



AdvaMed Advancements

Q1 2026 Report



A Note from Scott

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Dear Member,

As we close the first quarter of 2026, AdvaMed enters the year with strong momentum and a clear focus on delivering results for patients, members, and the medtech ecosystem.

This quarter underscored how quickly the policy and regulatory landscape can shift, and why a strong, credible, and proactive industry voice matters. From the U.S. Supreme Court's decision on IEEPA tariffs to advancing new reciprocal trade agreements, AdvaMed moved swiftly to help members navigate uncertainty while pressing for policies that support innovation, supply chain resilience, and patient access to care. We convened members in real time, provided actionable legal and policy guidance, and continued advocating for predictable, science-based trade and regulatory frameworks at home and abroad.

At the same time, we made meaningful progress on core regulatory priorities. Negotiations on MDUFA VI advanced significantly, with a shared focus on program stability, modernization of key submission pathways, and continued evolution of the Total Product Life Cycle approach. Across our Technology and Regulatory Affairs work, engagement with FDA leadership and global regulators remained robust, reinforcing AdvaMed's role as a trusted partner in shaping efficient, patient-centered oversight of medtech.

Globally, we deepened partnerships and removed barriers to market access. Engagements in Costa Rica, progress on regulatory alignment in Europe, clarification of procurement rules in China, and the removal of trade barriers in India all reflect our effective advocacy on behalf of you and the patients you serve. These efforts are critical to ensuring that innovative medtech can reach patients around the world without unnecessary delay or duplication.

We also continued to lead on legal and compliance issues that directly affect patient safety and innovation. From advancing litigation reform and protecting the integrity of medical device software, to addressing sterilization liability and global compliance frameworks, AdvaMed remains committed to policies that uphold science, safety, and accountability.

Across our divisions—Digital Health Tech, Imaging, Diagnostics, Accel, and our state and federal advocacy teams—we saw strong engagement, membership growth, and measurable wins. Whether advancing access to breast cancer imaging, supporting SBIR/STTR reauthorization, shaping diagnostics policy, or convening CEOs, regulators, and policymakers, the common thread is impact: translating innovation into better outcomes for patients.



A Note from Scott

We're grateful for the leadership of our Board, the engagement of our members, and the dedication of the AdvaMed team. Thank you for your partnership and trust. We look forward to building on this momentum in the months ahead as we continue to advocate for policies that put patients first and ensure the United States remains the global leader in medtech innovation.

Sincerely,

Scott



Scott Whitaker
President & CEO
AdvaMed

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MEMBER BRIEFING ON SCOTUS RULING AND TARIFF REFUNDS

The U.S. Supreme Court ruled that the International Emergency Economic Powers Act (IEEPA) does not authorize the President to impose tariffs, marking a significant development in U.S. trade policy. The decision introduces greater predictability in one area of the tariff landscape, while leaving open questions regarding alternative authorities for imposing tariffs and the potential for duty recovery on previously imposed IEEPA tariffs through U.S. Customs and Border Protection. The ruling comes as tariffs remain a central focus of the Administration's economic agenda.

AdvaMed convened a members-only emergency webinar, "The Supreme Court Struck Down IEEPA Tariffs: What MedTech Needs to Know," to brief members on the U.S. Supreme Court's decision holding that the International Emergency Economic Powers Act (IEEPA) does not authorize the President to impose tariffs. The webinar featured legal and policy analysis from Akin Gump and addressed key considerations for medtech companies, including implications for tariff exposure, supply chains, and near-term compliance.

NEW RECIPROCAL U.S. TRADE AGREEMENTS ADVANCE MEDTECH MARKET ACCESS

The Office of the United States Trade Representative (USTR) signed Agreements on Reciprocal Trade (ARTs) with Argentina, Ecuador, El Salvador, Guatemala and Bangladesh incorporating AdvaMed priorities and recommendations on regulatory outcomes to improve market access for U.S. medtech products. Once implemented, the agreements will reduce regulatory duplication and administrative barriers by codifying acceptance of FDA market authorizations, Medical Device Single Audit Program (MDSAP) audits, electronic Certificates to Foreign Government (eCFGs), adoption of Good Regulatory Practices (GRP), and the elimination of requirements for wet signatures or apostilles. Tariffs on U.S. goods will remain or go to 0 percent, and U.S. reciprocal tariff rates for Argentina, Ecuador, El Salvador and Guatemala are set at 10 percent.

Member Webinar: The Supreme Court Struck Down IEEPA Tariffs – What Medtech Needs To Know

Exclusive Member resource to learn the latest tariff updates and news impacting your organization.

NOW ON DEMAND



AdvaMed hosted a webinar for members covering the Supreme Court IEEPA tariff ruling and its impact on the medtech industry.



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The United States and Taiwan also signed an Agreement on Reciprocal Trade (ART) including favorable provisions advocated by AdvaMed for U.S. medtech products. The ART stipulates acceptance of FDA prior market authorization, transparency and procedural fairness (TPF) with respect to decisions regarding listing or setting reimbursement amounts for medical devices, and a commitment to streamline the approval process for self-pay procedure codes through the creation of a unified platform.

NEW 301 INVESTIGATIONS

The Office of the United States Trade Representative (USTR) opened two new Section 301 investigations covering (1) structural excess capacity in manufacturing sectors across 16 economies and (2) failure to prohibit imports produced using forced labor across 60 economies. AdvaMed analyzed the Federal Register notices and developed a briefing for internal stakeholders outlining the scope and implications of the investigations.

These investigations come as part of broader Administration trade policy considerations, including the potential for new or adjusted tariff measures following the expiration of the current global tariff framework later this year. AdvaMed is coordinating its approach to stakeholder submissions, with input due to USTR by April 15.



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Global Medical Technology Alliance (GMTA) and Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) members, including AdvaMed staff, participated in the International Medical Device Regulators Forum (IMDRF) meetings in March in Singapore.

MDUFA VI NEGOTIATIONS ADVANCE

AdvaMed continued our thorough negotiations with the FDA on the sixth iteration of the Medical Device User Fee Amendments (MDUFA VI). The negotiation meetings are now complete, with a focus on overall stability in the program. The work now involves refining and completing the MDUFA VI Commitment Letter, which is intended to clearly memorialize the agreed-upon points of the negotiation for eventual congressional consideration through legislation.

Of note, the agreement covers key *de novo* submission and pre-submission process reforms along with the next scaled phase of the Total Product Life Cycle (TAP) Advisory Program. Real-world evidence is still under discussion as both sides work toward completing the framework. AdvaMed is reviewing negotiation priorities and preparing for the next phase of the process, with the goal of finalizing the framework by early spring.



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STRONG MEMBER ENGAGEMENT THROUGH T&R BOARD LEADERSHIP

AdvaMed convened its Q1 Technology and Regulatory Affairs Board Committee meeting to update members on the evolving regulatory landscape, the progress of MDUFA VI negotiations, and FDA implementation of the Quality Management System Regulation. The meeting provided members with detailed insights into negotiation priorities, revised fee structures, enhanced reporting and accountability provisions, and next steps as negotiations move toward conclusion.

