AdvaMed
The Medtech Association

AdvaMed Advancements
Q1 2025 Report

A Note from Scott

Dear AdvaMed Member,

As we moved through the first quarter of 2025, AdvaMed remained steadfast in our mission to advance patient care through medtech innovation. We knew a new presidential administration and a closely divided Congress would present both challenges and opportunities for our industry. Without question, the biggest challenge AdvaMed has taken head on—since the day after Election Day 2024—is tariffs.

The uncertainty of the past several months makes it hard for you to do business and even harder to plan ahead. I've heard from many of you that your investment plans are on hold until tariff uncertainty is resolved. That is why tariffs quickly became our No. 1 priority here at AdvaMed.

At the highest levels of government, including meetings with the President and his chief of staff, U.S. Trade Representative Greer, other key leaders throughout the Administration, and leaders in the U.S. House and Senate, we have left no stone unturned in our work to communicate the uniqueness of our industry. We will continue to make our very strong case that medtech merits exemption from any tariffs.

While we cannot take full credit, of course, we united with others in the health care and business community to make our case, together, and there is no question that the cumulative impact of our advocacy and our powerful message weighed into the President's decision on April 9 to pause reciprocal tariffs for 90 days.

Of course, that fight is not over. Which is why we will not let up in our push to make clear that these policies jeopardize American leadership in medtech innovation and manufacturing, supply chain resilience, and patient access to the technology that is the backbone of our health care system. Success in this regard looks like this: An agreement with this administration, that where and when tariffs are contemplated, medtech should be exempted from those conversations and considerations.

Our work on this continues 24/7 into Q2!

Thank you to all of you for your membership. AdvaMed now represents more than 600 companies, from multinational corporations to the smallest startups, our largest membership ever. We're proud to visit the White House and the halls of Congress on your behalf. Our large, diverse membership presents strength and rock-solid credibility in our advocacy.

A Note from Scott

This industry has weathered storms before and prevailed. The unfair medical device tax, ultimately repealed, is a good example. Our commitment to our members and the patients you serve is unwavering, no matter what headwinds we face. We will continue driving innovation, shaping policy, and ensuring medtech continues to improve lives worldwide.

Thank you for your continued partnership and leadership.

Sincerely,

Scott

Scott Whitaker
President & CEO
AdvaMed

Tariffs

Senator Bill Cassidy and GE HealthCare President and CEO and AdvaMed Board Chair Peter J. Arduini

FULL-COURT PRESS ON TARIFFS

AdvaMed's push for a medtech exemption for all tariffs required the highest levels of engagement across the organization, working closely with our member companies for data on the impact of tariffs on their ability to serve patients to cite in our advocacy work. This work began even before the 2024 election, with the President's transition team, as we took very seriously his campaign rhetoric surrounding tariffs. And of course, the groundwork we laid pre-election took off in earnest the day after the election, and it hasn't let up since.

President and CEO Scott Whitaker, the Global Affairs team, the Federal Government Affairs team, the Accel division for small companies and startups, the Public Affairs team, all of us guided by our Board of Directors, set 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. As the backbone of our health care system, the medtech industry—and the patients we serve—simply would be hit by tariffs in ways significantly different from how they would hit every other aspect of our economy.

Tariffs

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.

