
AdvaMed
The Medtech Association
ANNUAL
REPORT
2025 Year in Review

A Note from Our President and CEO

Dear AdvaMed Member,

I am pleased to share AdvaMed's 2025 Annual Report and reflect on a pivotal year for our association and our industry.

Despite an unprecedented policy environment, marked by executive action and congressional gridlock, AdvaMed once again demonstrated that effective advocacy delivers results. When FDA workforce reductions threatened timely device review, we acted swiftly to help secure the rehiring of critical experts and protect patient access to innovation. We also led a sustained, high level effort on tariffs, making clear that trade barriers on medical technologies risk patient care and U.S. leadership in medtech. That work helped set an important precedent, with medtech tariff relief included in the U.S.-U.K. agreement.

2025 was also a landmark year for digital health and AI. With the release of AdvaMed's AI Policy Roadmap, we ensured medtech innovators had a seat at the table as policymakers shape the future of AI enabled care, while our advocacy supported meaningful progress on Medicare payment for digital therapeutics.

Globally, we advanced market access, strengthened supply chains, and navigated an increasingly complex trade environment. We also entered MDUFA negotiations from a position of strength and continued to lead on global regulatory harmonization.

Finally, 2025 also marked a defining moment for AdvaMed as the convener of the medtech world: At our most successful MedTech Conference to date, welcoming more than 3,700 participants from 38 countries, we celebrated our 50th anniversary—honoring five decades as your advocacy organization, all while looking ahead with energy and excitement toward the next fifty years.

The state of medtech is strong, not only because of the policy wins we achieved together, but because of the relentless pace of innovation happening every day within your companies. Together, we are shaping the future of health care—making it smarter, more personalized, more accessible, and more effective for patients everywhere.

Thank you for your leadership, your innovation, and your partnership with AdvaMed.

Sincerely,

Scott Whitaker

About AdvaMed

AdvaMed, the Medtech Association, is the world's largest trade organization representing medtech innovators. Our member companies develop, manufacture, and distribute the medical technologies (devices, equipment, diagnostic tests, and imaging) that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Based in Washington, D.C., AdvaMed has nearly 650 member companies that operate in all 50 states in the U.S. and around the world.

Our divisions are AdvaMedDx, for diagnostics companies; Accel, for emerging and early-stage companies; Digital Health Tech, which represents traditional medtech companies in the digital space, as well as non-medtech companies venturing into the digital health space (for example, wearables); and Medical Imaging.

AdvaMed member companies serve the entire health care ecosystem, from general medicine to every medical field and specialty: orthopedics, diabetes, cardiology, oncology, maternal health, neurology, ophthalmology, urology, gastroenterology, and much more.

Our organization advocates for policies that improve patient access to safe, effective, lifesaving, and life-enhancing medtech, so that our member companies can focus on what they do best: innovating. Our advocacy unfolds in the halls of the U.S. Congress, federal agencies, the White House, in every state legislature, and over the border and overseas as well.

AdvaMed is led by a board of directors from companies large and small and everything in between. Each division mentioned above is led by a board as well. Our stellar team leads dozens of working groups on specialized topics, driven both by perennial member needs (such as our working groups on regulatory policy and payment/coverage policy), and more urgent and unexpected needs (such as when Covid hit and when EPA proposed an update to the regulation governing the ethylene oxide sterilization process). Company representatives work directly with our expert staff to convey the impact of policy on their companies and the patients they serve, so that we can effectively relay those policy priorities to policymakers and regulators at every level of government. Together, we push for policies that promote access to medtech to every patient in need.

OUR FIELD

The United States is the largest incubator for medtech—the clear leader of a global industry. It is also a uniquely American success story: U.S.-made medical technologies supply around 70 percent of the U.S. medtech market, with 95 percent of medtech R&D by U.S. companies happening right here at home.

All 50 states have a medtech presence—from multinational corporations to the vast majority of medtech companies which are startups (94 percent) with fewer than 20 employees (82 percent). All play a critical role, from creating new technology to diagnose cancer and manage diabetes to supplying heart valves, knee replacements, and complex scanners to detect disease or injury.

About AdvaMed

Medtech is responsible for 3 million direct and indirect jobs nationwide. Medtech manufacturing jobs pay 49 percent more than any other industry and 18 percent more than other manufacturing jobs. Since the repeal in 2019 of the medical device tax, which hovered over the industry for years and threatened job growth, jobs in medtech have grown at three times the rate of other manufacturing jobs across the country. Medtech is a leading American industry in more ways than one!

OUR IMPACT

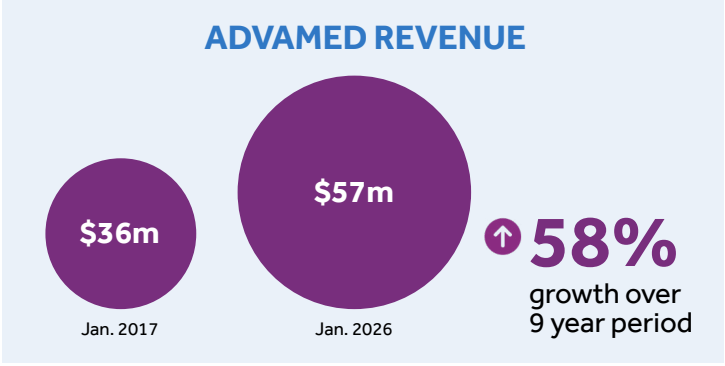
- Our innovations help patients worldwide live longer, healthier, and more productive lives.
- We improve the efficiency of health care systems through earlier disease detection and more effective treatments that reduce the economic burden of disease and the cost of care.
- We drive economic growth by creating high-paying manufacturing jobs in the United States and through net exports to other countries around the world.
- The market for our products is highly competitive, which helps keep our prices low. Millions of patients' lives are improved every day because of advancements in medtech.
- Fatalities from heart disease and stroke have been reduced by 49 percent since 1990.
- Fatalities from breast cancer have been reduced by almost a third since 1980.
- Improved screening technology has helped reduce:
  - breast cancer fatalities by 43 percent since their peak in 1989
  - prostate cancer fatalities by 53 percent since 1993
  - fatalities from cancer overall by 32 percent since 1990
- The duration of hospital stays has been reduced by 38 percent since 1980, from an average of 10 days to 6.2.
- Medical technology has helped increase life expectancy by five years in the last 30 years.
- Medical technologies and devices represent only a fraction of overall health care spending in the United States, at 5.2 percent in 2019.

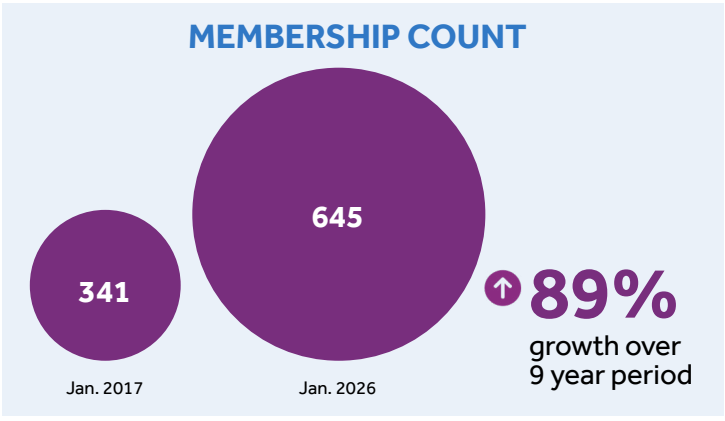
For more, please see advamed.org/medical-device-industry-facts/ or scan this code.