T&R MEETINGS FEATURED TIMELY, CONSTRUCTIVE DIALOGUE WITH FDA

In March, we held quarterly in-person meetings of the T & R Reg Group and Global Harmonization Working Group. Members received the latest updates and participated in productive exchange and interactive Q&A with nine FDA speakers across the Center for Devices and Radiological Health on the Agency’s work on advancing timely and efficient recalls, the Quality Management System Regulation and new inspection process, Real World Evidence, cybersecurity, patient preference, and digital health. The CDRH internal team also provided a readout of the IMDRF March Management Committee meeting and discussed upcoming global activities with other regulators.

ORTHOPEDIC CEO ENGAGEMENT WITH FDA AND AAOS LEADERSHIP

In early March, AdvaMed convened the Orthopedic Sector CEO Committee during the American Academy of Orthopaedic Surgeons (AAOS) Annual Conference in New Orleans, bringing together AdvaMed member CEOs and orthopedic industry leaders for an in-person, high-impact discussion on the key regulatory and policy priorities affecting the sector. The meeting featured FDA and AAOS senior leadership, enabling direct engagement with stakeholders and strengthening alignment to advance orthopedic sector initiatives.

IMDRF MEETING

AdvaMed participated in the meetings in Singapore. AdvaMed members planned and participated in a workshop on the IMDRF’s Reliance Playbook, with AdvaMed’s Carolyn Hull participating on a panel. Members also participated in a bilateral meeting of the IMDRF [Industry Group](#) with members of the [Management Committee](#), discussing reliance, change management, and other regulatory issues of interest to members.



Digital Health Tech

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THE INSIGHT SERIES: AI & Digital Health

Expert insights from **AdvaMed Digital Health Tech** leaders answering pressing questions about AI in health care and how it's transforming care and delivery. **This month, featuring:**



MELISSA CHA

Vice President,
Amazon Devices & Services



Taha Kass-Hout, MD, MS

Global Chief Science and Technology
Officer, GE HealthCare



The first edition of AdvaMed's Insight Series features a Q&A with Melissa Cha (Amazon) and Taha Kass-Hout, MD, MS (GE HealthCare) on how AI supports clinicians through workflow automation, clinical decision support, and patient care. Follow along to hear directly from leaders in this space in upcoming editions of this series.

DIGITAL HEALTH TECH AT CES AND VIVE

The Digital Health Tech division began the year with engagement at the Consumer Electronics Show (CES) and the ViVE Conference, joining other digital health tech leaders. Several DHT Board and AdvaMed members attended each conference. The events included meetings with prospective members and discussions with stakeholders, showcasing AdvaMed leadership in digital health and health tech.

FDA – DIGITAL HEALTH GUIDANCE AND LEADERSHIP

During Q1, the FDA announced new guidances for digital health and named a new digital health leader: In January, Dr. Marty Makary announced a new revised guidance on General Wellness Products. Also in January, the FDA released guidance on Clinical Decision Support Software. In addition, the FDA announced Dr. Rick Abramson as the new Director of the Digital Health Center of Excellence.

MEMBERSHIP GROWTH AND INDUSTRY ENGAGEMENT

AdvaMed welcomed Oura and Oracle as new members of the Digital Health Tech division during the quarter, showcasing the emerging diversity of digital health companies joining AdvaMed. The division and AdvaMed membership also continue to grow, adding many innovative smaller digital health companies.



Digital Health Tech

BOARD EXPANSION AND NEW MEMBERS

In Q1, the Digital Health Tech Board voted to expand the number of Board seats from 25 to 30 to accommodate the interest and growth of the division. Additionally, DHT added 4 new Board members in Q1: Laura O'Donnell (Verily), Jim Peichel (Medtronic), Frank Chan (Haemonetics), and James Teaff (Baxter). The division also welcomed two new Executive Committee members: Dawn Haake (Resmed) and Gretchen Jackson (Intuitive Surgical).

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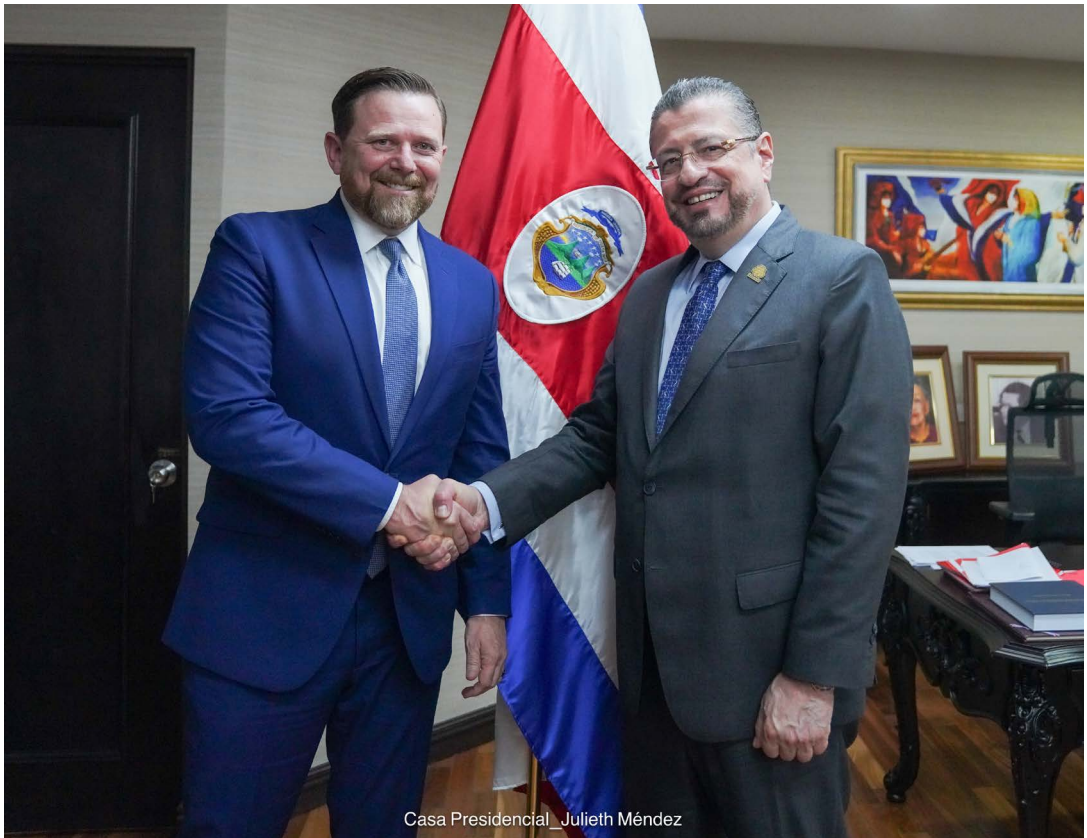
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Casa Presidencial _ Julieth Méndez

Scott Whitaker met with President Rodrigo Chaves during his visit to San José, where he discussed strengthening the medtech relationship between the United States and Costa Rica.

