ADVAMED HIGHLIGHTS OF 2016

FEBRUARY 18: Board of Directors names Scott Whitaker president and CEO of AdvaMed.

MARCH 18: Board of Directors appoints Patrick Daly of Cohera Medical as chairman of AdvaMed Accel.

APRIL 6: AdvaMed opens Payment Policy Conference on the challenges of demonstrating medtech’s value in a changing payer world. The event contributed to development of a draft framework for consistent and effective demonstration of value, to support positive coverage and payment decisions.

MAY 24: AdvaMed begins Global MedTech Compliance Conference in Dublin, Ireland, in collaboration with MedTech Europe. The event brought together over 300 compliance professionals to discuss global trends, and included a compliance boot camp for emerging small companies.

AUGUST 15: Completion of a pro-innovation FDA user fee reauthorization agreement, committing the agency to continued improvements in the efficiency, predictability and transparency of product review processes. The pact includes significant reductions for total review time goals for 510(k)s and PMAs.

OCTOBER 1: AdvaMed refocuses its year-long campaign on the medical device tax, pivoting from promoting the benefits of the two-year suspension of the tax, which saves our industry nearly $2 billion annually, to drive a more pointed message on the urgent need for action on full and permanent repeal.

OCTOBER 17: Launch of the AdvaMed Purchasing Group to help member companies save on purchases of commonly used goods and services from nationally recognized suppliers. Savings will help provide more resources for R&D, ensure a stronger bottom line, and support companies’ growth and success.

OCTOBER 17: Opening of our largest and most successful MedTech Conference ever in Minneapolis. The event drew over 2,650 attendees – 15% greater than last year and 8% above our previous record – including representatives of over 900 companies and stakeholder groups from 27 countries.

NOVEMBER 10: AdvaMedDx and the American Clinical Laboratory Association jointly convene the AdvaMedDx-ACLA West Coast Dx Summit in San Diego to spotlight important diagnostics regulatory and reimbursement policy solutions to key challenges, and the value of diagnostics to patient care.

NOVEMBER 21: China commits to improving its regulatory system and developing a harmonized approach to unique device identifiers (UDIs) during the U.S.-China Joint Commission on Commerce and Trade meeting. Harmonized UDIs will save our industry about $1 billion in compliance costs.

DECEMBER 7: Passage of 21st Century Cures legislation with a robust slate of pro-innovation reforms, including a breakthrough pathway to improve use of FDA’s Expedited Access program. The new law incorporates eight out of 10 of AdvaMed’s priority “Innovation Agenda” regulatory reform proposals.

DECEMBER 12: Launch of the AdvaMed Digital sector, dedicated to addressing the unique needs and challenges facing companies in the burgeoning digital health space. AdvaMed Digital will provide specialized expertise for companies at the leading edge of the digital health revolution.

DECEMBER 15-16: Based on the China Board’s recommendation, AdvaMed’s Ethics and International Board Committees approve phase-out of direct sponsorships for health care providers to attend third-party educational events under the China Code. We also secured sign-on to the Code from local China device association CAMDI.
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.
LETTER FROM THE PRESIDENT

Amid all the uncertainties and shifting political winds of a contentious election year, AdvaMed’s steady leadership on important policy solutions to the world’s health care challenges delivered extraordinary results in 2016 for our member companies and the patients we serve.

Led by our nearly 50-member Board of Directors, the Association began implementation of a new three-year strategic plan designed to open a new era in medical technology – one that will bring more life-changing innovations to more patients while continuing to reduce health care costs, create good-paying jobs and grow our economy. Throughout this report are compelling data points that demonstrate how our industry and our Association are creating value and advancing these objectives. With new executive leadership and a new vision for the future, AdvaMed is moving forward in fulfilling its mission.

Fulfilling our mission to create a policy environment that unleashes the power of innovation has never been more critical. Patient needs are expanding faster than ever, with aging populations around the world and explosive growth of the middle class in developing economies. Before us are boundless opportunities to continue our work to improve patients’ lives. But without an efficient regulatory process, without adequate coverage and payment, and without fair access to global markets, many patients will not receive the life-changing technologies they need. There is a direct tie between the policies we are fighting for in Washington and around the world,

TABLE OF CONTENTS

1 Our Mission
2-3 Letter from the President and Chairman
4 Membership
5 Events & Education
   AdvaMed Purchasing Group
6-7 Advocacy in Action
8-9 Technology and
   Regulatory Affairs
10-11 Payment and
   Health Care Delivery
12-13 International
14-15 Legal Affairs
16-17 Life Changing Innovation
18-19 State Affairs
19-21 Sector Spotlight
22-23 AdvaMedDx
   AdvaMedDx Board
   Executive Committee
24-25 Accel
   Accel Board
   Executive Committee
26-27 AdvaMed 2016
28-29 Board of Directors
   Executive Committee
and the countless individuals who need our help. Simply put, our goal is to bring the most advanced technologies in the most efficient way possible to the most people in need.

