



AdvaMedDx Year in Review: 2011

AdvaMedDx was launched in 2010 by the world's leading diagnostic manufacturers to advocate for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. Over the past year, AdvaMedDx doubled its founding membership to 75 companies and provided substantial value to its member companies through an aggressive program of public affairs and advocacy activities.

AdvaMedDx represents one of the most dynamic and innovative sectors in health care. Medical diagnostic tests are an integral part of our health care system. From the genetic tests that inform personalized cancer treatment to the blood analysis that identifies the right antibiotic to fight an infection, diagnostic tests provide vital insights at every stage of medical care — prevention, detection, diagnosis, treatment, and successful management of health conditions. Diagnostic tests are performed in laboratories, hospitals, physicians' offices, clinics, and in the home. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease, and often reduce overall health care costs.

Operating as a division of AdvaMed, the Advanced Medical Technology Association, AdvaMedDx is the only advocacy organization dedicated exclusively to the issues facing diagnostic companies both in the United States and abroad.

AdvaMedDx's Strategic Goals

- Create an understanding of the value of diagnostic tests.
- Ensure timely patient access to safe and effective diagnostic tests.
- Modernize payment systems for diagnostic tests.

AdvaMedDx successfully advanced these strategic goals in 2011 through a wide array of activities and accomplishments.

AdvaMedDx's vision is to be the world's leading advocate for patient access to innovative diagnostics that can enhance wellness, improve patient outcomes, and advance public health. Advances in genetic and molecular research are leading to many new and promising technologies, making it an exciting time for the diagnostics industry. Never before has the potential been so great for diagnostic technologies to enhance and transform patient care. Likewise, it has never been more important to build a greater understanding of the value of these tests for disease prevention and management.

– **Vincent Forlenza**, Chairman of AdvaMedDx, President and CEO of BD, *IVD Technology*, Spring 2011

WORKING WITH INDUSTRY

AdvaMedDx serves as the leading voice of the diagnostics industry in the United States, with a strong focus on federal advocacy in Washington, DC. We work with our member companies and their associations around the globe to advance patient access to innovative, safe and effective diagnostics worldwide. All member companies have the opportunity to serve on a range of work groups that further the work of the organization and ensure that AdvaMedDx policy is well-informed by industry experts.



AdvaMedDx | Honoring National Health Council

(pictured, from left) **Andrew Fish**, Executive Director, AdvaMedDx; **LaVarne Burton**, Vice Chair National Health Council; **Vincent Forlenza**, Chairman, AdvaMedDx

Board of Directors

Twenty leaders of the diagnostics industry serve on the AdvaMedDx Board of Directors, providing policy and strategic direction to the organization.

The Board of Directors met quarterly in 2011, including a meeting in Berlin held in conjunction with the International Federation of Clinical Chemistry's WorldLab meeting. Leadership from the diagnostics associations in Europe and Japan came together with the AdvaMedDx Board of Directors at this meeting to discuss mutual challenges and opportunities for collaboration. Other Board meetings throughout the year provided forums for engagement with Members of Congress, FDA leadership, patient advocacy organizations, the Gates Foundation, and other key stakeholders.

AdvaMedDx held its first annual membership meeting and reception during the September AdvaMed 2011 MedTech Conference, at which it elected the 2012-2013 Board of Directors (see page 3 for a complete list).

At this event, AdvaMedDx honored the National Health Council for its leadership on a legislative initiative to accelerate patient access to new diagnostics and therapies (See p. 6, Working with Capitol Hill). LaVarne Burton, President and CEO of the American Kidney Fund and Vice Chair of the National Health Council Board of Directors, accepted the award.

Global Diagnostics Industry

Expanded collaboration among the leading diagnostics associations in both developed and developing countries will be essential to future successes for the diagnostics industry. As a key contributor to improving health outcomes worldwide, the diagnostics industry is helping to shape the future of global health care.

In 2011, AdvaMedDx collaborated with other diagnostics associations around the world and continued to grow these relationships in support of a global industry community.

In addition to AdvaMedDx, the diagnostics associations that now plan to convene on a regular basis include those from Europe, Japan, Australia, Brazil, and Canada. Outreach continues to diagnostics industry organizations in other major regions of the world as well. AdvaMedDx and the European Diagnostics Manufacturers Association (EDMA) collaborate particularly closely under a memorandum of understanding executed in late 2010 to formalize a long-standing, positive working relationship between the two organizations.