ADVAMED MEETS WITH COSTA RICA LEADERSHIP TO ADVANCE MEDTECH PARTNERSHIP

AdvaMed met with Costa Rica’s President Rodrigo Chaves in San José to discuss strengthening the U.S.–Costa Rica trade partnership. The AdvaMed delegation, led by Scott Whitaker, also met with Vice President-Elect Francisco Gamboa Soto, Foreign Trade Minister Manuel Tovar Rivera, Deputy and Acting Minister of Health Allen Mora, Deputy Minister of Foreign Trade Indiana Trejos, and U.S. Ambassador to Costa Rica Melinda Hildebrand to press for a reduced medtech tariff burden and regulatory reforms, including alignment with FDA.

The trip included meetings with the El Coyoil Free Zone (the name of Costa Rica’s medtech hub), and a medtech site visit. Next steps include providing recommendations on regulatory reform and continuing to advocate for a Dominican Republic–Central America Free Trade Agreement (CAFTA-DR) qualifying rule as a way to ease the tariff burden.



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CLARIFICATION OF CHINA'S "DOMESTIC PRODUCT" PROCUREMENT RULES PRESERVES MARKET ACCESS FOR MEDTECH

AdvaMed's Global Affairs team analyzed China's Ministry of Finance's most recent implementation guidance to provinces stipulating that a domestic registration certificate from the National Medical Products Administration (NMPA) satisfies the "domestic product" criteria which maintains the status quo including for certain procurement processes. This clarification is important for member companies because procurement rules can determine whether foreign medtech manufacturers are eligible to participate in public hospital purchasing in China. Initial views from members on this special procedure are positive, as the local content level required under NMPA certification is not as stringent as it otherwise could have been and companies are already utilizing these criteria.

EUROPEAN COMMISSION LEGISLATIVE PROPOSAL INCLUDES KEY IMPROVEMENTS FOR ADVAMED PRIORITIES

After several years of industry advocacy, the Commission put forward a legislative proposal (Revision) for comprehensive changes to MDR/IVDR in late December 2025. The Revision contains many of AdvaMed's key priorities for maintaining the highest levels of safety while making the medical device and IVD reviews and approval processes more efficient, more predictable, more innovation friendly, and less costly. The Commission itself estimates that implementation of the Revision in its current form would result in annual cost savings of up to €3.3 billion per year for the medtech industry.

Key aspects of the legislative revision proposal include:

- Device certificates no longer expire after five years; reviews will be conducted in a periodic manner and proportionate to the risk of the device.
- A wider range of data will now qualify as clinical data, easing demonstration of clinical equivalency to existing devices.
- New assessment criteria for breakthrough and orphan devices.
- A new definition of "well-established technology" that will enable a much larger group of these devices to be subject to more proportionate requirements.
- Repackaging and relabeling of medical devices will no longer require a notified body certificate or re-review.
- Modification of classification rules to enable a larger group of products to be classified as "low risk."

The Revision must go through the EU's political process before becoming final requiring approval from Member States and European Parliament.

We recognize there are concerns around a provision on reprocessing which contains a presumption that products can be reprocessed. There is ongoing work to consider mitigation options for this provision.



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Our objective is to enable the passage of the revision this year with few or no changes. We will continue our advocacy with member states' embassies in D.C. as well as in coordination with MedTech Europe.

ADVAMED HELPED REMOVE A REGULATORY TRADE BARRIER IN INDIA THAT COULD HAVE DISRUPTED MEDTECH SUPPLY CHAINS

After years of AdvaMed advocacy and coordination with the Office of the United States Trade Representative (USTR), the Government of India rescinded two Quality Control Orders (QCOs) that pertain to spare parts and textile components for the medtech sector. The Government of India implemented the QCOs as a trade barrier to protect domestic industry. This is one of the priority issues championed by AdvaMed in the context of the U.S.-India trade talks.



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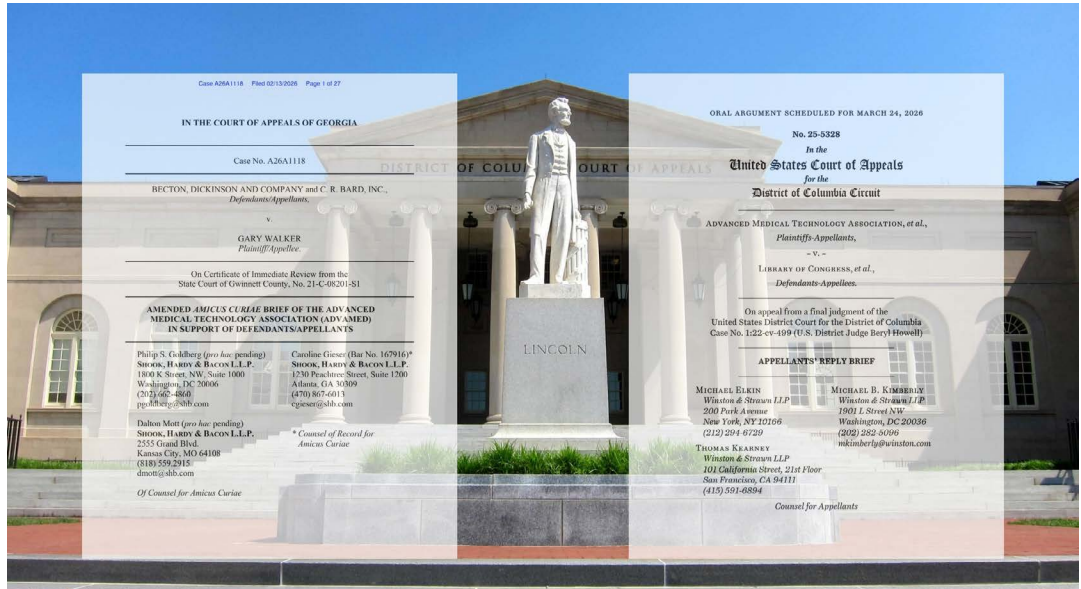
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AdvaMed has been active in courts across the country, including addressing expert testimony standards and medical device copyright protections.

DMCA LITIGATION APPELLATE ORAL ARGUMENT POSTPONED

AdvaMed sued the Library of Congress to overturn a Digital Millennium Copyright Act (DMCA) regulation [37 CFR 201.40(b)(15)] that allows unauthorized, unregulated independent service organizations (ISOs) to circumvent access controls on medical device software for the maintenance, diagnosis, or repair. Under the DMCA, bypassing technological protection measures on copyrighted software can otherwise expose a party to civil and criminal liability.

In July 2025, the D.C. District Court upheld the rule, adopting an expansive view of fair use that AdvaMed contends goes beyond copyright law's traditional framework. AdvaMed argues the court improperly treated repair-related copying as "transformative" simply because the user was an ISO rather than an OEM, even though the software is being used for the same intended diagnostic and repair purposes. AdvaMed also believes the ruling reflects policy preferences rather than a faithful application of the statute.

AdvaMed has appealed to the U.S. Court of Appeals for the D.C. Circuit. Oral argument was initially set for March 24, 2026, before Judges Henderson, Millett, and Ginsburg, but the Clerk notified the parties on March 20 that the argument had been postponed, likely until April. AdvaMed is working with the DMCA Litigation Steering Committee and outside counsel to prepare for oral argument.