As an organization, AdvaMed is better positioned today than at any time in its history to continue to advance our goal, with an expanding membership that stands as testament to the extraordinary value AdvaMed provides. Looking back on 2016, the Association marked key milestones that yielded important benefits to AdvaMed members and the patients they serve. These include:

• Implementation of a two-year suspension of the medical device tax, saving our industry nearly $2 billion annually, and ongoing messaging on the benefits of suspension to drive innovation, which has advanced our efforts for permanent repeal;

• Completion of a pro-innovation FDA user fee reauthorization agreement, committing the agency to continued improvements in the efficiency, predictability and transparency of review processes;

• Enactment of 21st Century Cures legislation with key regulatory reforms proposed by AdvaMed, including a breakthrough pathway provision to improve use of FDA’s Expedited Access program;

• Progress on AdvaMed’s value framework initiative, aimed at helping members demonstrate the value of technologies in a consistent and effective fashion, to support positive coverage and payment decisions;

• Launch of AdvaMed Digital to support members in the burgeoning digital health space, and debut of the AdvaMed Purchasing Group to help members save on commonly used goods and services;

• Ongoing AdvaMedDx advocacy for diagnostic regulatory reforms, effective implementation of laboratory test payment reforms and recognition of diagnostics in key public health initiatives;

• Continued advocacy through AdvaMed Accel for legislation – including revisions to the tax code – and regulatory, reimbursement and compliance initiatives that promote investment in small firms, alongside strategic partnerships that support the medtech innovation ecosystem;

• Achievement of key international objectives, such as implementation of a China-specific code of ethics, China’s commitment to improve its regulatory system and develop a harmonized system of unique device identifiers, and staving off price controls in key geographies; and

• Creation of our largest and most successful MedTech Conference ever in Minneapolis.

To build on our successes over the past year, AdvaMed has an exciting and ambitious agenda ahead. We recognize the challenges before us. But for us to succeed will require the engagement of all our members – from the largest multinationals to the smallest innovators – and all the creativity and ingenuity that is the hallmark of our industry. We hope that you will join us as an active participant, for the benefit of the industry, for the good of your company and for the sake of so many patients in need.
AdvaMed is the world’s leading medical technology trade association, with member companies that develop, manufacture and sell innovative medical devices, diagnostic tests and digital health products. AdvaMed supports the needs of members of all sizes – from the smallest start-ups to the largest multinationals – so they can provide life-changing technologies to more patients in need.

In 2016, the association continued to attract new members – up 9 percent from 2015 – by providing extraordinary value to our membership. AdvaMed provides a unified voice in advocating for principles that promote innovation and timely patient access to the latest advances, and offers 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. The Association also offers a range of opportunities for member interaction and professional development – including educational programs, conferences and the Women’s Executive Network – as well as services that help meet evolving member needs.

During the year, we launched the AdvaMed Purchasing Group, an exclusive member benefit that will help companies purchase commonly used goods and services – such as office supplies, lab supplies and clean-room services – as part of a collaborative to achieve discounted rates. The Association also launched AdvaMed Digital, a new product sector group, dedicated to meeting the unique needs of companies in the burgeoning digital health space.
PROFESSIONAL DEVELOPMENT

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 2016, AdvaMed conducted 30 in-person conferences and workshops, and several webinars, drawing more than 1,700 medtech professionals. Popular events included AdvaMed’s 2nd annual Payment Policy Conference in April, Women’s Leadership Development Conference in June, and Cybersecurity Summit in November. In 2017, AdvaMed will continue to expand programming, including additional geographic locations. Key topics and titles include:

- 510(k), PMA and IDE Submissions
- Digital MedTech Conference
- Payment Policy Conference
- Cybersecurity Summit
- Reimbursement 101 and 201
- Innovation Summit
- Medical Device & Diagnostic Statistical Issues Conference
- Women’s Executive Network Events
- Advertising & Promotion of Medical Devices
- Compliance Bootcamps and Leadership Training
- FDA Submission Strategy
- Human Factors & Design Control Workshop

ADVAMED PURCHASING GROUP

START SAVING

In 2016, the AdvaMed Purchasing Group (APG) debuted as a new members-only benefit to help medical technology companies save on purchases of the very best goods and services from nationally recognized suppliers. Such savings will provide more resources for development of life-changing innovations for patients, help ensure a stronger bottom line for members, and support companies’ future growth and success.

Leveraging the collective purchasing power of AdvaMed membership, APG-participating companies will save money and time through pre-negotiated contracts with leading suppliers – identified through a trusted and proven vetting system – for items ranging from office supplies and lab supplies to clean-room services. APG will help small- and medium-sized companies in particular be more competitive, by securing supplier rates generally reserved only for the largest companies.

Importantly, participation in APG requires no additional costs for AdvaMed members, and there are no minimum commitments required to participate.
In December 2016, Congress passed and the president signed the 21st Century Cures Act, putting the final capstone on two years of AdvaMed advocacy in support of the legislation. Championed by former House Energy and Commerce Committee Chairman Fred Upton (R-Mich.) and Committee Member Diana DeGette (D-Colo.), and Senate HELP Committee Chairman Lamar Alexander (R-Tenn.) and Ranking Member Patty Murray (D-Wash.), the new law aims to accelerate the discovery, development and delivery of 21st century cures for patients in need. AdvaMed played a prominent role – working in concert with many allied stakeholder groups – in proposing and advancing key provisions of the legislation that will help continue improvement of FDA regulatory processes and begin addressing significant reimbursement challenges at the Centers for Medicare and Medicaid Services (CMS).

The legislation includes a number of important FDA regulatory reforms from AdvaMed’s Innovation Agenda, led by the breakthrough pathway provision that will improve use of the agency’s Expedited Access program. There are also provisions to: raise the humanitarian device exemption cap; establish a process for FDA recognition of international standards; improve selection of experts on FDA advisory panels; update the Class I/II exemption list; allow for the use of central institutional review boards (IRBs) for device trials; require FDA to update its CLIA-waiver guidance; reinforce FDA’s use of the “least burdensome” principle in conducting reviews; clarify FDA regulation of software and certain digital health technologies; and improve the regulation of combination products. The package also provided $500 million in discretionary appropriations for FDA implementation of these and other provisions.

Importantly, the Cures Act also includes key health care delivery system reforms. For example, language requiring greater transparency in local coverage decisions (LCDs) represents a positive step forward on AdvaMed’s work to improve the LCD process. The legislation also includes a retroactive delay in the application of competitive bidding rates to non-competitively bid areas for durable medical equipment (DME) through the end of 2016. The latter provision mirrored AdvaMed-supported legislation previously introduced by Rep. Tom Price (R-Ga.) and John Thune (R-S.D.).

