AdvaMed
The Medtech Association

AdvaMed Advancements
Q3 2025 Report

A Note from Scott

Dear AdvaMed Member,

The third quarter of 2025, like the prior two quarters before it, created an extremely challenging policy landscape in Washington, D.C.

With the political environment more heated than ever, AdvaMed's role is to maintain an even temperature and to persuade policymakers on both sides of the aisle of the incontrovertible value of medtech, no matter the turbulence outside of our sphere. Regardless of anyone's politics, they want the best possible health for themselves and their loved ones. Medtech is essential to achieving that goal.

This quarter, we communicated that message everywhere as we sought policies promoting access to lifesaving, life-changing medtech: Congress, the White House and executive branch agencies, and state legislatures. The message is effective because it's backed by tangible results: the countless patients who beat cancer, whose mobility is restored, whose pain is relieved, because medtech provided a solution.

Just as the quarter ended, the U.S. Department of Commerce's Section 232 investigation of medical device imports as a potential national security concern was announced — even as the federal government barreled toward a shutdown, which remains in place with no clear end in sight.

AdvaMed immediately mobilized to prepare and submit detailed comments for the public record by the October 17 deadline and issued a media statement. Our comments covered our industry's robust domestic manufacturing base, investment commitments and resilient supply chain, making additional tariffs counterproductive to a U.S.-led industry and the patients we serve.

The medtech story does resonate with policymakers. Telling that story, AdvaMed was able to achieve several gains on your behalf this quarter. The momentum toward enacting legislation providing Medicare coverage for FDA-authorized breakthrough medtech is stronger than ever, with key U.S. House of Representatives committee passage in September. The United States-European Union trade framework suggests "important sectors" could receive reduced or Most Favored Nation tariff rates. The sixth Medical Device User Fee Amendments agreement discussions between the industry and FDA are proceeding on a positive track, back to stability after early concerns that unfounded criticism of user fees might derail the process.

A Note from Scott

Speaking of stability, these victories for medtech and the patients we serve are possible only because of your continued membership. Your faith in AdvaMed is essential to our successful advocacy work for you. Thank you for your support, as our organization maintains its presence as a steady force for telling the good word of medtech.

I hope you find this quarter's report informative and helpful.

Sincerely,

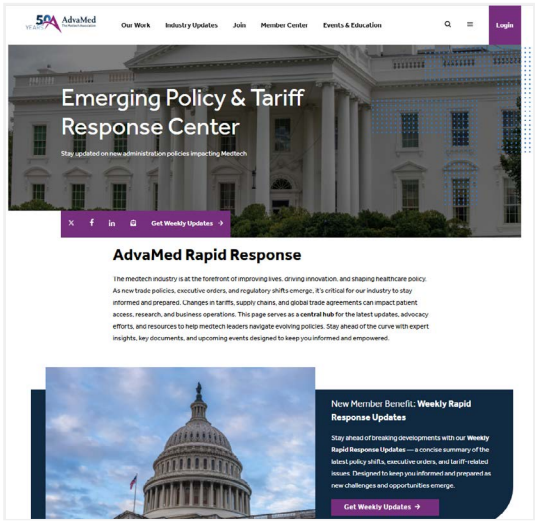
Scott

Scott Whitaker
President & CEO
AdvaMed

Tariffs

OUR ADVOCACY APPROACH

The message behind our advocacy on tariffs throughout the year has been twofold: One, medtech should not be subject to tariffs for humanitarian reasons, as traditionally has been the case. Two, if medtech is subjected to tariffs, the rates should be as low as possible, and the tariff regime should be transparent and predictable, allowing companies to adjust their supply chains and manufacturing locations to their best ability to serve their customers.



For more on our tariff policy response, go to www.advamed.org/emerging-policy-response-center/.

We also have made clear that adjusting supply chains and manufacturing sites is lengthy and expensive, given the highly regulated nature of our industry. With a key trading partner, the European Union, the United States held excessive tariff rates at bay this quarter, helped by aggressive advocacy from AdvaMed and allied groups. AdvaMed conducted high level meetings with the Administration, as it has since the onset of the tariffs debate, to explain the strength of the U.S. industry, impact of tariffs, including reciprocal tariffs, on medtech supply chains, patients' access to lifesaving medtech and potential delays in surgery and other treatment resulting from any supply disruptions, and the harm to U.S.-dominated medtech manufacturing and research and development.

SECTION 232 INVESTIGATION

As noted, the U.S. Department of Commerce's Section 232 investigation of medical device imports as a national security threat drew immediate mobilization from AdvaMed and member companies to develop a robust response in just over two weeks. Comments cover the industry's comprehensive domestic manufacturing base — with a presence in each of the 50 states — supporting three million jobs, directly and indirectly; billions of dollars in domestic investment commitments in 2025 alone; and the resilient supply chain our companies have developed over years to ensure U.S. hospitals and patients have the medtech necessary to provide around-the-clock care.

Industry's submission makes clear that any additional tariffs resulting from the Section 232 investigation would be counterproductive to a U.S.-dominated industry and the patients we serve. The response offers a series of policy recommendations the Administration could embrace to strengthen U.S. medtech, providing data points illustrating how U.S. medtech is a powerhouse of domestic manufacturing, R&D, U.S. investment, well-paying U.S. jobs, and exports. Thank you to all our members who contributed, resulting in a strongly argued, fact-based submission. AdvaMed will continue to keep you posted on the next steps as the investigation proceeds and continue our aggressive advocacy toward zero tariff rates in the meantime.

Tariffs

PROGRESS BETWEEN THE U.S.-E.U.

In August, the White House and the E.U. released a joint statement on a framework deal for trade and tariffs. As with the previous drafts and announcements, the framework did not specifically carve out medtech for exemptions from tariffs. However, AdvaMed was pleased to see new, explicit language specifying that both sides have agreed to continue discussions on tariff reductions or even zero duties for other sectors and products "important for their economies and value chains." USTR has reported that the European Commission continues to push for medtech to be included in this category.