Association Financials

AdvaMed continues to experience strong growth in both our membership and financial position, driven by our expansions of the Digital Health Tech, Medical Imaging, and Accel divisions, and the issue sets, and our success and continued progress on them, that drive value for these members and the industry at large.

Increased revenues ensure the amplification of medtech's voice in the states and Washington, D.C., championing improved payment pathways, improvements to the regulatory process our companies face, and the life-saving nature of our industry to policymakers in Congress and the Administration.





This momentum ensures we continue to lead in shaping policies that advance innovation and patient care.

Since 2017, AdvaMed has grown from a $36 million trade association to a $57 million trade association, with average, steady growth of 10 percent each year since 2020. The growth in funding strengthens our ability to execute and succeed on our top strategic priorities on members' behalf.

Since 2017, AdvaMed has grown from 341 members to 645.

RESERVES

AdvaMed maintains $17 million in reserves, which is equivalent to 3.9 months of operating expenses. This healthy level of funding ensures AdvaMed has the financial resources available for unexpected challenges, threats, and even opportunities faced by our industry. Reserves are essential for ensuring financial stability and also provide the flexibility to invest in strategic initiatives that benefit members without relying solely on annual revenue. Maintaining strong reserves safeguards the association's ability to support our members' long-term interests and priorities.

Tariffs

AdvaMed's policy, advocacy, and public affairs work urging a tariffs exemption for medtech generated significant media coverage. Watch the video of Scott's testimony here.

FULL-COURT PRESS ON TARIFFS

Even before the President officially took office, and months before he officially announced tariffs that would impact our companies and their patients, our advocacy started in full force. Our push for a medtech exemption or any level of relief from all tariffs did not let up in 2025.

AdvaMed President and CEO Scott Whitaker, the Global Affairs team, the Federal Government Affairs team, the Alliances Development team, the Accel division for small companies and startups, the Public Affairs team—all of us guided by our Board of Directors—got to work setting strategy to advocate for the tariffs exemption and executing that strategy.

We met with the President, the President's chief of staff, other White House leaders, and key Administration officials to discuss the uniqueness of our industry.

We held dozens of meetings with every leadership office in Congress, including committees of jurisdiction and senior administration officials, to make medtech's case. We secured meetings between medtech CEOs and U.S. senators, United States Trade Representative Jamieson Greer, White House Domestic Policy Council lead Vince Haley, and other senior officials to share our concerns.

In these conversations, we emphasized the potential harm to medtech customers, including hospitals and clinics, if increased costs make purchases unsustainable; the unique nature of our highly regulated industry; and the threat to U.S. status as the global leader in medtech innovation and manufacturing if tariffs inadvertently drive that work outside the United States.

Tariffs

ENGAGING TRADING PARTNERS

As tariff announcements evolved, we remained focused on sharing data with the Administration, demonstrating how past medtech tariff exemptions were appropriate, given the pivotal role of medtech in the U.S. health care system, and continued to urge a similar approach moving forward. Similarly, we were in communication with Mexico, Canada, the European Union, and other key trading partners, such as Japan, to urge an exemption from retaliatory tariffs.

In early April, Beijing placed 125 percent retaliatory tariffs on all U.S. imports. In response, AdvaMed's global team swiftly contacted the Chinese government flagging the risks to China's health care system and requesting an exemption for medtech. Thanks to our efforts, the Chinese government in late April quietly issued a set of exclusions for a quarter of U.S. medtech exports.

U.S.-EUROPE MEDTECH PROGRESS

The global team worked with MedTech Europe to secure support for reciprocal zero-for-zero tariffs for medtech, including a proposal, coordinated public statements, and a joint meeting with EU President Von der Leyen's health advisor. MedTech Europe and BVMed signaled their initial support. The EU's pause of the retaliatory measures is important for medtech, given the EU is the most critical import and export market for U.S. medtech. The pause also provides additional time to continue advocacy to persuade the EU Commission on the reciprocal zero-for-zero concept. AdvaMed also finalized joint statements with the UK and Swiss medtech associations on the importance of a reciprocal zero-for-zero arrangement and acceptance of U.S. FDA medtech approvals in these markets.

DEVELOPMENTS ON CANADA/ONTARIO PROCUREMENT RESTRICTIONS

AdvaMed's partner association MedTech Canada secured a pathway for U.S.-headquartered companies to qualify for the exemption from the Ontario retaliatory procurement restriction for companies with fewer than 250 Canadian employees. This measure provides a pathway to mitigate the impact of the procurement restrictions, albeit requiring additional administrative steps. AdvaMed will continue to monitor any member issues with the new policy.

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.

Tariffs

U.S.-UK 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 ... medical technology from Section 232 tariffs." While the agreement is prospective relative to the Commerce Department Section 232 investigation of medtech, we continued to press for more comprehensive relief from reciprocal tariffs as well.

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.

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

In November, the White House announced the United States would 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 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 has also 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 have 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.

ADVANCING FDA WORKFORCE RESTORATION

It was no surprise when the new administration launched an effort to reduce the federal employee headcount. However, the cuts extended to many CDRH staff and managers funded by the user fee agreement between FDA and the medical device industry. Eliminating these CDRH staff, many of whom were technical and scientific experts, would have caused delays in the agency's ability to provide timely decisions on medtech submissions and compromise its ability to meet its performance commitments.

The rehiring was the result of AdvaMed's concerted effort. We sent multiple communications to administration officials with our concerns and to explain the harm ultimately to patients deprived of helpful medtech if these job cuts were not reversed. In addition, along with member companies, we had many meetings with FDA, other administration leaders, and members of Congress to make the case. We also engaged selectively and strategically—and boldly and unapologetically—with the media to paint that same picture. We left no advocacy tool unused.

MDUFA VI NEGOTIATIONS ARE ON STRONG FOOTING

AdvaMed in 2025 began 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, and nine subsequent meetings held during the remainder of 2025.

Technology & Regulatory Affairs

AdvaMed's lead negotiators Janet Trunzo, Patrick Hope, and Zach Rothstein highlighted the breadth of medtech and its role in our health care system, the progress achieved for 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, AdvaMed 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.

AdvaMed's position has been well-received by FDA Commissioner Makary, who has stated that the medical device user fee program is a model for other user fee programs.

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. 2025 also featured the kick-off meetings of the newly formed IMDRF Industry Group, which has been a longstanding AdvaMed priority and reflects collaboration of the industry and global regulators.

DEVICE STERILIZATION

In July, the EPA announced a two-year presidential waiver from the NESHAP rule requirements for commercial sterilizers, explicitly recognizing the vital role of medtech in national security and US sterile infrastructure. This compliance extension provides an additional two years for compliance for facilities working in good faith to implement the updated standards.