AdvaMed’s leadership in assisting development and advancement of this important legislation from the beginning included Board member participation in multiple congressional roundtables and hearings that informed the legislative process. Led by our regulatory and government affairs teams, AdvaMed staff worked through final passage to encourage the strongest possible provisions for medical technology innovators and the patients we serve.
2016 began auspiciously with implementation in January of a two-year suspension of the innovation-crushing medical device tax, marking a key turning point in AdvaMed’s seven-year campaign to repeal this onerous tax. During the year, AdvaMed redoubled its advocacy on Capitol Hill to keep the urgent need for full and permanent repeal of the tax front-of-mind for policymakers.

Fundamental to this effort was educating lawmakers on how the nearly $2 billion in annual tax savings from the suspension was being redeplored by the medtech industry to develop the next-generation of treatments and cures for patients, and to create more good-paying American jobs. AdvaMed organized the industry behind a united message emphasizing the benefits of suspension and the need for permanent repeal to bolster future investments and economic growth. This included collecting broad survey data on the positive impact of suspension, as well as organizing dozens of individual examples of how specific companies were reinvesting. This message was carried through multiple Capitol Hill “fly-ins” with company CEOs and R&D executives, as well as a public affairs campaign inside the beltway and in key states, and echoed by our allies and partners in the patient and research group communities.

In the fourth quarter of the year, AdvaMed augmented this work with an even more pointed message to Congress on the need for full repeal, to position the issue for action in 2017. As a result, repeal of the device tax featured prominently in Republican blue prints for health care reform and tax reform in the 115th Congress.

Utah Senator Orrin Hatch was honored for his strong support of medical device tax repeal during an August tour of a C.R. Bard facility in Salt Lake City, accompanied by Chairman and CEO Timothy Ring and AdvaMed’s Scott Whitaker (at right).

Minnesota Senator Amy Klobuchar (at left) and Indiana Senator Dan Coats (at right) discuss device tax repeal and other priorities with members of AdvaMed’s State Medical Technology Alliance in March.

Minnesota Congressman Erik Paulsen (at left) discusses device tax repeal strategy with AdvaMed’s JC Scott on the sidelines of AdvaMed 2016 in October.
REGULATION THAT WORKS

From clinical trials and premarket reviews to post-market requirements, medical technology companies navigate an often challenging regulatory path to provide physicians and patients timely access to life-changing innovations. AdvaMed’s Technology and Regulatory Affairs department works with our members, FDA and its counterparts around the world, to help light the path to market and ensure regulatory processes that are efficient, predictable and transparent.

In 2016, the department’s signature accomplishments included spearheading successful negotiation of a pro-innovation FDA user fee reauthorization agreement, and congressional passage of 21st Century Cures legislation with a robust slate of pro-innovation reforms.

USER FEE REAUTHORIZATION

In preparation for reauthorization of the Medical Device User Fee Act (MDUFA) in 2017, and to continue to build on meaningful FDA reforms already achieved under MDUFA III, AdvaMed engaged in discussions with members and other stakeholders for nearly a year to identify data needs and develop strategic framework goals for negotiations with the agency. These negotiations culminated in an August reauthorization agreement between industry and FDA to continue to improve the efficiency, predictability and transparency of review processes. Key improvements in the agreement include:

- Significant reductions for total review time goals for 510(k)s and PMAs, and first-time goals for de novo products;
- Reforms to increase the consistency and timeliness of the review process, including FDA’s commitment to provide feedback to a company at least five days before a pre-submission meeting and a requirement for FDA to document the rationale for issuing a deficiency letter; and
- Greater accountability through two independent analyses of the agency’s management of the review process, and implementation by FDA of a quality system management approach.

Successful implementation of the agreement, once enacted through legislation, will advance the mutual goals of industry and FDA to provide health care professionals and patients more timely access to the life-changing innovations our members provide.
Capping nearly two years of AdvaMed advocacy, in December Congress passed and the president signed the 21st Century Cures Act, designed to accelerate the discovery, development and delivery of 21st century cures for patients in need. AdvaMed played a prominent role – working in concert with many allied stakeholder groups – in proposing and advancing key provisions of the legislation that will help continue improvement of FDA regulatory processes.

Key elements include a breakthrough pathway provision that will improve use of the agency’s Expedited Access program. There are also provisions that: raise the humanitarian device exemption cap; establish a process for FDA recognition of international standards; improve selection of experts on FDA advisory panels; update the Class I/II exemption list; allow for the use of central institutional review boards for device trials; require FDA to update its CLIA-waiver guidance; reinforce FDA’s use of the “least burdensome” principle in conducting reviews; clarify FDA regulation of software and certain digital health technologies; and improve the regulation of combination products.

AdvaMed’s leadership in assisting development and advancement of this important legislation included Board member participation in multiple congressional roundtables and hearings that informed the legislative process.
PROTECTING ACCESS TO INNOVATION

The advanced medical technology industry creates life-saving and life-enhancing innovations every day, and Medicare patients are a major beneficiary of these advances. AdvaMed’s Payment and Health Care Delivery department works closely with the Centers for Medicare and Medicaid Services (CMS) to ensure patient access to innovations through appropriate coverage, coding and payment policies – the importance of which is magnified when such policies are replicated by private payers.

ADVAMED’S VALUE INITIATIVE

In 2016, AdvaMed undertook an initiative to develop a comprehensive approach for assessing the value of medical technologies in new payment models, aimed at helping members demonstrate the value of products in a consistent and effective fashion, to support positive coverage and payment decisions. The initiative provides a counter perspective to other frameworks that focus on the cost impacts of technologies, and takes into account a broad range of technologies, stakeholder perspectives and value drivers, including clinical, non-clinical, care delivery economics, and public/population health impacts. In conjunction with ongoing work identifying gaps in medtech quality measurement, the initiative will better position AdvaMed members to compete in a rapidly changing care delivery environment.