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MEMBER GUIDANCE ON TRADE, SANCTIONS, AND COMPLIANCE

AdvaMed’s legal team convened a joint briefing for the National Security and Economic Sanctions Working Group, the International Policy Working Group, and members of AdvaMedDx. The session featured Matt Wetzel of Goodwin Procter and drew approximately 75 participants. The webinar addressed current sanctions and trade developments.

The team also hosted an emergency members-only webinar following the U.S. Supreme Court’s ruling that the International Emergency Economic Powers Act (IEEPA) does not authorize the President to impose tariffs. The webinar, featuring analysis from Akin Gump, provided members with guidance on how the decision could affect tariff exposure, supply chains, and compliance considerations.

LITIGATION REFORM

Amicus Brief Program:

- *Union Carbide v. Sommerville (SCOTUS):* AdvaMed filed a coalition amicus brief at the U.S. Supreme Court addressing Rule 702 expert testimony standards, supporting a framework that keeps unreliable expert evidence out of court. Coalition partners include the Chamber, NAM, PhRMA, and ACC.
- *Walker v. Becton, Dickinson and Company and C.R. Bard, Inc. (Georgia Court of Appeals):* At the request of BD, AdvaMed filed an amicus brief in Walker v. Becton, Dickinson and Company and C.R. Bard, Inc. (Georgia Court of Appeals) challenging the admission of unreliable expert testimony related to ethylene oxide (EtO) exposure. The brief emphasized EtO’s critical role in medical device sterilization and the importance of deference to FDA and EPA scientific oversight.

Sterilization Liability Protection – Model Legislation

Model state legislation (which was drafted by the AdvaMed Legal Committee) connected to the use of Ethylene Oxide (EtO) to sterilize medical devices was introduced in Nebraska. Recall, the model legislation was introduced and passed in Utah last year and provides manufacturers with liability protections for the use of EtO in the sterilization process.

Mass Tort Advertising Trends:

AdvaMed continues to track medical device litigation advertising as an early indicator of litigation risk. The Q1 report, which tracks Q4 2025 data, showed a strong start followed by a typical year-end decline, with pelvic mesh remaining the most frequently advertised category and hernia mesh leading overall spend. The report has been posted to AdvaMed’s Litigation Reform website for member access ([website](#)).



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GLOBAL COMPLIANCE AND ETHICS POLICY

AdvaMed convened member company global chief compliance officers to discuss India's Uniform Code for Marketing Practices in Medical Devices (UCMPMD) and developed a proposal recommending India's Department of Pharmaceuticals (DoP) lift the requirement that companies obtain pre-approval for company-conducted health care professional (HCP) training (foreign and domestic) in favor of post-event reporting to maintain transparency while addressing operational challenges the pre-approval requirement has created for companies to administer training. Our proposal was well received, and following recent AdvaMed meetings with the DoP, they requested proposed UCMPMD language to remove the pre approval requirement for foreign trainings (our primary request). This represents a significant step forward in addressing member concerns regarding interruptions in critical HCP training and other important HCP engagement. We are finalizing additional recommendations to be provided to DoP soon.

AdvaMed launched an updated benchmarking survey for 2026 on compliance policies regarding HCP travel. Forty-seven companies participated in the survey, which included thirty-nine questions on various related issues. AdvaMed is finalizing the survey report for distribution. We also began developing a benchmarking survey on compliance policies for commercial sponsorships, which is a new topic for our compliance benchmarking portfolio. The survey will launch in Q2. AdvaMed's compliance benchmarking program helps support company implementation of [AdvaMed's Code of Ethics on Interactions with U.S. Health Care Professionals](#).



AdvaMed Accel

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Accel member Sandra Saldana, PhD. (CEO Alva Health) speaks at a Capitol Hill event regarding the need for SBIR reauthorization.

ADVOCATING FOR SBIR/STTR REAUTHORIZATION

The AdvaMed Accel team engaged with Senate and House Small Business Committee staff regarding the reauthorization of the Small Business Innovation Research (SBIR) program and shared redlined changes to the proposed legislation to better address industry priorities.

Developing new medtech often requires years of research, testing, and regulatory review before reaching patients. For early-stage medtech startups, this lengthy development cycle can be difficult to finance. Programs such as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants help address this challenge by providing early-stage funding that allows small companies to advance promising technologies that might otherwise never reach patients. These programs play a critical role in the U.S. medtech innovation ecosystem. Approximately 80 percent of U.S. medtech companies are small businesses or startups, and nearly 90 percent of AdvaMed Accel survey respondents have applied for SBIR or STTR funding to support their research and development. Authorization for SBIR and STTR expired on September 30, 2025, creating uncertainty for startups that rely on these programs. Bipartisan action by the Senate and House to advance SBIR reauthorization is an important step toward restoring these programs. We continue to monitor progress of the reauthorization legislation as it goes through the last step, Presidential approval, before becoming law.



AdvaMed Accel

ADVOCATING FOR IMPROVED ACCESS TO WOMEN'S HEALTH TECHNOLOGIES

AdvaMed continues to promote improved coding, coverage, payment and access to technologies designed to improve the health of women. This work includes technologies developed exclusively for use in women, as well as those designed to treat and address conditions that differently or disproportionately impact women. We have been actively engaged with the Milken Institute's Women's Health Network on efforts related to investment in women's health as well as those focused on improving the coverage and payment environment for these technologies via our role as Co-Chair of the Coding and Reimbursement Workgroup. This group convened its first workshop where discussions and recommendations related to cardiovascular disease, cervical cancer, and endometriosis will be used to develop a play book to improve the women's health ecosystem.

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IMAGING BOARD APPROVES NEW STRATEGIC PLAN

The AdvaMed Imaging Board of Directors approved a comprehensive Strategic Plan for the sector anchored in four priority pillars: Digital Health, Service and Remanufacturing, Patient Access to Care, and Standards Development. This plan establishes a clear framework to champion AI-enabled imaging, ensure excellence and equity in service and remanufacturing, expand patient access through improved coverage and reimbursement, and unify the industry through strong technical standards. Under each pillar, the Board has defined targeted priorities—from advocating for right-to-repair policies that protect patients, to advancing reimbursement pathways for AI-enabled imaging technologies. Together, these initiatives position AdvaMed Imaging to lead on policy, innovation, and industry alignment in support of high-quality, accessible imaging care.



Peter Weems, Vice President, Imaging Government Affairs and Policy Strategy, led the Imaging Standards webinar.

RICH FABIAN, NEW IMAGING BOARD CHAIR

AdvaMed [announced the appointment](#) of Rich Fabian, President and CEO of FUJIFILM Sonosite, as Chair of the Imaging Board of Directors. Rich succeeds David Pacitti, whose leadership as the inaugural chair helped establish the division's strong foundation and policy direction. Having previously served as Vice Chair and Interim Chair, Rich brings deep industry experience and a strong commitment to advancing innovation, including AI-enabled imaging, that improves patient outcomes and healthcare efficiency. Under his leadership, the Board will continue to advocate for policies that support medical imaging innovation and deliver value for patients and providers.

