AdvaMed
The Medtech Association

AdvaMed Advancements
Q4 2024 Report

A Note from Scott

Dear AdvaMed Member,

As we look back on 2024, I am proud of AdvaMed's accomplishments in the fourth quarter. They underscore our commitment to creating an environment that advances patient care through innovation in medtech.

If there was one event that best captured a banner quarter and year, it was our annual MedTech Conference. The conference in Toronto—our first outside the U.S.—set a new standard for excellence. With a record-breaking 4,350 attendees from 1,926 companies across 48 countries, it was our largest and most global event to date.

The conference's "Medtech in Motion" theme came alive with over 2,500 partnering meetings, hundreds of hands-on demonstrations and inspiring keynotes, including a conversation with tennis legends Martina Navratilova and Chris Evert on resilience and leadership.

In addition to our successful conference, AdvaMed made meaningful progress on our Board-approved priorities in Q4: CMS approved new payment pathways, improving patient access to our industry's lifesaving technologies. We made progress on breakthrough technology legislation in Congress, increasing the bipartisan support for it in both bodies.

We intensified our work to educate new health care leaders in the incoming administration on medtech's critical role as the backbone of our health care system. Greater detail on all of this is in the following "AdvaMed Advancements: Q4 2024 Report."

These successes reflect the strength of our mission and the collective dedication of our members and partners. As we move through 2025 we will be celebrating our 50th anniversary and remain steadfast in driving innovation, fostering collaboration, and ensuring patients worldwide benefit from our transformative technologies.

Together, we are shaping the future of health care.

Sincerely,

Scott

Scott Whitaker
President & CEO
AdvaMed

Technology and Regulatory Affairs

Drives Year-End Regulatory Wins

AdvaMed's Technology and Regulatory Affairs (T&R) team wrapped up a busy quarter, advancing global regulatory standards while closing out anticipated regulatory announcements.

INSIDE LOOK FROM FDA LEADERS AT MEDTECH CONFERENCE

At The MedTech Conference 2024 in Toronto, AdvaMed delivered again—hosting multiple sessions, including the opportunity to hear directly from senior FDA/CDRH officials. This rare, face-to-face discussion always gives members an inside look at CDRH's strategic plan and priorities, and 2024 proved no different. The insights gained will help member companies navigate regulatory pathways more efficiently in 2025.

FDA ISSUES FURTHER GUIDANCE ON ETO STERILIZATION

Even after the updated EtO rule was issued last summer by EPA, AdvaMed's T&R team continued its work on the topic by participating in FDA's ongoing series of public discussions, keeping members informed on sterilization policy updates.

AdvaMed successfully worked with FDA as the agency issued its "Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices," which will continue to ensure access for patients while manufacturers transition to new EtO sterilization requirements.

Technology and Regulatory Affairs

FDA announced its intention to release further guidance in early 2025 with respect to EtO's impact on employees (whereas the rule released last year dealt with emissions). We have been working closely with the agency on this expected guidance.

QMSR MILESTONE ACHIEVED

We worked to ensure that FDA had all it needed as the agency finalized the Quality Management System Regulation (QMSR), adopting the ISO 13485 standard with a two-year implementation period. This long-awaited rule harmonizes global standards, reduces compliance burdens, and reinforces patient safety.

Digital Health Tech

Division Finishes Strong, Preps for 2025

Data and its critical role were front and center this past quarter for the DHT Division, culminating in a series of panels and discussions surrounding the topic to advance patient health.

BOARD APPROVES INDUSTRY GUIDING PRINCIPLES ON THE DEVELOPMENT OF HEALTH CARE AI

To ensure that AI innovation is delivering on the promise of personalized medicine and improving patient outcomes, it is critical that policymakers at all levels understand the issues and how best to appropriately regulate these swiftly advancing technologies. The medtech industry continues to lead on the development of health care AI solutions and identify the foundations necessary to develop AI products, acquire and appropriately utilize data, protect patient privacy, and increase patient access. AdvaMed and its Digital Health Tech Division developed three sets of principles, which can be found on our website, to outline medtech leadership in AI and set the foundations for AI policymaking moving forward.

Q4'S BIG AI FOCUS: WHEN WILL THE POLICIES CATCH UP WITH INNOVATION?