2012 BOARD OF DIRECTORS

Abbott Laboratories

Edward Michael, Executive Vice President, Diagnostics

Agendia

David Macdonald, President & Chief Executive Officer

Alere, Inc.

Ron Zwanziger, President & Chief Executive Officer

Bayer HealthCare, Diabetes Care

Jonathan Achenbaum, Senior Vice President, Global Strategic Marketing, Diabetes Care

BD

Vincent Forlenza, President & Chief Executive Officer

bioMerieux

Thierry Bernard, Senior Executive Vice President, Commercial Operations and Investor Relations

Bio-Rad

Norman Schwartz, President & Chief Executive Officer

Cardinal Health

Lisa Ashby, President, Category Management

Cepheid

John Bishop, Chief Executive Officer

Danaher

Tom Joyce, Executive Vice President

Gen-Probe

Carl Hull, President & Executive Officer

IRIS International

Cesar Garcia, President & Chief Executive Officer

Novartis Diagnostics

Carsten Schroeder, President, Diagnostics

Ortho Clinical Diagnostics

Nick Valeriani, Company Group Chairman, Worldwide Franchise Chairman

QIAGEN

Peer Schatz, President & Chief Executive Officer

Quidel Corporation

Doug Bryant, President & Chief Executive Officer

Roche

Daniel O'Day, Chief Operating Officer

Sekisui Diagnostics, LLC

Jerry Casey, Chief Operating Officer

Siemens Healthcare Diagnostics

Michael Reitermann, Chief Executive Officer

Sysmex America, Inc.

John Kershaw, President & Chief Executive Officer

AdvaMedDx also is working through the Global Medical Technology Alliance (GMTA), which provides a forum for national and regional medical technology associations to develop and advocate for policies that support innovation in medical technology and address patients' health care needs around the world.

Medical Technology Learning Institute

The Medical Technology Learning Institute (MTLI), AdvaMed's education arm, provides diagnostic courses for industry professionals and other interested parties. In 2011, MTLI organized a molecular diagnostics course and a diagnostics biostatistics workshop, both of which featured speakers from the FDA and industry.

RAISING OUR PROFILE

AdvaMedDx undertook a number of public affairs initiatives in 2011 to help meet its charge to be a world leader in diagnostics advocacy and create an understanding of the value of diagnostics.



AdvaMedDx | Diagnostics Symposium

Strategic Public and Government Affairs Plan

Under the leadership of the Board of Directors, AdvaMedDx established a strategic public and government affairs plan that provides a thoughtful framework for effective communications and advocacy.

Diagnostics Symposium

As a major stakeholder education and outreach initiative, AdvaMedDx hosted a symposium entitled *Diagnostics: Powering Discovery, Transforming Care*. Held in June in Washington, DC, the symposium featured some of the nation's top experts discussing the current and future science of diagnostics. Speakers explored how diagnostics are transforming our understanding of health conditions and revolutionizing the way we treat and manage our most challenging diseases. The symposium drew more than 140 people from advocacy associations, provider groups, federal agencies, trade press, industry, and others interested in learning about diagnostics. Senior executives from AdvaMedDx member companies, including Board Members Nick Valeriani of Ortho-Clinical Diagnostics and Don Pogorzelski of Sekisui Diagnostics, moderated the panel discussions.

Diagnostics Policy Primer

In conjunction with the diagnostics symposium, AdvaMedDx released a *Diagnostics Policy Primer*. This document provides a review of the regulation and payment of diagnostics and highlights current issues. AdvaMedDx has distributed this primer at various events and electronically and it is available on the AdvaMedDx website.

Establishing a Brand

AdvaMedDx initiated a branding effort to develop a new look and feel for the organization consistent with both its distinct diagnostics identity and its existence within the overall structure of AdvaMed. Over the course of several months, the branding initiative took form with a new logo and tagline, a completely new website, and a social media platform from which to increasingly engage key stakeholders. AdvaMedDx will launch this new brand at the beginning of 2012.

Media

AdvaMedDx engaged with key trade press throughout the year by issuing press releases, participating in interviews, and placing op-eds. Board Chairman Vincent Forlenza wrote an op-ed on AdvaMedDx that was published in the May issue of *IVD Technology*. Executive Director Andrew Fish was interviewed by *The Gray Sheet* for a feature article in June on AdvaMedDx and its priorities.

