AdvaMed Advancements

Q4 2025 Report

A Note from Scott

Dear Member,

The fourth quarter carried the year-long theme of work in our nation's capital through to the end: unpredictability and the disruption of business as usual. A federal Commerce Department investigation into medtech imports as a possible national security threat and the longest federal government shutdown in history brought fresh challenges to our policy advocacy on your behalf.

However, as usual, thanks to the leadership of the AdvaMed Board of Directors, division boards, and the engagement of our more than 600 member companies, we rallied to face the headwinds with evidence of the incontrovertible value of medtech as the backbone of our health care system, critical to saving and improving lives. Our resilience reflects the unwavering momentum in innovation and a unity of purpose across our diverse membership of companies of every size.

Consider the tangible results of that unity. Within three weeks in October, AdvaMed compiled a 30-page submission to the Commerce Department on the strength of the U.S. medtech manufacturing base, the extensiveness of our exports, and the importance of imports to the ecosystem, replete with compelling data and solid examples. Many of you contributed details of your companies' successes and U.S. expansion plans, totaling billions of dollars in 2025 alone, as firm data points educating the Administration on how much our industry contributes to the United States: to national security, to local, state, and federal economic growth, and to keeping and making Americans healthy, again and again.

The strength of our message attracted support from stakeholders across health care and beyond, generating more than 360 comments, the vast majority of which support our position that tariffs would disrupt patient care and the medtech supply chain. I am proud to note that 50% of those comments came from AdvaMed member companies, and 10 foreign governments even weighed in on our industry's behalf. We don't know whether the investigation will lead to new tariffs, but we do know our case is airtight, enabled by your participation and content. Thank you.

A Note from Scott

Another tangible result of our strong voice is expanded congressional and executive branch recognition of medtech, digital health, and AI as essential elements of improving health. The Health Tech Investment Act is now pending in both the U.S. House of Representatives and the Senate. The bipartisan legislation would increase access to AI-enabled health tech for Medicare beneficiaries, ushering in a new era of diagnostic precision and individualized care for that large constituency. And our bipartisan legislation to make it easier for "breakthrough"-designated medtech to be covered by Medicare passed a key House committee by an overwhelmingly bipartisan 37-3 vote. Stay tuned for more on our wins and progress in our upcoming 2025 annual report!

In closing, we are honored to be your advocate and partner, and we're committed to ensuring your innovations already serving an invaluable purpose reach even more patients, more efficiently, everywhere people need them.

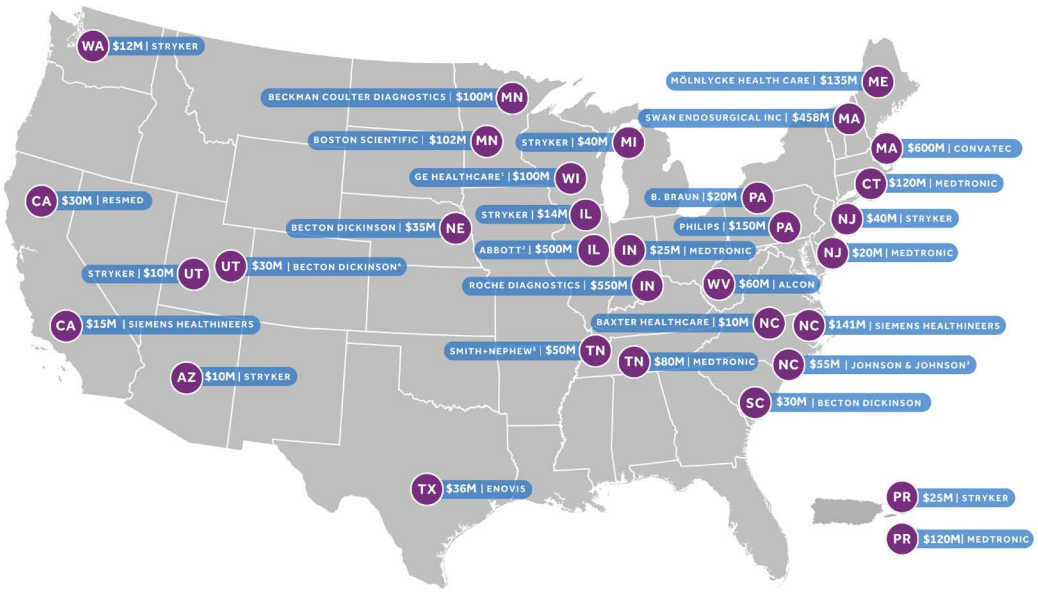
Looking forward to a productive 2026 advancing our cause.

Sincerely,

Scott

Scott Whitaker
President & CEO
AdvaMed

Tariffs



One of several custom-made visuals within AdvaMed's Section 232 submission is this map indicating new member company investments in 2025. Overall, AdvaMed's submission told the story of a U.S. medtech industry that is already very strong and is continuing to grow.

ADVAMED FILES RESPONSE TO SECTION 232 INVESTIGATION

In October, the AdvaMed global team took the lead in crafting AdvaMed's Section 232 submission to the Commerce Department, working in close collaboration with member companies and various AdvaMed departments. This 30-page document presents a compelling story of the U.S. industrial base for medtech, including a strong manufacturing footprint across all 50 states, robust exports, and high-skilled, well-paying jobs. The global team also worked with key trading partners, including Japan and the European Union, on their Section 232 submissions — 10 foreign governments in total submitted comments supporting our position.

U.S.-U.K. AGREEMENT INCLUDES MEDTECH TARIFF RELIEF

In early December, the Administration, through a U.S. Trade Representative press release, announced an agreement between the U.S. and the U.K. that includes medtech tariff relief. The language states: The "United States has agreed to exempt U.K.-origin pharmaceuticals, pharmaceutical ingredients, and medical technology from Section 232 tariffs and will refrain from targeting U.K. pharmaceutical pricing practices in any future Section 301 investigation for the duration of President Trump's term." As the quarter wrapped, AdvaMed was in discussions with the Administration to better understand the details of this agreement. While the exemption appears to be prospective relative to the Commerce Department Section 232 investigation of medtech, we continued to press for more comprehensive relief from reciprocal tariffs as well.

