Noel Zuniga, devoted husband, father and NCIS federal agent, suffered a heart attack following a routine run. Counting the seconds, his doctors identified a blockage and inserted a stent to keep his artery open, but in Noel's case it was not enough and he went into cardiogenic shock. Physicians then utilized an advanced medical technology – a minimally invasive pump – to allow Noel's heart to rest and recover, saving his life. Today, Noel has returned to an active and full life, thanks to medical technology innovation.
OUR MISSION

ADVAMED ADVOCATES ON A GLOBAL BASIS FOR THE HIGHEST ETHICAL STANDARDS, TIMELY PATIENT ACCESS TO SAFE AND EFFECTIVE PRODUCTS, AND ECONOMIC POLICIES THAT REWARD VALUE CREATION.
2015 was a year of significant progress for AdvaMed and the medical technology industry. From winning a two-year suspension of the innovation-crushing medical device tax, to House passage of FDA reforms in the 21st Century Cures Act, to elimination of significant tariffs on medtech exports via World Trade Organization expansion of the Information Technology Agreement, working together we achieved critical results on behalf of industry and patients everywhere.

Driving our efforts in 2015 was AdvaMed’s “Innovation Agenda,” created with input from our Board, with specific recommendations to renew and reinvigorate America’s medtech innovation ecosystem (see p. 5). Throughout this report are descriptions of each of the five pillars of our Innovation Agenda, as well as compelling patient stories that showcase how a healthy innovation ecosystem can make all the difference to the people we serve.

During the busy year, our industry continued to deliver life-changing medical advancements to patients in need. These innovations allow people to live longer and healthier lives, yield savings across the health care system by replacing more invasive procedures and reducing hospital stays, and help create good-paying American jobs. Communicating this simple but important message, that our industry is an engine of both public health and economic progress – bringing innovation and value to patients – is a key part of AdvaMed’s integrated advocacy approach to advancing public policies that support investment, innovation and patient access.

Looking back on the year, the Association succeeded in these efforts on many fronts, yielding important benefits to AdvaMed member companies and the patients they serve. Here are some the year’s highlights:
• Passage of a two-year suspension of the medical device tax, marking a major milestone in AdvaMed’s six-year campaign to repeal this onerous tax. Suspension will save the industry nearly $2 billion annually and provide new funds for investment in innovation.

• House passage of the 21st Century Cures Act with a full slate of regulatory reform proposals, including an expedited pathway for breakthrough technologies. If enacted, these reforms will increase the efficiency and predictability of the FDA review process, and improve patient access to the best in medical progress.

• Repeal of the Sustainable Growth Rate formula for Medicare physician payments, eliminating the pressure point from repeated, temporary patches that caused Congress to look to our industry for offsets. The Association also worked with member companies, CMS and lawmakers to develop and advance coverage, coding and payment proposals for legislation to help accelerate patient access to next-generation treatments and cures as part of congressional innovation initiatives.

• World Trade Organization expansion of the 1996 Information Technology Agreement, responding to AdvaMed advocacy, thus eliminating burdensome tariffs on $10 billion worth of U.S. medical technology exports.

• AdvaMed development of a China Code of Ethics on appropriate industry interactions with health care providers in China, and numerous tools and awareness materials to assist members with implementation and compliance certification. AdvaMed also launched a compliance app for mobile devices, with features to assist industry interactions and discussions with health care providers on issues under the AdvaMed Code of Ethics and Physician Payments Sunshine law.

• AdvaMedDx development of comprehensive policy on reforming diagnostics regulatory oversight. AdvaMedDx worked with FDA, key congressional committees and other stakeholders to advance oversight reform legislation, and also worked with CMS and other stakeholders to ensure effective implementation of diagnostics payment reform provisions of the Protecting Access to Medicare Act.

• Enactment of tax extenders legislation with provisions of particular benefit to the medtech industry’s emerging and early-growth enterprises, championed by AdvaMed Accel, including permanent extension of the R&D tax credit.

• And, finally, continued celebration of AdvaMed’s 40th anniversary year at our annual medtech conference and exhibition in San Diego, its first West Coast venue. AdvaMed 2015 attracted more than 2,300 attendees representing over 900 companies and stakeholder groups from 26 countries.
AdvaMed is the world’s leading medical technology trade association, with member companies that develop, manufacture and sell innovative medical devices and diagnostic products. AdvaMed supports the needs of members of all sizes – from cutting edge, entrepreneurial start-ups to emerging growth and mid-size companies to the largest innovators and manufacturers. As the voice for a unified industry, AdvaMed is uniquely positioned to advocate for policies that support value creation and patient access to innovation, to proactively address and shape laws and regulations, and to ensure the highest ethical standards for industry interactions with health care providers. From winning a two-year suspension of the medical device tax, to advancing legislation in support of 21st century cures, to increasing harmonization of global ethical standards, AdvaMed’s progress in 2015 reflects the Association’s ability to harness the collective view of its 300 members to achieve positive results for the industry and the economy, and for patient care.

Through its staff of more than 70 experts, AdvaMed offers members knowledgeable guidance in areas critical to industry’s success: technology and regulatory affairs, payment and health care delivery policy, legal and compliance, global strategy and analysis, and government and public affairs. AdvaMed also offers a range of opportunities for member interaction and cooperation, including the Women’s Executive Network, educational workshops and webinars, and industry-driven working groups and committees that help develop feedback and positions on policies that affect every sector of the medtech industry.

