Integrating Personalized Medicine into Health Care

A PMC/BIO Solutions Summit

Event Program

October 14, 2015 | Renaissance Hotel | Washington, D.C.
ABOUT THE SUMMIT

The Personalized Medicine Coalition (PMC) and Biotechnology Industry Organization (BIO) welcome you to the second in a series of summits that explore solutions to challenges facing the advancement of personalized medicine. Today's summit will identify the best practices for speeding the integration of personalized medicine into clinical care.

This full-day conference will bring together representatives from industry, patient groups and payers as well as the increasing number of academic health centers and community health care systems that are already delivering personalized care to discuss their work and highlight lessons that may be applicable to the entire health care system. These deliberations will inform future discussions on the advancement of the field.
The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system. The Coalition seeks to educate policymakers and the public about the power and potential of individualized health care and raise the profile of personalized medicine so that both patients and the health system will benefit from improved clinical care and increased overall value.

The Biotechnology Industry Organization (BIO) is the world’s largest biotechnology trade association. BIO is a non-profit organization headquartered in Washington, D.C. that provides advocacy, business development, and communications services for more than 1,100 members worldwide. It is BIO’s mission to be the champion of biotechnology and the advocate for its member organizations – both large and small. BIO’s membership includes companies from throughout the continuum of personalized medicine, including the developers of precision therapeutics, diagnostic kit manufacturers, and innovative, sole source clinical laboratories.
# Integrating Personalized Medicine into Health Care

## AGENDA

**October 14, 2015**

<table>
<thead>
<tr>
<th>TIME</th>
<th>SESSION</th>
<th>MODERATOR AND PANELISTS</th>
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<tr>
<td>8:00 – 9:00 AM</td>
<td>Networking Breakfast and Registration</td>
<td>All attendees</td>
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<td>Location: Foyer</td>
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<tr>
<td>9:00 – 9:15 AM</td>
<td>Welcome and Introduction</td>
<td>Edward Abrahams, Ph.D.</td>
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<td>Location: Congressional A/B</td>
<td>President, PMC</td>
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<td>9:15 – 9:45 AM</td>
<td>Introductory Speaker</td>
<td>Introduction</td>
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<td><em>Meeting the Challenges of Evidence and Coverage for Reimbursement: An Update</em></td>
<td>Phi Vu, J.D.</td>
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<td>Director, Diagnostics and Personalized Medicine Policy, BIO</td>
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<td>Bruce Quinn, M.D., Ph.D.</td>
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<td>Senior Director, FaegreBD Consulting</td>
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<td>9:45 – 11:15 AM</td>
<td>Panel 1</td>
<td>Moderator</td>
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<td><em>Evidence and Integration of Personalized Medicine into Health Practice: Issues Faced by CMS</em></td>
<td>Amy M. Miller, Ph.D.</td>
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<td>Executive Vice President, PMC</td>
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<td>Marc Hartstein</td>
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<td>Acting Director, CMS Hospital and Ambulatory Policy Group</td>
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<td>Erin Smith</td>
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<td>Senior Manager, Avalere Health</td>
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<td>Kenneth J. Bloom, M.D., F.C.A.P.</td>
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<td>Chief Medical Officer, Clarient</td>
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<td>11:15 – 11:30 AM</td>
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### TIME | SESSION | MODERATOR AND PANELISTS
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11:30 AM – 12:45 PM | **Panel 2**  
*Education Regarding the Use of Personalized Medicine Throughout the Health Care Continuum*  
As the number of personalized diagnostics and therapies increases, how do we ensure the widespread and adequate personalized medicine education among payers, providers, patients, their families, and other stakeholders? | **Moderator**  
*Ralph Snyderman, M.D.*  
Chancellor Emeritus & James B. Duke Professor of Medicine, Duke University  
**Panelists**  
*Wendy K.D. Selig*  
Founder and Chief Executive Officer, WSCollaborative  
*Jane Binger, Ed.D., R.N.*  
Senior Research Officer, Education, Research & Philanthropy, Sutter Health  
*Jeffrey Ross, M.D.*  
Medical Director, Foundation Medicine

12:45 – 1:15 PM | **LUNCH**  
Location: Grand Ballroom South |  

1:00 – 1:45 PM | **Luncheon Keynote**  
*Integrating a Total Health Solutions Approach*  
Industry leaders discuss building a strategy for the efficient use of personalized medicine information throughout the health care system. | **Introduction**  
*Phi Vu, J.D.*  
Director, Diagnostics and Personalized Medicine Policy, BIO  
**Moderator**  
*Turna Ray*  
Editor, GenomeWeb  
**Panelists**  
*Richard Klausner, M.D.*  
Senior Vice President and Chief Medical Officer, Illumina  
*J. Carl Barrett, Ph.D.*  
Vice President of Translational Sciences, AstraZeneca
### AGENDA, cont.