AdvaMed has been intensely involved in this issue for several years, filing formal comments with the EPA and holding dozens of technical meetings to educate EPA, FDA, the White House, and other parts of the prior administration, in addition to engaging hospitals, doctor organizations, and patient groups. This effort led to a challenging but workable final rule. AdvaMed has worked steadfastly to ensure patient access to life-saving sterile medical technologies and is continuing to emphasize our commitment to ensuring the sterilization process remains safe for facility employees and communities.

Digital Health Tech

The AI Policy Roadmap provides a comprehensive look at the regulatory landscape, outlining key policy recommendations for Congress to ensure transformative AI-enabled medtech continues to emerge and maximizes the potential to reach as many patients as possible for better health outcomes.

AI POLICY ROADMAP

While the full impact of AI on health care remains uncertain, one thing is clear: Thoughtful policy decisions will guide its evolution. In early 2025, we finalized our AI Policy Roadmap of recommendations for policymakers to lay the groundwork for progress.

These recommendations will help ensure AI in medtech advances patient care and remains accessible to all, regardless of their circumstances. We encourage those with AI-enabled technologies, or plans for them, to read the document carefully and share your thoughts with our teams. This document will help to ensure AdvaMed has a seat at the policymaking table, and we look forward to sharing it with key decision makers in Congress and the administration.

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

In addition to releasing the AI Policy Playbook publicly and educating media on its contents through a nationwide press conference, 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 were featured in the Accenture AI Leaders Podcast episode "AI in Medtech: Enabling the Future of Care."

The division also met with senior administration officials to discuss America's AI Action Plan, the Administration's plan for AI and innovation leadership.

DHT BOARD ELECTS NEW CHAIR AND ADVANCES 2026 STRATEGIC PRIORITIES

AdvaMed's Digital Health Tech 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.

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

U.S. and Japanese medtech and government leaders at the 9th Annual Ikigai Symposium in Japan.

INDIAN MARKET ACCESS

On February 13, 2025, Prime Minister Modi met with President Trump in Washington and launched the "U.S.-India COMPACT (Catalyzing Opportunities for Military Partnership, Accelerated Commerce & Technology) for the 21st Century" to drive key pillars of cooperation, including trade and investment, and the possibility of a trade deal by the end of 2025. As part of the launch of this trade initiative, we understand India will lift the prohibition on the import of refurbished medical devices and revert to its previous practice, one of our key advocacy asks.

CHINA: VOLUME-BASED PROCUREMENT

In China, we are continuing our efforts to improve the implementation of volume-based procurement. Our China office met with the National Healthcare Security Administration in Beijing to better understand its plan to review the policy's shortcomings and standardize best practices across provinces. Given the complexity of last year's national tender covering a diverse array of peripheral stents, we were successful in securing some extra time for members before needing to supply hospitals in several provinces.

CHINA: RARE EARTH ELEMENTS

In addition, the global team continued its work with member companies that have been impacted by constraints on rare earth elements (REE) as a result of China's export license regime, which the country has been using as leverage in tariff and trade negotiations with the United States. In addition to collecting data highlighting the impact of REE constraints, AdvaMed has raised this issue with senior officials at Commerce and the White House.

Global Affairs

GLOBAL MEDICAL TECHNOLOGY ALLIANCE

Global Medical Technology Alliance (GMTA) was featured on the opening panel of the World Health Organization's 5th Medical Device Forum. As co-chair of the GMTA, AdvaMed's Ashley Miller participated in the opening panel alongside the WHO's assistant director-general. Representing the industry, Ashley emphasized the sector's critical contributions to innovation, manufacturing, and global distribution. In collaboration with Medical Technology Europe (MTE), the team produced and premiered a video titled "What is Medical Technology?" during the forum's opening session. This two-day virtual event attracted more than 500 participants, including representatives from foreign governments, academia, and health care stakeholders.

INDIA QUALITY CONTROLS ORDER

AdvaMed secured an exemption for our industry on a new, worrisome Quality Control Order (QCO) for plastics that does not differentiate medical-grade plastic from other kinds. The new order and associated requirements would have made it challenging for our members to source the medical grade plastic they need in manufacturing. As a next step, we are working with USTR to resolve systemic issues with India's Quality Control Orders, including through tariff negotiations, so that our industry isn't limited to seeking exemptions.

RELIEF FROM NEW AND BURDENSOME EXPORT REQUIREMENTS IN MEXICO

As a result of expedited advocacy efforts working with partners in Mexico, including the Baja California Medical Devices Cluster, the Mexican Ministry of Economy announced a majority of the medtech products requiring Automatic Export Notices have been removed. Mexico's work with the U.S. government to ostensibly stop other countries from trans-shipping through Mexico and take unfair advantage of USMCA trade benefits created an onerous administrative system. It required companies to submit an automatic export notification for certain goods classified under 30 different Harmonized Tariff Schedule headings, which included certain medtech product categories. The measure was expected to introduce significant delays to medtech shipments by adding an additional layer of procedural complexity that could hinder cross-border movements.

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 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.

Global Affairs

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 D.C.

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.

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

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.

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.

Global Affairs

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.

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.

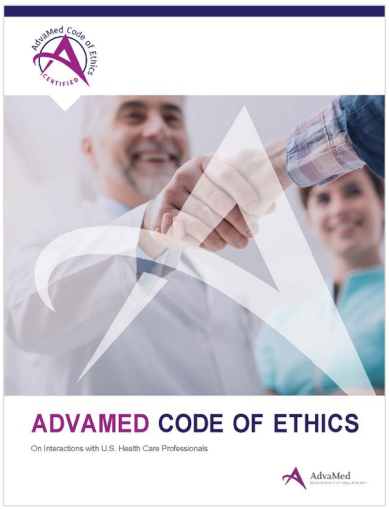
STRONG U.S. ADVOCACY PUSH ON JAPAN'S REIMBURSEMENT CYCLE

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.

Legal

ADVANCING LEGISLATION ACROSS STATES

Our coalition's success in securing the introduction of disclosure bills in 14 states is a huge win for our members and a critical step toward greater transparency and accountability in litigation. We also, in collaboration with the Washington Health Innovation Council, published a TPLF report, "A Look Beneath the Surface: The dark money and misleading tactics harming American patients." It is an in-depth look at the problem, and more importantly, what can be done to solve it.



ETO VICTORY IN COLORADO

Terumo won a complete defense verdict in an EtO case pending in Jefferson County District Court, Colorado. Four plaintiffs alleged that Terumo had negligently emitted EtO from its Lakewood, Colorado, facility, and caused them to develop cancer. These four plaintiffs were among hundreds recruited by plaintiffs' firms in the area surrounding the facility. The plaintiffs' counsel sought a jury award of $444 million, including compensatory and punitive damages. The jury returned a complete defense verdict. AdvaMed played a key role in helping to address these and other frivolous claims, including amicus brief activity.

FINAL DOJ DATA SECURITY RULE ADDS KEY ADVAMED-PROPOSED EXCLUSIONS

We obtained key carve-outs in the Jan. 8 DOJ Data Security Final Rule on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons for (1) regulatory approvals (including where de-identified sensitive data is required by the country of concern to be submitted through a local registered agent); (2) clinical investigations regulated by FDA or that support applications to the FDA; (3) post-marketing surveillance; and (4) "biospecimens" (human-derived material) in diagnostics and therapeutics (e.g., cell-based assay, plasma-derived therapeutic).