Tariffs

The outcome was consistent with the advocacy work AdvaMed has conducted for nearly a year, maintaining that medtech products should be exempt from tariffs for humanitarian reasons, as they traditionally have been, especially with key trading partners. The agreement sets an important precedent for future deals.

As the quarter closed, AdvaMed met with each U.S. Secretary of Commerce Howard Lutnick and U.S. Trade Representative Jamieson Greer on the importance of supportive trade policies to serving patients and promoting U.S.-led medtech innovation and manufacturing.

U.S.-SWITZERLAND TRADE AGREEMENT FRAMEWORK CUTS TARIFFS TO 15 PERCENT

In November, the White House announced the United States will cut its tariffs on goods from Switzerland to 15 percent from 39 percent under a new framework trade agreement. The tariff on Swiss exports was one of the highest rates set for any country, and Switzerland is a key medtech market for which we have been pressing for tariff relief. The 15 percent tariff will now be the same as the tariff the United States charges on goods from the European Union, which reached a trade deal in July. In addition, Switzerland agreed to accept U.S. FDA medtech approvals and clearances, which is an important outcome for global regulatory convergence with U.S. FDA and an important signal to other key regulatory authorities, for example, the U.K., where we are working toward a similar outcome.

U.S.-CHINA ONE YEAR AGREEMENT BRINGS STABILITY FOR MEDTECH

In late October, Presidents Trump and Xi reached a new agreement to roll back tariffs, export controls, and investigations for a period of one year. Most notably, the Chinese government will not increase its 10 percent counter-tariff on U.S. imports through November 2026 and will maintain a tariff exclusions process. China's Commerce Ministry also has begun issuing general licenses for the seven rare-earth elements subject to the April 2025 export controls. Looking ahead, Trump and Xi could meet as many as four times in 2026, beginning with Trump's April visit to Beijing. The one-year agreement and the upcoming exchange of leader visits has stabilized bilateral relations for now after a tumultuous 2025.

ASEAN RECIPROCAL TRADE AGREEMENTS INCLUDE REGULATORY WINS FOR MEDTECH

The White House announced reciprocal trade agreements with Malaysia and Cambodia, incorporating several medtech regulatory priorities long championed by AdvaMed, including commitments to: accept prior FDA approvals or clearances; exempt low-risk devices from unnecessary authorization; recognize Medical Device Single Audit Program quality management audits and certificates; accept FDA electronic CFGs; and, for Malaysia, adopt International Medical Device Regulators Forum technical guidance and eliminate halal certification requirements for medical devices. During the final negotiations, AdvaMed organized a roundtable for eight members with Malaysian trade officials from the Embassy to discuss tariffs, trade barriers, and other ease-of-doing-business factors in Malaysia.

Technology & Regulatory Affairs

Janet Trunzo (Senior Advisor to the President, Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed) moderating the FDA CDRH Town Hall at The MedTech Conference.

FDA ENGAGES WITH ADVAMED, DESPITE GOVERNMENT SHUTDOWN

Even as the federal government shutdown halted much of Washington's activity, FDA's Center for Devices & Radiological Health (CDRH) leadership remained deeply engaged with AdvaMed and the medtech community. Throughout The MedTech Conference, FDA senior officials — including CDRH Director Dr. Michelle Tarver — participated in regulatory panels, led the annual CDRH Town Hall, and joined a virtual fireside chat with the CEO of the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA).

MDUFA VI NEGOTIATIONS COMMENCE WITH MEDTECH PRIORITIES FRONT AND CENTER

AdvaMed provided statements at the public meeting, which marked the launch of the MDUFA VI negotiation process. The first MDUFA VI negotiation session took place at the end of October. AdvaMed emphasized that the MDUFA V framework continues to work well and requires only targeted refinement. Recommendations included redirecting one-time costs based on whether they add value to the program, improving performance consistency across Offices of Health Technology (OHTs), and strengthening the de novo program. FDA's opening proposals focused heavily on establishing FY25 funding as the foundation for MDUFA VI.

Technology and Regulatory Affairs

At the second negotiation meeting on November 4, FDA provided its initial proposals and resource needs for patient science and engagement, standards and the Accreditation Scheme for Conformity Assessment (ASCA) program, and digital health programs. The Agency reiterated plans to seek higher registration fees for foreign facilities.

KEY DE NOVO REFORMS IN NEGOTIATION MEETINGS

Ahead of the formal kickoff of MDUFA VI negotiations, AdvaMed's De Novo Subgroup met to discuss longstanding challenges with the de novo pathway, namely that de novo submissions have a significantly lower rate of marketing authorization than the other premarket programs. The group also identified three proposed solutions that are intended to address the challenges and improve predictability in the review process. It was subsequently agreed that these three solutions will be presented to FDA as the industry proposal to improve the de novo program in MDUFA VI. On November 20, AdvaMed presented the industry proposal package to FDA. In that meeting, FDA also presented its proposals, which are intended to address the low granting rate and create more efficiency. FDA and industry appear aligned on the underlying challenges with the de novo program. We are continuing discussions with FDA to refine the proposals.

Digital Health Tech

DHT Leaders Don Abbey (Dexcom), Ricky Bloomfield (OURA), Venk Varadan (Nanowear), David Amor (Apple), and Shaye Mandle (AdvaMed) participating in the "Future of Wearables" session at The MedTech Conference.

DHT BOARD ELECTS NEW CHAIR AND ADVANCES 2026 STRATEGIC PRIORITIES

AdvaMed's Digital Health Tech Board convened in October for a highly attended meeting featuring presentations from Mick Farrell, chairman and CEO, Resmed, and incoming chair of the AdvaMed Board of Directors; Accenture; and DHT leadership. The Board elected Robert Cohen, Vice President, Innovation and Technology, Orthopaedic Group, Stryker, as the incoming Chair to lead the division's next phase of growth.

CMS EXPANDS PAYMENT FOR DIGITAL THERAPEUTICS UNDER CY 2026 MEDICARE PFS FINAL RULE

CMS released its CY 2026 Medicare Physician Fee Schedule (PFS) Final Rule, expanding Medicare payment to cover FDA-authorized digital therapeutics for Attention Deficit Hyperactivity Disorder (ADHD). This is a positive step forward by CMS to expand the coverage of new technologies like digital therapeutics.

