
AdvaMed
The Medtech Association
ANNUAL REPORT
2024 Year in Review

A Note from Our Board Chair

Dear AdvaMed Member,

I am proud of what our team at AdvaMed, the Medtech Association, accomplished in 2024. In an unpredictable Washington, especially during an election year when typically not much gets done in our nation's capital, AdvaMed proved the exception to the rule.

The state of the organization is strong and getting stronger from every perspective: from the financials to our progress on policies that matter to our companies, from the top-notch leadership and staff to the constantly evolving and improving educational and networking opportunities they provide for companies of all sizes in our dynamic industry.

This report provides a fantastic overview of the issues AdvaMed tackled day in, day out, on our industry's behalf last year. It makes me proud to be a long-time member, and to serve as Chair of a Board of Directors that is so committed to doing what is best at every possible turn for the industry at large. It also makes me look forward to an even more exciting 2025 and beyond. AdvaMed's continued success in Washington and around the world helps create the policy environment our companies need, so we can stay focused on the mission I know we all share—to improve and save the lives of countless patients worldwide.

Sincerely,

Peter

Peter J. Arduini
President & CEO, GE HealthCare
Chair, AdvaMed Board of Directors

A Note from Our President and CEO

Dear AdvaMed Member,

I am excited to bring you this annual report, and to reflect on the extraordinary progress AdvaMed made in 2024. It was a pivotal year for our association and the medtech industry we proudly represent.

In 2024, we reached a historic milestone. With the full integration of our new Medical Imaging Division, established in 2023, as well as the full establishment of our Digital Health Tech Division, AdvaMed now represents the entire medtech industry. In every health care setting—from the clinic to the operating room, from home health to the wrist watch monitoring your vitals—AdvaMed, in 2024, solidified its position as the leading voice for medical technology innovators around the world.

In 2024, we welcomed the largest membership base in AdvaMed's history, a testament to the value and impact of our work. We made major gains in 2024, growing our membership past both the 500 and 600 marks in one year. AdvaMed now represents more than 600 companies across the medtech spectrum.

We also hosted the largest MedTech Conference ever, and our first conference outside the U.S., bringing together industry leaders, innovators, and investors from around the globe to showcase groundbreaking devices that improve patient outcomes. Another highlight was our summer showcase on Capitol Hill, where we demonstrated to policymakers that our industry truly is the backbone of the health care system they have the power to strengthen through the patient-centric legislation AdvaMed supports.

On the advocacy front, we delivered meaningful results at the policy level for patients and our companies alike. We made major strides at CMS, securing new payment pathways that expand access to your life-transforming technologies. On Capitol Hill, we advanced several of AdvaMed's strategic priorities, reinforcing our role as a trusted advocate for innovation in health care.

The state of the medtech industry is strong not merely because of our successes together at the policy level. Just as importantly, our industry is strong because of the tremendous strides you and your companies are making on the ground—and at a pace we have never seen before.

A Note from Our President and CEO

Medtech is now a nearly $600 billion industry—that is 44% larger than in 2019, the year before the pandemic. Last year saw a record number of FDA approvals—a perfect reflection of the improvements that have been made to the FDA regulatory process through our policy work together, and of your companies' relentless focus on innovation. Leading medtech investors predict a strong, healthy dynamic for medtech in 2025 and beyond.

As we move into this confident economic atmosphere for medtech, we are also celebrating AdvaMed's 50th anniversary. While we are proud of those 50 years, we are even more energized by the opportunity the next 50 give us to continue serving this incredible industry, to walk with you, side by side, as you develop the next generation of medtech. Together, we are shaping the future of health care. We are the future of health care.

On behalf of AdvaMed and countless patients worldwide, thank you for your remarkable work—and thank you for your partnership with AdvaMed, the Medtech Association.

Sincerely,

Scott

Scott Whitaker
President & CEO
AdvaMed

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 more than 600 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, a new addition to AdvaMed's membership offering.

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 leader of a global industry. Each state has 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 two million direct and indirect jobs nationwide and another additional one million jobs outside the United States. Medtech manufacturing jobs pay 49% more than any other industry and 18% more than other manufacturing jobs. Medtech is a leading 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.

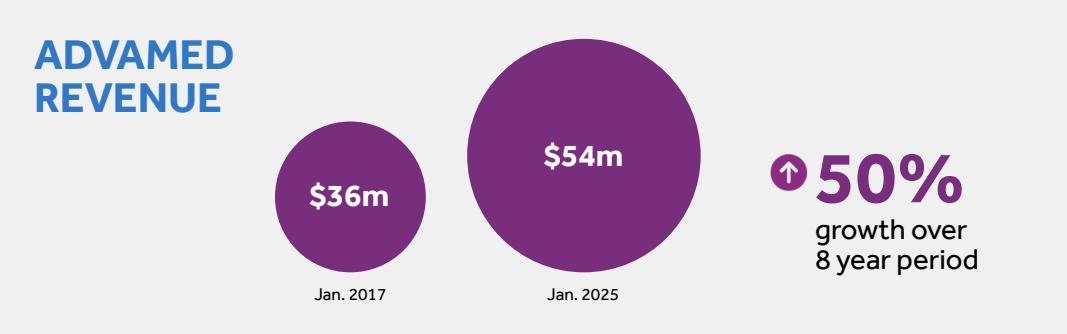
For more, please see advamed.org/medical-device-industry-facts/ or scan this code.