ADVANCING IMAGING STANDARDS TRANSITION WORK

The AdvaMed Imaging Standards Review Subcommittee has developed and launched a comprehensive plan to review and update 21 imaging standards spanning fluoroscopy, CT, mammography, MRI, molecular imaging, and ultrasound. The plan organizes standards into six sequential groups, with each standard progressing through a structured five-step process—from technical drafting and Board approval. The plan targets completion in 6–8 weeks per standard. Work began in January 2026, with the fluoroscopy standards (XR 27 and XR 31) leading the way as the first group through the pipeline; both are currently approved by the Board and are on track for publication by late March 2026. The full project is expected to run through the end of 2026.



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Medical device standards give manufacturers a consistent framework for demonstrating safety and effectiveness while reducing duplicative testing across global markets. The FDA recognizes consensus standards, permitting manufacturers to declare conformance as a means of satisfying applicable regulatory requirements. For imaging devices, these standards reflect decades of sustained industry investment in patient safety, spanning radiation dose management and the image quality benchmarks that underpin diagnostic accuracy.

ENGAGEMENT WITH FDA ON GLOBAL REGULATORY HARMONIZATION

Members of the Global Harmonization Working Group met with FDA's Center for Devices and Radiological Health international staff as part of ongoing MDUFA V Forum commitments. Discussions included potential future training opportunities with regulators with up-and-coming systems, as well as updates on the Medical Device Single Audit Program. They also provided updates on the work of the International Medical Device Regulators Forum, including preparation for the March meetings in Singapore. More information on these IMDRF meetings may be found here: <https://www.imdrf.org/meetings/singapore-hosted-hsa-singapore>.

ADDRESSING EMERGING POLICY AND CYBERSECURITY ISSUES

AdvaMed has integrated its workstreams on "right to repair" and medical device servicing into one Working Group that is open to all member companies. This Work Group will be responsible for advancing policy and standards that protect patient safety by ensuring safe and effective medical device servicing.

The division also briefed members of the Imaging Cybersecurity Committee on an upcoming transition in staff leadership responsibilities for the AdvaMed Cyber Working Group, the Information Sharing and Analysis Organization, and the Cybersecurity Summit.

The Imaging Cybersecurity Committee reviewed FDA's updated premarket cybersecurity guidance, focusing on QMSR alignment and inspection scope implications. Staff submitted a formal inquiry to FDA clarifying SBOM submission requirements around VEX/VDR and hash fields in Software Bill of Materials. Following Senate HELP markup of S. 3315, staff analyzed compliance burdens for HIPAA-covered entities, including MFA, encryption, and penetration testing requirements. In March, the AdvaMed ISAO met with FDA in response to the Stryker cyberattack.



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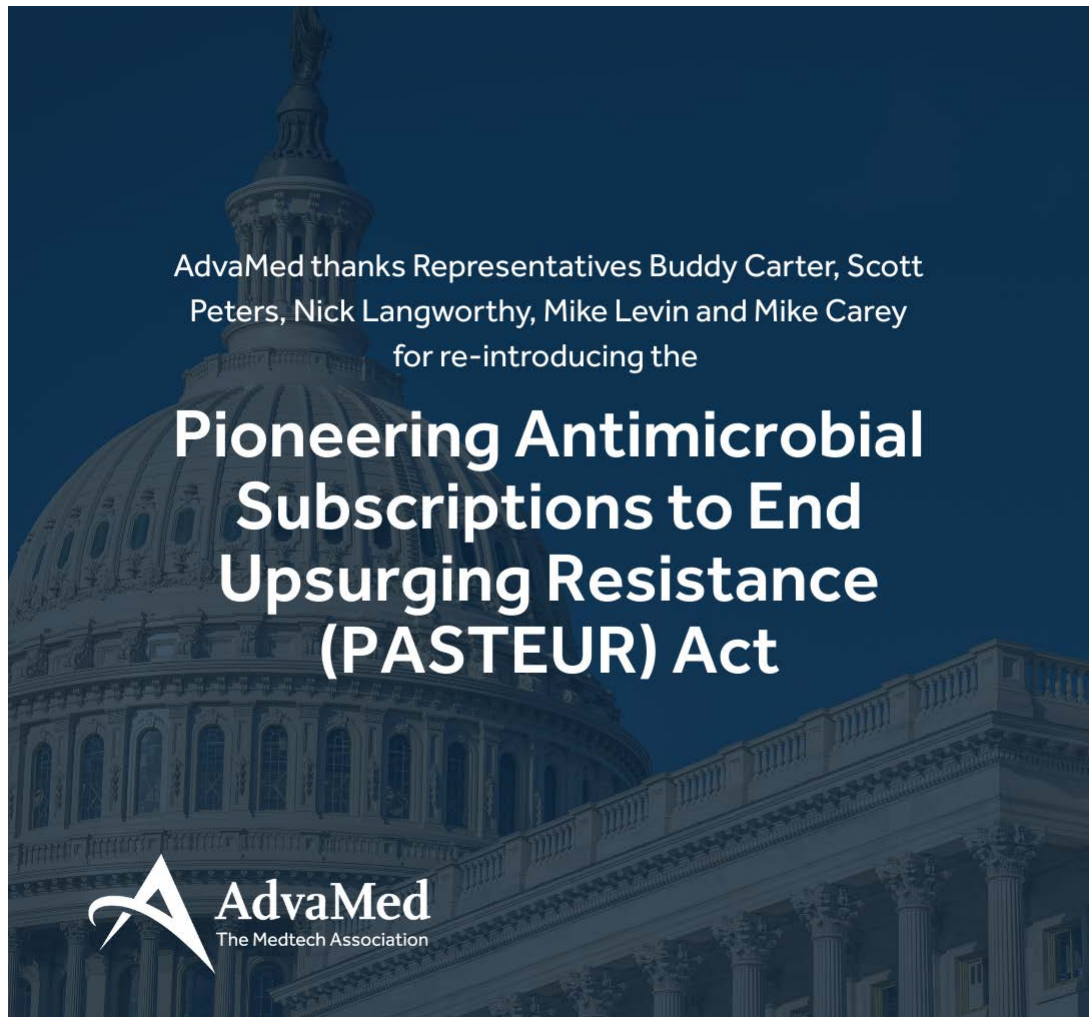
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AdvaMed thanks Representatives Buddy Carter, Scott Peters, Nick Langworthy, Mike Levin and Mike Carey for re-introducing the

Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act



AdvaMedDx welcomed the reintroduction of the bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act in the U.S. House of Representatives, led by Reps. Earl L. "Buddy" Carter (R-Ga.), Scott Peters (D-Calif.), Nick Langworthy (R-N.Y.), Mike Levin (D-Calif.), and Michael T.W. Carey (R-Ohio).

ADVOCATING FOR DIAGNOSTICS POLICY PRIORITIES IN CONGRESS

The Dx team engaged with Congress and key committees on legislative issues affecting diagnostics policy. The House Energy and Commerce Subcommittee on Health held a legislative hearing on the RESULTS Act and other bills related to laboratory policy AdvaMedDx submitted a statement for the record supporting the RESULTS Act and conducted outreach to emphasize the importance of congressional action ahead of potential payment reductions under the Protecting Access to Medicare Act (PAMA). Congress subsequently passed legislation delaying the implementation of PAMA rate cuts for one year. The legislation also shifted the data reporting period from 2019 to 2025 and delayed data collection from February 2026 to May 2026.