NATIONAL VISIBILITY THROUGH EVENTS AND THOUGHT LEADERSHIP

DHT strengthened its presence at major national health innovation forums this quarter. Shaye Mandle represented AdvaMed at the Arizona Health Innovation Summit, participating in a panel focused on AI in health care.

Digital Health Tech

UPDATED GUIDANCE REFLECTS EVOLVING DIGITAL HEALTH LANDSCAPE

On November 1, the AdvaMed Code of Ethics on Interactions with Health Care Professionals revisions took effect to include additional guidance on Digital Health Technologies. Recognizing the expansion of data-driven technologies, the updated Code expands on guidance for handling data responsibly, ethically, and transparently to deliver trustworthy technologies to patients; data use to benefit patient access and outcomes; protecting patient privacy; and managing data responsibly in accordance with best practices and international standards. AdvaMed's Code of Ethics provides timely, effective guidance that supports ethical business conduct across medtech, based on the cornerstone values of innovation, education, integrity, respect, responsibility, and transparency.

Global Affairs

Shawn Liu, AdvaMed China Executive Director; Jerry Wang, China Board Vice Chair and Siemens Healthineers Head for China; Alex Gu, China Board Chair and Medtronic China President; and Iris Lin, China Board Vice Chair and QuidelOrtho JAPAC Head, moderated the November 19 AdvaMed China Annual Event held at Medtronic's China headquarters in Shanghai.

SCOTT LEADS CEO DELEGATION TO JAPAN

Scott led a high-level member company CEO delegation to Tokyo, including leaders from Resmed, Olympus, and Johnson & Johnson. The group met with senior members of Japan's new government, including the Minister of Health, Ministry of Economy and Trade leadership, head of the Pharmaceuticals and Medical Devices Agency, and key health care policy lawmakers. Discussions centered on Japan's aging society, the value medtech provides to improving health outcomes, the importance of a stable reimbursement environment, and ongoing tariff challenges. The week concluded with the 9th Annual Ikigai Symposium co-hosted by AdvaMed, featuring a lively fireside chat with Dr. Ichiro Kamoshita, Former MP, and a briefing with more than a dozen member company general managers.

MEXICO IMPLEMENTS ACCEPTANCE OF SINGLE AUDIT PROGRAM FOR MANUFACTURING FACILITIES

In a significant AdvaMed trade advocacy win, the Mexican government formalized its acceptance of Good Manufacturing Practice (NOM-241), confirming that all medtech facilities located anywhere outside or inside of Mexico may now, with legal and regulatory certainty, use their MDSAP audit reports or ISO 13485 certifications in lieu of requiring Mexico-unique government inspections. USTR addressed this specific medtech trade concern via its tariff negotiations with Mexico and through extensive consultations with AdvaMed.

Global Affairs

ADVAMED CHINA OFFICE CONVENES INAGURAL ANNUAL MEETING

In mid-November, AdvaMed's China Office held its first-ever annual meeting in conjunction with its China Board meeting in Shanghai. The event featured panel discussions with thought leaders on medtech innovation and trends within China's medtech market. Officials from the central government and the Shanghai government also delivered presentations on medtech procurement and investment promotion policies, respectively. The gathering attracted over 150 attendees, including general managers and policy unit heads from three dozen member companies, hospital leaders, investors, and government representatives. Overall, the event served to showcase the industry's unique contributions to China's health care system.

ADVAMED TESTIFIES ON U.S.-MEXICO-CANADA AGREEMENT

AdvaMed testified at the U.S. Government's hearing on USMCA's review, emphasizing the importance of integrated North American supply chains to U.S. medtech manufacturing, innovation, and export competitiveness. The testimony detailed how Mexico supports U.S. medtech production and how Canada remains one of the top export markets for U.S. medical technology. The oral testimony was supported by AdvaMed's written submission, which outlined key provisions that have benefited the industry since the USMCA's implementation and recommended renewal of the agreement and priority areas for improvement.

STRONG U.S. ADVOCACY PUSH ON JAPAN'S REIMBURSEMENT CYCLE

Following months of targeted outreach, AdvaMed secured a letter from 14 members of the U.S. House Ways and Means Committee to Ambassador Yamada urging fair and predictable reimbursement policies in Japan. The letter's timing aligned with President Trump's visit to Tokyo and Scott Whitaker's member company CEO delegation to Tokyo, reinforcing the importance of U.S. medtech access for Japanese patients in the bilateral relationship. Scott met with Ambassador Yamada to brief him on our CEO delegation to Japan and reinforce our points on reimbursement.

ADVAMED FILES COMMENTS:

- With USTR on the USMCA Review (see above).
- With USTR for the 2026 National Trade Estimate Report, detailing global non-tariff barriers that impede medtech exports.
- With the U.S. Department of Commerce on its BIS "50 Percent Rule" governing affiliates of listed entities. Within hours, Treasury Secretary Bessent signaled that the United States and China had agreed to suspend implementation of the rule as part of de-escalation efforts — a significant development for member companies.
- With USTR on China's performance under the 2020 US-China Phase One agreement, per the 301 investigation. Our submission incorporates member

Legal

Sonal Matai, President, North America, KARL STORZ, kicks off AdvaMed's Bi-Annual Device and Diagnostics Compliance Group Meeting, setting the stage for two days of discussion and collaboration.

LEGAL AND STRATEGIC LITIGATION INITIATIVES

The Legal team advanced multiple strategic initiatives in Q4.

Sterilization Liability Protection Legislation. The Board approved a Special Assessment to fund expansion of Sterilization Liability Protection, building on the Utah model. The model establishes a robust legal framework that shields industry from undue litigation risks associated with sterilization procedures. With the approval of the special assessment, AdvaMed is moving to expand this model to additional states at the direction of the Legal Committee, ensuring continued protection for medtech innovation and patient access to safe, sterile devices and equipment.

DMCA Litigation. AdvaMed sued the Library of Congress to overturn a Digital Millennium Copyright Act (DMCA) exemption (37 CFR 201.40(b)(15)) that allows unregulated third-party servicers to circumvent encryption on copyrighted diagnostic software, data files, and service manuals in advanced medical devices — like CT scanners, MRI machines, and surgical robots — to perform unauthorized maintenance and repairs. Following the D.C. District Court's decision to leave the exemption in place, AdvaMed filed an appeal with the D.C. Circuit and submitted our opening brief on Nov. 11. Prevailing in this case is important for ensuring patient and health care provider safety and protecting the privacy and security of patient data.