Association Financials

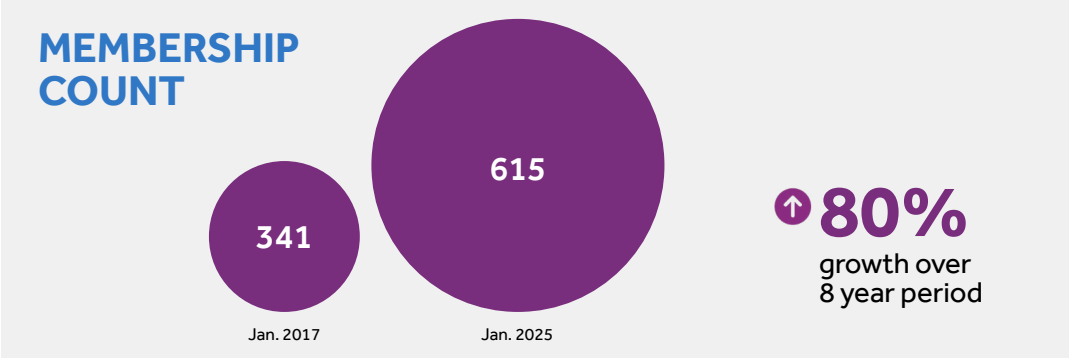
In recent years, AdvaMed has experienced strong growth in both our membership and financial position, driven by our expansions of the Digital Health Tech, Medical Imaging, and Accel divisions, and the issue sets that drive value for these members and the industry at large. This expansion has strengthened our ability to serve all of our members, enabling us to advocate more effectively at both the state and federal levels.

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 $54 million trade association, with average, steady growth of 10% 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 615.

Association Financials

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.

AdvaMedDx

AdvaMedDx's Zach Rothstein testifying in Congress

DIAGNOSTICS REGULATORY REFORM

A core focus this year was the VALID Act, which would reform diagnostics regulation. To advance this effort, AdvaMedDx built a coalition by partnering with Congress, patient advocates, and laboratory stakeholders. Zach Rothstein testified before the U.S. House Energy & Commerce Committee's subcommittee on health to emphasize the need for diagnostics reform.

The AdvaMed effort received bipartisan support including a congressional briefing led by staff from U.S. Representatives Larry Bucshon and Diana DeGette's offices, which featured insights from former FDA Commissioner Dr. Mark McClellan. Additionally, AdvaMedDx amplified our position with a high-profile op-ed that made a compelling case for diagnostics reform. Click HERE to read it.

It is essential to establish a modernized regulatory framework for diagnostics that prioritizes patient safety while fostering innovation. Moving forward, AdvaMedDx will continue its advocacy and coalition-building efforts until Congress enacts regulatory reform that aligns with the industry's vision and patient needs.

AdvaMedDx

STRENGTH IN PARTNERSHIP

AdvaMedDx strengthened its partnership with the Centers for Disease Control and Prevention (CDC) around key public health priorities.

As part of this collaboration, AdvaMedDx cohosted an "Industry Day" focused on diagnostics stewardship and antimicrobial resistance. We also engaged CDC leadership on various diagnostic initiatives, including the wastewater surveillance program designed for early disease detection.

Additionally, AdvaMedDx pushed for public health funding and support 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 the passage of the PASTEUR Act, which would strengthen our preparedness against antimicrobial resistance.

By working closely with the CDC and advocating for strong public health measures, AdvaMedDx is positioning diagnostics as a cornerstone of national health preparedness.

Moving forward, AdvaMedDx will continue expanding our partnerships with the CDC and advocating to ensure that diagnostics remain central to future public health policies and funding decisions.

Medical Imaging

AdvaMed hosted the U.S. Senate AI Demo Day, which highlighted the latest AI technologies from several AdvaMed members, demonstrating the value of AI-driven advancements in medical imaging.

AdvaMed has fully integrated the Medical Imaging division into the organization, making it officially the largest organization with representation across all sectors of the medical technology field.

Never before have technologies such as AI, digital health, and imaging been so interdependent and connected, and AdvaMed is uniquely prepared to represent them all.

ADVAMED: A STANDARDS DEVELOPER

AdvaMed earned accreditation in 2024 by the premier American National Standards Institute (ANSI) to develop industry standards. Achieving ANSI accreditation is a testament to AdvaMed's long history of advocating for and upholding the highest standards on behalf of the patients we serve. AdvaMed's ANSI-accredited standards will help ensure that the guidelines and specifications we develop reflect the consensus of imaging experts, aligning the practices and technologies of different manufacturers to foster uniformity and higher quality across the industry. AdvaMed will begin by developing standards for medical imaging technologies, including applications important to all of medtech, such as cyber security and artificial intelligence.

This positions AdvaMed as a trusted leader in developing standards that can be adopted not only nationally but globally, driving consistency across the industry worldwide.