AdvaMed continued to press our case through the quarter's end and will continue to do so as long as necessary.

Another positive development: The E.U. agreed to eliminate tariffs on all industrial goods and suspended any retaliatory tariffs, including on medtech, for six months, meaning that for U.S exports to the E.U., tariffs will continue to be zero. This quarter, AdvaMed pressed to maintain the suspension long-term.

The E.U. also agreed to lower its MFN tariffs on U.S. industrial goods, which includes contact lenses and some in vitro diagnostic-related products (otherwise, the E.U. already charges zero percent MFN tariffs for the vast majority of medtech).

STEEL, ALUMINUM, AND DERIVATIVES

In September, AdvaMed was among a coalition of 43 business trade associations urging the Commerce Department to rethink its addition of hundreds of product categories to those subject to 50 percent duties on steel, aluminum, and their derivatives, saying the new requirements imposed significant burdens on importers without sufficient time or "clear guidance" for how to comply.

NEXT STEPS

Our advocacy will continue into the fourth quarter and as long as needed to produce the best possible outcome on tariffs, allowing medtech innovations to reach as many patients as possible worldwide while maintaining U.S. leadership in medtech manufacturing and research and development.

Our goal is clear: to secure greater certainty and transparency on tariff rates as quickly as possible so our members can continue manufacturing and innovating to treat human suffering.

Technology & Regulatory Affairs

AdvaMed's Janet Trunzo, Patrick Hope, and Zach Rothstein present at FDA's August 4 public meeting to kick off negotiations on MDUFA VI.

MDUFA VI NEGOTIATION CONTINUES ON GOOD FOOTING

Even with tariffs consuming much attention in Washington, the Technology and Regulatory Affairs team this quarter kicked off negotiations with the FDA on the sixth version of the Medical Device User Fee Amendments agreement (MDUFA), with three AdvaMed experts speaking at the FDA's August 4 public meeting to launch the process. Janet Trunzo, Patrick Hope, and Zach Rothstein highlighted the breadth of medtech and its role in our health care system, the progress achieved for the timely review of medtech for safety and effectiveness by agency experts with each MDUFA agreement, and key goals for MDUFA VI. In addition to calling for continued progress in reducing the length of review timeframes to ensure the safety and effectiveness of medtech, the AdvaMed representatives noted the success of the current program, that major changes are not needed, and the importance of user fee revenues to be additive to the budget and to be used for hiring needed resources to support the review process.

The remarks were well-received by FDA Commissioner Makary, who has stated that the medical device user fee program is a model for other user fee programs.

Technology and Regulatory Affairs

Next steps in preparing for the MDUFA VI negotiations are scheduled to begin in late October and involve submitting edits to the proposed ground rules for the discussions. As of the end of the quarter, the FDA was reviewing T&R suggestions and requested data from AdvaMed and other industry associations. FDA expects a streamlined process for MDUFA VI, such that the negotiation process will conclude by January 2026.

REAL PROGRESS ON GLOBAL HARMONIZATION

In August, AdvaMed and the FDA held a forum to meet one of the global commitments under the Global Harmonization section of the MDUFA V commitment letter. Topics discussed included the public consultation on the UK reliance scheme, expected next steps on the Switzerland reliance scheme, FDA interest in third-party publications that clarify the rigor of the FDA regulatory framework, e-star expansion, and the Brazil reliance scheme.

KEEN CONGRESSIONAL INTEREST IN ADVAMED'S POSITION ON ELECTRONIC LABELING

Bipartisan U.S. Senate Hill staff asked for feedback on edits they made to the House-introduced electronic labeling legislation in anticipation of Senate introduction. The legislation would grant authority for electronic labeling for devices intended for use by persons other than health care professionals. Current authority applies only to professional-use devices. AdvaMed reached a consensus among our members and internal staff on the edits to the legislation. The Senate leads agreed with proposed industry changes to the bill and have sent the language to the FDA for technical assistance (TA). Sponsors plan to introduce the bill in the Senate once the agency sends back its TA guidance to the chamber.

Digital Health Tech

AdvaMed Public Affairs launched the "AI in Health Tech" social media campaign, spotlighting member companies and DHT Board leadership, including Dr. Taha Kass-Hout and Robert Cohen.

PROGRESS ON PAYMENT FOR DIGITAL THERAPEUTICS

The DHT division achieved a major policy milestone with CMS's recognition of digital therapeutics in the CY 2025 Hospital Outpatient Prospective Payment System (HOPPS), Ambulatory Surgical Center (ASC) and Medicare Physician Fee Schedule (PFS) final rules. For the first time, payment will be available for digital mental health treatment (DMHT) devices furnished as part of behavioral health treatment plans. While currently limited to DMHT, this establishes a precedent for broader coverage of digital therapeutics. CMS has also proposed in the CY 2026 Medicare PFS rule to expand DMHT payment to ADHD therapies and is seeking comment on coding and payment policies for digital therapies addressing gastrointestinal conditions, psychiatric sleep disturbances, and fibromyalgia.

DHT DRIVES NEW STANDARDS INITIATIVES

AdvaMed established a new Standards Management Committee and launched several key projects to advance clarity and trust in the digital health space. Current work includes projects on digital health nomenclature and patient notification model language, with upcoming initiatives planned for video surgery data standards and data quality, access, and interoperability.

Digital Health Tech

NATIONAL VISIBILITY THROUGH MEDIA AND EVENTS

AdvaMed also launched its "AI in Health Tech" social media campaign, spotlighting member companies and DHT Board leadership.

DHT leaders attended the Health AI+ 2025 Conference (sponsored by CTA, Rock Health, Johns Hopkins) and the Kansas Innovation Festival (BioKansas) and was featured in the Accenture AI Leaders Podcast episode "AI in Medtech: Enabling the Future of Care." The division also met with senior administration officials, including Bill Guidera, Deputy Assistant Secretary for Services at the International Trade Administration, to discuss America's AI Action Plan, the Administration's plan for AI and innovation leadership. America's AI Action Plan was released in July 2025.