MEMBERSHIP BREAKDOWN BY U.S. SALES:
- Associate Members = 10%
- Emerging Growth Members (< $100 mil.) = 66%
- Mid-size Members ($100 mil.-$500 mil.) = 12%
- Large Members (> $500 mil.) = 12%

PROFILE IN INNOVATION

At the age of 14, Joe Abdo began having seizures and was diagnosed with epilepsy. When medication proved ineffective, an MRI was ordered, revealing that Joe had a brain tumor. Doctors used intraoperative MRI technology to fully remove his tumor. Today, Joe is cancer-free and a proud husband and father, working at a molecular diagnostics company as a way to give back to a field that saved his life.
America’s medical technology industry creates life-saving and life-enhancing treatments and cures that drive efficiencies and cost savings in the health care system, improve the quality of patient care and generate high-quality jobs that contribute to economic growth. In this century of the life sciences, the opportunities for life-changing new treatments and diagnostics are breathtaking. But the innovation ecosystem that supports medical technology development today also faces unprecedented challenges that impede rather than speed our progress. To respond to these challenges, AdvaMed proposed in February a new Innovation Agenda.

AdvaMed’s Innovation Agenda – including a streamlined, seamless pathway at FDA and the Centers for Medicare and Medicaid Services (CMS) for significant breakthrough products – is a comprehensive program to unleash the potential of medical technology to extend and improve lives, reduce the cost and burden of disease, and maintain and enhance U.S. scientific and economic leadership.

AdvaMed’s Innovation Agenda consists of five “pillars,” each addressing a key component of the American innovation ecosystem. They include: improving FDA’s regulatory processes, restructuring CMS’s coverage and payment processes, reforming the U.S. tax system, improving access to international markets, and supporting the maintenance and growth of America’s R&D infrastructure.

Throughout this report are further details of these five pillars, which will guide the Association’s long-term advocacy activities. In 2015, AdvaMed worked with policymakers and other industry stakeholders, and with lawmakers in Congress, to advance our proposals and to help ensure the continued promise of breathtaking medical progress in this century of the life sciences.

PROFILE IN INNOVATION

Vanessa Ghigliotty was a recent college graduate and single mother working as a nanny when she was diagnosed with stage four colon cancer. Admitted to the hospital for a suspected burst appendix, an x-ray revealed tumors both inside and outside of her colon. One year later, a PET scan detected a recurrence. After eight surgeries and three years of chemotherapy, Vanessa is a cancer-free advocate for life-saving innovations.
In late 2015, Congress passed and the president signed a two-year suspension of the medical device tax as part of year-end tax extenders legislation, marking a major milestone in AdvaMed’s six-year campaign to repeal this onerous tax. Suspension will save the industry nearly $2 billion annually, freeing up funds for more next-generation treatments and cures. Securing full repeal remains a top priority. Nevertheless, suspension represents a major first step, as well as broad bipartisan recognition of the negative effects the tax has had on R&D, American competitiveness and innovation. AdvaMed’s repeal strategy has relied on an integrated advocacy approach from the very beginning:

H.R. 2029

“Consolidated Appropriations Act”
Signed December 18, 2015
As enacted by the Senate and House of Representatives of the United States of America in Congress assembled...

*Sec. 174, page 830-831:
DEVICE TAX MORATORIUM

- The tax...shall not apply to sales during the period beginning on Jan. 1, 2016, and ending on Dec. 31, 2017.
- The amendment made by this section shall apply to sales after Dec. 31, 2015.

CONGRESS
AdvaMed’s Government Affairs department led the way in building strong bipartisan support for repeal, holding hundreds of meetings with members of Congress and their staffs to educate them about the adverse effects of the tax on businesses and innovation. The Association organized dozens of Capitol Hill “fly-ins,” where member company execs met with congressional representatives and/or testified at hearings to drive home our message. AdvaMed also led a coalition of over 900 companies, associations, and patient, provider and research organizations, that worked together for repeal.

In the House, bipartisan repeal legislation sponsored by Rep. Erik Paulsen first passed in 2012 with 270 votes, including 37 Democrats. By the end of 2015, the House had passed device tax repeal five times, including a vote during the year that included 46 Democrats. In the Senate, a 2013 vote to include repeal in a non-binding budget resolution passed by an overwhelming majority of 79-20. By 2015, incoming Senate Majority Leader Mitch McConnell signaled repeal as a key priority for the year, and cosponsors of Senator Orrin Hatch’s bipartisan repeal bill reached 39. AdvaMed’s champions on the Hill also kept the need for repeal front-and-center during key fiscal inflection points and as part of the debate on fundamental tax reform, ultimately leading to device tax suspension at the end of 2015.

POLICY
AdvaMed’s opposition to the tax and education of policymakers about its harmful nature began before the tax was even enacted as one of many revenue offsets for the 2010 Affordable Care Act (ACA). The Association opposed the tax as part of the ACA, and has subsequently pursued every possible legislative opportunity for repeal, whether as part of corporate tax reform, stand-alone legislation, or part of another legislative vehicle.

Senator Patrick Toomey of Pennsylvania, chairman of the Senate Finance Committee’s Subcommittee on Health Care (at left), greets Bruce Heugel, senior vice president and CFO of B. Braun Medical, who testified before the subcommittee on the harmful nature of the device tax.

Senator Al Franken and his staff discuss the need for device tax repeal with Hallie Brinkerhoff, Zimmer’s director of advanced technology (at left) during an AdvaMed Capitol Hill fly-in.
RESEARCH

In today’s data-driven environment, winning policy debates depends on compelling, objective information. To that end, AdvaMed sponsored and leveraged studies from prestigious research organizations – including Battelle, the Pacific Research Institute, Ernst & Young, and the National Center for Policy Analysis – as well as AdvaMed member surveys in 2014 and 2015, to help quantify the device tax’s damaging effects. These effects included reduced R&D and delayed patient access to innovation. On the positive side, survey respondents indicated repeal would allow renewed investments in innovation. The findings were disseminated widely to members of Congress, the administration, the media and other health policy influencers.