ENGAGING TRADING PARTNERS

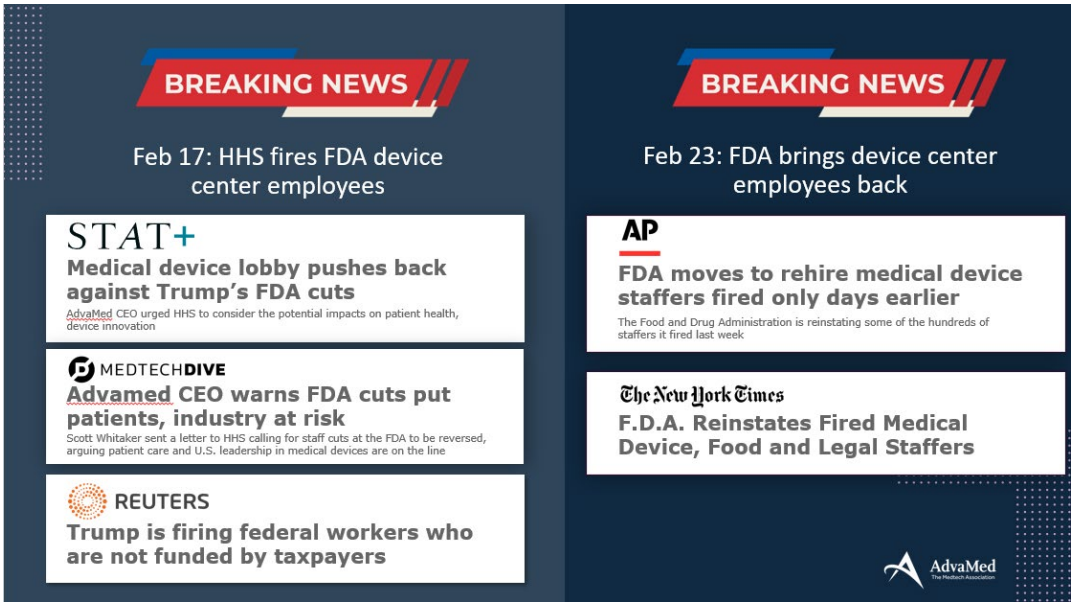
As tariffs announcements evolved, we remained focused on sharing data with the Administration, demonstrating how past medtech tariff exemptions were appropriate, given the pivotal role of medtech in the U.S. health care system, and continue to urge a similar approach moving forward. Similarly, we were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

ADVOCATING FOR SMALL COMPANIES

Because Accel member companies are small businesses and startups, they usually don't have staff in our nation's capital to inform them of policy developments. This quarter, the Accel team worked closely with the Global Affairs team to organize a well-attended webinar on tariff plans and their potential impact on medtech.

Conversely, the Accel team sought data and information points from Accel member companies on the potential impact of tariffs on their businesses to anonymize and share with policymakers. The impact of tariffs on small companies, which might make a single product as they get under way, is critically important to share with the White House, federal agencies, and Congress in our advocacy work.

Technology and Regulatory Affairs



FDA Firing Headlines from National News Outlets

ADVANCING FDA WORKFORCE RESTORATION

AdvaMed's multi-pronged advocacy effort was instrumental in the reinstatement of many of the CDRH staff who were previously cut.

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 are technical and scientific experts, would inevitably 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 shift came after a concerted effort to elevate industry concerns, with strong engagement from member companies and their teams. We sent multiple communications to administration officials to lay out the industry's concerns and explain the harm to timely review and 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 administration leaders, FDA, and members of Congress to bring this issue into focus. We also engaged selectively and strategically—and boldly and unapologetically—with the media to paint that same picture. Our advocacy efforts left no tool in the toolbox unused.

Technology and Regulatory Affairs

Despite this progress, challenges remain, but this development reinforces the importance of our advocacy in protecting the medtech ecosystem and ensuring regulatory stability.

NEW FDA COMMISSIONER

AdvaMed, on behalf of our members, welcomed U.S. Senate confirmation of Dr. Marty Makary as FDA commissioner. Our media statement is here.

DEVICE STERILIZATION

In March, the Environmental Protection Agency (EPA) announced plans to reconsider emissions standards for facilities that sterilize medical devices using ethylene oxide as part of a broader deregulatory agenda. The agency could revise the final rule issued last year under the prior administration while considering a two-year compliance exemption via the Clean Air Act for affected facilities as EPA goes through the rulemaking process.

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 will work with the EPA on its review of the rule, continuing to emphasize our commitment to ensuring the sterilization process remains safe for facility employees and communities.

Digital Health Tech

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. This quarter AdvaMed 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.

EDUCATING POLICYMAKERS ON DIGITAL HEALTH TECH

Policymakers might be only generally aware or even unaware of the vast array of digital health tech already providing value to patients and clinicians and the potential for much more in the right policy environment. To educate policymakers and inform their work, DHT is working closely with AdvaMed public affairs to explain and define digital health to policymakers and the media in a strategic campaign, using elements including television interview opportunities and opinion piece placement.