Medical Imaging

PAYMENT PATHWAY FOR AI TECHNOLOGY

Capitol Hill is increasingly aware, as a result of our advocacy work, of the value of AI in medtech and the need to ensure appropriate Medicare reimbursement for AI-enabled medtech. The House and Senate committees of jurisdiction incorporated AdvaMed's language urging CMS to establish a formal payment pathway for services provided through algorithm-based health services (ABHS). Our work with key members of Congress on both sides of the Capitol in 2024 put us in a position in 2025 to have legislation introduced to address payment and coverage for ABHS for the first time ever.

In addition, four Senators sent a bipartisan letter to the Centers for Medicare & Medicaid Services (CMS) to develop a formalized payment pathway for algorithm-based health services (ABHS) in the upcoming Hospital Outpatient Prospective Payment Systems (HOPPS) rulemaking cycle. Reimbursement will accelerate the adoption of these innovative technologies to provide better patient care.

CMS GREENLIGHTS RADIOPHARMACEUTICALS AND CT COLONOGRAPHY COVERAGE

As a result of our advocacy work with CMS, Medicare in 2024 expanded access to diagnostic radiopharmaceuticals by allowing for separate reimbursement to recognize the actual cost of these procedures, a longstanding priority of the Medical Imaging division. This change will improve the access of Medicare beneficiaries to advanced imaging for conditions such as Alzheimer's disease and cancer.

Medicare coverage, as a result of our efforts, also now includes virtual colonoscopies and blood-based biomarker tests, increasing colorectal cancer screening options. These new screening methods allow for less-invasive procedures and earlier diagnoses.

This expansion of coverage brings cutting-edge treatments and diagnostics to Medicare patients, improving accessibility and options for them, with a special focus on life-altering conditions like Alzheimer's and cancer.

Accel

FROM IDEA TO IMPACT

AdvaMed's Accel division has worked to create a better environment for small medtech companies by addressing regulatory, reimbursement, and tax challenges that limit early-stage investment.

To support this effort, AdvaMed developed toolkits for Capitol Hill that map the medtech innovation path from concept to patient access, giving members of Congress and their staff a clear view into the hurdles small medtech companies face along the path from innovation to market.

Approximately **82%** of medical device companies are small businesses

The team also partnered with government affairs and external stakeholders to make the tax policy needs of small medtech companies clear to the U.S. House Ways & Means Committee, setting up our advocacy for the debate in Congress in 2025 over the reauthorization of the Tax Cuts & Jobs Act passed in 2017. Additionally, Accel Board Chair Dr. Lishan Aklog testified before Congress in support of our AdvaMed-led breakthrough legislation (see the Federal Government Affairs section), which significantly benefits small companies.

Small companies play a crucial role in medtech innovation, yet funding barriers and policy limitations often prevent groundbreaking developments from reaching patients. Moving forward, Accel will strengthen investor engagement through quarterly meetings and networking events. The Investor Forum at The MedTech Conference, which saw record turnout in Toronto, will continue to be a key platform for fostering investment in early-stage medtech companies.

BRIDGING HEALTH GAPS

AdvaMed has advanced health equity by addressing disparities in product access and development, with a particular focus on neurovascular, cardiovascular, and women's health.

To drive this initiative, AdvaMed presented key findings to health policy organizations, shared a gap analysis at the Academy Health Conference, and used these insights to recommend policy revisions to the Centers for Medicare & Medicaid Services (CMS) aimed at improving coverage and access for beneficiaries.

Looking ahead, AdvaMed will expand collaborations with patient groups to jointly address health equity challenges and will continue working with CMS to refine policies that affect patient access.

Accel

NEW POLICIES ADVANCING WOMEN'S HEALTH

AdvaMed's women's health equity initiative has successfully pushed for policy changes and increased funding to support the development of women's health products.

As part of this effort, AdvaMed developed recommendations for the White House Initiative on Women's Health Research, leading to new policies that direct increased funding across federal agencies to advance innovation in women's health. Targeted funding and policy support for women's health can accelerate the development of products in historically underfunded areas, benefiting millions of women.

Federal Government Affairs

AdvaMed connected our board with influential policymakers, providing a platform for direct advocacy on medtech priorities.

Even as political pundits in January were already writing off 2024 as one of the least productive sessions of Congress in generations, the AdvaMed Federal Government Affairs team was strategically positioning the industry to secure long-sought victories in key sectors for our members.

The team knew early in the year that few congressional bills would become law given the partisan gridlock, all while recognizing that the regulatory agencies were busy finalizing rules and mandates that carried billion-dollar consequences, not to mention their impact on patients.

Whether the call was to help four member companies that comprise a small yet critical care area of medtech, or a provision that impacted 90+ percent of the industry, Federal Affairs tailored its advocacy to meet the needs of our members. From recruiting patient advocates to carry a specific message on right to repair, to presenting highly technical environmental scientists to EPA as it updated the ethylene oxide rule, to sponsoring a House/Senate-wide showcase on the wonders of medtech, to flying to key parts of the country to meet personally with lawmakers on an issue, to working with bill authors on specific provisions improving health policy for millions, the Federal team leveraged its entire advocacy arsenal, and produced lasting results.

When it's too hard for others, it's just right for AdvaMed Federal! Below is only a snapshot of the team's work in 2024.