Executive Newsletter

AdvaMedDx launched an *Executive Newsletter* in October, distributing the inaugural issue electronically to over 700 contacts in industry, patient and disease advocacy groups, professional societies, and other stakeholder organizations.

Conference Collaborations

Through various speaking roles, AdvaMedDx participated in key diagnostics conferences throughout the year to raise the organization's visibility and highlight issues important to the industry. AdvaMedDx also sponsored a booth at the July AACC Clinical Lab Expo, an event that attracted over 18,000 registrants.

- » Molecular Medicine Tri-Conference – San Francisco (February)
- » Partnering for Global Health – Washington, DC (June)

- » Next Generation Dx Summit – Washington, DC (August)
- » Harvard University's Personalized Medicine Conference – Cambridge, MA (November)

ADVANCING DIAGNOSTICS

AdvaMedDx advocates for risk-based regulation of all diagnostics by the U.S. Food and Drug Administration (FDA), and seeks payment reform that recognizes the full contribution of modern diagnostics to health care quality and outcomes. AdvaMedDx works closely with Congress, FDA, the Centers for Medicare and Medicaid Services (CMS), and other policy makers both in the U.S. and around the world to improve the policy environment for the diagnostics industry and patients who benefit from advances in diagnostics.

Working with the FDA

AdvaMedDx works directly with the FDA on a wide range of regulatory issues affecting the diagnostics industry. Dr. Alberto Gutierrez, Director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, joined the AdvaMedDx Board at its September meeting to discuss priority issues and continue the senior level dialogue established in earlier meetings during the year between Dr. Gutierrez and Board leadership.

AdvaMedDx organized three Industry Roundtable forum meetings with the FDA that featured presentations and dialogue with Dr. Gutierrez and senior FDA staff. A number of AdvaMedDx members also participated in an FDA Vendor Day hosted by AdvaMed, which provided a great opportunity to display products and interact with FDA review staff.



AdvaMedDx | FDA Vendor Day

Jeff Shuren, Director of FDA's Center for Devices and Radiological Health, meets with AdvaMedDx member company Nanosphere at the AdvaMed FDA Vendor Day.

AdvaMedDx's proposal for a modernized, risk-based approach to the regulation of diagnostics is a cornerstone of its regulatory advocacy. In 2011, FDA took action on two key elements of the risk-based approach.

- » FDA initiated expansion of Class I/II exemptions, a key element of the risk-based approach, by moving to exempt through guidance more than 125 low-risk, well-established tests. FDA also plans to exempt additional tests from pre-market review by regulation.
- » FDA announced plans to launch a diagnostics triage pilot in 2012 to expedite the diagnostics review process.

In addition to working with FDA on adoption of the risk-based approach, AdvaMedDx commented and testified on numerous regulatory matters, including research use only/investigational use only products, companion diagnostics, next generation sequencing, rapid TB test reclassification, chlamydia/gonorrhea testing, and blood glucose meter disinfection. Specific engagement and outcomes include:

- » Successfully advocated concerns with troponin notice to industry letter and achieved FDA agreement that no new requirements would be applied to current legally marketed assays.

- » Developed blood glucose disinfection and robustness study designs for acceptance by FDA to increase transparency of new requirements and allow for expedient use in additional devices and disinfectants.
- » Testified in support of down-classification of rapid tuberculosis testing as global health issue to FDA advisory panel, which voted to recommend down-classification.
- » Testified on risk-based approach application to next generation sequencing and secured industry participation on expert panels at FDA public meeting.
- » Met with FDA and provided comments regarding industry concerns with compliance aspects of draft research use only guidance.
- » Secured significant technical changes to final HPV guidance, including a new statistical appendix to assist developers.
- » Provided industry comments on companion diagnostics guidance and hosted panel session with FDA.

Working with Payers

AdvaMedDx advocates for improvements to diagnostics coding, coverage and payment, including reform of Medicare payment policy to recognize the full contribution of modern diagnostics to health care quality and outcomes. AdvaMedDx works closely with CMS and other payers and stakeholders.

AdvaMedDx was intensively involved in the American Medical Association's (AMA) molecular pathology coding initiative, securing a process for identifying individual manufacturers and successfully advocating for CMS to continue the use of stacking codes in 2012, rather than moving immediately to new codes developed by the AMA that would have created significant payment uncertainty.