21ST CENTURY CURES

In December, Congress passed and President Obama signed the 21st Century Cures Act, designed to accelerate the discovery, development and delivery of 21st century cures for patients in need. AdvaMed played a prominent role – working in concert with many allied stakeholder groups – in proposing and advancing key health care delivery system reforms, including language in the final bill that requires greater transparency in local coverage decisions, and a retroactive delay in the application of competitive bidding rates to non-competitively bid areas for durable medical equipment through the end of 2016.
COVERAGE, CODING & PAYMENT

AdvaMed continued to work with CMS on coverage issues related to FDA-approved investigational device exemption (IDE) clinical trials and successfully advocated for improvements. In 2016, CMS modified its policy to allow coverage for Medicare beneficiaries that participate in certain IDE trials where historically coverage had been denied for devices deemed experimental or investigational.

AdvaMed successfully engaged with the American Medical Association to establish a streamlined submission and updating process for laboratory codes in response to legislation revamping payments for laboratory testing services. These improvements will also allow codes for non-sole-source, FDA-approved in vitro diagnostic tests to go through a more streamlined process for descriptor development and approval.

As part of AdvaMed’s Innovation Agenda, the Association continued work developing legislative language to ease burdens associated with coverage of Category III codes and to ensure that breakthrough technologies receiving New Technology Add-on Payments and their associated services are covered and paid.

PAYMENT POLICY CONFERENCE

AdvaMed hosted its 2nd Annual Payment Policy Conference in April, highlighting innovation challenges for medical technologies. The conference included discussions on the impact of new payment models and their implications for device innovation, adoption and utilization. Speakers addressed a number of emerging areas including value, quality measurement under the new Medicare Incentive Payment System (MIPS), expanded bundling, and telehealth.
LOWERING BARRIERS IN GLOBAL MARKETS

AdvaMed’s Global Strategy and Analysis department works to open markets for medical technology companies 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 World Trade 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.

CHINA – In 2016, AdvaMed’s China Board held its provincial meeting in Kunming at the invitation of the Yunnan governor. Over 200 people participated, including 32 mayors and 120 local and central government officials, providing an excellent platform to develop relationships and exchange views on how best to spur medtech innovation. Successful AdvaMed advocacy led to key commitments from China at a subsequent meeting of the Joint Commission on Commerce and Trade. Most significantly, China agreed to develop a unique device identification system based largely on the U.S. system, saving our industry an estimated $1 billion in costs. China also committed to de-link indigenous innovation policies from government procurement preferences, strengthen government oversight of procurement activities, and treat foreign products fairly. The Association also worked to implement a China-specific code of ethics in 2016, and achieved official sign-on from the China medical technology association CAMDI to help broaden the reach and impact of the code.

Wang Lanming, director general of the China FDA’s department for medical device evaluation (center left, adjacent AdvaMed’s Ralph Ives), and other senior CFDA officials, visit AdvaMed in October to discuss China regulatory priorities.
**INDIA** – AdvaMed worked with the health ministry to develop globally harmonized rules for medical devices, an interim step to a comprehensive framework for regulation of devices as distinct from drugs. In coordination with industry stakeholders, the Association intensified its advocacy and PR efforts in opposition to mounting political pressures for coronary stent price controls, delaying their implementation and helping to protect patient access to innovation. The Association will continue to work with India’s government and other stakeholders to increase awareness of the value of medtech and improve patient access to needed care.

**JAPAN** – Successful AdvaMed advocacy helped ensure that Japan did not change its reimbursement rules in 2016 to move from biennial to annual rate adjustments, saving the industry hundreds of millions of dollars. Japan also continued to make progress under an AdvaMed-supported regulatory performance plan aimed at improving patient access to innovation.

**LATIN AMERICA** – In Brazil, AdvaMed partnered with medtech associations in the country to stave off price controls, promote the value of medtech, and evaluate regulatory and health technology assessment gaps to help improve access to innovation. AdvaMed also worked with industry across Latin America to strengthen codes of ethics and compliance throughout the hemisphere.

**EUROPEAN UNION** – As the EU moved toward completion of 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, which included organizing meetings between AdvaMed members and officials in EU member states, appeared to be successful in the final text.
ADVOCATING FOR INNOVATORS

AdvaMed’s Legal team advocates for a predictable legal environment that values innovative health care solutions, enhances public health and ensures patient access to advanced medical technologies. Working with over 1,500 in-house lawyers and compliance officers at member companies around the world, our team engages government regulators, physician specialty societies and other stakeholders to provide leadership and expertise on key legal issues. This includes advancing the highest global standards for ethical interactions between industry and health care professionals.

VALUE-BASED CARE

In 2016, AdvaMed expanded its advocacy for modernization of U.S. anti-kickback statute and safe harbor regulations to facilitate the health care system’s shift away from traditional fee-for-service models toward value-based models. We developed proposed legal reforms to enable medtech value-based collaborations with providers, educated policymakers and other stakeholders on the need for change, proposed policy solutions to the Senate Finance Committee, and met with the HHS Office of the Inspector General (OIG).

PHYSICIAN-OWNED DISTRIBUTORS (PODS)

In May, AdvaMed’s long-standing advocacy to address the fraud and abuse risks posed by PODs, and related dangers to patient safety, paid off when the Senate Finance Committee released an updated report on the entities that reflected the Association’s key policy priorities. AdvaMed leveraged the report to continue to raise awareness of PODs-related concerns in discussions with government regulators, allied groups and other stakeholders.
ETHICS & COMPLIANCE

AdvaMed leads the promotion of ethical business practices globally, consistent with the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the AdvaMed Code). Among the Association’s 2016 accomplishments:

- AdvaMed implemented a China-specific code of ethics and achieved official sign-on from the China medical technology association CAMDI to broaden the reach and impact of the code. In 2016, the code was advanced to phase-out direct sponsorships of health care professionals in China to attend third-party educational conferences, effective in 2018. AdvaMed developed various tools and awareness materials to assist members and Chinese stakeholders with implementation.