Global Affairs

EXEMPTING MEDTECH FROM CHINA'S "BUY LOCAL" PUSH

AdvaMed requested a medtech carve-out from China's new proposed measure that favors domestically produced products in government procurement. Our January public comment submission to the nation's Finance Ministry highlights our industry's unique nature and describes the risks to patients from compulsory localization. We also shared our concerns and submission with key U.S. government agencies and China's Embassy in Washington, D.C. In February, an AdvaMed delegation of general managers and senior company representatives met with Finance Ministry officials in Beijing to lay out our collective concerns. It was a constructive first engagement in view of the policy's long runway before actual implementation.

INDIA MARKET ACCESS

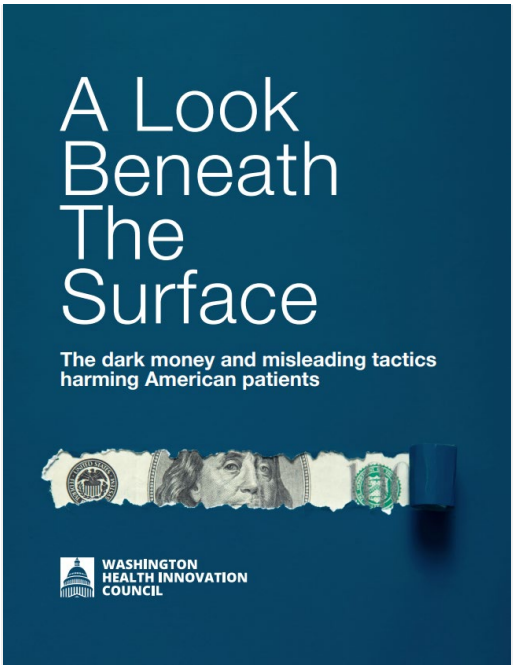
On February 13, 2025, Prime Minister Modi met with President Trump in Washington and launched the "U.S.-India COMPACT (Catalyzing Opportunities for Military Partnership, Accelerated Commerce & Technology) for the 21st Century" to drive key pillars of cooperation, including trade and investment and the 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.

Legal

THIRD-PARTY LITIGATION FUNDING

Third-Party Litigation Funding (TPLF) fuels abusive lawsuits that drive up costs, delay innovation, and threaten patient access to life-saving medical technologies. AdvaMed and our TPLF coalition are committed to opposing TPLF and advancing state-level reforms.

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.



STERILIZATION LIABILITY PROTECTION BILL ADVANCES IN UTAH

Working closely with our State Government Affairs team, we were successful in helping the Utah State Senate pass our draft legislation on ethylene oxide (EtO). The legislation establishes critical liability protections for businesses engaged in the health care industry, including medical device manufacturers, sterilization providers, and distributors. It requires plaintiffs to meet strict evidentiary standards, proving that the defendant was not in substantial compliance with federal EtO regulations, engaged in gross negligence or willful misconduct that caused an actual EtO exposure, and the actual exposure was the direct and proximate cause of the alleged injury. S.B. 266 was signed into law by Governor Cox and will take effect May 7.

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.

Legal

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.

RECOMMENDED WITHDRAWING BIDEN ADMINISTRATION PROPOSED RULE TO STRENGTHEN HIPAA SECURITY RULE

On March 7, we submitted extensive comments for the docket seeking the withdrawal of Biden Administration Proposed Rules to strengthen the HIPAA Security Rule and recommending collaboration with stakeholders to rewrite the proposed rule to address cybersecurity concerns in a more efficient and practical manner. Should the HHS decide to finalize the rule, we recommended changes to numerous problematic provisions that would impose staggering costs and burdens on all regulated entities subject to HIPAA.

ADVAMED CLE PASSPORT SERIES

In collaboration with Akin Gump LLP, AdvaMed launched its Continuing Legal Education (CLE) Program focused on providing customized legal education for the medtech sector. This year's CLE lineup features topics such as Trade and Tariffs, National Security, Executive Agency Law, and FDA/AI. This initiative ensures that our members gain industry-specific insights into pressing legal issues that have emerged this year. The first CLE webinar on March 19 drew 150 registrants. The CLE sessions are free for all AdvaMed members and offer CLE credit in multiple states.