Global Affairs

POSITIVE OUTCOME ON THE ITALY PAYBACK SETTLEMENT

AdvaMed helped secure a better outcome than expected in negotiations of Italy's law on medical device industry "payback" obligations for the years 2015–2018, achieving a payback rate of 25 percent, down from the originally proposed 48 percent. Companies that overpaid are entitled to receive credits moving forward. Final payment by September 9 resolved all related legal disputes. Small and Medium-Sized Enterprises (SMEs) may apply for state-backed financing to fulfill payment. A technical working group at the Italian Ministry of Economy and Finance is expected to reconvene later this year to address reimbursement issues from 2019 to 2025 and potentially eliminate the payback policy altogether. Global Affairs will continue to monitor and assist members on this issue.

One-pager on the global leadership of the U.S. medtech industry in innovation, jobs and manufacturing. To access this, go to the fact sheet.

CLEARING LOGJAMS IN RARE-EARTH-ELEMENT EXPORT LICENSES

The Global Affairs team marked progress in resolving certain license delays for exports involving rare-earth elements for medtech, following advocacy with senior U.S. government officials. Although some member companies have begun receiving approvals, concerns remain due to the ongoing U.S.-China trade tensions. AdvaMed will continue to press for improvements.

OPENING OF JAPAN'S PMDA OFFICE IN DC

AdvaMed worked with the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan to support the opening of its Washington, D.C., office. Industry stakeholders from both the medtech and pharmaceutical sectors attended. AdvaMed welcomed the proximity of the new office to our own headquarters and looks forward to ongoing productive engagement as a result.

Global Affairs

PROGRESS ON U.S.-U.K. REGULATORY RELIANCE

This quarter, AdvaMed submitted a technical response to the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom. In large part due to AdvaMed's advocacy and partnership with the FDA over the last several years, MHRA has recently signaled greater receptivity toward the use of a regulatory reliance model that would include reliance on FDA approvals and clearances. In its submission, AdvaMed emphasized the importance of regulatory reliance, advocating for MHRA to accept U.S. Food and Drug Administration (FDA) medical device approvals and clearances. The submission was developed in coordination with the Association of British HealthTech Industries (ABHI).

STRONG PUSH MADE ON COMMERCE DEPARTMENT'S "50 PERCENT RULE"

Global Affairs, in collaboration with AdvaMed's legal team and an outside law firm, hosted a briefing for member companies on a proposed rule from the Bureau of Industry and Security (BIS) at the U.S. Department of Commerce. The "50 Percent Rule" would require export licenses for subsidiaries that are 50 percent or more owned by companies on the Entity List or classified as Military End Users, significantly increasing licensing requirements and compliance obligations. Follow up included gathering member feedback on advocacy strategies such as requesting a license exception, a general license, and official Frequently Asked Questions (FAQ) clarifications. More to come on this important initiative.

Legal

AdvaMed's Ida Nassar and Pat Fogarty presenting the revised AdvaMed Code of Ethics at the 2025 Compliance Bootcamp in Washington, D.C., on September 17.

DEREGULATION AND EXECUTIVE ORDERS

AdvaMed is leveraging the Trump Administration's deregulatory executive orders to provide a platform for the medtech industry to identify regulatory barriers that hinder innovation and/or patient care and to advance regulatory relief from outdated, redundant and other regulations and processes detrimental to innovation and patient access. We submitted member-driven comments to multiple agencies, including CMS (June 10), HHS (July 14), DOJ (September 15), and OSTP (due December 12). Across these, we focused on modernizing Anti-Kickback Statute safe harbors, eliminating unnecessary Open Payments reporting, reducing duplicative credentialing requirements, and advancing supply chain and national security priorities.

LITIGATION REFORM AND TRANSPARENCY

The Utah sterilization liability protection language has been implemented with resounding success, establishing a robust legal framework that shields industry from undue litigation risks associated with sterilizing medtech. As a result, we have a strategic opportunity to leverage this success and pursue expansion into additional states where similar protections are both needed and politically feasible. The Legal Committee has designed a two-year strategic plan to expand the sterilization liability protection legislation to additional states.

Legal

The Legal team signed onto a coalition letter in support of the Tackling Predatory Litigation Funding Act (S. 1821/H.R. 3512). The letter is part of larger advocacy efforts to close the current loophole that allows U.S. and foreign litigation funders to pay the capital-gains or other tax-advantaged rate — or no U.S. tax at all — on litigation payouts.

The Legal team also continued its industry-leading litigation advertising monitoring through its Medical Device Litigation TV Advertising Report, which revealed a 61 percent decline in ad volume and a 71 percent reduction in spending since Q1.

STRATEGIC LITIGATION ENGAGEMENTS

AdvaMed filed amicus briefs to protect medtech innovation and prevent harmful legal precedents. In U.S. ex rel. Penelow v. Janssen, we cautioned against expansive False Claims Act liability theories that threaten innovation. In Langer v. Zimmer Biomet, we defended the lawful use of independent sales agents under the Anti-Kickback Statute, emphasizing their importance in expanding patient access.

ETHICS AND COMPLIANCE UPDATES

The Board Ethics and Health Care Compliance Committee unanimously approved updates to the AdvaMed Code of Ethics, including a new section on digital health, with final approval secured in October and an effective date of November 1, 2025. AdvaMed also hosted its MedTech Compliance Bootcamp in September, drawing 65 participants for practical compliance training. Globally, Ida Nassar represented AdvaMed at the APEC Business Ethics for SMEs Forum in Seoul, galvanizing regional stakeholders around high-standard integrity codes and fair competition.