STATE EVENTS

AdvaMed’s grassroots advocacy included taking our repeal campaign on the road and hosting events at member companies across the country to raise awareness about the effects of the tax on local economies, often with participation by members of Congress and other elected officials. Such events – in key states like Arizona, California, Colorado, Illinois, Indiana, New York, North Carolina, Ohio, Pennsylvania and Wisconsin – helped to educate and engage employees and policymakers alike, and increased the ranks of those able to speak with one voice on the urgent need for device tax relief.

MEDIA OUTREACH

Throughout the repeal effort, AdvaMed’s Public Affairs department expanded its range and use of multimedia to spread the word about the negative consequences of the tax and the positive value of medtech innovation – innovation the device tax put at risk. These efforts included creating compelling fact sheets, infographics, ads, videos and social media posts; helping to place op-eds and editorials by member company execs and others in key publications nationwide; and running print and on-line ads in influential Capitol Hill journals. In 2015, AdvaMed launched the United4Innovation campaign to amplify our message with new information, resources and allies, including a web portal that helped generate tens of thousands of letters from repeal supporters to Capitol Hill.

Caroll Neubauer, chairman and CEO of B. Braun Medical (at left) joins a device tax repeal rally in Philadelphia organized by state life science trade association Pennsylvania Bio, along with Pennsylvania congressmen Charlie Dent, Patrick Meehan and Ryan Costello, and PA Bio’s Christopher Molineaux, president and CEO (at right).

House Majority Leader Kevin McCarthy (second from right) meets with AdvaMed Capitol Hill fly-in participants to discuss device tax repeal, including Walter Rosebrough of Steris, AdvaMed Chair Vince Forlenza of BD, Dr. Michael Leong of the Stanford Pain Management Center, Nadim Yared of CVRx, Karen Prange of Boston Scientific, and Mike Genau of Medtronic.
Ensuring regulatory processes for medical technology that are efficient, predictable and transparent is essential for innovation to thrive and patients to benefit, and is the core focus of AdvaMed’s Technology and Regulatory Affairs department. Our team of regulatory experts works collaboratively with our members, and with FDA and its counterparts around the world, to help ease the often challenging regulatory path to market – from clinical trials and premarket reviews to post-market requirements – so that patients and physicians can have timely access to safe and effective innovations that save and improve lives.

CONGRESSIONAL INNOVATION INITIATIVES
In 2015, the T&R department leveraged its strong working relationships with FDA staffers at all levels to help develop and advance legislative proposals as part of the 21st Century Cures initiative in the House Energy and Commerce Committee, to increase the efficiency and predictability of the FDA review process and improve patient access to the best in medical progress. This effort paid off with House passage in July of the 21st Century Cures Act, including provisions to:

- Establish an expedited pathway for breakthrough technologies;
- Clarify valid scientific evidence requirements;
- Improve the standards recognition process;
- Allow the use of central institutional review boards to facilitate the conduct of multicenter clinical trials; and
- Revitalize the “least burdensome” standard for regulatory reviews.

Meanwhile, AdvaMed sought to advance similar provisions under the parallel Healthier Americans initiative in the Senate Health, Education, Labor and Pensions Committee.

USER FEE REAUTHORIZATION
AdvaMed continued to monitor implementation of the FDA user fee agreement of 2012, under which the agency committed to a number of strong, measurable performance goals to increase the efficiency and consistency of its review process. Achievements to date include significant improvements in PMA and 510(k) review times, and in approval times for investigational device exemption studies.

Donald St. Pierre, deputy director, new product evaluation, at CDRH’s Office of In Vitro Diagnostics and Radiological Health (at left); William Maisel, deputy director for science and CDRH chief scientist; and Jan Welch, deputy director for regulatory affairs at CDRH’s Office of Compliance, discuss regulatory proposals with AdvaMed members and staff in January.
In preparation for anticipated reauthorization of the user fee agreement in 2017, AdvaMed engaged in discussions with members and other stakeholders to identify data needs and develop strategic framework goals for negotiations. These goals include: pre-submission process improvements; goals for timing between a PMA “approvable” decision and issuance of an approval order; goals for de novo applications; improvements in the CLIA-waiver process and goals; and continuation of the independent assessment required under the previous agreement. Negotiations with FDA for user fee agreement reauthorization commenced in September.

GUIDANCE DEVELOPMENT
AdvaMed also met with FDA staff throughout the year to ensure consideration of important member goals as part of the agency’s development of several future guidance documents addressing the following topics: when to file a new 510(k) for a device modification; issues related to use of color additives in medical devices and colorant information requirements; and the type of modifications made to medical device software that require new 510(k) submissions.

Bill MacFarland, director, CDRH Division of Enforcement B, Office of Compliance (at right) and Kim Lewandowski-Walker, FDA Office of Regulatory Affairs, national expert investigator, discuss the case for quality at the AdvaMed 2015 conference in San Diego.

Janet Trunzo, AdvaMed senior executive vice president, technology and regulatory affairs (at right) leads a discussion of regulatory proposals with CDRH Director Jeffrey Shuren.

Michael Mussallem, chairman and CEO of Edwards Lifesciences (at right), discusses the need for regulatory and other reforms with Senator Bill Cassidy of Louisiana, prior to providing formal testimony before the Senate Committee on Health, Education, Labor & Pensions.
Programs administered by the Centers for Medicare & Medicaid Services (CMS) provide health care coverage to millions of Americans, enabling patients to benefit from life-saving innovations from the medical technology industry. AdvaMed’s Payment and Health Care Delivery department works closely with CMS to ensure appropriate patient access to these innovations through efficient and predictable coverage, coding and payment processes – the importance of which is magnified when such policies are replicated by private payers.

