more narrowly scoped language in the Senate's NDAA, which we believe will have fewer unintended consequences. AdvaMed sent a letter to the House and Senate Armed Services Committees expressing significant concerns with the House-passed language and urging adoption of the Senate's approach, with targeted modifications.

AdvaMed continues advocating for adoption of the Senate's more measured language and has led a broad campaign coordinating strategy and outreach amongst imaging and other companies to continue applying pressure as NDAA conference discussions continue.

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## INDUSTRY STRATEGY ON DMCA EXEMPTIONS

During Q3, two important developments have occurred in AdvaMed's Digital Millennium Copyright Act (DMCA) litigation, challenging third parties' ability to hack into medical devices and the 10th Triennial Rulemaking. First, the D.C. Circuit ruled against AdvaMed on September 1, upholding the current service repair exemption for independent service organizations. Importantly, the Court did not reject our legal theory; rather, it found that the evidentiary record was insufficient to establish the existence of a distinct market for repair software. Second, the ongoing 10th Triennial Rulemaking process provides AdvaMed and its members an opportunity to address that gap. AdvaMed is working with member companies to compile sworn declarations to strengthen the evidentiary record, countering petitioners' claims, and preserving our position for any future appeal. Comments are due September 28.

## HTIA ADVOCACY HELPS DRIVE HISTORIC CMS SHIFT TOWARD AI REIMBURSEMENT

AdvaMed's successful introduction of the bipartisan Health Tech Investment Act (HTIA) in both the House and Senate, coupled with an aggressive Capitol Hill strategy to educate lawmakers and build broad congressional support, helped catalyze a major policy shift at CMS. In a significant departure from longstanding reimbursement policy, CMS proposed recognizing certain software-based clinical technologies as separately payable medical services rather than treating them as embedded components of another service. This development represents the most consequential step to date toward establishing clear, predictable reimbursement pathways for FDA-authorized AI-enabled technologies, including algorithm-based health services, clinical decision support tools, and advanced diagnostic software. The proposal validates years of advocacy and positions the imaging industry for broader adoption of innovative AI-driven technologies that can improve patient care.

AdvaMed will evaluate the rule when finalized (anticipated to be issued in October 2026) and will determine whether future legislation is needed.

## ENGAGING ON IMAGING REIMBURSEMENT AND PATIENT ACCESS

AdvaMed Imaging continued its advocacy on Medicare reimbursement and patient access issues, engaging policymakers and regulators on the potential impact of site-neutral payment policies on access to imaging services and medical innovation. Following CMS's release of the CY 2027 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center proposed rule, the Division began reviewing targeted site-neutral payment policies affecting certain off-campus imaging facilities and is coordinating with member companies and stakeholders on a response aimed at preserving patient access and supporting continued innovation. AdvaMed also submitted comments to CMS opposing payment reductions for certain imaging services and met with the American College of Radiology's government relations team to align on reimbursement developments and identify opportunities for continued collaboration on shared advocacy priorities.

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## REPRESENTING IMAGING PRIORITIES IN 510(K) POLICY DISCUSSIONS

AdvaMed Imaging supported broader association engagement with Senator Bernie Sanders' staff regarding potential changes to the FDA's 510(k) pathway, particularly for AI-enabled devices. Staff is exploring possible legislative and Medical Device User Fee Amendments proposals involving substantial equivalence standards, the use of predicate devices, and increased transparency surrounding FDA reviews.

AdvaMed is working to ensure the medical technology industry's perspective is represented as these proposals develop, given their potential implications for medical imaging innovation, regulatory predictability, and patient access to AI-enabled technologies.

## ADVANCING STANDARDS THAT SUPPORT DEVICE INNOVATION AND PATIENT SAFETY

The Imaging Division continued moving priority standards through the review and approval process. The revised XR 22 and XR 23 mammography standards advanced toward Section voting. The revised UD 1 standard, Differentiation of Servicing from Remanufacturing: Guidance for Diagnostic Ultrasound Systems and Transducers, also advanced to a formal ballot. The Imaging Board is expected to vote on approval of the standards at its October meeting.