MEDICAL EDUCATION GUIDANCE

In August, AdvaMed convened the Medical Education Guidance Document Working Group to update outreach materials for health care professionals (HCPs), HCP organizations, and other stakeholders on the principles of the AdvaMed Code. More than 30 companies participated in a robust discussion that helped shape priority compliance areas. Working with outside counsel, we are finalizing draft guidance for working group review. This initiative supports the Board Ethics Committee's priority of strengthening relationships with HCPs and ensuring effective implementation of the Code.

AdvaMed Accel

Justin Klein, of Vensana Capital; Don Bobo, of Edwards Lifesciences; Amanda Walsh, of AdvaMed; Juliana Elstad, of NuVibe; and Lishan Aklog, of PAVmed Inc., after meeting on the importance of the Ensuring Patient Access to Critical Breakthrough Products Act for small and emerging medtech companies with U.S. Senator Alex Padilla (D-CA).

TAX POLICY VICTORIES IN THE "ONE BIG, BEAUTIFUL BILL ACT"

During this quarter, AdvaMed Accel helped secure a series of landmark policy wins that will significantly benefit early-stage medtech innovators. The One Big, Beautiful Bill Act delivered permanent restoration of research and development (R&D) expensing with retroactive treatment for small companies under $31 million in gross receipts — savings that will help Accel members stay in business and continue innovating. The measure also expanded the Qualified Small Business Stock (QSBS) tax incentive, permanently restored full expensing of new capital investments, and reinstated net interest deductibility.

AdvaMed Accel

SBIR/STTR REAUTHORIZATION LAPSES—FOR NOW

AdvaMed advocated for the reauthorization of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These programs represent a critical source of early-stage research funding, helping small companies to scientifically validate new technologies and secure additional venture funding. At the end of the fiscal year, the U.S. Senate failed to pass H.R. 5100, a bipartisan bill that would have provided a one-year, clean extension and the opportunity for further negotiations to ensure the integrity and continuity of these programs. Throughout the quarter, Accel engaged with congressional committees, hosted policy briefings, and supported Capitol Hill events to underscore the importance of these programs to medical technology innovation. With the lapse in congressional authorization, Accel will redouble our efforts to reinstate this vital source of early-stage capital. SBIR/STTR grants and contracts enable small companies to advance the design and development of new products and generate initial clinical data, which is essential to attract follow-on funding from private capital. A lapse of these programs threatens innovation in medtech and many other sectors of the economy.

FOCUS ON WOMEN'S HEALTH

Accel advanced its leadership role in women's health innovation by being selected to join the Milken Institute's Women's Health Network in September. Through this collaboration, AdvaMed will work alongside a diverse group of external stakeholders to address research, funding, and product development challenges in women's health technologies. Accel's participation builds on the release of its earlier white paper on women's health innovation.

Medical Imaging

Advamed's Janet Trunzo (front, center) and AdvaMed Imaging led the DITTA delegation to the International Medical Device Regulators Forum (IMDRF) meeting in Sapporo, Japan.

HEALTH TECH INVESTMENT ACT (HTIA) MOVES FORWARD

The Imaging division has recruited U.S. Rep. John Joyce (R-PA) as the lead for a House version of HTIA, and the congressman has publicly committed to introducing the bill. This legislation would establish a stable reimbursement pathway for FDA-authorized medical technologies that rely on artificial intelligence (AI) and machine learning (ML), also known as Algorithm-Based Healthcare Services (ABHS).

PROTECTING INNOVATION: RIGHT TO REPAIR

The division continues working with Congress to get important updates made to right to repair policy under consideration for the FY 2026 National Defense Authorization Act (NDAA) to mitigate unintended consequences for medical devices. The division also continued working with state legislatures to ensure medical devices are exempt from similar bills. These wins protect patient safety and preserve industry safeguards around device integrity.

Medical Imaging

MEMBER ENGAGEMENT AND BOARD DEVELOPMENT

Q3 featured robust member engagement and governance development. AdvaMed Imaging welcomed new member companies and held orientations for incoming Imaging Board of Directors members. The division also convened its Leadership Forum, bringing together board committee and division and issue working group leaders to review priorities and strengthen alignment. Highlights from the AdvaMed Imaging Leadership Forum included discussions on standards development and our advocacy efforts around digital health, service quality, and patient access. The board is focused on a strategic planning process for 2026-2027 surrounding our advocacy agenda. Imaging leaders were encouraged to attend the MedTech Conference and RSNA 2025.

GLOBAL IMAGING ENGAGEMENT

The division highlighted imaging priorities during the FDA's MDUFA VI public meeting and led member discussions with the Center for Devices and Radiological Health's (CDRH) global team on regulatory harmonization in the UK, Brazil, Switzerland, and the E.U.

Additional global engagement included submitting joint comments — alongside MedTech Europe and MECOMED — on the draft Continental African Union Reliance Framework. This document would be used by African Union members to shape their medtech regulatory systems.

AdvaMed Imaging led the DITTA delegation to the International Medical Device Regulators Forum (IMDRF) meeting in Sapporo, Japan. This included a bilateral meeting with the Management Committee of the IMDRF on regulatory topics of importance to members. Several AdvaMed Imaging members were in attendance. The IMDRF collaborates on documents that may become medtech regulations in jurisdictions worldwide.

BUILDING STRATEGIC PARTNERSHIPS

The division participated in the RSNA Corporate Relations Meeting in Chicago, engaging with companies including GE HealthCare, Siemens Healthineers, Canon, Philips, Samsung, and others. Discussions centered on future collaboration around AI, workforce, and geopolitical trends, further elevating the visibility of medical imaging within the broader health care innovation ecosystem. The RSNA Corporate Relations meeting is an annual meeting that brings together RSNA radiology leadership and industry leaders to discuss priorities and ways to collaborate in the future.

AdvaMedDx

AdvaMedDx Executive Director Zach Rothstein and AdvaMed's Tara Burke (Payment team), Kristina Shultz (Dx), Jamie Wolszon (Technology and Regulatory Affairs), and Kim Zimmerman (Federal Affairs) leading an interactive town hall discussion at The MedTech Conference on in vitro diagnostics (IVD) and the industry's most pressing policy and advocacy issues.