HEALTH CARE DELIVERY CHANGES
As the health care system transitions away from fee-for-service toward more risk-based, integrated health care delivery models – such as CMS’s bundled payment programs and accountable care organizations – AdvaMed seeks policy changes to ensure that incentives offered to providers for achieving savings embrace the full value of innovation in patient care, and that the formula for our health system is cost savings through medical progress, not cost savings instead of medical progress.

These efforts began to pay off in February when CMS announced it would allow payment adjustments in bundling pilots to help ensure access to products receiving new-technology add-on payments. Where there are significant gaps in quality measures that can prevent the full dimension of quality from being assessed by payers, AdvaMed continued to advocate for policies to help fill those gaps.

COVERAGE, CODING & PAYMENT
As part of AdvaMed’s Innovation Agenda, unveiled in February, the Association worked with member companies, CMS and lawmakers on Capitol Hill to develop and advance coverage, coding and payment proposals for legislation to help accelerate patient access to next-generation treatments and cures. These proposals include a streamlined, seamless path for CMS coverage and payment for breakthrough products; establishment of automatic coverage for FDA-approved clinical trials; expanded coverage of telehealth services including remote monitoring used in the home; a streamlined process for granting temporary outpatient and physician payment codes to new technologies, and many more.

Meanwhile, AdvaMed worked with CMS to smooth implementation of a centralized process for coverage of FDA-approved clinical trials, which began in January. Successful AdvaMed advocacy also resulted in the American Medical Association changing the wording of Current Procedural Terminology Category III codes so that non-coverage is no longer automatic.
In April, we saw repeal of the Sustainable Growth Rate formula for Medicare physician payments, eliminating the pressure point from repeated, temporary patches that caused Congress to look to the medtech industry for offsets. In June, the Association held a payment policy conference in Arlington, Va., to address the key challenges and opportunities of the evolving coverage and reimbursement landscape.

RESEARCH
In 2015, AdvaMed-supported research highlighted both the strong value of medical technology and rising evidence requirements for coverage that can impede patient access. A Tufts study published in the February issue of Health Affairs showed it is 20-times harder to get a favorable Medicare coverage decision than 10 years ago. A study by Avalere found that leading health systems are able to adopt the latest medical advances and provide technology-intensive care without having higher Medicare spending than hospitals using less technology. Another study affirmed earlier findings that medtech has comprised a relatively small and constant share of national health expenditures — about six percent — for more than two decades, and that medtech prices have grown at just one-third the rate of prices in the overall economy since 1989, underscoring how our intensely competitive industry helps keep prices low.

Gail Boudreaux, CEO and founder of GKB Global Health, and former CEO of United Healthcare (at right), and Michael Farrell, CEO of ResMed, discuss the needs of hospital CEOs and payers at the AdvaMed 2015 conference in San Diego.

Patrick Conway, CMS’s deputy administrator for innovation & quality and chief medical officer, discusses the importance of patient access to innovation at AdvaMed’s Payment Policy Conference in Arlington, Va.
AdvaMed’s Legal Committee works with in-house lawyers and compliance officers at member companies around the world to help foster a predictable legal environment that values innovative health care solutions, enhances public health and ensures patient access to the latest advancements in medical technology. The legal team also engages diverse stakeholder groups, including government regulators, physician specialty societies and others, to advance the highest global standards for ethical interactions between industry and health care professionals.

**U.S. PHYSICIAN PAYMENTS SUNSHINE ACT**

In 2015, AdvaMed engaged extensively with the Centers for Medicare and Medicaid Services (CMS) on implementation of the Sunshine Act, seeking to ensure an efficient disclosure process and that published data offers meaningful information to patients about industry-physician collaborations. The Association worked to resolve members’ implementation concerns, including a proposal to combine physician Medicare payment data and Sunshine Act data on the CMS website, which CMS deferred in response to AdvaMed advocacy, and the question of whether medical journal reprints and payments supporting continuing medical education should be reportable, which continues to be discussed.

**ETHICS & COMPLIANCE**

AdvaMed leads the promotion of ethical business environments in the medtech sector, consistent with the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the AdvaMed Code). Among the Association’s 2015 accomplishments:

- AdvaMed organized and led industry-wide distributor training sessions in Latin America and Southern Europe focused on unique anti-corruption risks faced by third-party distributors in emerging markets, as well as ethical interactions, best-practices and compliance tools.

- AdvaMed – jointly with MedTech Europe – released new anti-bribery/anti-corruption compliance guidance with hypothetical scenarios and examples of steps companies can take to minimize third-party risk.

- AdvaMed held its eighth annual Global MedTech Compliance Conference in May in Athens, Greece, which brought together more than 250 compliance professionals to discuss global trends facing the medtech industry. In February, we held our fourth annual Latin America Compliance Conference in Mexico City, Mexico.

- In the Asia-Pacific region, AdvaMed continued to play a leading role in the Asia-Pacific Economic Cooperation (APEC) business ethics initiative, working to advance 11 new high-standard codes of ethics that have been adopted by medical technology industry associations.

- AdvaMed launched its Code of Ethics on Interactions with Health Care Professionals.

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AdvaMed Senior Executive Vice President and General Counsel Chris White (at right) leads AdvaMed’s Latin America Compliance Conference in Mexico City with Pablo F. Davila, president of AMID, the Mexican Association of Innovative Medical Device Industries, who is also C.R. Bard’s head of Latin America North.
in China, which provides critical compliance guidance for medtech companies doing business in China, and developed numerous tools and awareness materials to assist members with China Code implementation.

- AdvaMed launched a compliance app for mobile devices (via iTunes) with features to assist industry interactions and discussions with health care providers on issues under the AdvaMed Code and Sunshine Act.