AdvaMed also increased its international standards of engagement. Staff launched a formal task force to develop coordinated industry comments on IEC 62304 Edition 2, Health Software – Software Life Cycle Processes. The task force is reviewing the approximately 120-page draft, coordinating Member input, and establishing a structured process to reconcile comments before submission to IEC. AdvaMed also completed and submitted its annual liaison report to IEC/SC 62A in advance of the subcommittee's November plenary.

The Division continued technical work on the MR standards portfolio, including MS 4, MS 8, and MS 14, while advancing a proposal to adjust the review schedule, so technical experts have sufficient time to complete the work. AdvaMed staff and Division Members also coordinated responses to technical concerns under IEC 60601-1.

AdvaMed Imaging strengthened collaboration with the medical physics community on radiation dose reporting. Division Members and external stakeholders identified opportunities to improve the consistency of Radiation Dose Structured Report data used by Dose Index Registries. The XR Section is exploring a potential project to define the information manufacturers should populate to support reliable dose tracking for fluoroscopy, CT, and digital radiography systems.

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# AdvaMedDx



*Tim Leahy and John Richter showcase bioMérieux's diagnostic technologies at AdvaMed's Medtech Showcase and Reception on Capitol Hill.*

## ADVANCING DIAGNOSTICS REGULATORY REFORM

AdvaMedDx reached an important milestone in advancing a technology certification pathway for diagnostics. Following extensive engagement with members, the team developed updated legislative language addressing eligibility for de novo tests, FDA review timelines, user-fee resources, cybersecurity, transparency, temporary holds, and the ability to use a test offered under technology certification as a predicate. Taken together, these updated provisions will enable our members to better utilize the proposed program and better align the legislation with current FDA thinking. In addition, we have secured Rep. Michael Rulli as a House Republican sponsor and Sen. Jim Banks as the lead Senate Republican sponsor.

## STRENGTHENING ENGAGEMENT WITH FDA

AdvaMed's OHT7 Vendor Day and educational program brought FDA reviewers and industry experts together for four industry-led educational sessions and direct engagement with participating companies. Approximately 60 FDA staff attended each session in person, with additional staff joining virtually. OHT7 Director Courtney Lias participated throughout the program, and CDRH Director Michelle Tarver visited the vendor's exhibits. Strong participation and positive feedback from members and FDA demonstrated the value of sustained educational engagement between regulators and the diagnostics industry.

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# AdvaMedDx

## ADVANCING AI IN THE LABORATORY

AdvaMedDx partnered with the Association for Diagnostics & Laboratory Medicine to host an executive roundtable during the ADLM conference focused on the integration and use of artificial intelligence in laboratories. The discussion brought together industry leaders to explore the opportunities and considerations associated with laboratory AI. Participants agreed to collaborate on a joint white paper and will reconvene in Q4 to continue advancing the work.

## DEEPENING PUBLIC HEALTH COLLABORATION WITH CDC

AdvaMedDx continued to strengthen its partnership with CDC's National Center for Emerging and Zoonotic Infectious Diseases. The teams met at AdvaMed headquarters to discuss antimicrobial resistance, wastewater surveillance, infectious disease testing, and other shared policy priorities. AdvaMedDx and CDC are also working on programming for this year's CDC Industry event, taking place at CDC's headquarters in Atlanta on November 5.

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# Public Affairs




*AdvaMed President and CEO Scott Whitaker explores technologies showcased by Cook Medical and Siemens Healthineers at AdvaMed's annual Medtech Showcase and Reception on Capitol Hill, where more than 30 exhibitors shared medical innovations with over 150 congressional staff members and four members of Congress.*

## BRINGING BREAKTHROUGH MEDTECH TO THE HILL

Public Affairs moved its annual Medtech Showcase and Reception on Capitol Hill from June to September to align with Congress's end-of-year legislative focus and made AdvaMed's top priority on breakthrough medical device Medicare coverage the centerpiece of the event. Thirty-two AdvaMed members demonstrated innovative technologies, including 10 FDA-designated breakthrough devices, to more than 150 congressional staff and four members of Congress, the highest congressional attendance to date. Senior FDA and CMS officials also took part. Thank you to our member companies for giving Congress and staff a firsthand look at the technologies shaping the future of patient care and putting AdvaMed's breakthrough policy message directly in front of policymakers at a critical point in the legislative calendar.