- The Association’s leadership in the Asia-Pacific Economic Cooperation (APEC) business ethics initiative achieved important strategic objectives during the APEC annual forum in Lima, Peru. These included: finalization of 24 medical technology codes of ethics, bringing more than 11,500 local companies under a code; a commitment from stakeholders in the region to focus on advancing and supporting ethical interactions with third parties; and a new partnership to expand business ethics efforts in the Western Hemisphere.

- AdvaMed held its ninth annual Global MedTech Compliance Conference in May in Dublin, Ireland, in collaboration with MedTech Europe (an alliance of European medtech industry associations). The event brought together over 300 compliance professionals to discuss global trends facing the medtech industry.

U.S. PHYSICIAN PAYMENTS SUNSHINE

Working closely with our members, AdvaMed engaged extensively with the Centers for Medicare and Medicaid Services to ensure effective implementation of the Sunshine Act. This included submission of comment letters related to the Act’s impact on PODs and corporate transactions, and participation in monthly meetings with the agency to discuss ongoing issues.
The medical technology industry creates life-saving and life-improving innovations that help patients live longer, healthier lives while reducing health care costs and creating good-paying jobs across America and around the world. From imaging systems and in vitro diagnostics to implantable devices like pacemakers, stents and joint replacements, advanced medical technologies are critical to diagnosing and treating illnesses and diseases that impact patients’ lives every day, from cancer and diabetes to heart failure, arthritis and other serious conditions.

AdvaMed’s Life Changing Innovation (LCI) campaign is the medtech industry’s flagship communications program to share our value story with policymakers, elected officials, patient and provider groups, and other stakeholders to help shape policies critical to our success.

In 2016, AdvaMed strengthened its value messaging through the release of compelling and informative materials on radiation therapy for cancer, medical technologies for chronic pain, and other innovations that improve patients’ health and quality of life.

Empowering people to share their stories about the benefits of medical progress is a key focus of the LCI campaign. During the year, we continued to expand our range and use of multimedia for interactive storytelling through the eyes of the patient – including people like Preston Anderson, a husband, father and former Duke football player who, at the age of 44, experienced a devastating heart attack. Preston’s doctors performed a minimally-invasive procedure to relieve the blockages and ease the pressure on his heart, a procedure that even a few decades ago would have required open heart surgery and a lengthy recovery period. Thanks to advances in medical technology, Preston was feeling better and able to return home to his family after just two days in the hospital.

During the year, AdvaMed co-hosted events with company employees, members of Congress and other stakeholders at member facilities in Georgia, California, Utah and Pennsylvania to expand awareness of our industry’s unique innovation ecosystem and how we can work together to ensure continued progress. One such event at the U.S. headquarters of AdvaMed member company Elekta spotlighted military veteran
The Importance of Diagnostic Tests in Fighting Infectious Diseases

Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi, and each year millions of Americans are affected by them. Many infectious diseases have minor complications if diagnosed and treated appropriately. But left untreated, others—including pneumonia, tuberculosis, HIV and meningitis—can be life-threatening. New bacteria, viruses, fungi and parasites emerge and evolve each year. Densely populated regions and easy travel accelerate the spread of infectious disease. Antibiotic resistance is a major global health concern. More than 2 million Americans develop drug-resistant infections each year. Human papillomavirus is linked to cervical cancer. Helicobacter pylori is linked to stomach cancer and peptic ulcers. Hepatitis B and C are linked to liver cancer.

Early and accurate diagnosis of infectious disease is critically important because:

1. Diagnosis can improve the effectiveness of treatments and avoid long-term complications for the infected patient.
2. Undiagnosed patients can unknowingly transmit the disease to others. Early diagnosis can help to prevent or stop an outbreak.
3. Widespread overuse and misuse of antibiotics contribute to antibiotic resistance. Diagnostic tests can determine when antibiotics are an appropriate treatment—and when they are not.
4. Test manufacturers are continually advancing and developing diagnostics to match the evolution and emergence of new infectious diseases. Recent advances enable health care providers to reach a diagnosis more quickly, improving patient outcomes and lowering associated health care costs.

Infectious diseases were associated with an economic burden of more than $120 billion in the U.S. in 2014 alone. Use of a diagnostic test for the early detection of MRSA enabled doctors to prescribe optimum antibiotics 1.7 days sooner, reducing the length of hospital stays by 6.2 days and lowering hospital costs by more than $21,000. Point of care (POC) testing allows patient diagnoses in the physician’s office, an ambulance, the home, the field or in the hospital. The results allow for rapid treatment. During the recent Ebola crisis, test manufacturers rushed to develop new POC rapid diagnostic tests to avoid multi-day delays in diagnosing affected patients. Between November 2014 and December 2015, four such tests were developed and approved by the World Health Organization; the U.S. Food and Drug Administration has authorized 10 tests for emergency use. Had these POC tests been used during the epidemic, researchers estimate that the scale of the epidemic could have been reduced by more than a third.

Infectious diseases pose a greater challenge today than they did even two decades ago. A few types of infections have been linked to a long-term increased risk of cancer.
ADVOCACY ACROSS AMERICA

AdvaMed’s State Government Affairs team works collaboratively with members to engage state lawmakers and regulators to advance our policy agenda. In 2016, this included advocating for state legislation to help ensure patient access to innovative new treatments and cures, and successfully opposing initiatives that would have created unnecessarily burdensome device distribution restrictions, product stewardship requirements and device warranty mandates.