PHYSICIAN-OWNED DISTRIBUTORS (PODS)
AdvaMed reconstituted its working group on PODs in 2015 and submitted written testimony to the Senate Finance Committee outlining long-standing industry concerns with the entities, which HHS’s Office of Inspector General determined “produce substantial fraud and abuse risk and pose dangers to patient safety.” The Association also advocated against hospital purchasing policies targeting PODs that unfairly discriminate against physician-owned small companies.

DEVICE TAX
In late 2015, AdvaMed advocacy led to a two-year suspension of the innovation-crushing medical device excise tax. To address issues surrounding implementation of the suspension, AdvaMed reconvened its Device Tax Working Group to consider the short-term legal effects, with plans to coordinate as necessary with the IRS and other stakeholders on interim guidance.

Leo Tsao, assistant chief of the fraud section of the U.S. Department of Justice, Criminal Division (at right), Colleen Conry, partner at Ropes & Gray, and Adam Morris, senior legal counsel, global investigations, at Medtronic (at left), discuss anti-corruption trends in emerging markets at AdvaMed 2015.

The Honorable David Pearce, U.S. ambassador to Greece (at left), addresses attendees of AdvaMed’s Global MedTech Compliance Conference in Athens, including Michael Mussallem, chairman and CEO of Edwards Lifesciences, and Jeffrey Dunn, president and CEO of SI-Bone (at right).
AdvaMed’s Global Strategy and Analysis department works to level the playing field for medical technology companies across borders by advocating for trade, regulatory and reimbursement practices that are fair, transparent and predictable worldwide. Our team of international policy experts works with U.S. and foreign health care and government officials, and organizations like the World Health Organization, the Asia-Pacific Economic Cooperation forum, and other international medical technology associations, to help ensure policies that facilitate worldwide patient access to life-changing innovations.

During the year, AdvaMed advocacy helped secure World Trade Organization expansion of the 1996 Information Technology Agreement, thus eliminating burdensome tariffs on $10 billion worth of U.S. medical technology exports. The team marked additional successes and progress points across the globe:

**CHINA** – Two CEO delegations in 2015 – led by AdvaMed Chairman Vince Forlenza of BD and International Board Committee Chairman Kevin Lobo of Stryker – focused on increasing alignment with global regulatory, tendering and reimbursement practices, including practices impacting clinical trials, approval times and unique device identification. In November, successful AdvaMed advocacy helped secure commitments from China at the high-level Joint Commission on Commerce and Trade to treat imported and domestic medical technology the same, expand clinical trial exemption catalogues, enhance the China FDA’s pre-submission consultation process, develop new rules more transparently, and provide annual regulatory approval performance reports. AdvaMed also developed a China code of ethics on appropriate industry interactions with health care providers and related implementation tools.

**LATIN AMERICA** – In October, AdvaMed participated in a delegation of business leaders pursuing reform and investment opportunities in the region, including high-level meetings in Bogota with Colombian President Juan Manuel Santos. In Brazil, AdvaMed partnered with the other three associations in ABIIS to stave off price control efforts, promote the value of medical technology and evaluate regulatory and health technology assessment gaps in an effort to improve access to medtech in Latin America.
JAPAN – Intensive AdvaMed advocacy helped ensure changes to Japan’s reimbursement rules were at the positive end of what was anticipated, and prevented adoption of a proposed “market expansion repricing rule” that would have led to deep reimbursement cuts for products with higher sales than projected. Japan also continued to make progress under an AdvaMed-supported regulatory performance plan aimed at improving patient access to innovation.

INDIA – AdvaMed continued to seek adoption of pending legislation that would carve out an appropriate, globally harmonized regulatory framework for medical devices, as distinct from drugs. AdvaMed also redoubled its efforts to address mounting political pressure for price controls in the country, forming a PR task force, enlisting the assistance of a new consulting firm, and initiating a study to examine barriers to patient access in India. The Association aims to work with India’s government and other stakeholders to increase awareness of the value of medical technology and improve patient access to needed care.

EUROPEAN UNION – As the EU continues to move toward significant revisions to its regulatory system for devices and diagnostics, AdvaMed worked in close collaboration with MedTech Europe (an alliance of European medtech industry associations) to address key issues and press for maintaining the safety and efficiency of the EU’s current, decentralized regulatory approach. These efforts included organizing meetings between AdvaMed members and officials in EU member states to help make our case.
Ensuring patients have access to innovative treatments and cures requires effective advocacy at all levels of government, including the state level. Accordingly, AdvaMed’s State Government Affairs team works to engage state lawmakers and regulators to advance our policy goals. In 2015, this included hosting a hearing by the California Assembly Select Committee on Biotechnology at the AdvaMed 2015 conference in San Diego focused on examining the state of the medical technology sector in California and policies influencing its continued vitality. Often working in concert with state and local medical technology groups, the team marked key successes across the nation:

**COVERAGE & REIMBURSEMENT**

In 2015, successful AdvaMed advocacy led to improved health technology assessment processes in New York and Washington to help protect patient access to life-changing innovations. This included passage of legislation in New York establishing advisory committee input on benefit coverage decisions. In Washington, AdvaMed was able to engage a broad group of stakeholders to help win a requirement for open meetings by one of the state’s technology assessment bodies, thus increasing transparency of the assessment process.

In Utah, AdvaMed advocacy also helped defeat a proposal that would have instituted a new tax on device manufacturers to offset the cost of Medicaid expansion.

**ENVIRONMENTAL**

AdvaMed continued to fight efforts by state and local governments – in California in particular but in other states as well – to impose costly manufacturer take-back programs for home-generated medical sharps waste and batteries. In Connecticut and Texas, AdvaMed advocacy contributed to the defeat of legislation that would have placed the onus for battery disposal on medtech manufacturers.