SECURED REIMBURSEMENT RATES FOR NEUROBIOMARKER TESTS

AdvaMedDx secured near-recommended Medicare Administrative Contractor (MAC) reimbursement rates for neurobiomarker tests ($116 – $129) following CMS's initial proposal of just $17. This achievement — driven through strategic engagement with CMS, Congress, and our alliance of patient advocacy groups — will enable patient access to Alzheimer's biomarker testing beginning January 2026.

APPROPRIATIONS LANGUAGE ADVANCES GLOBAL DIAGNOSTICS DEVELOPMENT

AdvaMedDx successfully secured U.S. House of Representatives Appropriations Committee report language directing funds under global health security programs toward the development of diagnostics for pathogens of pandemic potential. This marks a major recognition of diagnostics as a cornerstone of pandemic preparedness and global health security, reinforcing our leadership role in advocating for the integration of testing in public health strategy. As the bill makes its way through the House, and eventually the Senate, we will continue our work to secure funding for diagnostics through these programs.

AdvaMedDx

KEY LEGISLATIVE ACCOMPLISHMENTS

AdvaMedDx continued advancing its federal legislative agenda. The Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act was introduced, representing the latest effort to reform the Protecting Access to Medicare Act (PAMA) and protect patients' access to innovative diagnostics.

Additionally, we gained traction on our standalone technology-certification bill, with U.S. Senator Cassidy, chair of the Senate Health Committee, reaffirming his commitment to serve as the lead sponsor while FDA technical assistance is under review. Our advocacy also continues around point-of-care and CLIA waiver reforms, ensuring policymakers recognize the need for modernized regulatory pathways.

GLOBAL LEADERSHIP

AdvaMedDx reinforced its global role by formally joining the WHO Diagnostics Coalition, a new WHO-led initiative to continue implementation of the organization's 2023 Diagnostics Resolution. Our participation ensures that member company priorities are reflected in the WHO's efforts, particularly as the WHO lacks formal input from U.S. government officials.

Public Affairs

MEDTECH DRIVES THE MAKE AMERICA HEALTHY AGAIN AGENDA

AdvaMed Public Affairs launched a campaign built around a clear message: Medtech is the backbone of American health care and therefore essential to the Administration's Make America Health Again initiative.

The campaign kicked off with our CEO Scott Whitaker's op-ed in The Washington Times, along with targeted digital ads and a new landing page at advamed.org/medtechsaves/, featuring industry-wide data, facts, and messaging tools that members and policymakers can use to highlight the critical role of medtech in making Americans healthy again.

The Washington Times

AdvaMed

Medtech is vital to a healthier America

Scott Whitaker
July 29, 2025

America's chronic disease epidemic is rightly getting attention at the highest levels of our government. The Trump administration's "Make America Healthy Again" initiative is multi-faceted and spans the full spectrum of healthy living, and we commend this critical effort. From almost every angle, medical technology is the foundation of making and keeping Americans healthy and it always has been.

U.S. Health and Human Services Secretary Robert F. Kennedy Jr. recently illustrated this point with his vision that all Americans will have a health-and-fitness indicator a "wearable" within the next four years. It is a bold vision, and medical technology, or medtech, is already leading to achieve it.

Putting patients in the driver's seat with clear, instant, actionable information on their own vital signs? That's game-changing and lifesaving. I've seen this firsthand with our daughter who has Type 1 diabetes and has gone from requiring multiple painful finger sticks and insulin injections every day to wearing a continuous glucose monitor (CGM) with integrated insulin dispensing and alerts on her and her parents' phones of anything amiss.

From firsthand experience, the health benefits, convenience, cost-effectiveness and incalculable peace of mind of wearable medtech are remarkable.

Americans can now buy FDA-cleared CGMs over the counter to track their blood glucose levels and help them make necessary lifestyle changes to improve their metabolic health, all without the need for a prescription medication.

Wearables are proliferating across the range medical needs: A T-shirt with sensors that provide heart rate, breathing rate, and other data, with real-time AI analytics sent to a patient's doctor; a patch to monitor breathing in chronic obstructive pulmonary disease and asthma patients, alerting their care teams in real time of any concerns; and lightweight wearables, to treat chronic vertigo, warn of epileptic seizures, diagnose postpartum hemorrhaging, control essential tremors, and much more.

As impressive as that is, wearables are only a sliver of the medtech that serves as the backbone of patient care in America.

Consider these real-life examples: A heart transplant performed via surgical robot with minimal incisions, no chest opening or breastbone breaking necessary; a prostate cancer surgery performed robotically, with the patient and doctor 7,000 miles apart; catheters to correct an irregular heartbeat in a minimally invasive procedure that only recently would have required open-heart surgery; a blood test to diagnose Alzheimer's disease; a smart mat used at home for 20 seconds daily to help diabetic veterans avoid leg amputations; a focused ultrasound to destroy cancer cells without chemotherapy; sound waves to liquefy liver cancer tumors; bone regeneration; a pacemaker smaller than a grain of rice; diagnostic imaging powered by AI, producing accurate results in minutes rather than days or weeks; technologies that deliver accurate, detailed mammogram results in under an hour. And so much more.

AdvaMed.org AdvaMed @AdvaMedUpdate AdvaMed

Scott Whitaker's op-ed, "Medtech is vital to a healthier America," published in The Washington Times.

To ensure the message reached key decision makers, AdvaMed Public Affairs partnered with Applecart to deliver targeted messages directly to senior Administration officials across social and digital channels.

Subsequent phases of the campaign continued with ongoing social media amplification. In just two months, AdvaMed published more than 60 MAHA-focused posts across all major platforms, bringing more than 1,820 new policymakers, health leaders, and media influencers into our audience and generating 200,000 targeted impressions. Each interaction helped to reinforce the central message: Medtech is a key part of the solution in making Americans healthy again and always has been.