## "BREAKTHROUGH BLITZ" TO ADVANCE PATIENT ACCESS TO BREAKTHROUGH MEDTECH

The team worked with government affairs on a two-week communications and advocacy campaign to improve Medicare beneficiary access to breakthrough medtech and advance the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5343/S. 1717). The effort brought together media relations, paid and social media, congressional outreach, executive visibility, and member engagement to elevate the issue with policymakers. As part of the effort, Scott Whitaker met with key policymakers, including Sen. Todd Young, Sen. Ron Wyden, and House members.

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Public Affairs secured a television interview for Scott to discuss breakthrough policy and the Medtech Showcase with The 535 and Brody Mullins, a Pulitzer Prize-winning former Wall Street Journal reporter who launched The 535 to cover Congress and the pressing issues before it. The team also finalized a new Scott Whitaker op-ed in The 535, "*Breakthrough medtech innovation is here. Now Congress must help patients access it.*," calling for passage of the breakthrough bill.

## ADVAMED MAKES THE CASE FOR THE VALUE OF MEDTECH

As Washington focuses on lowering health care costs, it is critical that policymakers recognize the role medtech can play in improving outcomes and preventing the costly complications that drive health care spending. Public Affairs worked to elevate this message through targeted thought leadership and speaking opportunities for Scott that brought the value of medtech into the broader health care cost conversation.

Public Affairs worked with Scott to develop and promote his op-ed in *The Washington Times*, "Medtech: A great value in American health care," focused on the value of medtech and its role in improving patient care and addressing the broader cost of health care. The piece highlights how diagnostics, implants, monitors, and digital tools can help clinicians find disease earlier, treat patients more precisely, and prevent costly, late-stage complications.

The department also secured a speaking opportunity for Scott at Modern Healthcare's Leadership Summit, where he joined Modern Healthcare President Dan Peres for a one-on-one conversation about the future of health care, the value of medtech, how to improve CMS policy broadly and breakthrough policy specifically, and the need for the health care system to unite around the issue of cost and value.

## AN IMPORTANT VOICE ON RIGHT TO REPAIR

Public Affairs worked with Marine, Bronze Star recipient, and Bright Uro founder and CEO Derek Herrera to develop and place an op-ed in *RealClear Defense* opposing broad "right to repair" language affecting medical technology in the fiscal year 2027 National Defense Authorization Act. Drawing on his experience as a wounded veteran, patient, and medtech entrepreneur, Herrera urged Congress to protect patient safety, cybersecurity, and accountability by ensuring that sophisticated, FDA-regulated devices are serviced by qualified technicians under rigorous standards. The piece will be influential in a critical policy debate. Read the published piece.

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# Alliance Partnerships



*Adrienne Frederick (AdvaMed) joins Laura Gunter, president of NCLifeSci, at the NCLifeSci Annual Meeting in North Carolina. NCLifeSci is a state partner of AdvaMed through the State MedTech Alliance (SMTA).*

## STRENGTHENING ADVAMED RELATIONSHIPS WITH THE STATE MEDICAL TECHNOLOGY ALLIANCE (SMTA)

AdvaMed staff attended and sponsored several events hosted by members of the State Medical Technology Alliance (SMTA). These included the SMTA/CSBA Midwest Directors Retreat — which was attended by SMTA leaders from nearly a dozen states — the Georgia Life Sciences Summit, and the NCLifeSci Annual Meeting. Strong relationships with members of the SMTA are essential to building coalitions and activating in-state voices on medtech priorities across both state congressional delegations and state legislatures nationwide.