**DISTRIBUTION**

AdvaMed sought to mitigate the burden of changes to medical device distribution regulations under consideration by the Louisiana legislature. The Association was able to secure appointment of a device industry representative to the state board charged with implementing the law, and supported successful legislation establishing a study committee on device distribution. The study report included several AdvaMed recommendations.

AdvaMed’s State Medical Technology Alliance (SMTA), a growing network of state and regional trade associations, bolsters the industry’s grassroots reach and ability to engage effectively with legislators at the state and federal levels. In March, SMTA members participated in an annual Capitol Hill fly-in to engage with their congressional delegations on important topics, including the urgent need for relief from the innovation-crushing medical device tax.
As the educational arm of AdvaMed, Events & Education offers premier programs designed for today's medical technology professionals, addressing continuously evolving regulatory, reimbursement, legal and compliance challenges, and sales and marketing environments. AdvaMed's high-quality conferences, workshops and webinars offer members and nonmembers alike unmatched opportunities to network and learn from experts in government, industry and academia.

As the pace of innovation increases, so does the complexity of the many issues impacting our industry. Medtech professionals must continually seek new skills, insights and perspectives that will enable them not only to respond to change, but to anticipate it. AdvaMed's engaging and interactive programs are designed to fit the schedules of busy medtech executives, including both in-person and virtual events.

In 2015, AdvaMed conducted 24 in-person conferences and workshops, and several webinars, drawing more than 1,500 medtech professionals. In 2016, AdvaMed plans expanded programming, including additional geographic locations.

Key topics and titles include:

- 510(k), PMA and IDE Submissions
- Reimbursement 101 and 201
- The Innovation Summit
- Medical Device & Diagnostic Statistical Issues Conference
- Payment Policy Conference
- Women’s Executive Network Events
- Advertising & Promotion of Medical Devices
- Compliance Bootcamps and the Executive Speaker Series
- FDA Submission Strategy
- Technical Writing
One of the most important roles of the Association is to educate stakeholders about the tremendous value of the medical technology industry to patients, health care systems and the economy. Our industry is creating life-saving and life-improving innovations every day that help patients live longer, healthier lives while reducing health care costs and creating good-paying jobs across America and around the world. AdvaMed’s Life Changing Innovation campaign is the medtech industry’s flagship communications program to share our value story with the public, including policymakers, elected officials, patient and provider groups, and others, to help shape policies critical to our success.

Flyers and ads featuring patients and allied organizations supporting repeal of the device tax helped AdvaMed secure device tax relief in 2015.

Bill Walton, NBA hall of famer and back surgery patient, shares his perspective on life changing innovation with attendees of AdvaMed 2015.

Caroll Neubauer, chairman and CEO of B. Braun Medical (at right), hosts an LCI employee engagement event in May at the company’s Bethlehem, Pennsylvania facility, alongside AdvaMed’s Don May, executive vice president, payment and health care delivery policy.
This year, we strengthened our value message through the release of two AdvaMed-supported studies. One found that leading health systems are able to adopt the latest advances and provide technology-intensive care without having higher Medicare spending than hospitals using less technology. A second study affirmed that medtech has comprised a relatively small and constant share of national health expenditures – at about six percent – for more than two decades. We also bolstered stakeholder education through release of disease-specific communications toolkits on cancer, stroke, atrial fibrillation and chronic wounds, to highlight the extraordinary contributions of medtech innovation.

Empowering medtech employees to share their stories about the benefits of medical progress is a key focus of the LCI campaign, and in 2015 we continued to expand our range and use of multimedia for interactive storytelling. We hosted events with company employees, members of Congress and other stakeholders at AdvaMed member facilities in Pennsylvania, Arizona and Utah to expand awareness of our industry’s unique innovation ecosystem and how we can work together to ensure continued progress.

In 2015, AdvaMed also launched the United4Innovation campaign to amplify our message on the importance of repealing the innovation-crushing medical device tax, with new information, resources and allies, including a web portal that helped generate tens of thousands of letters from repeal supporters to Capitol Hill. Meanwhile, as part of an ongoing celebration of AdvaMed’s 40th anniversary year, we created an interactive timeline of key milestones of the Association and the industry over our four decades of advocating for innovation, as well as videos and compelling social media to spotlight our progress.

Compelling fact sheets and media toolkits help break through the din in Washington and elsewhere on issues of critical importance to our industry.

PROFILE IN INNOVATION

Grandmother Deborah Lee was in her 50s and suffering from severe pain and loss of mobility when she was first diagnosed with osteoarthritis. Physicians recommended that Deborah have both her hips and knees replaced. Today, following joint replacement surgery, Deborah is grateful for the innovative orthopedic implants that have relieved her pain, restored her mobility, and allowed her to dance again and play with her grandchildren.
Members of AdvaMed’s Ophthalmic Devices Sector are focused on creating technologies that preserve, restore and improve healthy eyesight. The Sector meets quarterly to discuss key priorities and is committed to ensuring patient access to these vision-enhancing products.

In 2015, the Sector met with FDA’s Division of Ophthalmic and Ear, Nose and Throat Devices, and the agency’s Office of Surveillance and Biometrics. They discussed how medical device reports of adverse events following laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) procedures can be updated and improved, and drafted a detailed follow-up document containing recommendations for the types of events that are reportable, in addition to alternative reporting methods and other considerations for LASIK procedures.

Orthopedic devices help patients by restoring mobility, relieving pain and improving quality of life. In 2015, AdvaMed’s Orthopedic Sector continued to support development and maintenance of a single central implantable arthroplasty device component database available to all arthroplasty registries. The Sector also approved participation by industry representatives in an initiative to explore creation of a single global hip and knee rating system to address ongoing concerns with the United Kingdom’s Orthopedic Data Evaluation Panel rating system.