Often working in concert with state and local medical technology groups, the team marked key successes across the nation:

**COVERAGE & REIMBURSEMENT**

In 2016, AdvaMed advocacy led to an improved health technology assessment (HTA) process in Washington state. Passage of legislation to require clinical expertise on the HTA panel will help protect patient access to life-changing innovations.

**WARRANTIES**

AdvaMed led a successful effort to block legislation in New York that would have required a five-year warranty for artificial hips and knees, as well as implanted electronic devices. AdvaMed worked with members and allies as it made a strong push that stopped the bill on the Senate floor.

**PRODUCT STEWARDSHIP**

AdvaMed continued to fight state and local government efforts to require costly manufacturer take-back programs for home-generated medical sharps waste and batteries. The Association was successful in helping to defeat a sharps take-back ordinance in Los Angeles County and in staving off harmful sharps and battery proposals in the Maine and California legislatures.

**DISTRIBUTION**

Proposals to restrict out-of-state medical device distribution continued to surface around the country in 2016. The Association was able to defeat legislative proposals in Arizona and Idaho that would have required suppliers of durable medical equipment to have accredited facilities in the same state served.
The State Medical Technology Alliance (SMTA), AdvaMed’s network of state and regional trade associations, continues to bolster the industry’s grassroots reach and ability to engage effectively with state and federal policymakers. At SMTA’s annual March Capitol Hill Fly-In, members engaged with the chairs of the congressional medical technology caucuses and thanked their state’s delegations for supporting device tax suspension and ongoing repeal efforts.

SECTOR SPOTLIGHT

State Medical Technology Alliance

In 2016, the Association created AdvaMed Digital to address and help shape critical policies that influence the business environment for digital health technologies and applications in the U.S. and key global markets. Establishment of the new Sector reflects the Association’s strategic commitment to being a leading digital health convener, thought leader and advocate.

Members of AdvaMed Digital convene to explore digital health trends and solutions; network and gain industry insights; engage with policymakers, thought leaders and stakeholders; address critical public policy issues; and advocate for the advancement of digital health for the benefit of patients and global health care systems.

During the year, AdvaMed Digital worked with FDA to establish the Digital Health Think Tank, a group of software engineers and regulatory professionals that will reimagine the FDA review process for digital health software. The Sector also worked closely with AdvaMed’s Software and Postmarket Policy Working Groups to develop the Association’s Cybersecurity Foundational Principles and Principles Regarding Use of Real World Evidence in the National Evaluation System for Health Technology. Sector members also participated in the negotiation and drafting of digital health provisions of the medical device user fee agreement (MDUFA IV) commitment letter.
WOUND HEALING & 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 2016, the Sector continued to advocate for effective use of wound technologies, as well as appropriate regulation, coverage and reimbursement policies. This was achieved in part through outreach and engagement with wound specialty groups on key topics, such as with the National Pressure Ulcer Advisory Panel on efforts to re-define wound terminology, and with the Association for the Advancement of Wound Care on their development of a white paper on appropriate clinical evidence. Through comments to CMS and FDA, the Sector also continued to advocate for appropriate reimbursement of skin substitute products and against the creation of additional regulatory barriers for wound dressings containing anti-microbial agents.

During the year, the Sector 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 2017 projects. The Sector also partnered with the organization to host a joint meeting in conjunction with their annual conference, and contributed to planning for a payment policy panel at the event.

SECTOR HEAD
FRANCOIS FOURNIER
President
U.S. Commercial Advanced Wound Management
Smith & Nephew

OPHTHALMIC

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.

Ongoing activities in 2016 included working with FDA on use of patient-reported outcomes (PROs). The agency’s device center and its ophthalmic devices division are expecting PRO endpoints to be included in clinical trials to support regulatory approvals. There currently are no validated PROs in the ophthalmic space, although many companies have tried to develop these instruments without success.

One option under consideration by the Sector would be to work with the agency to facilitate flexibility in the use of these endpoints and to develop a standardized guidance on developing and validating PROs.

A number of payment-related issues that could impact ophthalmic device makers also are being closely monitored by the Sector, including: hospital and ambulatory surgical center payments, Physician Merit-Based Incentive Payment System development, potential use of physician offices as valid sites for cataract surgery, and possible CMS interest in guidance memos.

SECTOR HEAD
JOHN KILCOYNE
President and Chief Executive Officer
ReVision Optics, Inc.
RADIATION THERAPY

In 2016, AdvaMed’s Radiation Therapy Sector focused on developing a strategic plan, building relationships and educating all stakeholders to help address the unique policy challenges facing this dynamic and growing area of medtech innovation. The Sector cohosted a Capitol Hill briefing with the American Society for Radiation Oncology (ASTRO) to increase awareness of the value of radiotherapy and how legislative issues impact the industry. The Sector also began planning additional Hill briefings for 2017, and continues to develop collateral materials, including a primer on Radiation Therapy, to further its education goals.

During the year, the Sector worked with the International Society of Arthroplasty Registries (ISAR) to support development of an international prosthesis library to eliminate the need for registry-by-registry data entry of hip and knee product information, and help make the process more efficient and less costly.

The Sector also worked in conjunction with AdvaMed’s Global Strategy and Analysis department, and collaboratively with U.S. Customs and Border Protection, to defeat a proposal by Colombia before the World Customs Organization (WCO) to classify some orthopedic screws and lumbar fixation devices as hardware instead of medical devices. Colombia’s proposal would have made the screws and fixation devices subject to import tariffs and potentially harm patient access.

Finally, the Sector monitored implementation by the Centers for Medicare and Medicaid Services of the agency’s bundled payment programs for hip and knee replacement procedures, and their impact on short- and long-term patient care outcomes.