## ADVAMED MOBILIZES PARTNERS TO PROTECT PATIENT ACCESS

AdvaMed strengthened collaboration with patient advocacy and industry partners in Q3 to address California's proposed inhalation unit risk factor for ethylene oxide (EtO). AdvaMed activated the California Chronic Care Coalition to submit comments to the California Office of Environmental Health Hazard Assessment, ensuring that patients' potential access concerns were represented in the public record.

AdvaMed also joined Biocom California and California Life Sciences in submitting formal comments on the proposal, accompanied by technical comments from Dr. Lucy Fraiser.

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## LAUNCHING THE INDUSTRY AND PATIENT ROUNDTABLE ON TECHNOLOGY & CANCER CARE

Building on the success of its other industry and patient roundtables — Patient Access to Alzheimer's Biomarkers, Diabetes Technology Access, and Policy Issues Impacting Cardiovascular Care — AdvaMed hosted the first meeting of the Technology & Cancer Care roundtable. This roundtable is designed to highlight the role of medical technology in the delivery of cancer care and identify opportunities for policy collaboration to improve patient access to these technologies. Members from multiple AdvaMed sectors involved in the delivery of cancer care attended, as did representatives from the American Cancer Society-Cancer Action Network, Brem Foundation to Defeat Breast Cancer, HealthyWomen, and ZERO Prostate Cancer.

The discussion identified several ideas for future collaboration that AdvaMed will continue to explore internally and with its alliance partners in the months to come.

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# State Affairs




*Evan Hoffman (Philips), Manny Heer (Illumina), Fatimah Rickert (AdvaMed), Jason Nippa (Abbott), Brent Eliason (Dexcom), and Virgil King (Dexcom) connected with state legislators, policymakers, and industry leaders at the 2026 NCSL Legislative Summit to discuss advancing medtech innovation and improving patient access to life-changing technologies.*

## STATE AFFAIRS SECURES KEY POLICY AND REGULATORY WINS

AdvaMed achieved important state policy victories in Q3 that protect medtech operations, preserve patient access, and ensure that statutory exemptions are implemented as intended. In Washington state, AdvaMed's advocacy successfully reversed an effort to narrow the medical device packaging exemption during implementation of the state's extended producer responsibility packaging law. This outcome is particularly significant as states increasingly seek to restrict medical device exemptions through the rulemaking process.

AdvaMed also secured the inclusion of all its key exemptions in Delaware's updated data privacy statute, which was signed into law during the quarter. Delaware was the only remaining state with a comprehensive privacy or health data law that lacked these critical provisions. The legislation's enactment represents an important step toward greater consistency across state privacy frameworks while protecting the medtech industry's ability to use data appropriately.

## ADVAMED PURSUES PFAS REPORTING RELIEF IN MINNESOTA

The State Affairs team continued working to address the unintended consequences of Minnesota's requirements for reporting products containing intentionally added per- and polyfluoroalkyl substances (PFAS). AdvaMed representatives met with the chief of staff, deputy general counsel, and lead environmental staff for Governor Tim Walz to discuss the potential for medical misinformation and other effects associated with the reporting requirements. The productive meeting resulted in several collaborative next steps.

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AdvaMed subsequently submitted a reporting-extension request on behalf of nearly 550 members. If granted, the extension would provide an additional 90 days — until December 14 — for members to report applicable products to the state. During that period, AdvaMed plans to seek a further extension through July 1, 2027, while pursuing a permanent legislative reporting exemption for medical technologies.

AdvaMed staff and outside counsel also met with legal staff and political appointees from the Minnesota Pollution Control Agency to evaluate potential legal pathways for providing additional reporting time. Although no formal decision was reached, the agency's concerns were policy-based rather than legal, preserving an opportunity for AdvaMed to continue pursuing relief.

### STATE AFFAIRS EXPANDS ENGAGEMENT WITH LEGISLATORS NATIONWIDE

The State Affairs team represented AdvaMed at the National Conference of State Legislatures Legislative Summit in Chicago, meeting with more than 20 legislators from across the country. The team discussed AdvaMed's priorities, including artificial intelligence, data privacy, and other emerging state policy issues affecting the medtech industry.