AdvaMed Accel

JP Morgan Healthcare Conference

FEDERAL RESEARCH FUNDING

AdvaMed Accel worked with members in Q1 to navigate evolving policies on federal research funding. With congressional authorization of the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs expiring in September, Accel worked with Government Affairs to identify Hill champions to secure these critical programs and support efforts to make them permanent, improve the efficiency of grant applications and awards, and increase National Institutes of Health (NIH) funding for small business.

Work to position SBIR/STTR for reauthorization happened alongside efforts to understand and respond to several recent changes to federal funding policies that have created concerns regarding the use and availability of NIH funding for scientific research. These policy proposals are creating uncertainty in medical research communities and have direct implications for SBIR/STTR grant awards and medtech research. Accel will continue to respond to and engage on these issues via advocacy and stakeholder collaborations.

INVESTOR ENGAGEMENT

AdvaMed again provided meeting space and hosted an executive reception for member companies and investors at the annual JP Morgan Healthcare Conference in San Francisco. We welcomed over 150 members and their guests and hosted over 300 partnering meetings during the three-day event. In March, the Q1 meeting of the MedTech Investment Working Group featured a discussion panel with leading investors on the resurgent medtech IPO market.

AdvaMed Accel

HEALTH EQUITY AND WOMEN'S HEALTH

Including and in addition to Accel members, in Q1, AdvaMed continued to work with our members to promote improved and appropriate access to the technologies needed to address the health concerns of all patients. We worked to finalize a white paper outlining factors impeding access to women's health products due to factors including investment challenges, research funding, and reimbursement levels. We also weighed in with the new Administration to support coverage of in vitro fertilization procedures. We continue to assess opportunities for engagement and to advance policy in areas including supplemental breast cancer imaging and other priorities to improve American health through collaboration and advocacy.

Medical Imaging

U.S. SENATE SCIENCE ACCELERATION INITIATIVE

AdvaMed was pleased to endorse the American Science Acceleration Project (ASAP), a national initiative sponsored by U.S. Senators Martin Heinrich and Mike Rounds to make American science ten times faster by 2030. The initiative cites medtech among the fields in which we need to "radically expedite the discovery and deployment of transformative advancements," using emerging technologies, especially AI. The senators co-chair the Senate's bipartisan Artificial Intelligence Caucus and recognize the importance of policies supporting AI, such as a formalized payment pathway in Medicare for algorithm-based health care services (ABHS).

ALGORITHM-BASED HEALTH CARE SERVICES

On ABHS, momentum is building for the development and implementation of such policies. The Medical Imaging division has selected an outside firm to assist in policy development and data modeling for AI/ABHS reimbursement under the Medicare Physician Fee Schedule.

Medical Imaging

Late last year, the U.S. House of Representatives' bipartisan Task Force on Artificial Intelligence urged CMS to develop a formalized payment pathway for AI-enabled medical devices. AI-enabled medical devices are FDA-cleared and produce clinical information to aid in patient diagnosis or treatment. Dr. Taha Kass-Hout, Global Chief Science and Technology Officer, GE HealthCare, and Chair of the AdvaMed Digital Health Tech™ Board of Directors, participated in an AI Task Force Panel examining health care applications.

RIGHT SCAN, RIGHT TIME ON INSTAGRAM

The "Right Scan, Right Time" initiative is now on Instagram! Please follow this new account to amplify the initiative's work with patient advocates nationwide to protect access to medical imaging services for all patients: instagram.com/right.scan.right.time