AdvaMedDx

ENGAGEMENT IN GLOBAL DIAGNOSTICS INITIATIVES

AdvaMedDx participated in the inaugural meeting of the World Health Organization's newly established Diagnostics Coalition Steering Committee. The Global Medical Technology Alliance/Global Diagnostics Alliance was selected as one of approximately 18 organizations to serve on the Steering Committee, which will help guide implementation of the WHO resolution focused on strengthening global diagnostics capabilities.

LEGISLATIVE DEVELOPMENTS ON ANTIMICROBIAL RESISTANCE

A revised version of the bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act was reintroduced in the U.S. House of Representatives by Reps. Earl L. "Buddy" Carter (R-Ga.), Scott Peters (D-Calif.), Nick Langworthy (R-N.Y.), Mike Levin (D-Calif.), and Mike Carey (R-Ohio). The legislation includes several provisions related to diagnostics and expands Centers for Disease Control and Prevention surveillance of antimicrobial resistance pathogens.

PANDEMIC PREPAREDNESS LEGISLATION

The Dx team developed a draft response to the Request for Information issued by Representatives Dunn and Trahan related to reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). The draft response was circulated to AdvaMedDx members for review and feedback prior to submission, ensuring the final filing reflects the priorities and perspectives of the broader diagnostics industry. The response underscores the critical role of diagnostic infrastructure in national biosecurity and public health emergency preparedness and includes specific recommendations on strengthening the diagnostic supply chain and modernizing regulatory pathways to address future health threats.

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MEDIA ENGAGEMENT AND THOUGHT LEADERSHIP POSITIONING

Public Affairs executed a virtual press conference introducing Mick Farrell as the new Board Chair to outline his key priorities: patient-centered innovation, accelerating digital transformation, expanding global access, expanding care, and personalizing health care journeys. The press event had a strong turnout, with over 20 reporters participating, including from The Washington Post, STAT News, POLITICO, and Forbes.

OP-EDS AND THOUGHT LEADERSHIP CONTENT

Public Affairs placed [Scott's op-ed](#) on breakthrough technologies in The Washington Times. In the op-ed, Scott highlights the gap between FDA authorization of breakthrough medical technologies and Medicare coverage decisions, which can leave Medicare beneficiaries waiting years to access life-saving innovations. The op-ed supports the Federal Affairs team's efforts in advancing the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5343/S. 1717) in Congress, a top AdvaMed priority.

The team also initiated and executed a plan to place an [op-ed by Peter Shen](#), Global Head of Commercial Operations and Senior Adviser for Digitalization and AI at Siemens Healthineers, in The Baltimore Sun on artificial intelligence and health care, in coordination with Government Affairs.

In addition, Public Affairs launched the [Digital Health Tech LinkedIn newsletter](#), which has already reached nearly 6,000 subscribers, and the first installment of the Insight Series on AI and digital health, featuring contributions from Melissa Cha of Amazon and Taha Kass-Hout of GE HealthCare. Members interested in participating in future op-eds or other social media initiatives are encouraged to connect with the [Public Affairs team](#).

The Washington Times



OPINION: Medicare must keep pace with FDA-authorized breakthrough medical technologies

Scott Whitaker
February 24, 2026

Every day, doctors across America diagnose Medicare beneficiaries with life-threatening or debilitating conditions, then face a frustrating reality: much of the most promising medical technology available to help those patients is already authorized by the Food and Drug Administration for patient use, yet still unavailable because Medicare coverage has not caught up.

The gap between FDA authorization and Medicare coverage is not an abstract policy problem. It is a real, persistent barrier that delays access to medtech-enabled care for those who could benefit from it the most. Too often, Medicare beneficiaries are forced to wait years for coverage of technologies the FDA has already reviewed and determined to be safe and effective for patients with serious unmet medical needs.

Congress recognized the importance of speeding patient access to transformative technologies when it created the FDA's Breakthrough Devices Program in the 21st Century Cures Act. The program was designed to accelerate the review of medtech that provides more effective treatment or diagnosis for conditions than currently exist, while maintaining FDA's rigorous standards for safety and effectiveness.

But while FDA has delivered on its end of that bargain, Medicare coverage has not kept pace.

Growing evidence shows that for technologies requiring a new Medicare coverage pathway, nearly six years can pass between FDA market authorization and Medicare coverage.

That means older Americans may wait the better part of a decade for access to innovations specifically designed to help patients like them. For those facing serious illness, that delay can mean fewer options, worse outcomes and missed opportunities for earlier intervention.

Some critics misunderstand the FDA's breakthrough program, suggesting it represents a shortcut to market or a weakening of evidentiary standards. That is not true. Breakthrough designation is not an approval, nor is it a waiver of FDA requirements. All breakthrough-designated devices must meet the same standards as any other medical technology—whether through the 510(k), de novo or premarket approval pathways. In fact, only a small fraction of breakthrough-designated devices ultimately receive FDA market authorization, underscoring the rigor of the process.

FDA evaluates compelling evidence—including clinical data, real-world evidence, and preclinical studies—to determine whether a device meets those criteria. Once authorized, these technologies are subject to ongoing post-market surveillance to ensure continued safety and effectiveness. Far from lowering the bar, FDA applies the global gold standard of scientific review.

Despite this rigorous process, Medicare patients still face long delays before they can benefit from these FDA-authorized innovations. These delays are especially challenging for small manufacturers and startups that drive much of America's medtech innovation and lack the resources to navigate years of uncertainty in coverage decisions.

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In this op-ed published in The Washington Times, AdvaMed President and CEO Scott Whitaker highlights the gap between FDA authorization of breakthrough medical technologies and Medicare coverage decisions, which can leave Medicare beneficiaries waiting years to access life-saving innovations.



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STRATEGIC COMMUNICATIONS AND RAPID RESPONSE

Public Affairs developed a coordinated response to a negative STAT article on the breakthrough program and related legislation, including a professionally designed redlined response incorporating input from subject matter experts across the organization. The Government Affairs team used the [redlined response](#) in its advocacy for the breakthrough legislation or a regulatory program increasing patient access to FDA-authorized breakthrough technology.

The team also supported AdvaMed's response to the U.S. Supreme Court ruling on tariffs through LinkedIn content emphasizing the importance of certainty and predictability in trade policy for medtech companies and patients.

In addition, Public Affairs led rapid-response communications following U.S. House of Representatives passage of legislation reauthorizing the SBIR and STTR programs important to small medtech companies and startups, including drafting a press release and LinkedIn content highlighting the bipartisan vote and its relevance to medtech innovation and patient access.



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ADVAMED LAUNCHES 2026 PATIENTS FIRST AGENDA

Building on last year's momentum, AdvaMed launched its state-focused 2026 Patients First Agenda that continues to focus on three key objectives: expanding access by removing barriers to the latest medical breakthroughs; advancing early detection through diagnostics that can identify diseases like Alzheimer's sooner; and partnering with patient advocacy groups and medical societies to drive meaningful policy change. Significant progress has already been made this year including:

- Increasing access to supplemental and diagnostic breast cancer screening in Alabama and Wisconsin
- Improving patient access to biomarker testing in Mississippi
- Advancing legislation helping ensure coverage of remote maternal care technology in Virginia

ADVAMED HOSTS 2026 FLY-IN OF STATE MEDTECH TRADE ASSOCIATION EXECUTIVES

Leaders from a dozen members of the State Medical Technology Alliance (SMTA) gathered in Washington, D.C., for their annual fly-in that is hosted and organized by AdvaMed. Each state in attendance scheduled meetings with members of their congressional delegation to bring the voice and unique perspective of their home state to broader industry priorities. Issues attendees addressed in their meeting include Medicare coverage of Breakthrough technology, the Health Tech Investment Act, electronic labeling, and tariffs.