The summit also provided opportunities to connect directly with AdvaMed member companies and attend legislative panels featuring lawmakers' priorities for upcoming sessions. These engagements strengthened relationships with policymakers, provided insight into developing legislative trends, and positioned AdvaMed to engage proactively as state legislatures prepare for their next sessions.

The State Affairs team also participated in the Council of State Governments' Medicaid Academies and Women in Government's Medicaid Policy Symposium. Both events provided opportunities for the team to connect with legislators who are active on health care-related committees.

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*During an AdvaMed-organized fly-in, Kirsten Tullia (AdvaMed), Robert Cohen (Stryker), Christian Eusemann (Siemens Healthineers), and Sarah Killeen (AdvaMed) met with ONC and FDA officials to discuss health AI data access and the path from FDA authorization to CMS reimbursement.*

## TARIFF ADVOCACY CONTINUES ON ALL FRONTS

As the Commerce Department continued its formal 232 investigation of medical technologies and the national security implications, the Federal team amped up its efforts in ensuring every agency and congressional office involved in the process knew not only of industry's present manufacturing footprint in the U.S. (70% and growing), but also the outsized role industry plays in public health delivery. Federal led the way in meetings with key White House and Commerce officials, highlighting industry facts that officials acknowledged would play a role in their final decision-making. Thanks to the coordinated input from our members, the Federal, Global, and other teams have all been able to keep the Administration's focus on industry's core asks as the report is finalized for the fourth quarter of this year. More to come here.

## ADVANCING MDUFA VI AND PRIORITIES

The Federal team reached an important milestone in Q3 as the Medical Device User Fee Amendments VI agreement cleared the Office of Management and Budget and was published in the Federal Register. This enabled AdvaMed to begin discussing the agreement's details with Congress and launch outreach to leadership and members of the House Energy and Commerce and Senate HELP committees.

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The team also secured Sen. Jim Banks (R-Ind.) as the lead Republican on AdvaMed's technology certification rider for MDUFA VI in the Senate, strengthening support for this priority as congressional consideration moves forward.

In addition, the Department of Health and Human Services' Unified Agenda indicated that FDA plans to pursue rulemaking on electronic labeling for medical devices. This regulatory activity complements AdvaMed's continued advocacy for the bipartisan Medical Device Electronic Labeling Act, introduced in both the House and Senate, which would modernize labeling requirements while preserving access to paper instructions upon request.

## RAPID COVERAGE PATHWAY MOVES FORWARD

For several years now, Federal has been working with multiple Congresses and multiple Administrations on producing a workable, substantive coverage pathway for breakthrough technologies. In August, CMS released its proposed procedural notice for the Regulatory Alignment for Predictable and Immediate Device, or RAPID, coverage pathway, marking another development in AdvaMed's work to improve patient access to innovative medical technologies.

Following the release, the Federal team coordinated closely with the Payment team and AdvaMed's consultants to assess the proposal and deploy congressional outreach. Engagement included congressional leadership, committee staff, bill sponsors, and members of the relevant committees, ensuring policymakers understood both the pathway's potential and the areas requiring further refinement.

As proposed, RAPID would provide an accelerated Medicare coverage pathway for certain FDA-designated Breakthrough Devices by aligning FDA and CMS evidence expectations earlier in product development. CMS' stated goal is to issue a proposed national coverage determination at the time of FDA market authorization, with final coverage decisions targeted approximately 60 days later for eligible Class II devices and 90 days later for eligible Class III devices. AdvaMed continues working to ensure the pathway includes predictability, accountability, and the effective implementation necessary to meaningfully improve patient access.

## CONTINUED ADVOCACY ON RIGHT-TO-REPAIR PROVISIONS

AdvaMed maintained intensive engagement throughout Q3 on right-to-repair language included in the FY 2027 National Defense Authorization Act. The Federal team sent a letter to the House and Senate Armed Services committees outlining significant concerns with the House language and urging lawmakers to adopt the more narrowly focused Senate approach, with additional changes to protect patient safety, cybersecurity, and intellectual property.