ENSURING STERILIZATION CAPABILITY FOR BILLIONS OF MEDICAL INNOVATIONS

When it comes to assessing the potential impact of federal regulatory rulemaking, few issues carry the label of "existential." Yet that is the exact threat the industry faced when EPA set out in 2018 to overhaul the way medtech sterilizers disinfected more than 20 billion medical innovations through a chemical known as ethylene oxide (EtO). Working with several AdvaMed departments, the Federal team spearheaded a multi-year, multi-million dollar effort to set the record straight not just on the

Federal Government Affairs

safety of EtO in the communities where our members sterilized, but also in signaling just what was at stake for American public health, should EPA, FDA, and the Administration get the policy wrong. Six years later, AdvaMed secured not one but two landmark provisions that continued protecting the communities surrounding these facilities while ensuring needed capacity to sterilize medtech for decades to come.

A BREAKTHROUGH ON TCET

Although Congress failed to enact legislation to improve Medicare access to FDA-approved breakthrough technologies in 2024, Federal Affairs secured significant wins on the measure, setting the stage for consideration in 2025.

Some of the key accomplishments include a record number of bipartisan supporters, with more than 90 sponsors, and the bipartisan introduction of the measure in the Senate. AdvaMed also hosted a briefing that was attended by more than 50 Senate staff members and achieved the first-ever Congressional Budget Office (CBO) score (i.e., its official projected cost to the government) for the measure.

By making breakthrough technologies eligible for Medicare coverage, millions of patients will gain faster access to life-saving innovations, improving early diagnosis and treatment. Moving forward, AdvaMed will continue advocating for the finalization and implementation of TCET guidance in 2025, expanding Medicare's reach to cover transformative treatments and diagnostics.

RIGHT TO REPAIR ... PREVENTED

AdvaMed successfully prevented the inclusion of a "right to repair" provision in the final National Defense Authorization Act (NDAA), safeguarding the integrity of medical devices.

To achieve this outcome, the Federal Affairs team met with key staff from the House Armed Services Committee (HASC) and the Senate Armed Services Committee (SASC) to emphasize the risks of unauthorized repairs to device safety and thus to patients. This advocacy effort was particularly impactful, as few others were actively advocating against the provision.

Ensuring that only authorized repairs are permitted protects patient safety from risks associated with improperly maintained or modified medical devices. This is especially crucial for life-supporting and high-risk technologies that require precise maintenance to function safely and effectively.

BURDENSOME SHORTAGE REPORTING REQUIREMENTS AVERTED

In various policy circles throughout the year, lawmakers would push arbitrary requirements for more reporting of medical device shortages, without stipulating the goals, the reasons behind the mandates, nor the intended use beyond what member companies already provide to the government. The Federal team was able to stifle every attempt at the effort, highlighting instead the many ways medtech manufacturers assist the government in what potential gaps in production they see, as well as efforts they take each day to mitigate potential supply disruptions.

Federal Government Affairs

PAHPA AND SAFETY STREAMLINING

Often times, there are simply bad policies that come out of Washington. Federal Affairs successfully prevented the inclusion of the FDA's proposed shortage reporting requirement in the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), avoiding additional burdens on providers.

Additionally, Association lobbyists fought to include Medicare lab cut reversals. Reversing these cuts helps protect access to essential diagnostic tests for Medicare beneficiaries, ensuring that patients receive timely and critical lab services for better health outcomes.

FEDERAL TEAM LOBBIES TO LOCK IN KEY REIMBURSEMENT PROVISIONS IN JAPAN

Federal advocacy does not stop at our nation's shores. For more than two years, Federal worked with our Global team to carry an important issue surrounding fair and reasonable reimbursement rates in the country of Japan for our members manufacturing there. AdvaMed Federal took to the Hill, pushing a broad bipartisan letter among key House and Senate leaders calling on Japan through the State Department and other entities to address a critical issue facing companies overseas. The advocacy resulted in new rates announced in 2024 impacting hundreds of medtech manufacturers.

QUICK ACTION TO POTENTIALLY INJECT HUNDREDS OF MILLIONS TO CARE FOR ALZHEIMER'S PATIENTS

One of the world's most debilitating and pernicious diseases came face to face with a new enemy recently in the form of new neuro-biomarker tests created by AdvaMed members. The test codes promised to help the 14 million-plus Americans suffering from or potentially predisposed to Alzheimer's over the next 5 years. Yet when CMS published its preliminary forecasts on how much the agency would be willing to pay to cover the tests, it was well below the market-based rationale AdvaMed Dx members argued for. AdvaMed's Federal team did not sit by, instead storming the Hill, holding briefings among lawmakers and staff to educate on the advent of this new marvel, and how the proposed CMS reimbursement threatened to stall this potentially lifesaving test. The efforts proved effective, with CMS later bowing to the pressure and signaling the agency would reevaluate its decision, potentially raising the reimbursement to reflect appropriate rates and helping speed the tests to millions of Americans.

MEDICARE CUTS AVOIDED ON CRITICAL CLINICAL LAB TESTS

Finally, just before Congress adjourned for the year, Federal Affairs was able to push through a measure to defer Medicare reimbursement cuts of up to 15% for clinical laboratory tests. The scheduled cuts would have further dampened our Dx members from making the investments needed to keep innovating in the IVD test space. Working with AdvaMed members and the policy departments, the team was able to enumerate just how harmful the cuts would be, and where innovation would suffer the most.