AdvaMedDx also:

- » Testified at the CMS Clinical Laboratory Open Door Public Meeting in July 18 regarding the new molecular diagnostic test codes.
- » Analyzed Medicare clinical laboratory data to refute the Medicare Payment Advisory Commission's (MedPAC) assertions with respect to the growth of in-office diagnostic tests.
- » Submitted a comment letter to Medicare regional contractor Palmetto regarding Palmetto's precedent-setting initiative to identify and establish coverage and reimbursement for molecular diagnostic tests (Molecular Diagnostic Services Program).
- » Initiated a series of activities designed to further stakeholder understanding of issues related to evidence supporting the use of diagnostics.

Working with Capitol Hill

AdvaMedDx worked with key Members of Congress and their staff to educate them on the value of diagnostics, represent the diagnostic industry's interests during the legislative process, and advocate for legislative measures that would improve patient access to innovative, safe and effective diagnostic tests.

AdvaMedDx worked closely with the National Health Council on the development of legislation recently introduced in the House of Representatives that would reform diagnostics payment for new tests by establishing new payment-setting criteria for CMS that incorporate elements of market value and take into consideration the impact of on patient care. Congressman Leonard Lance (NJ-7) introduced the

MODDERN Cures Act, HR 3497, on November 18.

Consistent with its policy that FDA should adopt a risk-based approach to regulation of all diagnostics, AdvaMedDx took a strong position against legislation introduced in the House of Representatives that would prohibit FDA from regulating laboratory developed tests (LDTs) and instead expand CMS oversight of LDTs. AdvaMedDx developed educational materials for Congress covering distinctions between FDA and CMS oversight of LDTs and explaining evaluation of risk with respect to diagnostics.

In addition to ongoing lobbying activities, AdvaMedDx:

- » Organized Congressional meetings for AdvaMedDx Board leadership.
- » Participated in a stakeholder roundtable discussion with Senator Orrin Hatch (R-UT) on regulation of diagnostics.
- » Held a Capitol Hill fly-in for the AdvaMedDx Board of Directors to press industry messages and policies with key Congressional offices and raise the profile of the diagnostics industry.

Building Alliances

AdvaMedDx places a high value on partnering with stakeholders and building alliances with organizations that have mutual interests in assuring patient access to new, innovative diagnostics. AdvaMedDx has identified over one hundred stakeholder organizations for general outreach, and is focused on expanding collaborations with a core group of patient and health care professional organizations, as well as professional societies.

In 2011, AdvaMedDx stakeholder outreach included the following:

- » Held a widely attended diagnostics symposium to educate key stakeholders;
- » Hosted two receptions for informal stakeholder networking;
- » Collaborated closely on payment reform legislation with the National Health Council, a broad-based organization that includes numerous patient advocacy organizations;
- » Hosted a luncheon discussion with key patient advocacy groups to raise awareness of key diagnostics regulatory issues; and
- » Met individually with a number of patient and disease advocacy organizations.

AdvaMedDx also is developing relationships with leading organizations who are tackling global development issues related to diagnostics, including the Gates Foundation, BIO Ventures for Global Health, the Results for Development Institute, and the Foundation for Innovative New Diagnostics.

Collaborating with Federal Agencies

AdvaMedDx continues to expand its outreach to the numerous federal agencies that work on diagnostics and related topics. In 2011, AdvaMedDx directly engaged with the Institute of Medicine, the National Institutes of Health, the Department of Commerce, and the Biomedical Advanced Research and Development Authority (BARDA) at the Department of Health and Human Services.

AdvaMedDx activities with federal agencies included the following:

- » Met with the Department of Health and Human Services and the White House Office of Management and Budget regarding diagnostics regulation.

- » Successfully influenced National Institutes of Health Genetic Testing Registry developmental plans to ensure explicit recognition of FDA cleared and approved tests in the database.
- » Presented AdvaMedDx key regulatory modernization proposals to the Institute of Medicine.
- » Met with the Department of Commerce on the World Health Organization Pandemic Influenza Preparedness (PIP) Framework and submitted comments on implementation of the PIP Framework.
- » Participated in a Department of Defense workshop on identifying barriers to development of diagnostics well suited for deployment and use in low resource environments around the world.
- » Met with BARDA to identify opportunities to increase AdvaMedDx member company participation in BARDA's work on developing medical emergency responses and countermeasures to pandemic threats and biological, chemical and nuclear attack.