SECTOR HEAD
JOSHUA LEVINE
President and Chief Executive Officer
Accuray

ORTHOPEDIC

Orthopedic devices help patients by restoring mobility, relieving pain and improving quality of life. In 2016, AdvaMed’s Orthopedic Sector worked to advance key priorities, including ongoing support for the American Joint Replacement Registry and ensuring that each manufacturer has access to their own patient-level registry data.

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SECTOR HEAD
JUAN-JOSE GONZALEZ
President
DePuy Synthes, U.S. Johnson & Johnson

SECTOR HEAD
FRANCOIS FOURNIER
President
U.S. Commercial Advanced Wound Management
Smith & Nephew
DIVIDING SOLUTIONS

Operating as a division of AdvaMed, AdvaMedDx is focused exclusively on issues facing diagnostics manufacturers, advocating on their behalf and promoting the value of diagnostic tests for better health and better care. Diagnostics guide 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 2016, AdvaMedDx advocacy was critical to supporting diagnostics developers and working towards major policy reforms. These efforts included:

• Continuing work 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 the 21st Century Cures Act, which was signed into law in December.

• Working closely with the Centers for Medicare and Medicaid Services (CMS) and other key stakeholders to ensure effective implementation of clinical diagnostic laboratory test payment reforms under the Protecting Access to Medicare Act and a related final rule issued in June.

• Partnering with the American Clinical Laboratory Association to host a one-day diagnostic summit at Hologic’s headquarters in San Diego that featured leaders from the clinical laboratory and diagnostic manufacturing sectors, government and commercial payers, the investor community, and Rep. Scott Peters.

• Organizing a Capitol Hill briefing focused on domestic infectious disease and the critical need for diagnostic tests to protect patients and the public.

• Partnering for the second year in a row with the American Cancer Society Cancer Action Network on a series of roundtables on personalized medicine in Utah, Georgia, Oregon, Nevada and Connecticut.

• Creating and promoting several new educational materials, including primers on diagnostic test technology and the role of diagnostics in cancer care, as well as fact sheets on infectious disease, antibiotic resistance, and cervical cancer.

AdvaMedDx continued its advocacy and public affairs activities in the U.S. by partnering with stakeholder organizations and producing new educational materials. In 2016, AdvaMedDx focused on areas of critical importance to patient and public health, including antibiotic resistance and precision medicine. Specific initiatives included:

• Working closely with the Centers for Medicare and Medicaid Services (CMS) and other key stakeholders to ensure effective implementation of clinical diagnostic laboratory test payment reforms under the Protecting Access to Medicare Act and a related final rule issued in June.

AdvaMedDx Chairman John Bishop of Cepheid participates in a panel on diagnostics at an American Association for Clinical Chemistry meeting in Philadelphia in August.

Beth Bell, director of the National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention, speaks at a March Capitol Hill briefing on infectious disease threats and the value of diagnostics, adjacent AdvaMedDx’s Andy Fish (at right).
DX EXECUTIVE COMMITTEE

* as of December 31, 2016

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Chief Executive Officer
Cepheid

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Diagnostics Products
Abbott

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Chief Operating Officer
Hologic, Inc.

ARND KALDOWSKI
President,
Beckman Coulter Diagnostics
Danaher

ALBERTO MAS
Executive Vice President
& President, Life Sciences
BD

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Executive Vice President,
Worldwide Quality,
Regulatory and Compliance
Ortho Clinical Diagnostics, Inc.

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Grifols Diagnostic Solutions

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Agendia

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Janssen Diagnostics
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Corporate Vice President
Americas,
President and
Chief Executive Officer
bioMerieux, Inc.

FRANZ WALT
President
Laboratory Diagnostics
Siemens Healthineers

STEPHANE ZAMIA
Chief Executive Officer
Head of All Americas
Diagnostica Stago
ACCELERATING SMALL BUSINESSES

AdvaMed Accel is the division within AdvaMed committed to accelerating the growth and success of small medical technology companies. Accel is dedicated to providing 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 member engagement with peers, subject matter experts and policymakers, as well as strategic partners and investors, to help small companies thrive.

RESEARCH
AdvaMed Accel released a report in October spotlighting key challenges in the medtech innovation ecosystem that impact small companies in particular, and helping to advance effective solutions. Entitled “A Future at Risk: Economic Performance, Entrepreneurship, and Venture Capital in the U.S. Medical Technology Sector,” the research reflected input from multiple industry stakeholder roundtables on capital formation challenges faced by small companies.

CONFERENCES & SEMINARS
Building on its partnership with MedTech Innovator – the industry’s global competition and accelerator program – AdvaMed Accel facilitated the Innovation Showcase and MedTech Innovator Finals Competition at AdvaMed’s annual medtech conference. Accel also organized a leadership seminar at the conference to focus on solutions to critical management issues facing emerging companies.

During the year, Accel supported key events to advance capital formation and strategic partnerships in our industry. For example, Accel leveraged its relationships with Silicon Valley Bank, Vivo Ventures and Piper Jaffray to present the Healthcare Capital Connections Summit in Shanghai, China, providing members unique opportunities to explore fundraising and market access in this fast-growing market.

POLICY DEVELOPMENT
In 2016, Accel and its members contributed to AdvaMed advocacy in favor of key provisions of the landmark 21st Century Cures Act, including regulatory and reimbursement reforms to ease small companies’ path to market. In preparation for reauthorization of the Medical Device User Fee Act (MDUFA), Accel advocacy also helped ensure a pro-innovation agreement with FDA that commits the agency to improved review time goals, with continued reduced fees for small companies.