The Orthopedic Reimbursement Work Group met with Center for Medicare and Medicaid Innovation (CMMI) Deputy Director Rahul Rajkumar to discuss how gainsharing financial incentives in the Bundled Payments for Care Improvement (BPCI) and Comprehensive Care for Joint Replacement (CJR) programs may compromise beneficiary access to the devices they need, in addition to reports that some BPCI providers are purchasing almost exclusively lower-utility devices without considering patients’ long-term needs. They also discussed CMMI’s plans to monitor patient care in bundled payment programs and the need for more transparency around BPCI implementation.

The Sector’s Working Group on Unique Device Identifiers (UDIs) also worked to address issues related to UDI implementation. FDA confirmed that companies that distribute non-sterile devices in trays (e.g., spine, trauma and craniomaxillofacial devices) may use a “cross-reference” approach to meet the requirement to provide UDIs at the point of use. This cost-effective mechanism will enable companies to continue to use existing stock. In another cost-saving effort, FDA confirmed that devices consigned or loaned prior to their UDI implementation date are not subject to the UDI rule, thus preventing these products from being discarded or having to be reworked to be UDI compliant.
RADIATION THERAPY

In 2015, AdvaMed created the Radiation Therapy Sector to address the unique policy challenges facing this dynamic and growing area of medtech innovation, including radiotherapy, brachytherapy and proton therapy technologies. The Sector largely focuses on addressing reimbursement and regulatory issues, as well as promoting the benefits and value of RT, in both U.S. and international markets.

The Sector worked with stakeholders in the RT community to oppose significant proposed Medicare payment cuts, including an advocacy campaign that resulted in more than 200 members of Congress weighing in against the reductions. Ultimately, the proposed cuts were scaled back, and the Sector continues to address other payment concerns included in the final rule.

In concert with the Association for the Advancement of Medical Instrumentation, the Sector also works on critical standards development. In 2015, two standards were in progress, with discussions for future projects also underway.

WOUND HEALING AND TISSUE REGENERATION

AdvaMed’s Wound Healing and Tissue Regeneration Sector is focused on ensuring patient access to innovative therapies for the treatment of chronic and complex wounds. In 2015, the Sector provided comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) on changes impacting multi-component surgical dressings in response to a shift in local coverage policy. The Sector re-engaged on the best strategy for addressing ongoing concerns with appropriate evidence challenges posed by FDA, CMS and other payers, including potential revisions to a previously generated whitepaper and partnering with clinical experts to advance the issue.

In addition, the Sector approved and collected additional funding for the American College of Wound Healing and Tissue Repair, a non-profit organization committed to advancing the field of wound care through education, research and advocacy, to support the organization’s 2016 projects.

Lastly, the group finalized and distributed an infographic that communicates the value of medical technology in wound treatment, expounding upon how advanced wound therapies can improve lives and save costs.
Operating as a division of AdvaMed, AdvaMedDx advocates on behalf of the world's leading diagnostic manufacturers to promote the value of diagnostic tests for better health and better care. Diagnostics guide the delivery of the right treatment to the right patient at the right time, improving outcomes for people around the world while, in many cases, lowering overall health care costs.

In 2015, AdvaMedDx continued proactive initiatives to support diagnostics developers and bring about major payment and policy reforms. These efforts included:

- Working closely with the Centers for Medicare and Medicaid Services (CMS) and other key stakeholders to ensure effective implementation of diagnostics payment reform provisions of the Protecting Access to Medicare Act, including assignment of unique identifiers to existing and new tests, and use of temporary codes to expedite coverage decisions and facilitate payment.

- Developing comprehensive policy on reforming diagnostics oversight and working closely with FDA, key congressional committees and other stakeholders to advance reform legislation. AdvaMedDx also supported a number of innovation provisions included in 21st Century Cures legislation in the House.

AdvaMedDx continued its high visibility advocacy and public affairs activities in the U.S. and abroad by partnering with stakeholder organizations. In 2015, AdvaMedDx focused on areas of critical importance to patient and public health, including the threat of infectious diseases and antibiotic resistance, as well as developments in precision medicine, in which diagnostics play a cornerstone role in dramatic advances in care and treatment. Specific initiatives included:

- Partnering with the administration on the Combating Antibiotic-Resistant Bacteria initiative, including participating in the White House Forum on Antibiotic Stewardship, to help educate policymakers on the critical role of diagnostics in fighting antibiotic resistance.

- Organizing a diagnostics day at the Centers for Disease Control and Prevention to forecast the future development of diagnostic tests that can contribute to the fight against antibiotic resistance and better understand how to overcome barriers to development and utilization of such tests.

- Partnering with the American Cancer Society Cancer Action Network on a series of roundtables on personalized medicine in Ohio, California, Pennsylvania, North Carolina and Florida.

- Supporting two U.S.-based briefings in partnership with leading cancer organizations focused on precision medicine and how patients, physicians, the diagnostics industry, and others can work together to give health care providers the tools and information they need to make personalized treatment decisions for their patients.

- Conducting the fourth annual diagnostics briefing at the World Health Assembly focused on the role of diagnostics in global infectious disease outbreaks.
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* as of December 31, 2015

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AdvaMed Accel – formerly the Emerging Growth Company Council – was rebranded in 2015 to better reflect its ongoing commitment to accelerating the growth and success of small medical technology companies. Leveraging the resources of the entire Association, Accel is the only organization of its kind focused specifically on the unique needs and challenges of emerging and early growth enterprises – the lifeblood of the medtech industry. Accel provides advocacy for a policy environment more conducive to capital formation and innovation; insight into ever-changing regulatory, reimbursement, compliance and business environments; and opportunity for more member engagement with peers, subject matter experts and policymakers, to help small companies prosper.