INDUSTRY & PATIENT ROUNDTABLE ON CARDIOVASCULAR-FOCUSED POLICY ISSUES

AdvaMed convened members and alliance partners for a roundtable discussion focused on policy challenges affecting patient access to cardiovascular care. Held during American Heart Month, participants highlighted opportunities for industry, patient advocacy groups, and physician societies to work more closely together to drive awareness and improve outcomes, as well as the continued positive impact of medtech innovation on patients' lives. Importantly, the discussion also surfaced multiple opportunities for continued partnership.

PATIENTS FIRST AGENDA 2026

Millions of patients' lives are improved every day because of advancements in medical technology. AdvaMed supports state legislation addressing gaps in access and coverage of critical medical technologies to bring safe, effective, and innovative healthcare to patients across the country.

ACCESS

- ZERO-COST SHARING FOR SUPPLEMENTAL CANCER IMAGING & DIAGNOSTICS**
The fear and frustration of unexpected or high out-of-pocket costs should not prevent or delay patients from seeking recommended follow-up care. Unfortunately, this is the reality for too many patients. AdvaMed supports legislation eliminating cost sharing obligations for patients enabling patients and their families to focus on what is best for their health—and not only what they can afford.
- INCREASED AVAILABILITY OF AEDS FOR YOUNG ATHLETES**
Sudden Cardiac Arrest (SCA) is the number one cause of sudden death among young athletes. Though SCA can lead to death in minutes, immediate CPR can triple the chance of survival—including with an Automated External Defibrillator (AED). AdvaMed supports legislation improving AED access and ensuring that coaches can receive CPR education, including AED training.
- REQUIRED FENTANYL SCREENING IN EMERGENCY ROOMS**
Currently, if a patient presents in the emergency room, and the provider orders a urine drug test, the provider may not be aware fentanyl requires a separately ordered test. AdvaMed supports legislation closing this gap, helping to save lives and providing critical data in helping to combat illicit fentanyl use.

COVERAGE

- COVERAGE OF INNOVATIONS FOR ALZHEIMER'S:**
Innovation is rapidly advancing in detecting and treating Alzheimer's disease and it's critical patients and their families have access to the best available care. AdvaMed supports legislation ensuring patients can access critical diagnostic testing and innovative treatments for Alzheimer's and other serious conditions, helping each patient get the right treatment at the right time.
- COVERAGE OF BIOMARKER TESTING**
Biomarker testing is used in the detection, treatment, and monitoring of many diseases, including cancer and Alzheimer's disease and new, actionable biomarkers are discovered frequently. AdvaMed supports legislation ensuring coverage of medically appropriate biomarker testing, helping each patient get the right treatment, in the right dose, at the right time.
- COVERAGE OF REMOTE MATERNAL CARE TECHNOLOGY**
The maternal health crisis in the United States is no secret. For too many women access to their physician or medical support team is compromised by distance or other inhibitors, threatening the healthy outcome of their pregnancy. AdvaMed supports clarifying the coverage of remote medical technologies as part of improving outcomes for moms and babies, no matter where they live.
- COVERAGE OF SEIZURE DETECTION DEVICES**
Primarily wearable devices, seizure detection devices are an emerging technology that notify others when a seizure is happening. This can be especially helpful at night for children when sleeping. This technology can be costly, deterring some patients from using it despite potential benefits. AdvaMed supports legislation authorizing Medicaid coverage of any FDA-regulated seizure detection device, along with associated monthly costs.

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AdvaMed's 2026 Patients First Agenda



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AdvaMed and LifeSciencesNY hosted the first Life Sciences Innovation Exhibition at the New York State Capitol.

STATE AFFAIRS DELIVERS WINS ON KEY POLICY ISSUES

State legislatures are in full swing and AdvaMed is engaged across the country on proposed policies impacting the medical technology industry and the patients we serve. The State Affairs team has delivered wins on several key issues including:

- Defeating a medical device-specific right to repair bill in Vermont
- Securing an FDA-product exemption in producer-pay battery recycling legislation in Indiana
- Aligning proposed legislation affecting IV bags and tubing in multiple states – including Pennsylvania and Washington – with existing state laws
- Amending consumer data privacy legislation in Oklahoma to avoid unintended consequences for patient health data

The AdvaMed State Affairs team works closely with AdvaMed members and in-state stakeholders to ensure state policymakers continue putting patient safety and access to needed medical devices first.



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INCREASING PATIENT ACCESS TO MEDICAL IMAGING

AdvaMed continues to actively support state policy efforts focused on expanding access to supplemental and diagnostic breast imaging. Removing barriers for patients to access this imaging is increasingly recognized as essential for early detection, especially for women with dense breast tissue or elevated risk factors. AdvaMed supported legislation eliminates patient cost-sharing for these services, ensuring individuals can access timely diagnostic exams without financial barriers and improving population level cancer outcomes.

Thanks to the efforts of AdvaMed and many patient advocacy organizations, both Alabama and Wisconsin have enacted laws in 2026, joining more than two dozen others in eliminating cost sharing for supplemental and diagnostic breast cancer screenings.

MEDTECH INNOVATION DAY AT THE NEW YORK STATE CAPITOL

On March 11, AdvaMed and LifeSciencesNY hosted the first Life Sciences Innovation Exhibition at the New York State Capitol, where leading New York companies showcased their healthcare and medical device innovations that are developed and manufactured in New York. The exhibition gave legislators, staff, and the public an opportunity to engage directly with company representatives and learn how the life sciences and medtech industry improves patient care while strengthening New York's economy and communities. AdvaMed had six members that participated in the exhibition: Baxter, BD, Johnson & Johnson Medtech, Medline, Philips, and Siemens Healthineers. Over 25 legislators came through the exhibition, including Al Stirpe, Chair of the Assembly Committee on Economic Development, Job Creation, Commerce and Industry. After the exhibition, LifeSciencesNY and AdvaMed met with staff from Assemblyman Stirpe's office as well as staff from Steven Otis' office, who chairs the Assembly Science and Technology Committee.



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Scott Whitaker sharing remarks at the AdvaMedPAC reception during the CEO Summit.

LABORATORY CUT MORATORIUM AND MEDICARE POLICY PROVISIONS ENACTED

Congress passed and the President signed appropriations legislation that included several AdvaMed priorities. The package included:

- A moratorium on laboratory cuts for two years. The delayed implementation impacts approximately 800 tests used for diagnosing and managing cancer, diabetes and heart disease to name a few. A fifteen percent proposed cut was scheduled to take effect January 31. AdvaMed is working closely with ACLA in support of the RESULTS Act to ensure patients have continued access to the latest laboratory testing innovations.
- An extension of Medicare telehealth flexibilities for two years. This funding ensures continued coverage for home-based telehealth, removes geographic restrictions, allows audio-only visits and maintains expanded provider types.
- An enactment of multi-cancer early detection (MCED) legislation. This bill creates a Medicare pathway for FDA-approved multi-cancer early detection tests.