At AdvaMed's MedTech Conference, an important conversation with leaders in attendance—including FDA's head of digital health, Troy Tazbaz (pictured above, far right)—was why AI-enabled medtech is lagging in its ability to reach more patients. The panel tackled three major roadblocks: data access, regulation, and reimbursement. Current data models and lack of standards are stalling innovation and patient access, experts explained.

Digital Health Tech

FLEXIBLE APPLICATION OF REGULATORY MODELS

As the current technology advances, one question the Division also addressed this quarter was: how to apply existing federal agency regulations to AI/ML innovation advancements. One panel at the Toronto conference went deep on how regulatory models such as PCCP can be flexibly applied to advance these new technologies.

MENTAL HEALTH EXPANSION

In Q4, AdvaMed DHT worked with officials which resulted in CMS giving the green light to extend coverage for certain Digital Mental Health Technologies (DMHT). Medicare patients will now be able to access mental health treatment through digital tools—a huge step forward for tech-driven mental health care for patients in need.

AdvaMed Global

Diversification and Manufacturing

ADVAMED CELEBRATES 10-YEAR ANNIVERSARY OF CHINA OFFICE

In November, AdvaMed Board Chair **Peter Arduini**, ResMed CEO **Mick Farrell**, Johnson & Johnson's EVP and Worldwide Chairman of MedTech **Tim Schmid**, Zimmer Biomet's CEO **Ivan Tornos** and **Scott Whitaker** traveled to China. AdvaMed celebrated 10 years with an office on the mainland, helping member companies navigate their manufacturing needs and market access. The visit also included meetings with high-level officials from both China and the United States. This work – and the need for the AdvaMed office – will only grow in 2025 given the incoming Trump administration.

CHINA MANUFACTURING: TIME TO DIVERSIFY

At October's MedTech Conference, our Global department led many discussions and one panel session surrounding the risks and rewards of diversifying manufacturing outside China. Given the incoming Trump administration's focus on China, these discussions last quarter will help inform members for the coming year.

SUPPLY CHAIN AWARENESS—THE WORK CONTINUES

AdvaMed's global team continued its work in Q4 with federal partners in real time to highlight major challenges to the medtech supply chain. A great example was the work of the team in the wake of Hurricane Helene and its catastrophic impact in western North Carolina. We were instrumental in raising awareness with the federal government, as well as working to mitigate any supply disruptions.

AdvaMed Global

REGULATORY CONVERGENCE: THE FINAL COUNTDOWN

AdvaMed concluded the four-year Medical Device Regulatory Convergence (MDRC) project which reduced redundant Latin American regulatory costs by $235M annually and sped up device approvals.

VIETNAM EXTENDS IMPORT LICENSE VALIDITY FOR MEDICAL DEVICES

AdvaMed-led efforts, including a letter from our CEO and joint letters from international ambassadors, urged the extension. Specifically, Vietnam's Ministry of Health will extend import license validity for medical devices set to expire by the end of 2024, with a formal regulation expected soon. This extension ensures devices can remain on the market.

Legal

Top Compliance Concerns for Medtech Leaders: At the MedTech Conference in Q4, AdvaMed's legal team hosted a dynamic and fast-paced breakout session titled Chief Compliance Officer Lightning Round: Top Compliance Concerns for Medtech Business Leaders.

The highly attended session was a roundtable discussion featuring four seasoned compliance officers who delved into a wide range of the most pressing legal and compliance issues facing the medtech industry today.

KEY TAKEAWAYS:

- **DOJ/Government Enforcement Trends:** The panel discussed recent shifts in government enforcement and provided key insights regarding concerns and compliance strategies in light of these changes.
- **Geopolitical Impacts:** With a special focus on China, the discussion explored how geopolitics are increasingly influencing compliance requirements and issues for businesses to factor in managing these challenges, particularly with regards to manufacturing, trade, and foreign policy risks.
- **DOJ's Policies on Self-Disclosure and M&A Safe Harbor:** The panelists unpacked the Department of Justice's latest policies, including the implications of self-disclosure for medtech companies and the M&A Safe Harbor provisions, sharing practical considerations for navigating these regulations.