GEORGIA CONSUMER PRIVACY PROTECTION ACT LEGISLATION REVISED TO INTEGRATE ALL ADVAMED MODEL EXCLUSIONS

The original version of the bill (SB 473) lacked two AdvaMed model exemptions for (1) Information treated in the same manner as protected health information maintained by a covered entity under HIPAA and (2) limited data sets. Following a January 6 meeting and exchanges with state Senator John Albers, a new version of the bill (SB 111) was introduced on Feb. 6 that integrated all AdvaMed model exclusions.

STERILIZATION VICTORY IN UTAH

AdvaMed's legal team achieved substantial legislative and regulatory outcomes in a key state with the passage of our liability protections for the use of ethylene oxide in Utah, setting a precedent for similar efforts in other states. The measure requires plaintiffs to meet strict evidentiary standards, including willful misconduct, to be held liable for harm. 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.

Legal

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 (Sept. 15), and OSTP (due Dec. 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.

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.

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.

ADVAMED CODE UPDATES

The Board Ethics and Health Care Compliance Committee had unanimously endorsed significant updates to the AdvaMed Code of Ethics. Notably, these enhancements included the addition of a comprehensive new section dedicated to digital health, reflecting the Committee's commitment to staying ahead of industry advancements. The final approval for these revisions was secured in October, and the effective date was set for November 1, 2025, ensuring ample time for members to prepare for full implementation.

COMPLIANCE ENGAGEMENT AND MEMBER OUTREACH

In May, the Spring DDCG Meeting took place at Terumo Blood and Cell Technologies in Lakewood, Colorado. Nearly 90 attendees participated in the spring meeting, where the agenda addressed hot topics, including enforcement trends, fostering a culture of compliance amid changes in the enforcement landscape, the role of compliance, and emerging challenges industry compliance teams face.

Legal

In September, AdvaMed and PORZIO hosted their annual MedTech Compliance Bootcamp, which drew 65 participants for practical compliance training. The event offered attendees valuable insights into evolving regulatory requirements and facilitated dynamic peer discussions, strengthening industry best practices and compliance culture.

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

INTERNATIONAL COMPLIANCE ENGAGEMENT

Americas. AdvaMed continued to strengthen global compliance connections. In November, Ida delivered keynote remarks to MedTech Canada's Compliance Steering Committee, emphasized the value of regular alignment with AdvaMed, and shared best practices across jurisdictions. This engagement was part of a broader effort that leveraged AdvaMed's expertise and reinforced high-standard compliance programs globally across the industry. Additionally, the Inter-American Coalition for Business Ethics met on December 17. The meeting agenda included discussions of Codes of Ethics updates that advanced global harmonization of Codes across the Americas.

China. AdvaMed developed a three-to-five-year strategic plan to advance its advocacy and member resources related to 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 convene 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 implemented 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 provided the dedicated resources needed to advance our compliance policy objectives on the ground in China.

APEC. In late September, 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. The forum provided an opportunity for the medtech industry to engage with governments, patient and physician groups, and other healthcare stakeholders on the importance of leveling the playing field across the APEC region to ensure a fair and competitive environment and better outcomes for patients.

Accel

DeChane Dorsey, Executive Director of AdvaMed Accel, speaking at the Milken Institute's Future of Health Summit.

In 2025, AdvaMed's Accel division delivered tangible results for early stage and emerging medtech companies by helping members protect critical funding, secure meaningful financial relief, and elevate their voices with policymakers. Through sustained advocacy, targeted engagement, and close coordination with members, Accel helped companies navigate an increasingly challenging operating environment while preserving their ability to innovate, raise capital, and grow.

PROTECTING AND STRENGTHENING FEDERAL RESEARCH FUNDING

A central focus throughout the year was protecting access to federal research funding that many Accel members rely on to advance early-stage innovation. As authorization for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs approached—and ultimately lapsed—Accel worked closely with members to identify congressional champions, communicate the real-world impact of these programs, and advance strategies to support reinstatement and long-term stability. Accel also elevated member concerns related to evolving NIH foreign risk review policies, which introduced uncertainty for grant recipients and research partnerships. By translating member experiences into clear advocacy priorities, Accel helped ensure these issues remained front of mind for Congress and federal agencies.

SECURING MAJOR TAX POLICY WINS FOR EARLY STAGE COMPANIES

AdvaMed also delivered major tax policy wins for members in 2025 with the passage of the One Big, Beautiful Bill. Through sustained advocacy alongside external partners, Accel helped secure permanent restoration of R&D expensing with retroactive relief for small companies and expanded incentives for Qualified Small Business Stock. Together, these wins improved cash flow, reduced tax burdens, and provided greater certainty—helping early-stage medtech companies preserve capital and continue investing in innovation.

Accel

DEEPENING MEMBER ENGAGEMENT AND ADVOCACY

In parallel, Accel expanded high value engagement opportunities for members, delivering timely policy updates, investor focused briefings, and targeted programming aligned with member needs related to fundraising, manufacturing, and commercialization. Accel members were also well represented in advocacy fly ins and Capitol Hill showcase events, strengthening direct connections with policymakers.

LOOKING AHEAD: 2026 POLICY PRIORITIES

Looking ahead, Accel will continue to prioritize outcomes that matter most to members, including securing SBIR/STTR reinstatement and long-term stability, ensuring NIH policies are applied transparently and predictably, and defending recent tax wins. Accel will also advance work on Coverage Reform, Breakthrough legislation, capital formation, and investor access—ensuring early stage medtech companies are positioned to grow, compete, and deliver lifesaving technologies to patients.

PROTECTING PATIENT ACCESS TO APPROPRIATE CARE

AdvaMed continued to advance work to ensure that all patients have timely access to appropriate care and treatments. We continued to work with members to advocate for policy changes, including expansion of screening for breast cancer, that impact care. We were also accepted as members of the Milken Institute's Women's Health Network where we have been charged with co-leading efforts around coverage and reimbursement of women's health technologies. Throughout the year AdvaMed engaged with external stakeholders, published a white paper, drafted comments, developed MedTech Conference content, and participated in speaking engagements in support of the continued need for representatively developed technologies.

Imaging

ADVAMED IMAGING BOARD APPROVES STRATEGIC PLAN

The AdvaMed Imaging Board approved a comprehensive strategic plan centered on four priority pillars: Digital Health, Service and Remanufacturing, Patient Access to Care, and Standards Development. Together, 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 through robust technical standards. The Strategic Priorities seek to:

AdvaMed's Peter Weems, Vice President of Imaging Government Affairs and Policy Strategy, explains why the Health Tech Investment Act is critical to expanding patient access to FDA-authorized AI-enabled medical devices.