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REFINING THE 119TH CONGRESSIONAL INNOVATION AGENDA

The Federal team worked with internal policy leads to update the second year of AdvaMed’s 119th Congressional Innovation Agenda. These priorities were shared with congressional offices and leadership, and feedback was incorporated to inform continued engagement.

ENGAGEMENT WITH HOUSE ENERGY AND COMMERCE

AdvaMed’s Federal team conducted outreach to the House Energy and Commerce Committee ahead of its legislative hearing on the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act, the Saving Our Access to Rehabilitation (SOAR) Act, and policies related to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The team prepared a statement for the record supporting these efforts and continues to engage with the Committee and members as these proposals move toward markup.

COMPETITIVE BIDDING

AdvaMed’s Federal team has worked with our members impacted by the various categories in the competitive bidding program to develop appropriations report language around countries of concern and supplier verification. We also worked to develop language on countries of concern to be included in the FY2027 National Defense Authorization Act (NDAA).

AdvaMed worked with our members to coalesce around program delay language put together by AAHome Care for CGMs, insulin pumps, ostomy and urological supplies. We are working with the other trade associations and patient groups to push this legislation on the Hill, so we are ready if a health care package comes together.

PUSHING ADVOCACY THROUGH THE PAC AT ANNUAL CEO SUMMIT

AdvaMed hosted its fourth annual Political Action Committee (PAC) reception during the CEO Summit to make an early push for what promises to be a busy year on the legislative and administration fronts. Now more than ever, access to key policymakers matters, particularly when congressional calendars hold limited days and legislative vehicles are few. Our work continues in raising money for bipartisan events for only those solutions-minded lawmakers committed to protecting patients and advancing medtech for them.



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Dx industry stakeholder dinner at the February AMA CPT Editorial Panel meeting with members and other stakeholders, including: Tara Burke (AdvaMed), Shannon Curtis (American Medical Association (AMA)), Karen Ruszkoski (Cepheid), Bruce Quinn (Bruce Quinn Associates), Deborah Godes (McDermott+, Member Consultant), Christopher Naso (bioMerieux), Gail Alexander (LabCorp), Leanna Harmon (LabCorp), Sarah Thibault-Sennett (Hologic), Samantha Peterson (Association for Molecular Pathology (AMP)), Lee Hilborne (Quest Diagnostics), Zoe Guengerich (AdvaMed), Michelle Wynn (Hologic), Ester Stein (Abbott), Victoria Pratt (Agena Bioscience), Danielle Scelfo (Lucid Diagnostics), Charlie Adams (Beckman Coulter), Jerry Garner (Beckman Coulter), Joan Keizer (American Clinical Laboratory Association (ACLA)).

ADVOCATING FOR IMPROVEMENTS TO MEDICARE COVERAGE FOR INNOVATIVE TECHNOLOGIES

AdvaMed continued engagement with CMS, HHS, and the White House on policies affecting coverage for innovative medical technologies. During the quarter, AdvaMed leaders met with officials from the Office of Management and Budget, CMS, HHS, and the White House Domestic Policy Council to discuss accelerated coverage for novel medical technologies and broader efforts to improve CMS' coverage processes.

ADVANCING MEDTECH ENGAGEMENT IN AMA CPT CODING POLICY

AdvaMed continued its work with the American Medical Association (AMA) on issues related to the Current Procedural Terminology (CPT) coding process. The association submitted a letter to the AMA highlighting member concerns with the widespread use criterion and recommending several approaches to provide greater clarity and predictability in the coding process.

AdvaMed also participated in the AMA's February CPT Editorial Panel meeting, where staff engaged with AMA representatives and member companies on a range of coding issues affecting medical technologies including potential future updates to AMA's taxonomy for AI-related codes.



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ENGAGING ON ALTERNATIVE PAYMENT MODELS

AdvaMed leadership met with leadership from the Center for Medicare and Medicaid Innovation (CMMI) to discuss the ACCESS model and opportunities to improve access to digital health technologies within Medicare. These discussions explored ways AdvaMed and CMS could work together to address issues related to evidence generation and coverage pathways for digital technologies. AdvaMed also hosted a member webinar with Jacob Schiff, CMMI's Chief AI & Technology Officer, and Dr. Courtney Lias, Director of FDA's Office of In Vitro Diagnostic Devices, to discuss ACCESS and the FDA TEMPO Pilot.



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Mick Farrell and Andrew Huberman at AdvaMed's CEO Summit in Arizona.

STRONG MEMBER ENGAGEMENT DURING JP MORGAN WEEK

AdvaMed delivered a strong presence during the J.P. Morgan Health Care Conference, hosting 285 meetings in its dedicated member space. The team also convened a standing-room-only Executive Reception featuring FDA Commissioner Dr. Marty Makary, and hosted a first-ever Mayo Clinic lunch-and-learn. AdvaMed maintained a visible presence across various other partner and industry events throughout the week.

CEO SUMMIT SUCCESS

AdvaMed delivered a highly successful CEO Summit with increased participation from industry CEOs, including a record number of CEOs from the 75 largest medtech companies, increased CEO participation from our Accel membership and a strong contingent of sponsors, investors, and other key stakeholders. Notable speakers included Dr. Andrew Huberman, Patrick Harker, Professor at UPenn Wharton and former President & CEO of the Federal Reserve Bank of Philadelphia, Jan Easterly, CEO of RSAC, the world's most influential cybersecurity convening platform, and Lieutenant General H.R. McMaster (Ret.), former assistant to the President for National Security Affairs.



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CRITICAL UPDATES AND TIMELY MEDTECH PROGRAMMING

AdvaMed continues to deliver critical updates and timely medtech programming across in-person and virtual formats, ensuring members and the broader industry stay informed, connected, and equipped to navigate a rapidly evolving landscape. Through its expanding Events & Education portfolio, AdvaMed hosted several webinars and virtual programs aligned to key industry priorities—many of which are now available on demand to extend access and maximize value beyond the live event. Recent programming addressed urgent and evolving topics such as U.S. Supreme Court decisions impacting tariffs and global trade, as well as direct engagement with CMS Innovation Center and FDA leadership on emerging reimbursement and care delivery models, including ACCESS and TEMPO.

In February, AdvaMed hosted its Medical Device Submissions Workshop as a virtual event, offering Regulatory Affairs Professionals Society (RAPS) credits across multiple tracks, including 510(k), IDE, and PMA. The workshop featured 17 expert speakers, including FDA officials, reinforcing AdvaMed's role as a trusted source for high-quality regulatory education.

Building on this momentum, the team delivered a well-attended AdvaMed Standards Webinar in March, highlighting the association's growing standards program and its role in advancing innovation, regulatory alignment, and global market access.

Together, these efforts reflect AdvaMed's continued investment in scalable, accessible education—delivering timely insights and expert guidance when and where the industry needs it most.