AdvaMed-led Win Through the Patent and Trademark Office (PTO): Following AdvaMed's filed comments, the PTO withdrew its proposed rule on terminal disclaimer practice in December. This is a win for incentives to invest in and develop new medical technologies in the U.S.

AdvaMed Continues to Watch the Courts: AdvaMed filed two amicus briefs in Q4. One was with the U.S. Court of Appeals in the EcoFactor case, supporting fair and balanced patent damages. The other was in a brief with the Supreme Court that raises questions about the proper scope of the Hatch-Waxman Act's regulatory safe harbor.

AdvaMed Accel

TURBOCHARGING INNOVATION FOR SMALL MEDTECH COMPANIES

Accel continues its mission to empower small and mid-sized medical device companies by shaping policies that fuel innovation, streamline regulatory processes, and drive investment. Here's how we accomplished that in Q4 of 2024:

COVERAGE REFORM: FASTER PATHS FOR PATIENTS

Innovators need predictability. And Accel in Q4 pushed for coverage reforms that make it faster and easier for breakthrough technologies to reach patients—and for investors to back them.

> **Legislative Action:** The division advocated for HR 1691 ("the breakthrough bill") to lock in expedited coverage for FDA-designated breakthrough devices.
>
> **Team Effort:** Members have been taking this issue to Congress and CMS—through letters, meetings, and grassroots advocacy—to ensure small companies are heard.

In Q4 2024, investors made clear that implementation of an expedited coverage process would create coverage assurances regarding the treatment of devices. They also stressed that, once on the market, these technologies would benefit the investment ecosystem for small and mid-sized companies.

AdvaMed Accel

INVESTMENT CLIMATE IS STRONG

With more than 300 investors in attendance, The MedTech Conference in Toronto helped connect small companies with funding opportunities.

New Allies: Welcomed Deerfield and RC Capital as investor members, with more VC firms in the pipeline.

Fighting for Fair Tax Rules: Working to reverse tax provisions such as R&D amortization and exploring other critical fixes before the Tax Cuts and Jobs Act expires in 2025.

ENGAGEMENT: SMALL COMPANIES, BIG VOICES

More Ways to Connect: From board meetings to events, Accel is making it easier for members to share insights and stay involved.

Diversity in Focus: Developing resources to support partnerships with diverse-led companies, showcasing how inclusion drives innovation.

Medical Imaging

AdvaMed at the RSNA 2024 Annual Meeting

A QUARTER OF MILESTONES AND VICTORIES

AdvaMed Imaging hosted a booth at RSNA's Chicago Annual Meeting in December that provided an opportunity to demonstrate AdvaMed's driving force of medtech innovation.

From advancing patient safety to securing better access to life-saving diagnostics, AdvaMed Imaging made big moves in Q4 that will impact both patients and providers.

CMS WINS: IMAGING PRIORITIES SECURED FOR PATIENTS

With AdvaMed pushing all along the process, CMS finalized two major provisions in the 2024 HOPPS rule that are sizable wins for patients. These new reimbursement provisions will improve access to care and improve outcomes for millions of Medicare beneficiaries.

Separate Payments for Radiopharmaceuticals: AdvaMed Imaging was successful in securing separate reimbursements for radiopharmaceuticals, a huge win and long-time priority of AdvaMed Imaging advocacy.

CT Colonography Coverage: This coverage improves outcomes for millions of Medicare patients.

Medical Imaging

WHITE PAPER: X-RAY SAFETY RISKS

AdvaMed's first ANSI-accredited white paper warns against third-party modifications of interventional X-ray equipment, citing risks to patient and operator safety.

> **Key takeaway:** Unauthorized modifications could lead to unforeseen negative consequences for care.

BREAST CANCER ADVOCACY: EQUITY IN FOCUS

Screening Saves Lives: AdvaMed Imaging is doubling down on breast cancer screening advocacy. Earlier in Q4 2024, Imaging sent a letter to CMS which called for supplemental imaging coverage for women with dense breast tissue to address health equity gaps. Further, the division co-signed a letter of support for the Find It Early Act, pushing insurers to eliminate out-of-pocket costs for diagnostic imaging.