**TAX EXTENDERS LEGISLATION**
Long-standing AdvaMed advocacy paid off in December when Congress passed – and the president signed – year-end tax extenders legislation with key provisions of particular benefit to small medical technology companies. These provisions included: a two-year suspension of the innovation-crushing medical device tax; a permanent extension of the R&D tax credit; a permanent small-business expensing limitation and phase-out amount at the $500,000 and $2 million level, respectively; a permanent exclusion of 100 percent of the capital gain on certain small business stock; and extended bonus depreciation.

**ROUNDTABLES & CONFERENCES**
AdvaMed Accel convened an industry roundtable in conjunction with the Piper Jaffray Health Care Conference in November to discuss opportunities for reinvigorating the medtech innovation ecosystem for the 21st century. The roundtable – which included small and large companies, investment banks, and venture capital firms – discussed challenges and opportunities related to key issues, including: medtech reimbursement and venture capital funding; educating Congress and policymakers in support of vital policy goals; facilitating partnerships and other business opportunities; and shifting Wall Street’s mindset to ensure greater focus on R&D pipelines. It is anticipated that these topics will be revisited at future roundtables in 2016 and beyond.

Meanwhile, AdvaMed’s annual MedTech Conference included expanded programming for small companies, with unmatched opportunities to gain insight and make business connections. The Innovation Showcase featured presentations by 48 emerging growth companies, while the MedTech Innovator finals highlighted four early-stage firms vying for over $300,000 in prizes.

**PHYSICIAN-OWNED INNOVATORS**
In 2015, the Association furthered its advocacy efforts with regard to hospital purchasing policies targeting physician-owned distributors (PODs) that also unfairly discriminate against physician-owned medical technology manufacturers. AdvaMed organized meetings with Senate Finance Committee staff to educate them on the issue, provided related resources on the Association’s website, and submitted written testimony for a Finance Committee hearing that included discussion of the importance of differentiating between PODs and physician-owned innovators.
ACCEL EXECUTIVE COMMITTEE

* as of December 31, 2015

Scott Brooks
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Chief Executive Officer
Regenesis Biomedical, Inc.

Ann Bunnenberg
President and
Chief Operating Officer
Electrical Geodesics, Inc.

Michael Dale
President and
Chief Executive Officer
GI Dynamics, Inc.

Patrick Daly
President and
Chief Executive Officer
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John Kilcoyne
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Cathy Burzik, general partner at Targeted Technology and former president and CEO of Kinetic Concepts (at left), participates in an AdvaMed 2015 “CEOs Unplugged” panel on the innovation ecosystem with Caroll Neubauer, chairman and CEO of B. Braun Medical (at right).
AdvaMed's annual conference and exhibition travelled across the country to San Diego in 2015, its first time on the West Coast. This year’s conference represented a spectacular celebration of AdvaMed’s 40th anniversary, with an audience of over 2,300 attendees representing over 900 companies and stakeholder groups from 26 countries. The conference also featured its largest-ever exhibit hall, with more than 140 exhibitors displaying their latest products and services, demonstrating once again that AdvaMed 2015 was “the place to be.”

Attendees were drawn by the unique combination of participants and presenters – including those from small, medium and large companies; local, national and international governments; academia; and the financial community – that provided unmatched opportunities to gain insight, network and make business connections. Highlights included 35 world-class educational panels addressing key regulatory, reimbursement, compliance, legal, business and international issues, with special tracks focusing on in vitro diagnostics, emerging growth companies, finance, e-health and other areas.

Through such popular and informative offerings as the CEOs Unplugged Series and Entrepreneurship Boot Camp, attendees had the opportunity to hear from and interact with some of the key movers and shakers in our diverse and dynamic industry.

New to this year’s conference, the Innovation Showcase featured presentations by 48 emerging growth companies, giving attendees, potential investors and partners a compelling glimpse of the latest...
in cutting-edge medical technologies. In another first for the conference, AdvaMed 2015 hosted the MedTech Innovator finals, with four early-stage company finalists presenting their products, vying for over $300,000 in prizes, and a winner – MobileODT – selected by live audience vote.

Of particular interest was AdvaMed 2015’s stellar line-up of distinguished plenary speakers, who shared their unique insights on diverse leadership and business challenges, including General Stanley McCrystal (retired), Michael Eisner, former head of the Walt Disney Company, and Eric Topol, renowned physician and author. The conference also featured an interactive “Town Hall” forum with FDA Center for Devices and Radiological Health Director Jeffrey Shuren and other senior device center leaders, focused on the future direction of the agency and medtech innovation, while CMS’s Tamara Syrek Jensen, director of the Medicare agency’s Coverage and Analysis Group, discussed the evolving reimbursement landscape with conference attendees.

One of the most engaging and moving events of AdvaMed 2015, however, was the recognition of one of the industry’s true pioneers – renowned cardiovascular surgeon, balloon catheter inventor and entrepreneur Thomas J. Fogarty – with the third annual AdvaMed Lifetime Achievement Award.

Eric Topol, renowned physician, author, and director of the Scripps Translational Science Institute, speaks at a plenary lunch on “The Future of Health Care.”

Ariel Beery, CEO and cofounder of MobileODT (at right), accepts the MedTech Innovator grand prize from Paul Grand, managing director at RCT Ventures and producer and emcee of the awards.

Renowned cardiovascular surgeon, balloon catheter inventor and entrepreneur Thomas J. Fogarty (center) receives AdvaMed’s third annual Lifetime Achievement Award, alongside AdvaMed 2015 Co-Chair Michael Mussallem, chairman and CEO of Edwards Lifesciences (at right), and Barry Liden, vice president of government affairs at Edwards Lifesciences (at left).
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<tr>
<th>Name</th>
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<td>Robert Abernathy</td>
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<td>Brik Eyre</td>
<td>Corporate Vice President and President, Hospital Products Baxter International</td>
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