Global Policy

BD's James Deng, longtime chair of AdvaMed's China Board, receiving an award from AdvaMed's Scott Whitaker at the Celebration of the 10th anniversary of our China Office.

POSITIVE JAPAN REIMBURSEMENT RESULTS

Our top goal was to limit Foreign Average Pricing (FAP) price reductions, and we successfully achieved this goal with 2024 FAP reductions 81% lower than the cuts in 2022. This means that fewer products sold by AdvaMed members in Japan had their reimbursement rates cut, and the cuts that were applied were not as severe as they could have been.

Only 9 product categories will be subject to foreign average pricing (FAP) reductions, compared to 19 categories last cycle. This is the lowest number of category reductions since the FAP system was introduced in 2002.

RUSSIA LICENSE EXCEPTION

AdvaMed has been working with the U.S. Department Of Commerce and other key federal agencies since May when the Bureau of Industry and Security (BIS), in an unprecedented step, placed export controls on much of our industry, significantly hampering our companies' ability to deliver medical devices to civilian patients. The new rule is in line with, and in some cases goes further than, AdvaMed's own proposals to Commerce.

FROM POLICY TO PROGRESS: NATIONAL REGULATORY LEADERS CONVENE FOR UNPRECEDENTED DISCUSSIONS

The Medical Device Regulatory Convergence team hosted a virtual training session for over 100 representatives of new and prospective IMDRF national regulatory authority representatives. This is the first such training that the IMDRF has conducted with these new and prospective NRAs – achieving a long-standing AdvaMed priority and request.

Global Policy

INDIA JOINS IMDRF AS AN AFFILIATE MEMBER

This is an important strategic development for global harmonization initiatives. AdvaMed assisted with the application process and will work with FDA on the onboarding process.

NATIONAL SECURITY AND ECONOMIC SANCTIONS (NS&ES) WORKING GROUP UNDER WAY

Working in partnership, the Legal and Global teams hosted our first meeting of the NS&ES working group and immediately jumped into two pressing items – the Notice of Proposed Rulemaking (NPRM) for data security and expansion of end-user rules for exports to several key countries.

CELEBRATING 10 YEARS

In November, AdvaMed marked the 10th anniversary of our China Office with an event in Shanghai. This occurred alongside the seventh China International Import Expo (CIIE) and drew more than 250 guests from the government of China, the U.S. Consulate General in Shanghai, hospitals, and 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 AdvaMed's Scott Whitaker.

Worth noting was our first-ever Industry Innovation Leadership Award recognizing contributions to health care in China. James Deng, Senior Vice President and General Manager of BD China, was the deserving recipient for serving as our first China Board Chair for almost a decade, from the establishment of AdvaMed's office in China through the COVID-19 pandemic.

Technology & Regulatory Affairs

AdvaMed's Janet Trunzo speaking at an IMDRF event.

The Technology & Regulatory Affairs department achieved several advances in 2024 that will help medtech companies better serve patients.

MEDICAL DEVICE STERILIZATION CAPACITY

In the spring, the EPA issued its final rule regulating ethylene oxide (EtO) in medical device sterilization, impacting the critical processes for keeping medical technologies safe for patients.

As initially proposed, this rule could have reduced sterilization capacity by 30 to 50 percent, creating a significant risk to patients' access to sterile, life-saving devices. Reduced capacity could have delayed surgeries and critical procedures, affecting patient safety nationwide.

AdvaMed and member companies took action with over 45 technical meetings with the EPA, FDA, and administration officials to share the medtech perspective with regulators, demonstrate the limitations of current alternatives, and to collaborate with health care stakeholders, including doctors, hospitals, and health groups, to emphasize patient needs.

Technology & Regulatory Affairs

EPA adjusted the rule to maintain a stringent standard that protects environmental and public health while preserving sterilization capacity. This balanced approach safeguards patients' access to sterile devices without the severe limitations initially proposed.

QUALITY MANAGEMENT SYSTEM REGULATION HARMONIZATION

In 2024, FDA issued the long-awaited Quality Management System Regulation (QMSR) that promotes global harmonization and reduces technical burdens while ensuring patient safety and public health.

The final rule eliminates the need for member companies to maintain multiple quality systems. FDA has estimated the rule will result in savings of over $500 million a year because of the regulatory alignment with other jurisdictions. Issuance of the final rule with a two-year implementation period will result in efficiencies for industry to facilitate innovation while still guaranteeing patient safety.

The International Medical Devices Regulators Forum (IMDRF) accepted the Industry Proposal – led by AdvaMed – that included recommendations for establishing an industry advisory group and ways in which the group can engage and support the shared industry and IMDRF goals for regulatory convergence.

GLOBAL HARMONIZATION

AdvaMed played a leadership role at both the spring and fall meetings of the International Medical Device Regulators Forum (IMDRF) in 2024, given the FDA's role last year as chair of the organization. IMDRF is a collection of medical device regulatory bodies from around the world with the mission of accelerating regulatory harmonization across borders.

AdvaMed was proud to lead advocacy for the creation of the IMDRF Industry Group to create more formal and clear engagement opportunities for the industry with the IMDRF management committee. This group was approved by IMDRF in December.