PHYSICIAN-OWNED INNOVATORS
In May, Accel’s long-standing advocacy to address fraud and abuse risks posed by physician-owned distributors (PODs) paid off when the Senate Finance Committee released an updated report on the entities reflecting key small-company priorities. Importantly, the report included an unambiguous statement that “hospitals must be able to recognize that certain physician ownership in legitimate innovator companies is allowable, and to differentiate legitimate physician-owned businesses from problematic POD arrangements.”
* as of December 31, 2016

Martha Shadan of Rotation Medical and Nadim Yared of CVRx participate in a CEOs Unplugged panel at AdvaMed 2016 on sustaining the medtech innovation ecosystem.

ACCEL EXECUTIVE COMMITTEE

SCOTT BROOKS
President and
Chief Executive Officer
Regenesis Biomedical, Inc.

ANN BUNNENBERG
President and
Chief Operating Officer
Electrical Geodesics, Inc.

PATRICK DALY
President and
Chief Executive Officer
Cohera Medical, Inc.

LISA EARNHARDT
President and
Chief Executive Officer
Intersect ENT, Inc.

JOHN KILCOYNE
President and
Chief Executive Officer
ReVision Optics, Inc.

NADIM YARED
President and
Chief Executive Officer
CVRx, Inc.

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MARTHA SHADAN
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Chief Executive Officer
Rotation Medical

JOHN F. SOMERS
President and
Chief Executive Officer
Harmac Medical Products, Inc.
AdvaMed’s 10th annual conference and exhibition was our best and largest ever! Held in Minneapolis, the conference showcased Minnesota’s innovative medical technology cluster, one of the largest medtech hubs in the world, and drew over 2,650 attendees – 15% greater than last year and 8% above our previous record.

The conference also featured its largest-ever exhibit hall with 174 booths, achieved its highest-ever number of sponsors at 96, and set a new record of over 1,200 business development meetings – a 32% increase over last year!

Attendees representing over 900 companies and stakeholder groups from 27 countries – including those from small, medium and large companies; local, national and international governments; academia; and the financial community – were once again drawn by the conference’s unmatched educational, networking and business development opportunities.

Highlights included 44 world-class educational panels addressing key regulatory, reimbursement, legal and compliance, business development and finance, and international issues, with compelling topics ranging from cybersecurity and digital health, to molecular diagnostics development and clinical trial design.

Through such popular offerings as the CEOs Unplugged Series and AdvaMed Accel Leadership Seminar, attendees had unfettered access to some of the key executives and decision makers in our diverse and dynamic industry.

For the second year in a row, the conference hosted the Innovation Showcase and MedTech Innovator awards finals. After a highly competitive process, 48 emerging growth companies were selected to present during the Innovation Showcase, giving attendees, potential investors and partners a compelling glimpse of the latest cutting-edge medical
technologies. The MedTech Innovator finals included four early-stage company finalists making their pitch for over $300,000 in prizes, and a winner – Green Sun Medical – selected by live audience vote.

AdvaMed 2016 featured a stellar line-up of distinguished plenary speakers who shared their unique insights on the future of health care, including Omar Ishrak, chairman and CEO of Medtronic; Deborah DiSanzo, general manager, IBM Watson Health; John Noseworthy, president and CEO of the Mayo Clinic; Richard Migliori, executive vice president of medical affairs and chief medical officer, UnitedHealth Group; Aneesh Chopra, president of NavHealth; and Tommy Thompson, CEO of Thompson Holdings and former secretary of the U.S. Department of Health & Human Services.

Highlights also included an interactive “Town Hall” with Jeffrey Shuren, director of FDA’s device center, and other senior device center leaders, focused on the future direction of the agency and medtech innovation.

One of the most engaging and moving events was the recognition of two of our industry’s true pioneers – Boston Scientific Co-Founders John Abele and Pete Nicholas – with the fourth annual AdvaMed Lifetime Achievement Award.

AdvaMed 2016 also honored two of the industry’s most ardent supporters on Capitol Hill – Senator Amy Klobuchar (D-Minn.) and Rep. Erik Paulsen (R-Minn.) – with the Association’s MedTech Innovation Congressional Award for their outstanding work promoting medical innovation and repeal of the device tax.
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<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Company/Position</th>
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<tr>
<td>ROBERT ABERNATHY</td>
<td>Chairman and Chief Executive Officer</td>
<td>Halyard Health</td>
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<td>NACHO ABIA</td>
<td>President and Chief Executive Officer</td>
<td>Olympus Corporation Of The Americas</td>
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<td>F. MICHAEL BALL</td>
<td>Division Head and CEO of Alcon Novartis</td>
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<td>ANDRE-MICHEL BALLESTER</td>
<td>Chief Executive Officer</td>
<td>LivaNova</td>
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<td>BRIAN BLASER</td>
<td>Executive Vice President, Diagnostics Products</td>
<td>Abbott</td>
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<td>TIMOTHY DUGAN</td>
<td>Managing Partner</td>
<td>Water Street Healthcare Partners</td>
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<td>DENNIS DURMIS</td>
<td>Vice President, Radiology Commercial Operations, Americas Region,</td>
<td>Bayer HealthCare</td>
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<td>LISA EARNHARDT</td>
<td>President and Chief Executive Officer</td>
<td>Intersect ENT, Inc.</td>
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<td>BRIK EYRE</td>
<td>Corporate Vice President and President, Hospital Products</td>
<td>Baxter International</td>
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<td>MICHAEL FARRELL</td>
<td>Chief Executive Officer</td>
<td>ResMed</td>
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<td>TODD FRUCHTERMAN</td>
<td>President and General Manager, Critical &amp; Chronic Care Solutions Division</td>
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* as of December 31, 2016
EXECUTIVE COMMITTEE

PETER J. ARDUINI
President and
Chief Executive Officer
Integra LifeSciences

JOHN L. BISHOP
Chairman and
Chief Executive Officer
Cepheid

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