Regulatory Progress: Imaging also submitted comments to the FDA on how imaging standards can drive health equity and improve device performance.

AdvaMedDx

Delivers: Innovation, Advocacy, and Industry Leadership

From shaping legislative agendas to working with US and global leaders, AdvaMedDx drove policy to improve public health outcomes in Q4 of 2024.

THE 2025-27 INNOVATION AGENDA

AdvaMedDx established its 2025-27 Innovation Agenda, which identifies and explains our regulatory, payment and public health priorities. The agenda will be shared with the new Administration and Congress to convey our diagnostics priorities, including streamlining FDA processes to enable tests to reach patients quicker, modernizing CMS processes to ensure coverage of new and innovative diagnostics, and funding critical public health programs.

Breakthrough Progress: Senators Young (R-IN) and Padilla (D-CA) introduced a breakthrough technologies bill, including diagnostics—thanks to relentless AdvaMed advocacy. This legislation will serve as the compass for Congress in 2025.

PUBLIC HEALTH & CDC PARTNERSHIPS

AdvaMedDx hosted a blockbuster CDC/Industry Day, with 20 member companies and 50+ CDC staff tackling antimicrobial resistance and diagnostic excellence.

AdvaMedDx

Federal Focus: We also advocated for the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), full funding for the President's Emergency Plan for AIDS Relief (PEPFAR), and passage of the PASTEUR Act. This included signing on to a stakeholder letter with 110 other organizations to push for the reauthorization.

Dx also pushed for the highest possible CDC funding level for advanced molecular detection through wastewater surveillance programs along with other stakeholders.

REGULATORY PUSH: ALZHEIMER'S ADVANCEMENTS

AdvaMedDx engaged with Sen. Cassidy's team and Alzheimer's advocates to advance Dx regulatory reform priorities.

- **FDA Watch:** Participated in litigation briefings and IVD roundtables, while engaging CLIAC on biosafety recommendations.

PAYMENTS & COVERAGE: WINNING FOR ALZHEIMER'S PATIENTS

AdvaMedDx pushed hard for favorable CMS rates for five neuro-biomarker CPT codes critical to Alzheimer's testing. Specifically, the team secured support from key lawmakers such as U.S. Reps. Crenshaw and LaHood and U.S. Senators Collins and Markey. Finally, by partnering with patient groups and industry stakeholders, Dx was able to solidify the widest and strongest possible coalition of advocates.

Public Affairs

Medtech's Storytellers

REVITALIZED BOARD INDUSTRY COMMUNICATIONS COMMITTEE

Public Affairs reconstituted the Board Industry Communications Committee (ICC) in the second half of 2024. The eight-person committee met twice and renewed its commitment to keeping members informed regarding AdvaMed's wins and advising on how to raise the industry's profile and drive messages to medtech's largest and most important audiences.

ICC In Action: The committee offered guidance that helped to shape messaging on how tariffs could harm supply chains and patient care. Further, ICC members offered reactions to an upcoming comprehensive policy packet on AI/ML initiatives Congress will consider in 2025.

MEDTECH POV: ADVAMED'S AWARD-WINNING PODCAST

What happened: Public Affairs recorded three new episodes of the *Medtech POV Podcast*, featuring high-profile guests and compelling storylines. Listen and Subscribe.

- Tennis greats **Martina Navratilova** and Chris Evert shared their cancer journeys and discussed the medtech behind their care.
- **Jake Leach** of Dexcom highlighted breakthrough diabetes tech, including the first OTC glucose biosensor.
- **Rep. Brad Wenstrup** reflected on his impactful career and his support of our industry in Congress, as well as how he saved U.S. House Majority Leader Steve Scalise's life at a congressional baseball practice.

These episodes boosted listenership, thanks to engaging content and strategic promotion. Expect even bigger spotlights on future episodes in 2025.

AI ADVOCACY TOOLKIT: READY TO LAUNCH

Collaborating across AdvaMed, public affairs is finalizing an AI toolkit that explains AI-enabled medtech, addresses policy concerns, and offers actionable recommendations for Congress.