Public Affairs

AdvaMed's Scott Whitaker interviewing tennis legends Chris Evert and Martina Navratilova for AdvaMed's Medtech POV podcast.

Heading into 2024, the Public Affairs Department set out with a clear two-pronged strategy: 1) promote and defend the industry in every media outlet, no matter its size; and 2) seek creative, alternative ways in this new media environment to put a spotlight on the technologically superior aspects of our member companies and how they serve patients.

In every corner – from our weekly press releases and desk-side briefings with reporters to our can't-miss Medtech Showcase – we took advantage of every opportunity to tell our industry's incredible story.

DEFENDING A CRITICAL PROCESS THAT MAKES 20 BILLION MEDICAL TECHNOLOGIES SAFE FOR PATIENTS

As EPA worked over the past 5 years to update its regulation governing the ethylene oxide sterilization process, the AdvaMed public affairs team engaged directly in education-and-awareness efforts to help media understand this highly complex public health issue. Our work consisted primarily of working directly with the dozens of reporters around the nation covering the issue. When EPA released its final rule in Spring 2024, this foundation-laying work culminated in AdvaMed's viewpoint being included in 75% of the 1,300+ stories covering the EPA's finalized rule. We set out to ensure AdvaMed's voice would be front and center as part of our advocacy surrounding the rule—and we succeeded.

Public Affairs

DEMONSTRATING THE POWER OF MEDTECH TO OUR NO. 1 AUDIENCE: CAPITOL HILL

Our traditional, annual Medtech Showcase on Capitol Hill was paused for several years by the pandemic—and it made a powerful comeback in 2024.

This year's theme was selected not merely for its policy importance but for its newsworthiness as well: Expanding access to medtech for every patient in need, regardless of background or location, is our industry's highest mission. The second theme – artificial intelligence's role in health care – is top of mind for regulators and lawmakers in Washington. Demystifying the technology for those seeking to regulate it was a top priority of 2024's event, and it was a success: More than 250 congressional staff and members of Congress attended a standing-room-only event featuring 44 member companies in the historic Cannon Caucus Room on Capitol Hill.

BRINGING 50 YEARS OF INNOVATION TO LIFE AT THE MEDTECH CONFERENCE

As AdvaMed celebrates 50 years of advocacy, the public affairs team helped bring AdvaMed CEO Scott Whitaker's keynote address to life in front of an audience of more than 1,500 attendees. For 8 minutes, the audience was treated to a visually stunning "before and after" journey through the incredible strides medtech has made in patient care since AdvaMed's founding in 1974—as well as a sense of what awaits patients on the horizon. Click HERE to watch the video tribute to you and your innovations as they have evolved over the past 5 decades.

TELLING THE STORY OF MEDTECH—THROUGH YOUR TECHNOLOGIES

Heading into 2024, we launched a social campaign called #DeviceOfTheWeek, an opportunity for member companies to share their remarkable technologies on our social media channels. It proved to be our most popular campaign in years, leading to a tripling of impressions on LinkedIn within one month of launch, and a nearly 25% increase in followers in 2024 (compared to the "industry average" of 12% follower growth in a typical year). Engagement—defined as a follower liking, sharing, or commenting on a post—is a good gauge of a social media channel's value to its followers: Engagement on our AdvaMed LinkedIn page doubled in 2024 compared to 2023. And this growth was purely organic.

CELEBRATING INDUSTRY GIANT CAROLL NEUBAUER'S EXTRAORDINARY CAREER IN MEDTECH

At every MedTech Conference, AdvaMed honors one individual who has had an outsized impact on patients as a leader in medtech throughout their career. This year, AdvaMed honored Caroll Neubauer, who served on the AdvaMed Board of Directors for more than 15 years and for multiple years as chair of The MedTech Conference. AdvaMed public affairs produced the video honoring a great friend to AdvaMed, to the industry he loves, and to the countless patients he has spent his entire career serving (click HERE to watch).

Public Affairs

REVITALIZED BOARD COMMITTEE FOCUSED ON PUBLIC AFFAIRS, MEDIA

In mid 2024, AdvaMed revitalized the Board-level Industry Communications Committee (ICC) under the leadership of Board member Tim Dugan of Water Street Healthcare Partners. The committee is instrumental in advising AdvaMed's public affairs team on its strategy, messaging, and tactics as we tell the story of medtech through all forms of media. The committee's 2024 revamp sets AdvaMed public affairs up for an even more successful 2025 telling the story of medtech.

Payment & Coverage Policy

AdvaMed's Carol Blackford, GE HealthCare's Taha Kass-Hout, and the FDA's Troy Tazbaz.

AdvaMed achieved significant progress on key payment policy initiatives in 2024. New payment pathways are vital for ensuring patients have timely access to our companies' products. Ultimately, new payment models empower health care providers to deliver the best possible care, driven by innovation and tailored to individual patient needs.

The team secured Centers for Medicare & Medicaid Services (CMS) participation in multiple high-profile events, including AdvaMed's Spring Policy Forum, Board meetings, and a webinar on the Final Transitional Coverage for Emerging Technologies (TCET) notice.