Legal

Amicus Program, Smith v Terumo. In March, we filed a brief with the Colorado Court of Appeals in a medical monitoring claim (Smith v Terumo). In the brief, we highlighted: Traditional tort-law principles preclude medical monitoring as a claim of remedy without present physical injury. And expanding tort recovery to uninjured plaintiffs leads to unbounded litigation and unwarranted burdens on the judicial system.

In late October, the Court affirmed the trial court's decision and held "a plaintiff cannot establish standing to sue under Colorado law based solely on an allegation that the defendant's actions have increased the plaintiff's risk of future illness or disease." This is a big win for industry, as it prevents the expansion of liability to plaintiffs who have no present injury and helps maintain predictable, evidence-based standards for tort claims.

Surgical Instrument Service Company v Intuitive Surgical. On November 5, we filed a brief with the 9th circuit in an Intuitive Surgical case connected to aftermarket servicing. The case raises interesting antitrust concerns, but our brief focused on the safety concerns connected to third parties modifying/servicing products without FDA clearance to do so, as well as FDA evidence admissibility at trial. In the brief, we explained that (1) it is common industry practice for manufacturers to require authorized servicing; (2) that common practice serves vital public interests, because unauthorized servicing poses serious risks; (2a) third-party servicers are not FDA-regulated; (2b) third-party servicers lack crucial capabilities to ensure proper maintenance; and (2c) improper servicing risks serious harm. And we concluded that inhibiting manufacturers from ensuring authorized servicing would threaten patient safety and innovation.

DATA STEWARDSHIP & PRIVACY

On October 27, AdvaMed submitted comments to the White House Office of Science and Technology Policy (OSTP) recommending regulatory reforms to promote the adoption and oversight of artificial intelligence in health care. The privacy-focused recommendations included amending the HIPAA regulations to enhance de-identification flexibility, clarifying and mending the definition of "health care operations" under HIPAA, clarifying the permissible use of PHI with AI for treatment, payment, and health care operations, and clarifying and adjusting individual rights obligations under HIPAA in the AI context, among others.

The Data Stewardship & Privacy Working Group also supported State Affairs efforts with the New York Governor's Office to address AdvaMed's concerns in the New York Health Information Privacy Act.

TAX POLICY AND NATIONAL SECURITY AND ECONOMIC SANCTIONS

In collaboration with the Supply Chain Working Group, the Tax Policy WG and NS/ES WG have finalized comments on OSTP's RFI on the national strategic plan for advanced manufacturing to submit by the December 12, 2025, deadline.

Legal

INTELLECTUAL PROPERTY

The IP Working Group will meet virtually with the U.S. Government Accountability Office on December 17 to discuss the patent application backlog at the U.S. PTO and the long pendency rates for patent examinations, the negative impacts on the medtech industry, and suggestions for policymakers to make patent examination more efficient.

CLE PASSPORT PROGRAM AND LEGAL EDUCATION

AdvaMed wrapped up its 2025 CLE passport program through its November 18 webinar, "Supreme Court Term in Review: Implications for the Medical Technology Industry," which provided participants with timely analysis of key Supreme Court developments affecting the medtech sector. The program featured expert perspectives on regulatory, enforcement, and litigation trends shaping industry risk and compliance strategies. Strong member company participation reflected sustained interest in high-level legal education and reinforced AdvaMed's role as a trusted convener for practical, forward-looking legal insights.

CODE OF ETHICS UPDATES

The Board approved updates to the AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals. The updates, which became effective November 1, included a dedicated section on Digital Health Technologies, reaffirming the industry's commitment to the highest ethical business standards. AdvaMed republished and distributed the Code to members, followed by a press release and LinkedIn amplification, as well as a toolkit of implementation materials widely adopted by members. Ida Nassar, VP, Assistant General Counsel, Head of Global Ethics & Compliance Policy, has also been notifying and briefing industry stakeholders, including during a panel at the Pharma and Med Device Ethics and Compliance Congress in Washington, D.C., highlighting the Code update, the medtech industry's continued leadership in ethics and compliance, and AdvaMed's robust program to support Code implementation.

COMPLIANCE ENGAGEMENT AND MEMBER OUTREACH

Two events this quarter demonstrated sustained company interest in compliance topics such as enforcement trends, trade compliance, and AI governance. On October 1, a joint Device & Diagnostics Compliance Group (DDCG) and Health Care Industry Representative (HCIR) Credentialing Working Group call brought together over 100 participants to discuss two recent OIG Advisory Opinions, resulting in support for outreach to hospital associations and exploring the development of related guidance.

In November, the Fall DDCG meeting at KARL STORZ in Goleta, California, attracted maximum registration of 70 attendees, further underscoring the high level of engagement. Additionally, the Global Compliance Steering Committee also met onsite to finalize 2026 compliance policy priorities, including the benefit of an on-the-ground compliance expert in China, funded via a voluntary special assessment.

Legal

INTERNATIONAL COMPLIANCE ENGAGEMENT

Americas. AdvaMed continued to strengthen global compliance connections. In November, Ida delivered keynote remarks to MedTech Canada's Compliance Steering Committee, emphasizing the value of regular alignment with AdvaMed and sharing best practices across jurisdictions. This engagement is part of a broader effort to leverage AdvaMed's expertise and reinforce high-standard compliance programs globally across the industry. Additionally, the Inter-American Coalition for Business Ethics will meet on December 17. The meeting Agenda includes discussion of Codes of Ethics updates to advance global harmonization of Codes across the Americas.

China. AdvaMed developed a three-to five-year strategic plan to advance our advocacy and member resources related to the implementation of the AdvaMed China Code of Ethics and anti-corruption compliance. This initiative supports on-the-ground engagement with government stakeholders in key compliance policy areas (e.g., government compliance guidance, regulatory proposals, etc.), engagement with local medtech associations and other stakeholder groups to level the playing field, and convening regular compliance member meetings and benchmarking on compliance topics to support implementation of the AdvaMed China Code.