Ensure Service and Remanufacturing Excellence
- Advocate for right-to-repair guidelines that protect patients
- Support equal expectations for all imaging service providers

Champion Digital Health Use in Imaging
- Advocate for policies that support adoption of best in class imaging technology
- Promote awareness of the benefits of AI enabled imaging

Enhance Patient Access to Imaging
- Support broader coverage for patients
- Ensure appropriate reimbursement for overall imaging services
- Implement appropriate reimbursement for AI enabled imaging devices

Unify Imaging Through Standards & Insights
- Create technical standards that enable industry alignment and device consistency
- Refine existing standards to further strengthen industry alignment and consistency

TOP PRIORITY HEALTH TECH INVESTMENT ACT INTRODUCED

The Medical Imaging division advanced one of its top legislative and regulatory goals through the introduction of the Health Tech Investment Act (S. 1399/H.R. 6197), aimed at establishing a Medicare coverage pathway for AI-enabled imaging technologies.

The bill garnered bipartisan support and favorable media coverage, including a letter from 23 patient organizations, including Right Scan Right Time and Patients Rising. The letter "strongly urge(s) Congress to prioritize and pass this legislation, recognizing its transformative potential for the health and well-being of patients while fostering innovation in healthcare."

AdvaMedDx

During an annual advocacy fly-in meeting, U.S. Rep. Scott Peters (D-Calif.) pointed out memorabilia to diagnostic company leaders.

GLOBAL LEADERSHIP

AdvaMedDx secured a major win for the industry by successfully advocating for the exclusion of in vitro diagnostic (IVD) tests and equipment from China's retaliatory tariffs. This direct intervention, facilitated through our China office, protects market access and alleviates significant financial burdens for our members.

AdvaMedDx also reinforced its global role by being selected as a founding member of the Steering Committee of 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 given the limited formal input from U.S. government officials. We also continued our advocacy in Congress to secure sustained funding for diagnostic testing through the President's Emergency Plan for AIDS Relief (PEPFAR) program.

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.

KEY LEGISLATIVE ACCOMPLISHMENTS

AdvaMedDx continued advancing its federal legislative agenda on multiple fronts. 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.

AdvaMedDx

We also gained traction on our standalone technology-certification bill, with Senator Bill Cassidy, chair of the Senate health committee, reaffirming his commitment to serve as lead sponsor while FDA technical assistance is under review. On CLIA waiver and point-of-care reforms, Senator Jon Husted (R-OH) agreed to lead our efforts on legislation to streamline the path to CLIA-waiver status for point-of-care tests.

The Agriculture/FDA appropriations bill, included in the November 12 continuing resolution, contained amended report language on over-the-counter diagnostic testing that now specifically includes point-of-care tests because of our advocacy. This language requires the FDA to provide a comprehensive analysis of current regulatory barriers faced by these diagnostic tests.

Additionally, AdvaMedDx secured House Appropriations Committee report language directing funds under global health security programs toward the development of diagnostics for pathogens of pandemic potential—a major recognition of diagnostics as a cornerstone of pandemic preparedness. As the bill makes its way through the House and eventually the Senate, we will continue working to secure funding for diagnostics through these programs.

MEMBER ENGAGEMENT

AdvaMedDx held four productive Board meetings throughout the year and saw strong member participation in AdvaMed's annual advocacy fly-in in June. During fly-in meetings with key members of Congress and executive branch officials, we advanced our agenda for diagnostics regulatory reform across all of these priority areas.

LAUNCH OF THE ADVAMEDDX LIFETIME OF LEADERSHIP AND SERVICE AWARD

AdvaMedDx 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 in early November, with generous funding provided by Tim Ring and Kathryn Gleason to support the program for the next five years.

Public Affairs

ADVAMED LEADS IN NEWS COVERAGE OF MEDTECH

For every five news stories about medtech, AdvaMed was mentioned or quoted in at least one—and AdvaMed mentions in 2025 increased by 54 percent over 2024. The next closest advocacy organization was mentioned in just 2 percent of all stories. AdvaMed aggressively seeks opportunities to drive and shape the medtech message around the country in the publications policymakers read most.

ADVAMED MEDIA STRATEGY ADVANCES POLICY PRIORITIES

Two major issue areas important to medtech generating headlines demanded an aggressive yet careful public affairs approach: the workforce reduction of FDA CDRH employees and tariff announcements.

By releasing our concerns in a media statement and engaging key reporters and securing expert interviews on the FDA workforce concern, driven by significant attention to AdvaMed CEO Scott Whitaker's post on LinkedIn, we helped shape accurate, high-impact coverage in Bloomberg News, The New York Times, and other top-tier outlets. Many of these essential employees were rehired within days, demonstrating the power of combining strong advocacy with tactful media messaging to drive policy change.

On tariffs, our swiftly issued, well-covered media statement, combined with strategically selected media interviews, and other advocacy on the administration's tariffs reinforced the industry's concerns, ensured our voice was heard at the highest levels. Also, AdvaMed responded to the White House's April 2 global tariff announcement with coordinated communications and successfully promoted CEO Scott Whitaker's op-ed on the need for relief from tariffs in *The Baltimore Sun* – widely seen as an influential paper of record for the Trump Administration.

PUBLIC POLICY PAPERS

In February, we launched AdvaMed's Medical Innovation Agenda for the 119th Congress, outlining key priorities to expand patient access to life-saving medtech.

Working across teams, we also finalized the AdvaMed AI Policy Roadmap offering concrete recommendations to Congress to maximize AI's potential in diagnostics, personalized treatment, and digital health. Supported by leading voices from our Digital Health Tech division's board, this initiative is equipping policymakers with the insights needed to get AI policy right, ensuring patients reap the full benefits of medtech innovation.

Public Affairs

A SHOWSTOPPING MEDTECH SHOWCASE ON CAPITOL HILL

Public Affairs organized a widely attended Medtech Showcase and Reception on Capitol Hill, featuring medtech from 37 companies and some of the largest medtech systems ever exhibited at this traditional annual event. At least two members of Congress attended, representing Minnesota and California, two states with a large medtech presence, along with hundreds of congressional staff, patient advocates, and medtech company representatives. The showcase achieved its goals of cementing among policymakers the critical role of medtech in patient care.

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 Healthy Again initiative.

The campaign kicked off with 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.

Subsequent phases of the campaign continued with ongoing social media amplification. In just two months, AdvaMed published dozens of MAHA-focused posts across all major platforms, bringing more than 800 new policymakers, health leaders, and media influencers into our audience and generating millions of 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.

PROMOTING MEDICARE COVERAGE FOR BREAKTHROUGH INNOVATION

Throughout 2025, 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.

To maximize impact, we also provided social media toolkits to allied 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.

Alliance Partnerships

AdvaMed's Bobby Patrick, VI presented the Alliance for Aging Research Silver Innovators Award to Dr. Foluso Fakorede, the Chief Executive Officer of Cardiovascular Solutions of Central Mississippi.

PATIENTS FIRST AGENDA

AdvaMed released its "Patients First Agenda," a series of state-level policies aimed at improving lives and patient outcomes through increasing access to medical technology, accurate diagnostic testing, and safe and effective treatments. Each policy is a key priority for patient advocacy organizations or professional medical societies, further underscoring the initiatives' importance in improving patient lives and outcomes. Partners are the American Cancer Society Cancer Action Network, Alzheimer's Association, American College of Emergency Physicians, LUNGevity, Fight Colorectal Cancer, Epilepsy Foundation of America, and the Brem Foundation to Defeat Breast Cancer.