ADDING RESEARCHED CONTENT TO TARIFFS DELIBERATIONS

This quarter, Public Affairs worked closely with the Government Affairs team to promote the advancement of the Ensuring Patient Access to Critical Breakthrough Products Act in the U.S. House Ways and Means and Energy and Commerce committees, using targeted news releases and social media to spotlight industry priorities.

Public Affairs

To maximize impact, we also provided social media toolkits to Alliance partners and member companies, ensuring the medtech industry spoke with one voice. This helped amplify members' priorities, strengthen our influence with policymakers, and explain the value of increasing patient access to breakthrough innovations.

ADDING RESEARCHED CONTENT TO TARIFFS DELIBERATIONS

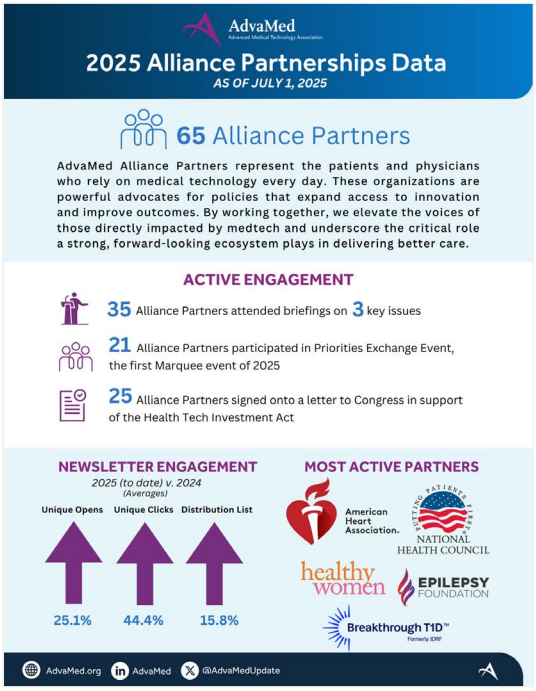
Public Affairs worked closely across teams to support the industry's response to the U.S. Department of Commerce Section 232 investigation of medtech imports as a national security concern. For example, the team compiled a running tally of U.S. medtech investments announced in 2025 alone and helped create a map plotting the impressive investment dollar amounts across the United States.

Earlier in the quarter, PA also supported the development of a new advocacy strategy focused on the impact of any increased costs of medtech resulting from tariffs on already struggling rural hospitals and the millions of patients they serve.

Alliance Partnerships

BREAKTHROUGH ADVOCACY

AdvaMed organized and led a coalition sign-on letter urging CMS to issue a rule expanding Medicare coverage of breakthrough technologies. This letter was signed by 67 organizations — the most on this topic to date — including patient organizations like the Alzheimer's Association, American Cancer Society-Cancer Action Network, American Diabetes Association, Breakthrough T1D, and the National Health Council. The letter was also signed by more than two dozen members of the State Medical Technology Alliance (SMTA).



The mid-year progress report for Alliance Partnerships.

LEADING THE WAY

SMTA Chair Kelvyn Cullimore worked closely with AdvaMed staff to draft and secure publication of an op-ed in the Utah Deseret News in support of the sign-on letter to CMS. This publication came shortly after congressional hearings on related legislation, further bolstering AdvaMed's message and providing another vehicle for amplifying the positive impact of our industry and this legislation.

GROWING OUR IMPACT

AdvaMed continues to develop and grow its relationships with patient organizations and physician societies. Our mid-year update indicates both an increase in total partner numbers, as well as interest in our offerings — including increased readership of our Alliance Partnership-focused newsletter and attendance at policy briefings.

State Affairs

AdvaMed's Geeta Pamidimukkala presenting on "Demystifying AI in Medical Devices" at the 2025 NCSL Legislative Summit in Boston. Five AdvaMed member companies – Johnson & Johnson MedTech, Medtronic, Philips, Stryker, and Zoll – featured medtech at the conference.

ADVAMED SHOWCASES MEDTECH AT LARGEST STATE LEGISLATOR EVENT

In early August, the largest annual gathering of state policymakers and staff — the National Conference of State Legislatures Legislative Summit — took place in Boston, and they were greeted by a showcase of medical technology. AdvaMed partnered with five member companies to enable conference attendees to feel and experience the latest in innovative medical technology. AdvaMed also hosted a "Learning Hub" presentation to educate state policymakers on FDA regulation of AI in medtech and the potential consequences of unnecessary state regulation of the same.