To ensure the success and sustainability of our efforts, we are implementing a Special Voluntary Assessment to retain a Compliance and Ethics Counsel from a leading law firm in China to report to AdvaMed headquarters' Office of General Counsel and provide on-the-ground support for our advocacy. This collective investment will provide the dedicated resources needed to advance our compliance policy objectives on the ground in China.

AdvaMed Accel

Sebastian Bachmann (Angel Investor; Principal Consultant, Hilltop MedTech Consulting), Christian Haller (Vice President Mid Atlantic, Southeast, & Texas, Keiretsu Forum), Maureen Mulvihill (President & CEO, Actuated Medical), Alperen Ozalp (Head of Partnerships, Life Science Angels), Shri Raghunathan, PhD (President & CEO, Noctrix Health), speaking at the AdvaMed Accel Leadership Seminar and Networking Breakfast in the "Decoding the Angel Investor Mindset in MedTech" session at The MedTech Conference.

ADVANCING SBIR/STTR AND NIH STRATEGY

During Q4, AdvaMed Accel continued its focused advocacy on early-stage research funding, specifically the reinstatement of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, which lapsed on September 30. From October through November, the team engaged with congressional staff, including meetings with key members and committees, outreach to federal agency staff, and coordinating Accel member advocacy engagement to advance strategies to get these critical programs reinstated. Accel worked closely with DLA Piper to identify member examples and develop actionable approaches to mitigate the negative impacts of the questionable application of foreign risk review criteria. Notably, Accel refined negotiation points for U.S. Sen. Joni Ernst's engagement on SBIR, incorporating viable options into redlines of the Investing in National Next-Generation Opportunities for Venture Acceleration and Technological Excellence "INNOVATE" Act. In an already difficult funding environment, passage of this or other legislation is essential for these programs, which are an important source of research funding for many small medtech companies, to continue.

AdvaMed Accel

COMMUNICATIONS AND MEMBER ENGAGEMENT

Accel continued to support engagement and awareness of our members through a variety of communication mediums including policy updates, our newsletter, and advocacy engagement. We also continued to meet the needs of our members, and prospective members, through the development and execution of tailored MedTech Conference programming and events — including the Accel Leadership Seminar. These tailored communications and member events enable members to stay aware of developments around critical issues for small companies including breakthrough legislation, SBIR reinstatement efforts, and investment trends.

Medical Imaging

AdvaMed's Peter Weems, Patrick Hope, Ann-Marie Nwabudike, Jennifer Tomasello, Adrienne Frederick, Amy Perry, and Wintana Zerai represented AdvaMed's Medical Imaging division at the Radiological Society of North America (RSNA) annual meeting in Chicago.

STRATEGIC PLANNING

The AdvaMed Imaging Board is advancing a comprehensive strategic plan focused on four priority pillars: Digital Health, Service and Remanufacturing, Patient Access to Care, and Standards Development. These pillars will guide initiatives to promote AI-enabled imaging adoption, strengthen servicing and remanufacturing practices, expand patient access through improved coverage and reimbursement, and unify the industry with robust technical standards. The Board is now working to identify must-deliver initiatives under each pillar and will bring an action plan for approval at its next Board meeting.

GOVERNANCE AND LEADERSHIP ENGAGEMENT

The Imaging Division held its second Leadership Forum of the year with the Chairs and Vice Chairs of various Committees/Sections to discuss the Division's Strategic Planning, promoting standards development within the division, and planning for RSNA 2025. This was an opportunity for all imaging leaders to come together to collaborate, share ideas, and discuss advocacy strategy on advancing medical imaging priorities.

In addition, the division welcomed Tracy Bury of Samsung as a new member of the Imaging Division Board of Directors, with a dedicated orientation to integrate her into ongoing initiatives.

Medical Imaging

DIGITAL HEALTH

AdvaMed applauded the bipartisan introduction of H.R. 6197, the House version of the Health Tech Investment Act, led by Representatives John Joyce, Beth Van Duyne, Jay Obernolte, Brad Schneider, Scott Peters, and Angie Craig. This legislation aims to improve health outcomes for Medicare patients by establishing a clear and consistent reimbursement pathway for innovative, unique subset of FDA-authorized AI-enabled medical devices that provide clinical information that would otherwise not be available. The bill addresses current barriers to adoption caused by inconsistent CMS reimbursement policies and seeks to ensure that advanced technologies can reach more health care professionals and patients, enhance diagnostic accuracy, and drive better patient outcomes. H.R. 6197 mirrors legislation, S. 1399, introduced in the Senate by Senators Mike Rounds, Martin Heinrich, and Marsha Blackburn earlier this year. For more details, read the official AdvaMed press release and the press release from Rep. Joyce.

GLOBAL AND REGULATORY ENGAGEMENT

AdvaMed Imaging maintained its leadership on global regulatory and policy issues. Patrick Hope, alongside Janet Trunzo, Zach Rothstein, and member company representatives, participated in the first MDUFA VI negotiation session with the FDA, advancing critical discussions on medical device user fees and regulatory processes. MDUFA VI negotiations are critical to the medtech imaging industry because they shape FDA review timelines, user fees, and regulatory predictability, directly impacting innovation speed and patient access to advanced imaging technologies.

The division also continued to lead DITTA Board activities, including important governance updates to bylaws and the transfer of the Treasurer role to COCIR.

STANDARDS

AdvaMed Imaging began active revision of several key standards (Remanufacturing of Ultrasound Medical Devices (UMD-P1); X-ray equipment for interventional procedures - User Quality Control Mode (XR-27); and Standard Attributes on X-ray Equipment for Interventional Procedures (XR-31)) at the direction of the Imaging Board. Publication of updated standards is expected to begin Q1 2026. Planning for the development and publication of new industry standards is also in the works.

REMANUFACTURING AND "RIGHT TO REPAIR"

An important win for the imaging division was a provision included in the 2026 spending bill language directing FDA to report to Congress within 90 days on how it has been implementing its May 2024 final guidance on remanufacturing. FDA is expected to report on matters such as its efforts to educate stakeholders on their regulatory responsibilities when remanufacturing medical devices, trends the Agency has observed on remanufacturing activities, and other related matters. This report will help guide us toward greater transparency, accountability, and education around medical device remanufacturing and servicing.