AdvaMedDx

June 2024 Biomarker Summit

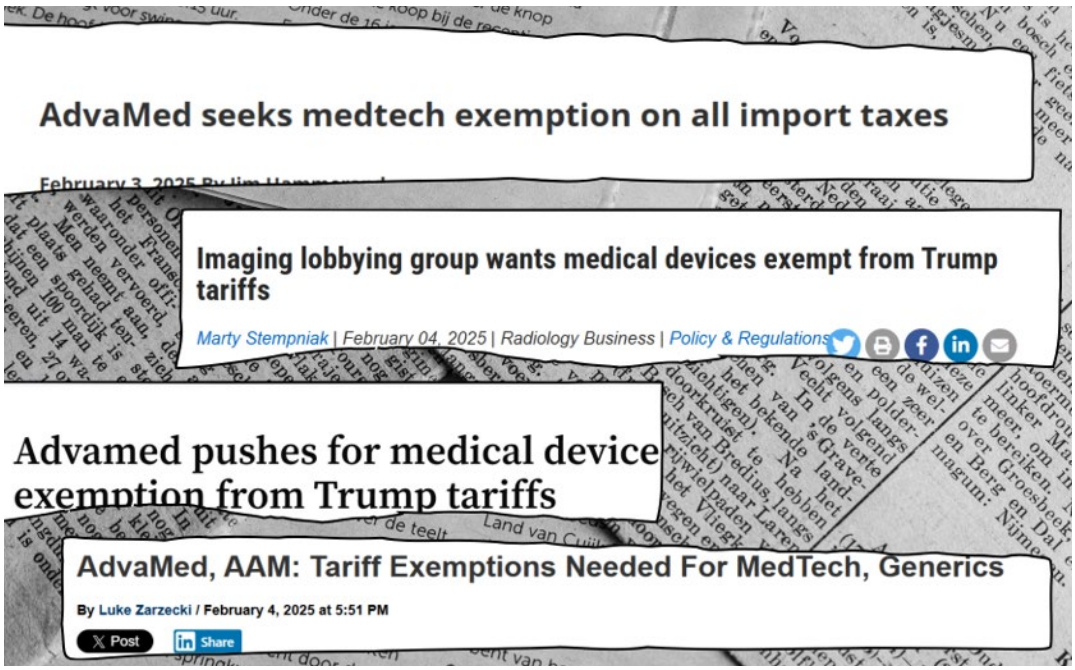
IN VITRO DIAGNOSTIC TEST REFORMS

AdvaMedDx worked closely with Government Affairs to set our advocacy agenda for the new Congress. We finalized our congressional leave-behind documents for our FDA technology certification pathway and CLIA/point-of-care legislative proposals, which would remove regulatory barriers to the introduction of innovative point-of-care tests. We met with members of Congress interested in and/or with jurisdiction over these important legislative updates.

ALZHEIMER'S BIOMARKER SUMMIT

At AdvaMed headquarters, we hosted an Alzheimer's biomarker summit with patient groups, member companies, and other stakeholders. This was the second meeting of the group, and we identified areas of common interest to collectively work on, including coverage and reimbursement of the biomarker tests, patient privacy, and provider education.

Public Affairs



Tariff Exemption Headlines

ADVAMED LEADS IN NEWS COVERAGE OF MEDTECH

For every five news stories about medtech this quarter, AdvaMed was mentioned or quoted in at least one. The next closest advocacy organization was mentioned in just 2 percent of all stories. The significant media coverage reflects the agility and expertise to anticipate and respond to news developments with the medtech perspective.

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 President and 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 and ensured our voice was heard at the highest levels.

Public Affairs

Increasingly, earned media coverage is referring to AdvaMed as the "largest," "leading," and "top," "main" medtech trade association. The outreach and coverage demonstrate AdvaMed's trajectory toward becoming the only medtech trade organization, as far as media is concerned.

DR. OZ ON BREAKTHROUGH DEVICE COVERAGE

Public Affairs moved quickly on Dr. Mehmet Oz's positive comments at his confirmation hearing on AdvaMed's top priority to streamline Medicare coverage of breakthrough medtech, posting the video on YouTube and promoting it on our social media accounts and with reporters. We hope Dr. Oz's strong statement of support bodes well for a significant improvement of CMS's breakthrough coverage policy.

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.

2024 ANNUAL REPORT

The Public Affairs team worked closely with the Marketing Department and President's Office to launch the 2024 Annual Report far and wide, capturing a year of tremendous achievements across AdvaMed.