CMS FINALIZES ADVAMED-BACKED BREAKTHROUGH

More than three years after repealing the prior administration's AdvaMed-backed Medical Coverage of Innovative Technologies (MCIT) rule, CMS released its replacement rule in August 2024. The new Transitional Coverage of Emerging Technologies (TCET) process with improved transparency, while not as robust as MCIT, mirrors AdvaMed's recommendations and is a step further down the road toward the more expansive policy we continue to advocate for.

Payment & Coverage Policy

The team also supported the legislative efforts mentioned in the Federal Government Affairs section, including breakthrough coverage policies, through strategic Hill engagement and expert analysis.

PAYMENT WIN ON RADIOPHARMACEUTICALS

Through an AdvaMed-wide effort, we were able to secure separate payment pathways for radiopharmaceuticals in the Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) final rule as well as securing coverage for Digital Mental Health Technologies, a subset of digital therapeutics, through the Physician Fee Schedule final rule.

PARTNERING WITH AMA FOR PATIENTS

Our team's engagement with the American Medical Association (AMA) focused on improving recognition of medtech in Current Procedural Terminology (CPT) coding, especially for diagnostic and digital technologies.

Notable achievements include participation in the CPT Pathology Coding Caucus and the Digital Medicine Coding Committee, alongside leadership of "Horizon 2030," which updates AI taxonomy in CPT codes.

Advocacy efforts with CMS on Medicare Advantage (MA) priorities emphasized transparency in prior authorization processes, particularly around the use of AI in prior authorization reviews. Several AdvaMed recommendations were included in the CY 2026 MA/Part D proposed rule, and plans for 2025 include expanding commercial payer engagement.

Legal

AdvaMed General Counsel and Chief Policy Officer Chris White and Christine Wilson, former FTC Commissioner.

ADVAMED UPDATES CHINA CODE OF ETHICS FOR MEDTECH

AdvaMed has updated its China Code of Ethics, reaffirming the medtech industry's dedication to ethical and compliant partnerships with health care providers in China. The update ensures that the code reflects the evolving legal, regulatory, and operating environments.

AdvaMed's China code sets a clear framework for ethical operations, promoting trust and compliance in the developing medtech landscape.

DMCA CIRCUIT COURT DECISION

In AdvaMed's challenge to exemptions permitting third-party repair companies to bypass copyright protections on medical devices, the D.C. Circuit Court of Appeals ruled favorably, holding that exemptions to the Digital Millennium Copyright Act (DMCA) are subject to judicial review.

While there are additional trial court actions to come, this ruling strengthens medtech innovation by ensuring regulations impacting patient safety and intellectual property are subject to judicial oversight. It also reinforces patient safety.

ADVAMED LEGAL TEAM BY THE NUMBERS: DRIVING INDUSTRY SOLUTIONS

AdvaMed's legal team delivered education and collaboration opportunities that reached thousands of members, ensuring member companies stay informed, compliant, and ready to address legal, regulatory, and policy changes.

Legal

- More than 600 participants joined webinars on critical topics like the Supreme Court's Chevron decision, FTC rulings, and compliance education, gaining insights to stay ahead of the curve.
- Over 2,000 members engaged through working groups and committees, shaping policy, sharing expertise, and collaboratively solving industry challenges.

AdvaMed's numbers tell the story: a robust legal policy program driving real-world solutions for medtech companies.

Digital Health Tech

Front row: Dawn Haake, ResMed; Taha Kass-Hout, GE HealthCare, DHT Board Chair; second row, Venk Varadan, Nanowear; Anila Lingamneni, Haemonetics.

BIG STEP FORWARD FOR DIGITAL MENTAL HEALTH SERVICES

In a big win for AdvaMed and patients after several years of advocacy, CMS issued a final rule extending coverage to a subset of digital therapeutics, specifically for Digital Mental Health Technologies (DMHT). This expansion will allow Medicare patients to access innovative mental health treatments via digital tools, marking a major step in advancing mental health care through technology.

Extending Medicare coverage of Digital Mental Health Technologies will enhance access to digital mental health tools for Medicare patients, addressing a critical need for accessible, technology-driven mental health solutions.

Critical advocacy partners included the Consumer Technology Association, the Digital Therapeutics Alliance, and the American Psychological Association. We thank them for their partnership on this big step forward for patients suffering from mental health issues.

Digital Health Tech

ESTABLISHMENT OF THE CONGRESSIONAL DIGITAL HEALTH CAUCUS

As the industry has expanded into the digital health space, AdvaMed began to advocate for a congressional caucus focused on advancing the integration of digital health technologies into our health care system. The U.S. House "Caucus of Digital Health Champions" was formed in early 2024, and soon thereafter convened a panel discussion that included AdvaMed Digital Health Tech Board Member David Rhew of Microsoft. AdvaMed also cohosted a panel with the caucus on remote patient monitoring. AdvaMed continues to work with caucus leadership, U.S. Representatives Troy Balderson and Robin Kelly, and the entire group of lawmakers to aid their mission to "ensure all Americans have access to safe and effective digital health technologies."

ADVAMED DHT DELIVERS DIGITAL HEALTH PRINCIPLES

AdvaMed's release of three sets of digital health principles this past fall underscores our commitment to advancing innovation while ensuring patient safety, data security, and the ethical use of AI in medtech.