AdvaMedDx

Scott Whitaker, Zach Rothstein, and Ray Briscuso present Chuck Fleischman with the first AdvaMedDx Lifetime of Leadership and Service Award.

LAUNCH OF THE ADVAMEDDX LIFETIME OF LEADERSHIP AND SERVICE AWARD

AdvaMedDx successfully launched a new annual Dx Lifetime of Leadership and Service Award to honor individuals who have made extraordinary contributions to the diagnostics industry. The inaugural selection committee — industry veterans and current and former Board members, Vince Forlenza, Brian Blaser, and Scott Garrett — selected Charles "Chuck" Fleischman as the 2025–2026 recipient. The award was formally presented to Chuck in early November, with generous funding provided by Tim Ring and Kathryn Gleason to support the program for the next five years.

AdvaMedDx

SUCCESSFUL BOARD MEETING AT THE MEDTECH CONFERENCE

AdvaMedDx convened its Q3 Board meeting at The MedTech Conference with nearly full participation from Board members. The meeting featured 12 speakers, including QuidelOrtho China GM and AdvaMed China Board Vice Chair Iris Lin, as well as Bakul Patel of Google, who is also a member of the AdvaMed Digital Health Tech Board. These discussions strengthened global, regulatory, and digital health alignment across the association and reinforced AdvaMedDx's convening power on the most pressing issues in diagnostics.

CONGRESSIONAL LEADERSHIP SECURED FOR CLIA WAIVER AND POINT-OF-CARE LEGISLATION

AdvaMedDx gained a key legislative champion as Senator Jon Husted (R-OH) agreed to lead our efforts on the Clinical Laboratory Improvement Amendments (CLIA) Waiver and Point-of-Care legislation. His commitment marks a major step toward advancing modernized pathways that will support broader access to innovative, decentralized testing. Congressional legislative counsel is currently reviewing the bill text, which AdvaMedDx developed. We will continue working closely with Senate staff as this initiative advances.

KEY LANGUAGE SECURED IN CONGRESSIONAL REPORT LANGUAGE

The Agriculture/FDA appropriations bill was included in the Nov. 12 short-term continuing resolution that ended the government shutdown. The bill included amended language in the over-the-counter diagnostic testing report language, which now — and as a result of our advocacy — specifically includes point-of-care tests as well. This report language requires the FDA to provide a comprehensive analysis of the current regulatory barriers faced by these types of diagnostic tests.

CBO ENGAGEMENT ON BREAKTHROUGH DIAGNOSTICS

The AdvaMedDx and AdvaMed Payment teams met with the Congressional Budget Office to discuss the landscape of FDA-authorized breakthrough diagnostics. The briefing detailed analytical trends, clinical value, and payer costs to ensure CBO's methodology to determine the cost of the inclusion of diagnostics in the bill is fair and meaningful. This engagement ensures diagnostics remains central in congressional efforts to accelerate patient access to transformative technologies.

Public Affairs

ACCELERATING THE MAHA-MEDTECH ALIGNMENT THROUGH TARGETED VIDEO OUTREACH

This quarter, Public Affairs elevated medtech's profile across Washington with the launch of a new 30-second ad positioning the industry as essential to improving national health outcomes through improved prevention, diagnosis, and management of chronic conditions. The video launched in early November and was promoted across high-impact social-media and TV-streaming channels.

The campaign delivered strong results: Connected TV placements on Hulu, Peacock, Roku, and Paramount produced nearly 200,000 impressions among high-level Administration officials, with a video completion rate above 98 percent, ensuring our message is landing and being watched in full. The highest concentration of views came from staff inside CMS, HHS, the White House, and the FDA — precisely where it matters most.

To deepen engagement with industry stakeholders, Public Affairs also promoted Scott Whitaker's LinkedIn post featuring the medtech video, delivering more than 20,000 impressions to employees at AdvaMed member companies and achieved double the standard click-through-rate benchmark — with notable engagement from Edwards Lifesciences, Medtronic, Stryker, Boston Scientific, Johnson & Johnson MedTech, and GE HealthCare.

DRIVING VISIBILITY AND INFLUENCE THROUGH THE MEDTECH CONFERENCE

Throughout Q4, Public Affairs executed a coordinated set of initiatives designed to elevate medtech's role in national health policy discussions and strengthen AdvaMed's profile with key decision-makers. The quarter opened with the annual MedTech Conference (MTC) in San Diego, where PA launched the first phase of a strategic social media campaign designed to raise awareness within the Administration, position our subject matter experts as trusted leaders in medtech policy, and advance priority policy outcomes. Over the following eight weeks, the team amplified MTC content through earned and owned media featuring AdvaMed leadership and staff. The result was a substantial surge in digital visibility, with over 1,000 new LinkedIn followers, which generated engagements from the audiences that matter most: congressional staff, federal agency officials, policy advisers, health system executives, medtech leaders, and top-tier reporters. These interactions reinforced a clear message: AdvaMed's experts are shaping the national medtech conversation.

Public Affairs

Also at MTC, PA organized a media availability with Scott Whitaker and the reporters covering the conference. The media availability attracted high reporter turnout and resulted in significant media coverage on topics including a call for certainty in tariffs policy, an important message to convey to the Administration.

ELEVATING DIABETES AWARENESS MONTH THROUGH A COORDINATED NATIONAL CAMPAIGN

In November, Public Affairs led a comprehensive National Diabetes Month campaign that united the diabetes medtech sector around a clear, unified message and reinforced medtech's critical role in early detection, prevention, and chronic disease management — key pillars of the MAHA agenda. The campaign emphasized the importance of early diagnosis, showcased how diabetes technologies empower patients, and advocated for expanded access to proven tools that improve outcomes for millions of Americans.

To maximize impact, PA coordinated closely with member companies and leading patient advocacy organizations, to synchronize content, cross-promote posts, and amplify our messaging. The team also promoted a letter to CMS from the bipartisan, bicameral congressional diabetes caucuses urging expanded access to CGMs and insulin therapy.

Diabetes remains one of AdvaMed's largest and most vital sectors, with member companies producing some of the most innovative and advanced medtech solutions that 136 million Americans living with diabetes and prediabetes rely on — addressing one of the nation's most urgent chronic disease challenges.