ALLIANCE PARTNER PRIORITY EXCHANGE

AdvaMed brought together two dozen patient and physician groups to share their policy and regulatory priorities for 2025. This inaugural annual event was designed to facilitate priority awareness and highlight opportunities for collaboration between alliance partners, as well as with AdvaMed.

SMTA FLY-IN

The State Affairs team hosted our annual state medtech association fly-in to Washington, marshalling representatives from all over the country to meet with more than 80 members of Congress and their staff. Members of Congress don't always realize medtech has a presence in each of the 50 states and that 80 percent of medtech companies are small. Hearing from their home state industry makes a big difference in policymakers' mindset to support medtech innovation.

SPECIAL ATTENDANCE AT THE MEDTECH SHOWCASE

Numerous patient advocacy group representatives attended AdvaMed's medtech showcase and reception on Capitol Hill, responding to outreach from the AdvaMed team. A participating member company representative commented on having productive conversations with patient advocates at the event.

Alliance Partnerships

WIDE SUPPORT FOR THE HEALTH TECH INVESTMENT ACT

Nearly two-dozen organizations – including patient and physician groups – signed an AdvaMed-led letter in support of the U.S. Senate-introduced Health Tech Investment Act (S. 1399), legislation that drives increased patient access through creating consistent reimbursement for the use of AI in certain medical technology.

PATIENT ENGAGEMENT SYMPOSIUM HIGHLIGHTS MEDTECH; INFORMATIVE BRIEFINGS

AdvaMed President and CEO Scott Whitaker was a featured panelist at the National Health Council's Science of Patient Engagement Symposium, where he highlighted the medtech industry's focus on putting patients first and the continued need for collaboration to help drive patient-centered innovation.

AdvaMed hosted briefings on two key issues – tariffs and AdvaMed's AI Policy Roadmap – for alliance partners, including members of the State Medical Technology Alliance (SMTA), that were attended by more than two dozen groups.

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).

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.

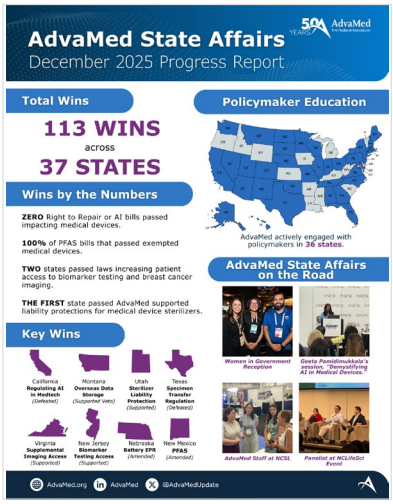
BREAKTHROUGH COVERAGE CAMPAIGN

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 Deseret 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.

State Affairs

UTAH ADOPTS MODEL LEGISLATION IMPACTING STERILIZER LIABILITY

The Beehive State recently enacted AdvaMed-supported legislation impacting liability for the use of ethylene oxide for sterilization by the health care industry. This new law, which took effect on May 7, 2025, limits liability for anyone in the health care industry for the use of ethylene oxide, unless certain criteria are demonstrated by the preponderance of the evidence – including causing actual exposure to ethylene oxide by gross negligence or willful misconduct. This first-in-the-nation law also specifies pleading requirements for bringing forward a claim in an ethylene oxide-related action.



AdvaMed State Government Affairs key legislative wins in 2025.

WINS IN STATES ACROSS THE COUNTRY

Every state legislature was in regular session this year, and the AdvaMed State Affairs team was active in dozens of them, working to strengthen and protect patient access to innovative medical technology. These wins include:

- Ensuring Right to Repair legislation does not apply to medtech in Alaska, Connecticut, Texas, and Washington;
- Helped enact laws expanding patient access to supplemental breast cancer imaging in Florida and Virginia;
- Derailing legislation seeking to regulate use of artificial intelligence in Maryland, Texas, and Virginia.

CALIFORNIA LOBBY DAY PRECEDES KEY WINS IN MULTIPLE STATES

AdvaMed's state-level advocacy remained active and effective across diverse policy challenges. The spring opened with a California Lobby Day and Showcase in collaboration with California Life Sciences. In Indiana, AdvaMed helped secure the removal of provisions that posed risks to medtech reimbursement and would have created burdensome reporting requirements.

OVERREACHING DATA, RIGHT TO REPAIR VICTORIES

The team successfully limited overreaching data regulations in five states (including Louisiana, Montana, and Nebraska), while our advocacy successfully exempted medical devices from right-to-repair legislation in three others (Connecticut, Texas, and Washington).

PFAS EDUCATION CONTINUES

The state affairs team worked with the technology and regulatory affairs team to present AdvaMed's position on PFAS and work to date on PFAS regulation on the state level to scientific and regulatory staff at the U.S. Department of Defense. The team educated state lawmakers from around the country, as part of the Women in Government conference, on FDA regulation of medtech and how additional state regulation could negatively impact patient access.

State Affairs

TEXAS CADAVER MORATORIUM LIFTED

Finally, the state affairs and legal teams led successful efforts to lift the Texas cadaver moratorium that prevented medtech companies from receiving permitted access to cadavers and other specimens for research and training.

These coordinated efforts showcased AdvaMed's ability to shape complex state policy landscapes to protect patient access and industry innovation.

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 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 AI 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.

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

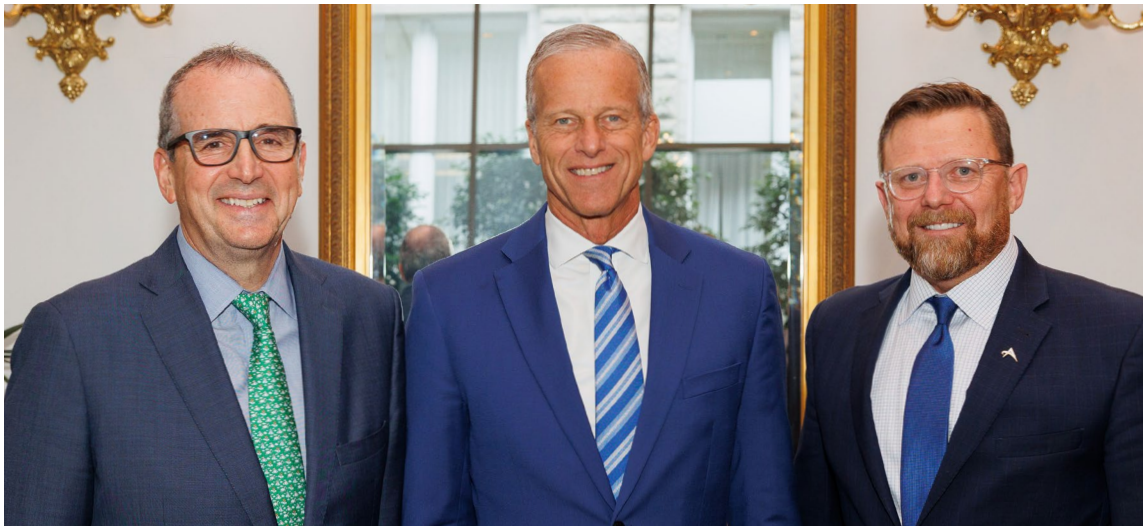
AdvaMed continued to defend responsible, patient-focused AI policy by engaging with the office of a key New York state senator to outline why medtech should be exempt from broad legislation governing AI deployment. Our messaging focused on the extensive regulation of AI in medtech by the FDA and builds on our multi-state strategy to prevent duplicative or overly burdensome regulation that could slow clinical innovation.