These principles provide a clear framework for policymakers, health care providers, and industry leaders to navigate the rapidly evolving digital health landscape with confidence and responsibility. AdvaMed is driving the future of digital health in a way that enhances patient outcomes and strengthens trust in medical technology. Read the principles HERE, HERE, AND HERE.

State Affairs

Colorado State Capitol

PATIENT SAFETY, PRIORITIZED

AdvaMed successfully prevented any state from applying right-to-repair laws to medical devices in 2024.

In Colorado and Oregon, both states passed right-to-repair laws that included robust exemptions for medical devices, ensuring patient safety remained a priority. Additionally, AdvaMed led successful efforts to defeat right-to-repair legislation specifically targeting medical devices in both Hawaii and Washington.

DUPLICATIVE AI REGULATION, DEFUSED

Several states, including California and Florida, attempted to pass legislation regulating the use of artificial intelligence. AdvaMed actively opposed these measures and ultimately helped defeat them.

In Colorado, the state enacted a broad law regulating AI but incorporated existing FDA regulations on AI in medical devices. This "carve-in" effectively prevented the Colorado law from applying to medical devices, ensuring regulatory consistency with federal oversight.

State Affairs

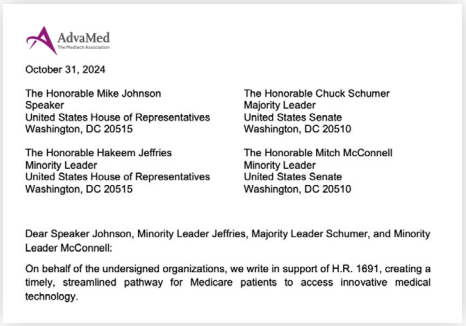
PATIENT ACCESS, INCREASED

AdvaMed joined patient advocacy organizations to expand patient access to biomarker testing and supplemental breast cancer imaging and diagnostics across multiple states.

In the area of biomarker testing, states such as Colorado, Florida, and Indiana passed laws expanding coverage, improving access to critical diagnostic tools for patients.

For breast cancer imaging, Alaska, Kentucky, Massachusetts, New Hampshire, and Vermont enacted laws eliminating patient cost-sharing for supplemental breast cancer imaging and diagnostics, reducing financial barriers to essential screenings.

Alliance Partnerships



AdvaMed

October 31, 2024

The Honorable Mike Johnson
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
Minority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

Dear Speaker Johnson, Minority Leader Jeffries, Majority Leader Schumer, and Minority Leader McConnell:

On behalf of the undersigned organizations, we write in support of H.R. 1691, creating a timely, streamlined pathway for Medicare patients to access innovative medical technology.

Patients are at the center of our industry, and bringing their voices into our policy and regulatory work only makes it stronger. Reflecting this, AdvaMed consistently engages patient advocacy organizations both to better understand their challenges and perspectives, and to advocate together for policy solutions that benefit them. These engagements thread throughout AdvaMed's work and range from listening sessions and briefings to coalition letters and meetings on Capitol Hill. Elevating patient voices on the impact of medtech for policymakers is critical to our success, and AdvaMed is building an industry-leading effort to do just that.

ACTIVATING FOR PATIENT ACCESS

AdvaMed organized a letter, signed by more than 60 organizations, in support of including legislation to increase patient access to breakthrough medical technologies (H.R. 1691) as part of a congressional end-of-year package.

CONVENING FOR PATIENT ACCESS

AdvaMed hosted separate roundtables with patient advocacy organizations and AdvaMed members to address two key patient access issues: Alzheimer's biomarkers and diabetes technology.

For Alzheimer's biomarkers, the discussion focused on identifying challenges that limit patient use of biomarkers for Alzheimer's disease and exploring opportunities for collaboration to address these barriers.

Regarding diabetes technology access, the conversation centered on building upon recent policy successes that have expanded patient access to continuous glucose monitors (CGMs) and identifying ways to coordinate action across different levels of government.

LAYING A FOUNDATION FOR INCREASED PATIENT ACCESS

Throughout the year, AdvaMed convened patient advocacy and physician society groups for discussions on the regulation and use of artificial intelligence in medical technology. These conversations also explored opportunities for additional educational initiatives and collaboration.

By fostering these discussions, AdvaMed continues to build trust as both a reliable source of information and a strong partner in advancing policies that enhance patient access to AI-enabled medical technology.

Conferences & Education

The MedTech Conference, 2024

AdvaMed's Conferences & Education offering has emerged from the Covid era stronger than ever, achieving remarkable success in rebuilding in-person engagement and attendance. This past year, AdvaMed hosted the largest MedTech Conference in our association's history, setting new records for participation – 25 percent larger than any previous conference – and showcasing the industry's resilience and innovation. Revenue from The MedTech Conference was $7.4 million.

Additionally, the CEO Summit is a premier annual forum for medtech CEOs to exchange ideas, discuss industry challenges, and strengthen their professional networks. In 2024, AdvaMed saw record participation at our March CEO Summit, reflecting its growing importance as a platform for collaboration and professional – as well as company – growth. As the medtech industry continues to evolve, the CEO Summit plays a critical role in fostering innovation and shaping the future of the medical technology world.