Alliance Partnerships

Bobby Patrick, VI, Jennifer Pollack, and Cassandra Ricci speak on the panel "Forging Alliances: MedTech, Patient Advocacy, and the Future of Policy" during The MedTech Conference in San Diego.

MOBILIZING INDUSTRY VOICES ON THE 232 INVESTIGATION

In October, AdvaMed led a coordinated stakeholder recruitment effort that delivered a major show of force on the federal Commerce Department Section 232 investigation of medtech imports as a possible national security threat. The campaign helped generate more than 400 identifiable comments from stakeholders across the health care ecosystem, the states, and thought leaders into the federal docket, none of which supported additional tariffs on advanced medical technology. This strong, unified response underscores the deep concern that tariffs would disrupt patient care and the medtech supply chain.

BREAKTHROUGH COVERAGE CAMPAIGN

AdvaMed organized patient group partners and members of the State Medical Technology Alliance (SMTA) to elevate the importance of enacting a program delivering Medicare coverage of FDA-authorized breakthrough medtech and ensuring diagnostics are included as part of it. The campaign included SMTA Chair and BioUtah CEO Kelvyn Cullimore writing an op-ed in the Desert News and National Health Council (NHC) CEO Randy Rutta publishing a blog on AdvaMed's website, both stressing the importance of this program for patients. Additionally, the Alzheimer's Association sent its own letter to the U.S. House of Representatives Energy and Commerce Committee echoing the messages in both pieces and engaged U.S. House of Representatives Ways and Means Committee members and staff on the same critical point.

Alliance Partnerships

ALLIANCE PARTNER ENGAGEMENT: MEDTECH CONFERENCE, BRIEFING ON MEDICAL IMAGING

AdvaMed actively engaged its Alliance Partners throughout the quarter, highlighted by the 2025 MedTech Conference and a briefing on medical imaging and AdvaMed's policy priorities in the space:

- 2025 MedTech Conference: AdvaMed's Alliance Partners were front and center in San Diego, including a panel focused on successful strategies for industry and patient advocacy group engagement on policy priorities. Bobby Patrick, VI, AdvaMed's Head of Alliance Partnerships, moderated this panel with Cassandra Ricci, Senior Manager, Alliance Development and Federal Government Affairs at Roche, and Jennifer Pollack, Director, Access Policy and Alliance Development, at the Alzheimer's Association, serving as panelists, where they touched on an effort that successfully led to the Centers for Medicare and Medicaid Services' increasing Medicare reimbursements for Alzheimer's biomarkers and best practices to drive successful industry and patient advocacy group collaborations.
- Briefing on Medical Imaging: AdvaMed hosted a briefing for its Alliance Partners on the medical imaging industry, including how it is regulated, how reimbursement works, and what AdvaMed's key priorities are in the space, such as the pending Health Tech Investment Act to increase access to AI-enabled technology for Medicare beneficiaries and site-neutral Medicare reimbursement policies.

State Affairs

State Rep. Brenda Carter (MI), Rebecca Birch, Hilary Gee Goeckner, and Joslyn Chaiprasert-Paguio speaking on the Roche Diagnostics-sponsored panel "Women's Preventative Health: Expanding Access to Breast & Cervical Cancer Screenings that Save Lives" at the Women in Government Leadership & Innovation Summit in La Jolla, California.

COLORADO ALIGNS WITH FEDERAL ETO STANDARDS AFTER TARGETED ADVOCACY

Following sustained multi-year advocacy, extensive member coordination, and expert testimony, Colorado is now poised to directly reference the U.S. Environmental Protection Agency's National Emission Standards for Hazardous Air Pollutants (NESHAP) in its ethylene oxide (EtO) permitting framework. This marks a significant shift from the state's earlier direction and represents a substantial win that helps avoid the creation of conflicting state-level EtO standards.

ADVANCING SMART AI POLICY IN NEW YORK

AdvaMed led a coalition of patient groups, providers, and industry in securing a veto of legislation in Montana that would have unnecessarily restricted where companies could safely store patient health care data. This veto was significant in preventing a patchwork of state laws on the topic and provides momentum for our position heading into 2026.

State Affairs

SUPPORTING MEMBERS THROUGH THE RURAL HEALTH TRANSFORMATION PROGRAM

With the close of the application period for the Rural Health Transformation Program (RHTP), AdvaMed began collecting and sharing state application materials with members. These resources — building on previous work, including AdvaMed's Rural Health Transformation Program Medtech State Toolkit — will guide industry analysis and support member engagement as states begin considering program implementation. AdvaMed also is engaging with states to better understand the process each will use to award the grants received through this program. The insights gathered this quarter will help shape AdvaMed's strategy on RHTP and rural health policy more broadly going into 2026.

Federal Government Affairs

RESULTS Act Hill Day with Meghan Riley (NILA), Amanda Walsh (AdvaMed), Mary Lee Watts (ACLA), Holly Bruggen (ACLA), and Hannah Grow (MGMA) to advocate against clinical lab cuts.

SHAPING BREAKTHROUGH POLICY THROUGH DIRECT ENGAGEMENT WITH CBO

Federal Affairs, alongside AdvaMedDx, engaged in a confidential discussion with Congressional Budget Office analysts to address longstanding challenges in scoring diagnostics — a key factor in the breakthrough bill. The conversation opened the door for future dialogue and may provide valuable insight into CBO's methodology and assumptions, informing AdvaMed's strategic approach as breakthrough coverage efforts progress.

PROTECTING FDA RESOURCES AND SECURING KEY REPORT LANGUAGE IN FUNDING AGREEMENTS

Congress approved a continuing resolution that will keep the government funded through January 30, 2026, including full-year appropriations for certain government agencies including FDA. Two key AdvaMed priorities that had expired were reauthorized for the length of the CR:

- Hundreds of clinical laboratory tests faced reimbursement cuts of up to 15 percent on January 1, 2026, because of flawed methodology in legislation that was passed in 2014. AdvaMed has been working with Congress to pass new legislation that would provide a more sustainable, market-based system that would mitigate the cuts and ensure better access to testing for patients. This extension will provide additional time to work with Congress to address the long-term problem.
- The spending bill extended Medicare coverage of telehealth services allowing patients to receive care from home without geographic restrictions.