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 will help shape AdvaMed's strategy on RHTP and rural health policy more broadly going into 2026.

Federal Government Affairs



Peter J. Arduini, president and CEO of GE HealthCare and then-chair of the AdvaMed Board of Directors, and Scott Whitaker, AdvaMed president and CEO, met with U.S. Senate Majority Leader John Thune (R-S.D.), center, during the annual advocacy fly-in.

IMPACT ADVOCACY MAKING A DIFFERENCE

Impact Advocacy has been the calling card of Federal Government Affairs for years, driving toward meaningful, measurable outcomes that better position the industry to help patients and their providers.

The Federal team wasted no time, engaging with new members of Congress and key officials in the incoming administration well before the year began—anticipating a fast-moving policy landscape. The success of that strategy quickly became evident. From workforce reductions to tariffs to both emerging threats and opportunities, the team jumped into action, eager to share how proposed policies would impact the ecosystem.

ADVAMED STEPS IN ON FEDA REDUCTION IN FORCE THREAT

In February, administration officials acted on directives to massively reduce the FDA workforce inside CDRH, potentially harming the ability of device review teams and other key segments from continuing their work. When AdvaMed learned many of those eliminated fell under the MDUFA V agreement, the association quickly jumped into action. Armed with a letter of concern from Scott, Federal made the case on why those positions needed reinstatement in several Hill meetings with committees of jurisdiction. As a result, just days later, the administration told more than 85 percent of those employees whose positions were eliminated to return to work, quickly restoring this important facet of medtech review and decision-making.

Federal Government Affairs

ADVAMED CEO TESTIFIES IN THE U.S. SENATE ON TARIFFS

Scott Whitaker met with senior senators to press for an exemption from tariffs for medtech. In May, he testified before the U.S. Senate Finance Committee on trade and supply chains and focused on the effects of tariffs on medtech. He was initially not named as a witness when the hearing was noticed, so the federal team quickly helped secure an invitation for the industry to testify. Medtech was the only health care field invited to testify. The team worked closely with the public affairs and global teams to prepare Scott's testimony and anticipate senators' questions and answers. He received questions from the chairman and ranking member and three additional senators.

RENEWED PUSH FOR BREAKTHROUGH COVERAGE

Much ground was won last year and last Congress on the industry's finally securing coverage of breakthrough technologies. In early January, AdvaMed Federal set out to renew relationships and gauge interest in pushing again for bill introductions in both chambers, coupled with early initiatives before the new CMS leadership structure stressing just what the policy meant for both innovation and for patients. In several meetings with senior agency officials, Scott and member company CEOs shared firsthand accounts of how coverage policy could be improved and the difference those changes would make. The work sets the stage for later in the year, when a broader modernization push will continue in this important policy sphere.

DR. OZ EXPRESSES SUPPORT FOR BREAKTHROUGH COVERAGE

Related, during Dr. Mehmet Oz's confirmation hearing to serve as the Centers for Medicare and Medicaid Services (CMS) administrator, he was asked about his support for Medicare coverage for breakthrough technologies. Dr. Oz responded, "... the gap between when the FDA says this is a good product that can save lives, and when the American people, beneficiaries of Medicare or Medicaid programs within the states, are able to access those ... we should make it easier for industry to create lifesaving tools by aligning when the FDA approves a product with when CMS begins to fund it for beneficiaries. Because that's our job ..."

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.

TAX PROVISIONS IN THE "BIG BEAUTIFUL BILL"

Just after Q2 ended, Congress passed and President Trump signed into law the nearly 900-page "Big Beautiful Bill." The new law contains key provisions for medtech.

Federal Government Affairs

- R&D expensing made permanent. The final measure restores and makes permanent full expensing of domestic research and development efforts. Without restoration of immediate 100 percent expensing, businesses were only allowed to expense 40 percent of the cost for 2025 before it was scheduled to fall to 20 percent in 2026. Small companies with gross receipts under $31 million can retroactively expense from 2022 to 2025; this will save many of the earliest stage medtech companies a significant tax burden and keep several Accel members in business. This retroactive treatment is a big win for our Accel members.
- Full expensing of new capital investments made permanent. This provision will help many Accel members by permanently allowing manufacturers to expense 100 percent of the cost of qualified property acquired. Without restoration of 100 percent expensing, businesses could only expense 40 percent of the cost for 2025, and this percentage would fall to 20 percent in 2026. It also increases the maximum amount a manufacturer can expense under Section 179 to $2.5 million.
- Net interest payment deductions made permanent. The law restores and makes permanent interest deductibility by allowing manufacturers deducting net interest payments to include depreciation and amortization costs for taxable years beginning after December 31, 2024. Since 2017, the amount of interest deductions that businesses can take became limited to only using earnings before interest and taxes, representing a significant tax increase on manufacturers.
- Qualified Small Business Stock (QSBS) expanded. Expansion of the Section 1202 exclusion from capital gains of qualified small business stock will support early-stage companies in raising capital and hiring talent, by reducing the 5-year holding period for capital gains exemption-- allowing a lower percentage exemption at years 3 and 4. This represents another significant win for Accel members.

The law makes significant reductions in Medicaid spending through provider tax changes and other initiatives that will impact hospitals and other customers our member companies serve. Our payment team is studying the extent of those provisions and will work with our member companies to mitigate the changes' impact in the months to come.

ELECTRONIC LABELING BILL INTRODUCED

In 2025, AdvaMed welcomed the introduction of the bipartisan Medical Device Electronic Labeling Act, H.R. 1539, introduced by Reps. Jay Obernolte (R-Calif.), Kevin Mullin (D-Calif.), Rep. Dan Crenshaw (R-Texas), and Rep. Angie Craig (D-Minn.). The bill is a longstanding AdvaMed priority to serve patients and clinicians with definitive, expert information about how to use each lifesaving innovation.

TOP-FLIGHT ADVOCACY FLY-IN

In June, our annual advocacy day fly-in featured 43 CEOs on eight teams in 34 meetings, including with White House Chief of Staff Susie Wiles; CMS Administrator Dr. Mehmet Oz; EPA Administrator Lee Zeldin; Jim Goyer, director of the White House Office of Public Liaison; Ways and Means Committee Ranking Member Richard Neal; House Democratic Caucus Chair Pete Aguilar; Chair of the House Energy and Commerce Health Subcommittee Buddy Carter; and down dais members of the Ways and Means and Energy and Commerce committees. Issues covered included tariffs, digital health, breakthrough device coverage by Medicare, and small business concerns.

Federal Government Affairs

AdvaMed also hosted political events during the board week for U.S. Senate Majority Leader John Thune and U.S. House of Representatives Ways and Means Health Subcommittee Chairman Vern Buchanan.

ADVANCING MEDTECH PRIORITIES DESPITE GOVERNMENT GRIDLOCK

The fall of 2025 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 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.

The House action followed the Senate version of the bill, S. 1717, introduced earlier in 2025. 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 (2026). 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 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.