Alliance Partnerships

SMTA Fly-in

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.

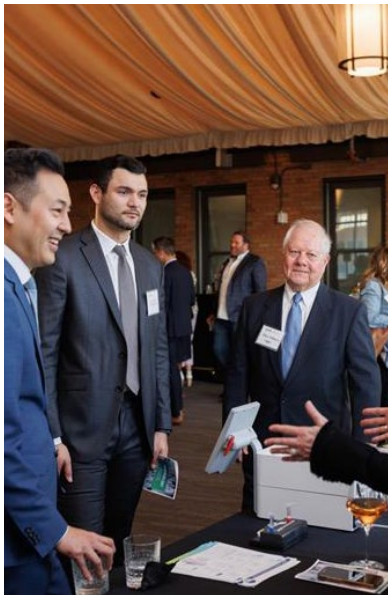
ALLIANCE PARTNER PRIORITY EXCHANGE

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.

State Affairs



California Lobby Day

CALIFORNIA MEDTECH LOBBY DAY & SHOWCASE

AdvaMed and California Life Sciences (CLS) co-hosted the annual Medtech Lobby Day & Showcase in Sacramento. Throughout the day, members of AdvaMed and CLS met with California legislators on key issues for industry, including regulation of Artificial Intelligence and inclusion of PFAS in products. The day concluded with a reception where members showcased their technologies for legislators, so they could see first-hand how these innovations are used to improve patient lives and outcomes.

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 takes 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.

WINS IN STATES ACROSS THE COUNTRY

Every state legislature is in regular session this year, and the AdvaMed State Affairs team has been 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 and Texas;
- Advancing bills expanding patient access to supplemental breast cancer imaging in Virginia;
- Derailing legislation seeking to regulate use of artificial intelligence in Maryland, Texas, and Virginia.

Federal Government Affairs

Michael Mahoney, Chairman and CEO, Boston Scientific Corporation; Geoff Martha, Chairman and CEO, Medtronic; Vince Haley, Director of the White House Domestic Policy Council; Scott Whitaker, President and CEO, AdvaMed; and Peter J. Arduini, President and CEO of GE HealthCare and chair of the AdvaMed Board of Directors

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.

For this quarter, 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 FDA 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.

POLITICO
02/18/2025

Earlier this year, the medical device industry group AdvaMed protested when hundreds of probationary FDA employees funded with industry user fees were laid off. The agency rehired many of them after AdvaMed CEO **Scott Whitaker** complained.

Federal Government Affairs

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 ..."

ELECTRONIC LABELING BILL INTRODUCED

Earlier this quarter, 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.

LEADING ASSOCIATION LOBBYIST

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

Payment

Dr. Oz Testifying

NEW CMS ADMINISTRATOR

We're looking forward to working with Dr. Mehmet Oz as administrator of the Centers for Medicare and Medicaid Services (CMS). As a heart surgeon and medtech innovator, he understands the importance of federal care programs and policy in reaching patients with lifesaving medtech. We are encouraged by Dr. Oz's comments at his confirmation hearing regarding the need to streamline access to innovative technologies.

The Payment team created a list of regulatory recommendations that supports the new administration's goal of increased efficiency and better performance for the American people. We are offering our subject matter expertise, and that of our member companies' staff, as a resource to the administration in making positive policy changes.

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.

Payment

HHS REORGANIZATION AND STAFF REDUCTIONS

Payment closed the quarter analyzing Department of Health and Human Services Secretary Robert Kennedy Jr.'s announcement of a broad reorganization of HHS and its umbrella agencies, including significant staff cuts. While the announcement materials say the reorganization and staff reductions will not affect Medicare and Medicaid, the reforms could have unintended effects on those programs.

We will continue to monitor the information coming out of HHS and CMS, watching closely for any unintended impact on patients' access to innovative medtech.

Fighting chronic disease and otherwise restoring Americans to good health requires coverage and reimbursement of high quality medtech-centered diagnostic and treatment procedures, including the transformative AI-enabled solutions coming onto the market.