Federal Government Affairs

Federal Affairs successfully secured several pieces of critical report language in the agreement, including:

- Securing the inclusion of point-of-care testing to a provision encouraging FDA to prioritize premarket review of over-the-counter tests to address infections where there is no OTC diagnostic authorized, including a report and briefing for staff on efforts to expand access to OTC diagnostics.
- A requirement that FDA adhere to the Federal Advisory Committee Act and provide quarterly briefings on spending, staffing, and user fee implementation — language advanced through a coalition effort in which AdvaMed played a leading role.
- The preservation of House and Senate directives on medical device remanufacturing, including requirements for FDA to report on outreach, surveillance, inspection activity, and registration trends associated with the 2024 final guidance. The report must be completed within 90 days and posted publicly.

Although FDA's overall budget decreased for FY26, the Center for Devices and Radiological Health (CDRH) received a funding increase. This is because our user fee agreement requires that medical device user fees supplement — not replace — congressional appropriations, ensuring CDRH's funding remains strong. Thanks to AdvaMed's advocacy for a strong user fee program, CDRH is the only FDA division to receive a budget increase, with Congress adding $8.21 million to reinforce FDA's ability to review medical devices efficiently.

Payment

Driving policy wins for the AdvaMed Payment Team: From securing CY2026 payment reforms and lab fee updates to shaping future IPPS rules, advancing coverage transparency, and amplifying member voices through advocacy and engagement.

RULEMAKING YEAR IN REVIEW

CMS issued several CY2026 final rules in Q4 with policies relevant to medtech. The Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule included a request for comment on a longstanding AdvaMed priority of establishing future payment policies for software as a service (SaaS) and other software-based technologies.

The Medicare Physician Fee Schedule (PFS) Final Rule finalized several AdvaMed requests, including appropriate payment rates for pediatric tympanostomy technologies and an expansion of payment pathways for digital mental health treatment (DMHT) technologies. The Clinical Lab Fee Schedule (CLFS) Final Determinations finalized all AdvaMed-requested rates.

The Home Health Prospective Payment System and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Final Rule established a timeline for the next round of DMEPOS Competitive Bidding and was a top AdvaMed advocacy priority across Q3 and Q4.

Looking ahead, the Payment team began pre-rulemaking discussions with members in October to develop early comments in advance of the FY 2027 Inpatient Prospective Payment System (IPPS) proposed rule to ensure CMS receives our input while the proposed rule is still in development, timing that provides the greatest opportunity for our recommendations to be reflected in the proposed rule.

Payment

CBO ENGAGEMENT ON BREAKTHROUGH DIAGNOSTICS

The Payment team, in collaboration with AdvaMedDx, prepared a detailed presentation to the Congressional Budget Office. The briefing outlined AdvaMed's analysis of FDA-authorized breakthrough diagnostics, underscoring the clinical and economic value these innovations bring and reinforcing the importance of including diagnostics in the House and Senate breakthrough legislative proposals.

ADVOCACY FOR GREATER TRANSPARENCY IN LOCAL COVERAGE DECISIONS

AdvaMed continued pressing for clearer, more predictable CMS coverage processes. In early November, the Payment team finalized and submitted comments to multiple Medicare Administrative Contractors on four local coverage determinations affecting medtech manufacturers. These submissions reinforce AdvaMed's long-standing calls for transparency, consistency, and stronger evidentiary standards across the MAC network.

QUARTERLY PAYMENT WORKGROUP MEETINGS DRIVE INDUSTRY ALIGNMENT

The Payment team convened its three Q4 workgroup meetings, each focused on priority issues including accelerated coverage pathways, digital health technology coding and reimbursement, and proposed changes to the DME Competitive Bidding program. A major highlight was a guest briefing from Zach Hochstetler of the American Medical Association, who discussed ongoing CPT coding modernization efforts and improving collaboration with industry — particularly around issues such as the widespread use criterion. AdvaMed's engagement with AMA CPT ensures AdvaMed members stay informed and have early opportunities to provide input on proposed CPT code changes and updates to CPT code requirements and scope. Since CPT codes ultimately impact how procedures and services are reimbursed, this engagement helps ensure that new and emerging medical technologies are accurately represented in the coding system, enabling appropriate reimbursement and broader patient access to innovative health care solutions.

Conferences, Events, & Marketing

Thank you to the 3,700 attendees who joined us in San Diego this year at MTC25 including more than 150 participants who took part in the 5K Fun Run sponsored by Zimmer Biomet.

THE MEDTECH CONFERENCE

AdvaMed delivered its largest and most successful MedTech Conference in the United States to date in San Diego, setting new records for member engagement and sponsor participation. Under the theme "Medtech Redefines the Future of Health Care," the conference convened thousands of industry leaders, innovators, and policymakers for high-impact dialogue, strategic insights, and collaborations that will shape the next era of patient care. The conference also marked a significant milestone — celebrating AdvaMed's 50th anniversary and honoring five decades of leadership in advancing medical technology. Building on this year's momentum, planning is already under way for the next U.S. MedTech Conference, which will take place in Boston from October 18–21, 2026, positioning the association for continued growth and even greater influence in the years ahead.

Conferences, Events, & Marketing

STRENGTHENING PARTNERSHIPS ACROSS THE INDUSTRY

In November, AdvaMed hosted more than 80 medtech professionals for our largest-ever Cybersecurity Summit in Washington, D.C., with both in-person and virtual participation options. The Summit delivered a highly successful, content-rich program featuring premier experts from the FDA, leading medical device manufacturers, cybersecurity innovators, and major health care delivery organizations. Sessions underscored the rapidly advancing regulatory landscape, the growing complexity of cyber threats, and the industry's collective commitment to strengthening medical device cybersecurity across the full product lifecycle.

In partnership with California Life Sciences and to continue to engage the California medtech community, AdvaMed sponsored the Converging Technology of the Year Award at the California Life Sciences Pantheon Awards on November 6 in San Francisco. The event attracted several hundred industry leaders, and our table hosted executives from Somnics, Johnson & Johnson MedTech, Medtronic, BD, CLS, iSono Health, Butterfly Biosciences, and others. AdvaMed Past Board of Directors Chair Mike Mussallem was honored with the organization's Lifetime Achievement Award, reinforcing the association's deep connection to the innovators shaping the future of medtech.