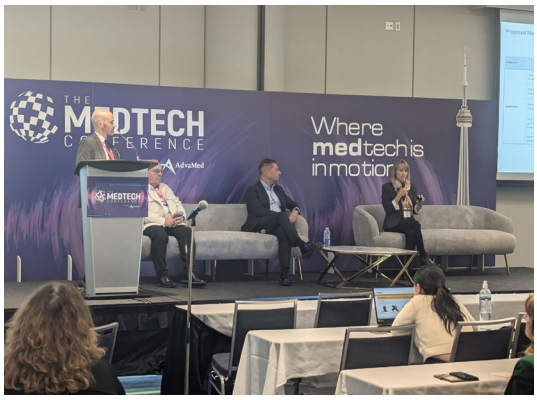
Set to debut in early Q1, the toolkit positions AdvaMed as a leader in shaping AI policy while promoting patient access to groundbreaking technologies.

GOT AN IDEA?

Public Affairs thrives on collaboration. Do you have ideas for podcast guests, issue collateral, or newsworthy moments? Bring them our way. We're always here to amplify medtech's voice—including yours. Email Jim Jeffries at jjeffries@advamed.org!

Alliance Partnerships

Effective engagement of patient voices means more than activating them when needed to achieve policy objectives. It means being a trusted source of information, a strong, reliable supporter of policies positively impacting patient access and outcomes – beyond industry's primary priorities – and building relationships through listening and learning what matters to them. AdvaMed's activities focus on effectively engaging patient voices and highlighting them in all areas of our work.



PATIENT ENGAGEMENT WORKSHOP: MEDTECH 2024

AdvaMed hosted its second annual Patient Engagement Workshop at The MedTech Conference last year in front of a sold-out crowd.

Attendees heard from patients, patient advocacy groups, and AdvaMed members on the need to engage patients throughout the medical device life cycle and shared best practices for doing so.

This workshop builds on the year-long Patient Engagement Initiative that regularly brings together more than 75 AdvaMed members and nearly 200 attendees to discuss, share, and learn about effective patient engagement.

- **See you in San Diego:** This workshop will be back, and likely bigger, in 2025 with increased attention on effective advocacy.

Alliance Partnerships

STRONGER TOGETHER: PATIENT ACCESS TO DIABETES TECHNOLOGY

AdvaMed convened a group of patient advocates and AdvaMed members to discuss recent policies impacting patient access to diabetes technology and opportunities for collaboration to continue increasing both access and adoption.

We made significant strides in patient access to continuous glucose monitors (CGMs) through Medicare and Medicaid coverage. While works remains, attention is needed to increase patient adoption of the technology and in identifying the next policy challenge. The group identified several opportunities for collaboration and expressed a desire to convene to discuss these in the coming months.

State Affairs

Though the end of the calendar year is typically slow for state policymaking, 2025 is expected to ramp up quickly. Significant shifts in partisan makeup in key states, state regulation of AI coming to the forefront, and a new presidential administration are key elements of what will be a very busy 2025 at the state level, with all 50 statehouses being in regular session.

KEY VICTORY FOR PATIENTS IN Q4

Massachusetts patients will have increased access to, and reduced cost-sharing for, supplemental breast cancer imaging thanks to a newly enacted state law led by AdvaMed.

Cost is frequently cited by women as a reason they do not seek follow-up care following an initial breast cancer screen; this law removes that obstacle. AdvaMed strongly supported this legislation and will continue to advocate for similar legislation in states nationwide.

2024 STATE ELECTION RESULTS: IMPACT ON MEDTECH

Eighty-six legislative chambers were on the ballot in November; just two changed party control.

Eleven governors' offices were on the ballot in November; none changed party control.

The party makeup of legislatures significantly impacts the potential for state-level activity on policies impacting medtech.

Here is a breakdown of key states where the election (likely) most impacted medtech's issues:

California Assembly: No shift in party control (Democrats maintain the majority), but a shifting caucus makeup is likely to shift the chamber's approach to medtech's issues.

Arizona House & Senate: Republicans maintained their legislative majorities, avoiding a Democratic trifecta in this growing medtech hub.

Michigan House: Following two years of a Democratic trifecta, Republicans regained control of the lower chamber likely resulting in a slower approach to several key policies.

Minnesota House: The Democratic trifecta ended by a change in House control. It will ultimately be a tied (67-67) chamber, slowing consideration of some issues, such as AI.