Global

AdvaMedDx addressed a range of global issues of concern to diagnostic companies during 2011.

A significant breakthrough was made regarding the World Health Organization's (WHO) approach to its pre-qualification program for diagnostics that aims to identify diagnostic technologies of assured quality that are appropriate for use in resource limited settings. AdvaMedDx, working through the GMTA and with EDMA, developed a position paper advocating for a "fast-track" approach for the WHO pre-qualification tendering process for diagnostics already approved by Global Harmonization Task Force (GHTF) member countries. This position paper became the basis for new policy for the Global Fund – the largest purchaser of health care products for United Nations tenders. This policy will set an important precedent for future tenders.

On other fronts, AdvaMedDx:

- » Advocated in China on an adverse services pricing issue, which is a concern to diagnostics companies, and has not been implemented.
- » Reduced registration time in Mexico.
- » Achieved APEC support for a program on healthcare associated infections (HAI) which was a major win for diagnostics companies.
- » Secured a commitment from China to pursue down-classification of certain diagnostic tests. AdvaMedDx has been working in the US-China Joint Commission on Commerce and Trade (JCCT) to convince China that it is classifying some diagnostic tests in risk categories that are too high. This work has involved seminars and training sessions with China's State Food and Drug Administration (SFDA) to help them understand the nature of diagnostics and show them the classification system and categories in other countries. At a senior-government official level meeting of the JCCT in November, the Chinese Vice Premier agreed that SFDA would submit a proposed list of diagnostic tests for down-classification by June 2012.
- » Coordinated comments with EDMA and Eucomed on the European Commission's consideration of revisions to its regulatory system for diagnostics and medical devices.
- » Developed a comprehensive joint response with EDMA on diagnostics standardization studies to the Consortium of Laboratory Medicine Journal Editors to support ongoing collaboration and participation in international diagnostics harmonization efforts.

2011 AdvaMedDx Member Companies

3M Health Care
Abbott Laboratories*
AccuNostics Ltd.
AdvanDx
Affymetrix, Inc.
Agendia, Inc.*
Alere Inc.*
Allegro Diagnostics, Inc.
Alverix, Inc.
Aperio Technologies, Inc.
Bayer Healthcare LLC*
BD*
BioBehavioral Diagnostics Company
BioMark Technologies, Inc.
BioMarker Strategies, LLC
bioMerieux, Inc.*
Bio-Rad Laboratories*
Boreal Genomics
Canon U.S. Life Sciences, Inc.
Cardinal Health*
CardioDx, Inc.
Celera
Cellphire, Inc.
Cepheid*
Ceres Nanosciences, Inc.
Claro Scientific, LLC
CoaguSense, Inc.
Covidien
Danaher Corporation*
DEKA Research & Development Corporation
DexCom, Inc.
DNA Genotek, Inc.
Exact Sciences Corporation
FAST Diagnostics
Fujirebio Diagnostics, Inc.
Flextronics International, FlexMedical
GeneNews Limited
Gen-Probe Incorporated*
Idaho Technology, Inc.
Illumina, Inc. Immucor, Inc.*
Instrumentation Laboratory
Interface Biologics, Inc.
Invendo Medical gmbH
IRIS International, Inc.*
KRONUS, Inc.
Lumora Ltd.
Maine Standards Company, LLC
MBio Diagnostics, Inc.
MedMira, Inc.
Medtronic, Inc.
Nanosphere, Inc.
Neogenix Oncology, Inc.
NEUROMetrix, Inc.
Novartis Diagnostics*
NovioGendix Molecular Diagnostics
Novo Nordisk, Inc.
Ortho Clinical Diagnostics*
Pfizer, Inc.
QIAGEN Sciences*
Quidel Corporation*
Response Biomedical Corporation
RNA Diagnostics, Inc.
Roche*
Sakura Finetek U.S.A., Inc.
Sekisui Diagnostics, LLC*
Siemens Healthcare Diagnostics*
StarFish Medical
Streck, Inc.
SuperNova Diagnostics, Inc.
Sysmex America, Inc.*
Tosoh Bioscience, Inc.
Ventus Medical, Inc.
Vermillion, Inc.
Vigilant Biosciences
Wave 80 Biosciences
* Indicates Board of Directors companies