Federal Government Affairs

PROTECTING FDA RESOURCES AND SECURING KEY REPORT LANGUAGE IN FUNDING AGREEMENTS

Congress approved a continuing resolution that kept 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 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.

LEADING ASSOCIATION LOBBYIST

Congratulations to Greg Crist, named a 2025 Leading Association Lobbyist from Association TRENDS.

Payment

AdvaMed's payment team worked with CMS Administrator Oz and his agency staff on key policies promoting patient access to lifesaving medtech.

AMA CODING FIXES

The American Medical Association has hired an outside firm to interview medtech founders, executives, leaders, and investors about their experiences applying for a Category I CPT code, specifically regarding the widespread use requirement. Meeting this requirement is a significant barrier for medtech, resulting in delays in obtaining a CPT code, which ultimately delays access to medical technologies. We met with the contractor to discuss its outreach to medtech executives and leaders and distributed information to members of our coding work group for their input.

ROBUST ENGAGEMENT IN PAYMENT DEBATES

The team hosted the 2025 Payment Policy Forum on May 20-21. The event featured timely review sessions on key payment issues for medtech including participant experiences from the Transitional Coverage for Emerging Technologies (TCET) pilot, insights from the American Medical Association (AMA) Current Procedural Terminology (CPT) and congressional offices, and a roundtable discussion on prior authorization in Medicare Advantage.

The team continues its robust engagement with AMA CPT, from its seat on the Pathology Coding Caucus to the Digital Medicine Coding Committee (DMCC). In May, the DMCC released a new coding proposal for algorithmic analysis, which has broad implications across medtech sectors. As AMA seeks stakeholder feedback and continues to refine the proposal, AdvaMed has engaged with members and provided detailed input to AMA to help achieve a workable solution for members.

PAYMENT WORK ON TCET, PARKINSON'S DISEASE, DIGITAL HEALTH AND AI-ENABLED MEDTECH

Since the finalization of the Transitional Coverage for Emerging Technologies (TCET) policy in August 2024, CMS's Coverage and Analysis Group (CAG) has been very active. We continue to support timely release of open national coverage analyses, and we are closely tracking CAG's activity throughout 2025.

Payment

Additionally in late June, CMS held a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting to examine clinical endpoints used in studies for management of tremor in patients with Parkinson's disease or essential tremor. AdvaMed submitted comments urging the MEDCAC to consider all technologies in this space and urged CMS to update related NCDs, as they have not been updated in over twenty years.

The team continues to advocate for advances in coverage and payment for digital health and AI-enabled technologies. In addition to continuing advocacy for expanded access to digital therapeutics through direct engagement with CMS, including a meeting with Alec Aramanda, principal deputy director of CMS, in May, the payment team has expanded its advocacy for AI-enabled technologies and coordinates closely with AdvaMed government affairs on opportunities to engage with legislators on their role in reforming CMS coverage policy. The team has also continued efforts to better educate AdvaMed members and staff on different potential avenues for digital health technology coverage, including deep dives into the durable medical equipment space, which would expand patients' ability to access these technologies in the home setting.

HIGHLY INVOLVED IN MEDICARE PAYMENT RULES

Payment has been highly engaged in comment opportunities from the U.S Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS). The team submitted comments in response to: the fiscal year (FY) 2026 Inpatient Prospective Payment System (IPPS) proposed rule; deregulatory requests for information (RFIs) from the Office of Management and Budget (OMB) and CMS; and a health technology ecosystem RFI from the Office of the National Coordinator (ONC). Rulemaking activity will continue throughout the summer, and the team continues to monitor proposed rule activity related to durable medical equipment (DME) competitive bidding, the Outpatient Prospective Payment System (OPPS), and the Medicare Physician Fee Schedule (PFS).

DIALOGUES WITH CMS ON ACCELERATED COVERAGE PATHWAYS

Scott and the payment and federal government affairs teams talked with CMS Deputy Administrator John Brooks regarding accelerated coverage pathways. During the call, AdvaMed advocated for greater transparency and predictability in Medicare coverage pathways. The team conducted a successful Q2 Board Payment Committee meeting and fly-in meeting with CMS Administrator Dr. Mehmet Oz on the importance of accelerated coverage and clear reimbursement pathways for new technologies. As a practitioner, he understands the critical role of medtech in serving patients and the health care system. Members of the payment team also supported a meeting with Ken Callahan, chief of staff to the deputy secretary at HHS, and HHS policy advisors on expanding access to novel technologies under the Medicare program.

Payment

THOUGHT LEADERSHIP ACROSS THE PAYMENT SPECTRUM

In addition to our Administration-focused advocacy, the team continues to expand AdvaMed's prominence as a thought leader on coding, coverage, and payment issues. Our team members both lead stakeholder coalitions (the Prescription Digital Therapeutics Coalition) and serve as key opinion leaders on external committees (like the Digital Medicine Coding Committee mentioned above). Team members have also participated in multiple speaking engagements across the payment landscape, including: HealthyWomen's 8th Annual Educational Event; the American Telemedicine Association's 2025 Nexus Conference; the Voices for Non-Opioid Choices Solutions Summit; and the 2025 Maryland State of Reform Conference.

PROGRESS ON CODING ADVOCACY, PRODUCING LASTING CHANGES FOR MEDTECH

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.

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.

Payment

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.

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.

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.

Conferences, Events, and 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.

CELEBRATING 50 YEARS OF MEDTECH INNOVATION

To celebrate AdvaMed's 50th anniversary both online and in person, we launched a dynamic timeline showcasing the milestones and breakthroughs that have defined medtech over the past five decades. From the earliest CT scans to today's AI-driven technologies, this timeline reflects an industry rooted in relentless innovation and impact. Explore AdvaMed's timeline to see how far we've come and where we're headed next. We also celebrated our rich history of attracting industry's top leaders to serve on the AdvaMed Board of Directors by inviting and hosting nine former AdvaMed Board Chairs and numerous past members of our Executive Committee and Board of Directors.

2ND ANNUAL PAYMENT POLICY FORUM

AdvaMed hosted its second annual Payment Policy Forum in May, achieving a 21 percent boost in attendance over 2024. The program featured leading experts who addressed complex reimbursement challenges during a pivotal time in the evolving health care payment landscape for medtech.

RAPID RESPONSE ONLINE RESOURCE CENTER

AdvaMed continues to lead with real-time guidance and member support, sharing dozens of targeted resources, member communications, and webinars in response to shifting policies and global challenges. From supply chain disruptions to evolving trade regulations, our rapid response tools help medtech companies adapt quickly, protect patient access, and stay mission-focused.

Conferences, Events, and Marketing

CONVENING THE MEDTECH ECOSYSTEM: MOST SUCCESSFUL 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 event also served as a milestone moment to celebrate AdvaMed's 50th anniversary, honoring five decades of industry leadership and innovation.

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. 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.

STRENGTHENING PARTNERSHIPS ACROSS THE INDUSTRY

In November, AdvaMed hosted more than 80 medtech professionals for our largest ever Cybersecurity Summit, with both in-person and virtual participation options. The Summit delivered a highly successful, content-rich program featuring premier experts from 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 in an effort 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.


AdvaMed
The Medtech Association