Pennsylvania Senate: Republicans held onto their majority in the upper chamber of the Keystone State, maintaining split control of state government – thus forcing a compromise approach to policymaking.

Federal Government Affairs

ADVAMED SECURES WINS FROM LEAST PRODUCTIVE CONGRESS IN A GENERATION

While Washington headlines lamented the 118th Congress as one of the least productive in the Republic's history, AdvaMed Federal Affairs was still able to push through notable wins on behalf of industry.

BREAKTHROUGH COMES CLOSE BUT REMAINS TOP BIPARTISAN PRIORITY

AdvaMed-backed HR1691 – the breakthrough bill – was close to congressional approval this in 2024, yet the team still secured notable gains, including a first-ever CBO score and a record number of bipartisan sponsors in the House and Senate.

GA TEAM STRIPS HARMFUL RIGHT-TO-REPAIR LANGUAGE FROM NATIONAL DEFENSE BILL

Earlier in 2024, bad policy surrounding right-to-repair was included in the annual defense authorization package. AdvaMed quickly engaged, meeting with Hill offices to get the language threatening patients removed in the final package, which occurred just before the session ended.

PAHPA INCLUDED IN FINAL CONGRESSIONAL BILL ENACTED BEFORE SESSION ADJOURNS

AdvaMed Federal Affairs also secured an extension of the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization into 2025, setting the initiative up for further consideration next year.

CLINICAL LAB FEE SCHEDULE (CLFS) TO BE RECONSIDERED BY CMS

When lifechanging diagnostic biomarkers to battle Alzheimer's disease were created, CMS initially stated it would only reimburse Dx companies at a fraction of what market determinants suggested. AdvaMed Federal Affairs in Q4 secured the support and voices of several senators and members to push CMS to reconsider the set fees, something the agency later committed to doing.

Payment

MOVING FORWARD ON MODERNIZATION

AdvaMed continued its progress on a Board-approved framework to modernize CMS through improving transparency, predictability, and accountability.

With the Board's December approval, we will turn our efforts to detailing specifics such as the relocation of the Coverage and Analysis Group inside CMS, as well as outlining a Council of Innovation Advisors to improve FDA-CMS coordination. We are also engaging key external champions to ensure representation of our Innovation Agenda priorities across industry, stakeholder, and patient group communications with the agency.

Looking ahead, we are working with both CMS staff and incoming HHS/CMS administration leadership to ensure key components of our Innovation Agenda are reflected in their priorities for 2025 onward. In the short term, we are engaging CMS staff on key coverage issues, including the need for more timely release of National Coverage Determinations and ensuring the Transitional Coverage for Emerging Technologies (TCET) program functions as intended. In the longer term, we are working with senior staff and incoming administration leadership to demonstrate the value of medtech as a mechanism for expanding patient access to care, improving patient outcomes, and reducing program cost.

EXPANDING REIMBURSEMENT OPPORTUNITIES FOR ADVAMED MEMBERS

Consistent with the agency's annual rulemaking processes, the Q4 months also meant a host of comments and regulatory decisions from CMS on medtech payment priorities. This annual rulemaking to set coverage and payment for the following year is a critical component of AdvaMed's advocacy, where we can weigh in on the agency's policy direction and advocate aggressively for policies to expand patient access to medtech.

We worked with our members and CMS to secure wins on:

- Obtaining unique coding and coverage for a subset of digital therapeutics (called "digital mental health treatment" devices, or DMHT) under the Physician Fee Schedule, securing patient access to these technologies for the first time under Medicare.
- Expanding coverage of diagnostic radiopharmaceuticals by paying separately for these products, which reduces financial barriers to nuclear imaging for millions of Medicare patients.
- Enhancing colorectal cancer screening coverage by securing coverage for computed tomography colonography and expanding the definition of a "complete colorectal cancer screening" under Medicare, both of which expand patient access to these screening services.
- Reversing CMS's preliminary determination on payment for five Alzheimer's related biomarker tests under the Clinical Lab Fee Schedule. Securing gapfill on these codes creates a pathway in 2025 for a more appropriate payment rate to be set and preserves patient access to these diagnostics.