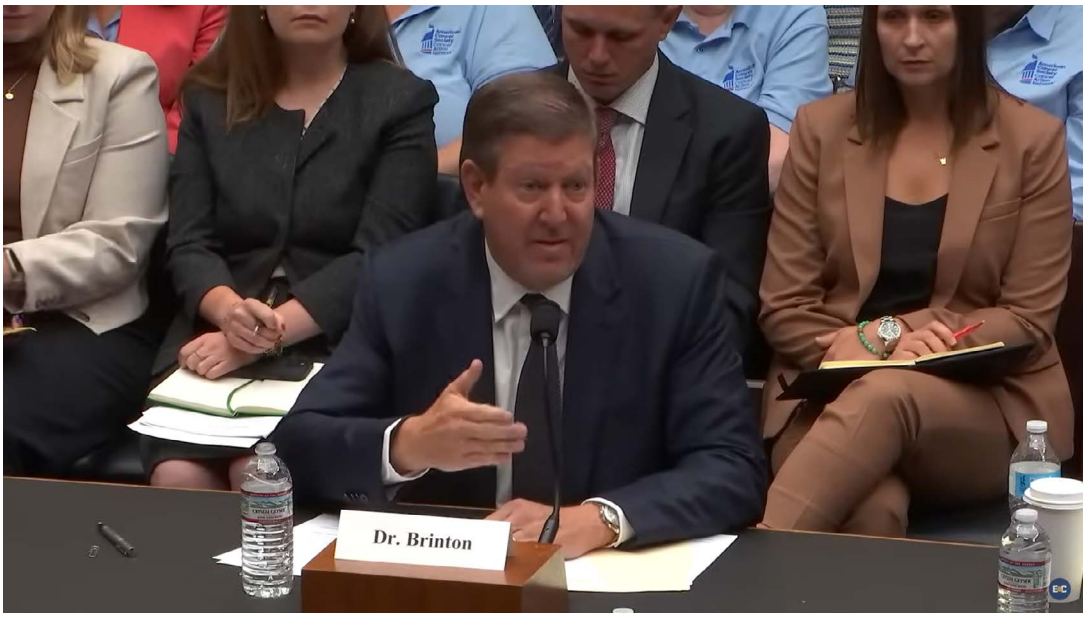
A WIN FOR PATIENTS IN BIG SKY COUNTRY

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.

PROTECTING PATIENT-FOCUSED A.I. IN CALIFORNA

The AdvaMed State Affairs team was also able to prevent passage of legislation impacting the use of AI in health care (including by devices) by requiring certain disclosures ahead of deployment in the Golden State. This was the third consecutive year our team has derailed consequential AI legislation in California.

Federal Government Affairs



Dr. Todd Brinton, MD, of AdvaMed member company Edwards Lifesciences, testifying during the U.S. House Committee on Energy and Commerce Health Subcommittee hearing on the Ensuring Patient Access to Critical Breakthrough Products Act.

ADVANCING MEDTECH PRIORITIES DESPITE GOVERNMENT GRIDLOCK

The past few months saw impressive movement on a longtime AdvaMed priority: Medicare coverage of breakthrough medtech the FDA has authorized as safe, effective, and ready for patients.

In the same week in September, the House Ways and Means Committee passed the Ensuring Patient Access to Critical Breakthrough Products Act, H.R. 5343, on an overwhelming 38 to 3 vote. The momentum continued later in the week when the House Committee on Energy and Commerce Health Subcommittee also released a discussion draft version of the legislation and held a hearing, including the signature issue as a key priority for improving seniors' health.

The subcommittee hearing featured testimony from AdvaMed member Dr. Todd Brinton, MD, of Edwards Lifesciences, who shared the story of a patient who experienced a "complete quality-of-life transformation" after receiving an FDA-designated breakthrough heart valve treatment.

Federal Government Affairs

The House action follows the Senate version of the bill, S. 1717, introduced earlier this year. With bipartisan, bicameral support for breakthrough medtech coverage in Congress, and support of the concept in the executive branch from FDA Commissioner Makary and CMS Administrator Oz, AdvaMed is optimistic about moving the proposal over the finish line as early as this year. Even if the Congress remains gridlocked on other distractions, Federal Affairs will continue to leverage the legislative process to keep the pressure on the Administration to act as soon as possible to speed this enhanced access for beneficiaries.

ENGAGING THE HIGHEST OFFICE IN THE ADMINISTRATION ON TARIFFS

Tariff relief remained a top priority in Q3. The team maintained ongoing conversations with the White House, National Economic Council (NEC), the Departments of Commerce and Treasury, and USTR's lead negotiators to press for medtech inclusion in U.S.-EU trade negotiations. Throughout the quarter, Scott Whitaker and other medtech champions close to the President spoke directly with senior administration officials, including calls from medtech champions with the President and NEC Director Kevin Hassett, to advocate for tariff relief. Federal Affairs is currently working with the President's scheduling team on a meeting in the West Wing to continue the conversation and make our case directly to the President on the need for relief.

ENGAGING ON INTERNATIONAL TRADE AND REIMBURSEMENT

Federal Affairs worked with House Ways and Means Trade Subcommittee leaders Adrian Smith (R-Neb.) and Brad Schneider (D-Ill.) to co-lead our biannual letter to the Japanese Ambassador on medtech reimbursement. AdvaMed continues to work with the Senate to draft a similar letter with the Senate Finance Trade Subcommittee. The letter highlights that U.S. medtech manufacturers provide a large percentage of Japan's medical devices and shows how continued lower reimbursement could impact patient care. AdvaMed has been a champion on this issue and led the efforts with Congress for many cycles of reimbursement over the past decade. Without AdvaMed's efforts, we would expect deeper cuts on our members' products in Japan. The letter formalizes the industry's intentions and serves as a great vehicle to enact a more favorable reimbursement environment for members in Japan.

Payment

AdvaMed's Tara Burke leading a session on the CMS Transitional Coverage for Emerging Technologies (TCET) pathway for FDA-authorized breakthrough medtech at The MedTtech Conference, alongside panelists Steven Farmer, MD, Arthi Chandran, Christine Song, Christopher Brooks and Lindsay Bocksted.

PROGRESS ON CODING ADVOCACY, PRODUCING LASTING CHANGES FOR MEDTECH

This quarter, the Payment team continued its leadership in payment and coding debates, particularly around the American Medical Association's (AMA) discussion of a proposed new code set on "Clinically Meaningful Algorithmic Analyses" (CMAA). This proposal, if adopted as originally proposed, could significantly reshape reimbursement for digital health and AI technologies. Through the team's work with the AMA Digital Medicine Coding Committee, AdvaMed secured rapid access to the draft proposal, convened stakeholders, and coordinated member company feedback. Importantly, AdvaMed successfully persuaded AMA CPT leadership to designate the CMAA proposal as "For Discussion Only," as opposed to a code change application that is voted upon during the meeting, at the September Editorial Panel meeting, giving members additional time to assess the proposal's impact prior to any vote on the proposal.

Payment

CMS COVERAGE PATHWAY IMPROVEMENTS

AdvaMed built on longstanding efforts to improve CMS coverage pathways, with continued advocacy for accelerated coverage for breakthrough technologies and improvements to the National Coverage Determination process. AdvaMed met with senior leaders, including Chief Operating Officer Kim Brandt and CMS Principal Deputy Director Alec Aramanda, to advance AdvaMed's recommendations for more transparent, predictable coverage.