The House subsequently passed its version of the NDAA by a vote of 216–212. The legislation included Section 861, which was intended to address military equipment repair but raised concerns about unintended consequences for medical technologies. AdvaMed continued targeted congressional outreach and member coordination as the House and Senate prepared to reconcile their respective bills.

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*Dx industry stakeholder dinner at the September AMA CPT editorial panel meeting with members and other stakeholders, including: Zoe Guengerich (AdvaMed), Amber Stock (AdvaMed), Ester Stein (Abbott), Charlie Adams (Danaher Beckman Coulter), Erik Schulwolf (Hogan Lovells Cadwalader, Member Consultant), Joan Kegerize (American Clinical Laboratory Association), Victoria Wallace (Hogan Lovells Cadwalader, Member Consultant), Sarah Thibault-Sennett (Hologic), Christina Arenas (Roche), Shawn Carlson (Roche), Bruce Quinn (Bruce Quinn Associates, Member Consultant), Deb Godes (Hogan Lovells Cadwalader, Member Consultant), Jennifer Archer (Artera), Paul Gerrard (LabCorp), Lee Hillborne (Quest Diagnostics).*

## ADVANCING PAYMENT POLICY THROUGH CY 2027 MEDICARE RULEMAKING

The Payment Team led AdvaMed's response to a significant slate of Medicare proposed and final payment rules in Q3. The team rapidly reviewed the CY 2027 End-Stage Renal Disease, Home Health, Hospital Outpatient, and Physician Fee Schedule proposed rules, issued timely alerts, convened members to identify priority issues, and coordinated formal comments to CMS.

AdvaMed's Physician Fee Schedule comments addressed payment for laboratory software-as-a-medical-service (SaMS) technologies, potential significant reimbursement reductions for remote monitoring technologies, and CMS requests for information on the AMA Current Procedural Terminology coding process and duplicate laboratory and imaging services. The Physician Fee Schedule and Hospital Outpatient proposals formally recognized SaMS and proposed approaches for defining and paying for these technologies, reflecting AdvaMed's longstanding advocacy for appropriate Medicare recognition and reimbursement of software-based medical technologies.

The team also reviewed the FY 2027 Hospital Inpatient Prospective Payment System final rule, in which CMS finalized the repeal of the alternative New Technology Add-On Payment pathway and Transitional Pass-Through payment pathway beginning in FY 2028. CMS also finalized a Unique Device Identifier measure for electronic health record reporting beginning in CY 2027.

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### ADVANCING THE RAPID COVERAGE PATHWAY

CMS released its public notice for the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway on August 7, with the complete framework published in the Federal Register on August 11. The Payment Team promptly alerted members and convened an issue-spotting meeting to evaluate the proposal and inform AdvaMed's response.

The team coordinated closely with policy divisions, Federal Government Affairs, and Public Affairs on member communications, formal comments, and external advocacy. This cross-functional work supports AdvaMed's continued efforts to secure a predictable and timely Medicare coverage pathway for innovative medical technologies, and official comments will be submitted to CMS in advance of the October 13 deadline.

### ADVANCING DME REFORM AND RESTORING SUPPLIER ENROLLMENT

CMS allowed the national durable medical equipment supplier enrollment moratorium to expire on August 27, enabling DMEPOS supplier enrollment applications to be accepted again. AdvaMed had actively advocated against extending the moratorium as part of its broader DME reform efforts. The expiration represents an important advocacy win for manufacturers that distribute products directly to patients and helps ensure that program-integrity policies do not create unintended barriers to patient access.

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# Conferences, Events, & Marketing




*MedTech Conference 2026 attendees enjoyed a variety of in-depth programming and medtech exhibits.*

## RECORD-BREAKING MEDTECH CONFERENCE 2026

The momentum of the global medtech industry was on full display in Boston, October 18–21, as AdvaMed convened the largest MedTech Conference in its history. Building on the close of Q3, the event welcomed more than 4,470 attendees representing 2,050 companies and 40 countries, marking more than 30 percent attendance growth over 2025.