The team also engaged directly with CMS's Coverage and Analysis Group leadership on reforms to the MCIT/TCET program and submitted proposals to streamline National Coverage Analysis reconsideration requests. AdvaMed also filed detailed comments on three major proposed rules: DMEPOS Competitive Bidding, Hospital Outpatient Payment, and Physician Payment.

ALZHEIMER'S NEUROBIOMARKER TEST REIMBURSEMENT WIN

AdvaMed secured a major win for patient access with CMS's release of final MAC payment determinations for Alzheimer's neurobiomarker testing. CMS raised its reimbursement rates from an initial proposal of $17 per test to between $116 and $128 per test, just below AdvaMed's recommended $130 rate. This outcome, effective January 1, 2026, represents a sustainable reimbursement level that will support expanded patient access to Alzheimer's diagnostics.

EXPANDING COVERAGE FOR DIGITAL MENTAL HEALTH TREATMENT

AdvaMed's advocacy helped secure expanded coverage for Digital Mental Health Treatment (DMHT) technologies, including ADHD treatment, in the CY 2026 Physician Fee Schedule proposed rule. CMS also issued a Request for Information on "Software as a Service" payment pathways across the Hospital Outpatient Prospective Payment System and Physician Fee Schedule proposed rules — language closely aligned with AdvaMed's recommendations in prior comment letters. On Capitol Hill, the U.S. House prepared to introduce a companion bill to the Senate's Health Tech Investment Act, which would create a dedicated Medicare reimbursement pathway for FDA-authorized AI- and ML-enabled devices.

CMS'S PROPOSAL TO RESTART THE DME COMPETITIVE BIDDING PROGRAM

On June 30, 2025, CMS released its Calendar Year (2026) Home Health Prospective Payment System and DME Competitive Bidding Proposed Rule. This proposed rule, expected to be finalized by November 1, contained several proposals impacting medical devices, including a proposed expansion of the scope of the program to include tracheostomy, urology and ostomy supplies, moving CGMs and insulin infusion pumps to the frequent and substantial services payment category, and restructuring the bidding methodology to further reduce pricing and the number of supplier contracts awarded. AdvaMed submitted extensive comments on the proposed rule and is scheduling meetings with CMS staff to discuss industry concerns with its proposals.

Conferences, Events, & Marketing

Scott Whitaker of AdvaMed and Arnold Schwarzenegger and Ivan Tornos of Zimmer Biomet at their keynote remarks on the importance of movement in maintaining good health and mobility.

BIGGEST U.S. MEDTECH CONFERENCE EVER

AdvaMed's largest and most successful MedTech Conference in the United States took place in San Diego, setting new records for member and sponsor participation. Hosted under the theme "Medtech Redefines the Future of Health Care," the conference convened thousands of leaders, innovators, and policymakers to chart the industry's path forward. The goal was clear: to gather the global medtech community for critical dialogue, timely insights, and meaningful connections that advance patient care and strengthen our sector. The event also served as a milestone moment to celebrate AdvaMed's 50th anniversary, honoring five decades of industry leadership and innovation.

Conferences, Events, & Marketing

Abbott Senior Vice President and Group President—Medical Devices, Lisa Earnhardt (third from left, front row) with fellow panelists Philip Oettinger of Wilson Sonsini Goodrich & Rosati, AdvaMed's FDA policy lead Janet Trunzo, and Josh Makower of Stanford's Mussallem Center for Biodesign at our Wilson Sonsini-hosted event held in Palo Alto.

CONFERENCE STRATEGY AND PARTNERSHIPS

AdvaMed's marketing and acquisition strategies — ranging from targeted regional campaigns to global digital outreach — helped drive record engagement, new audiences, and stronger conversion across member and non-member segments. These efforts supported the team's strategic sponsorship strategy, fueling the highest-ever sponsor participation and the largest exhibit hall in conference history, underscoring the event's growing influence across the medtech ecosystem. With the additional support of top sponsors — including Abbott, BD, Dexcom, Johnson & Johnson MedTech, Medtronic, Solventum, and Zimmer Biomet — the conference cemented its position as the premier destination for collaboration among medtech leaders, innovators, and policymakers.

The path to success was built on coordination with a wide network of partners, including leadership from the Steering Committee, Program Committee, Host Committee, and Local Committee; regional partners such as Biocom California and California Life Sciences; and dozens of committed media partners who elevated visibility across the industry. This collective effort was reinforced by the California CEO Road Show, engaging with 300 CEOs and connecting more than 160 executives across San Diego, Orange County, Los Angeles, and Palo Alto. Hosted by leading medtech CEOs and regional company partners, these events built excitement for San Diego, strengthened relationships with senior leadership, and underscored the importance of connecting at both the national and local levels.

Conferences, Events, & Marketing

CONFERENCE OUTCOMES

The 2025 conference welcomed 3,700-plus participants from 38 countries and 44 U.S. states, with diverse titles representing the full breadth of the medtech ecosystem — from CEOs and C-Suite leaders to policy, regulatory, and innovation teams. Nearly half of attendees were senior executives, underscoring the quality of engagement. Expanded programming in the Medtech Campus, including new features such as the start-up pitch competition and enhanced networking opportunities, created more ways for participants to connect, share insights, and showcase innovation. With record member participation and strong delegations from the largest medtech companies to early-stage innovators, the conference reinforced AdvaMed's role as the industry's convener and voice. The outcomes were clear: strengthened partnerships, deeper cross-border collaboration, and momentum that will carry forward into the policy, innovation, and growth priorities of our members in the year ahead.

ADVANCING COMPLIANCE AND EDUCATION

In September, we successfully hosted our annual Compliance Workshop at AdvaMed headquarters, drawing record participation. The event delivered timely, high-value programming and highlighted the association's role in providing trusted compliance education for our members.