Beyond record attendance and the highest participation ever from outside the United States, the conference demonstrated significant growth in the caliber of participation and depth of industry engagement, with record representation from CEOs and other C-suite executives, investors, and AdvaMed member companies. Expanded international participation and the largest Medtech Campus to date further underscored the conference's evolution as a premier destination for industry leadership, innovation, investment, and business development.

Under the theme "Medtech Moves Us," the conference reflected the strength of an industry driving innovation, attracting investment, and building partnerships to shape the future of health care. Its continued growth reinforces AdvaMed's role in bringing together the people, ideas, and opportunities moving the industry forward — all in support of helping patients live healthier, longer, fuller lives.

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## CONFERENCE STRATEGY AND PARTNERSHIPS

The conference continued to grow as a destination for business development, investment, and industry collaboration. Bank of America's expanded investor and dealmaking programming strengthened that focus, alongside a fireside chat between Brian Moynihan, chair of the board and CEO of Bank of America, and Geoff Martha, chairman and CEO of Medtronic, on the economy, investment, and opportunities ahead for medtech. Support from sponsors, including Bank of America, Abbott, BD, Dexcom, EY, Johnson & Johnson MedTech, Medtronic, PwC, Philips, and Solventum, helped make this year's gathering possible.

Conference leadership included steering co-chairs Mike Mahoney of Boston Scientific, Ashley McEvoy of Insulet, and Jonathan Rennert of ZOLL; program committee chair Sonal Matai of KARL STORZ; host committee chair Brian Johnson of MassMEDIC; and Mick Farrell of ResMed. Their leadership, together with contributions from sponsors, exhibitors, speakers, attendees, member companies, AdvaMed Board members, committee leaders, and the AdvaMed team, supported the conference's success.

## CONFERENCE OUTCOMES

Partnering activity increased 25 percent over 2025, with 3,880 scheduled meetings supporting business development, investment, and industry collaboration. More than 600 speakers, more than 185 company presentations, and 24 corporate reverse pitches connected attendees with industry leaders, emerging innovations, and new business opportunities.

Programming addressed critical issues shaping medtech's future, including artificial intelligence and digital health, diagnostics, imaging, regulatory policy, coverage and payment, global market access, supply chain resilience, and patient access to medtech.

The expanded Medtech Campus showcased emerging technologies, hands-on demonstrations, and patient perspectives through experiences including the Patient Pavilion and Tech in Motion Hub. The military health-focused Pitch & Pour Start-up Pitch Competition featured 12 early-stage companies, while dedicated NextGen programming engaged students, veterans, and early-career professionals.

The conference concluded with the annual FDA Center for Devices and Radiological Health (CDRH) Town Hall, providing attendees direct access to CDRH Director Dr. Michelle Tarver and other senior FDA leaders.

Together, these outcomes demonstrated how AdvaMed translates its convening power into meaningful member value, connecting companies with decision-makers, accelerating business development and investment opportunities, and fostering collaboration that advances medtech innovation and improves patients' lives.

Award recipients reflected the leadership and innovation behind "Medtech Moves Us":

- Vince Forlenza (formerly BD) received the Lifetime Achievement Award;
- Scott Garrett (Water Street Healthcare Partners), the Dx Lifetime of Leadership & Service Award;
- John Jaeckle (GE HealthCare), the AdvaMed Imaging Röntgen Award;
- Jessica Queen (TRIAGE360), the Pitch & Pour Start-up Pitch Competition winner;
- PolyVascular, the Virginia Shymer Rybski Award;
- Karny Ilan (Feminai), the 2026 Medtech Innovator Early-Stage Grand Prize; and
- Dr. Ibraheem Badejo (Johnson & Johnson MedTech), the MedTech Color Champion Award.

The next MedTech Conference will take place in San Francisco, October 3-6, 2027.