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<td>1:45 – 3:15 PM</td>
<td><strong>Panel 3</strong>&lt;br&gt;<strong>Demonstrating the Value of Personalized Medicine in Clinical Practice</strong>&lt;br&gt;How can we build the recognition of the value of personalized medicine among health care providers and provide appropriate incentives for personalized clinical decision-making?</td>
<td><strong>Moderator</strong>&lt;br&gt;<strong>Shefali Shah</strong>&lt;br&gt;<em>Health Policy Advisor</em>&lt;br&gt;&lt;br&gt;<strong>Panelists</strong>&lt;br&gt;<strong>Peter Maag, Ph.D.</strong>&lt;br&gt;<em>President and CEO, CareDx, Inc.</em>&lt;br&gt;&lt;br&gt;<strong>Michael Kolodziej, M.D.</strong>&lt;br&gt;<em>National Medical Director for Oncology Solutions, Aetna</em>&lt;br&gt;&lt;br&gt;<strong>Bonnie J. Addario</strong>&lt;br&gt;<em>Chair and Founder, Bonnie J. Addario Lung Cancer Foundation</em>&lt;br&gt;&lt;br&gt;<strong>Funda Meric-Bernstam, M.D.</strong>&lt;br&gt;<em>Medical Director, Khalifa Institute for Personalized Cancer Therapy, MD Anderson Cancer Center</em></td>
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<td>3:15 – 3:30 PM</td>
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| 3:30 – 4:45 PM | Panel 4  
*Health Systems Infrastructure and Information Challenges Related to Personalized Medicine*  
How do we develop and implement effective infrastructure and program operations for the delivery of personalized medicine, and what are some of the best ways to manage the large amounts of data associated with personalized care so that it is comprehensive, useful, and user-friendly? | Moderator  
**Andrea Ferreira-Gonzalez, Ph.D.**  
Chair, Molecular Diagnostics Division, Virginia Commonwealth University  
Panelists  
**Laura Housman, M.P.H., M.B.A.**  
Global Head, Pharmaceutical Business & Senior Vice President, Commercial Development, Molecular Health  
**Jonathan Hirsch**  
Founder and President, Syapse  
**Gary D. Koch, M.D, J.D.**  
Partner, Health Industry Team, Foley & Lardner LLP  
**Jonathan Sheldon, Ph.D.**  
Global Vice President, Health Sciences, Oracle Corporation |
| 4:45 – 5:00 PM | Concluding Session  
Overview of solutions discussed during today’s summit and next steps | **Daryl Pritchard, Ph.D.**  
Vice President, Science Policy, PMC  
**Kay Holcombe**  
Senior Vice President, Science Policy, BIO |
| 5:00 – 6:30 PM | RECEPTION  
Location: Congressional C |
EDWARD ABRAHAMS, PH.D., is President of the Personalized Medicine Coalition (PMC). Representing innovators, scientists, patients, providers, and payers, PMC promotes the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health system. It has grown from its original 18 founding members in 2004 to over 225 today.

Previously, Dr. Abrahams was Executive Director of the Pennsylvania Biotechnology Association, where he spearheaded the successful effort that led to the Commonwealth of Pennsylvania’s investment of $200 million to commercialize biotechnology in the state. Earlier he had been Assistant Vice President for Federal Relations at the University of Pennsylvania and held a senior administrative position at Brown University.

Dr. Abrahams worked for seven years for the U.S. Congress, including as a legislative assistant to Senator Lloyd Bentsen, an economist for the Joint Economic Committee under the chairmanship of Representative Lee Hamilton, and as a AAAS Congressional Fellow for Representative Edward J. Markey.

The author of numerous essays, Dr. Abrahams serves on the editorial board of Personalized Medicine and has also taught history and public policy at Brown University and the University of Pennsylvania.

JAMES C. GREENWOOD is President and CEO of the Biotechnology Industry Organization (BIO) in Washington, D.C., which represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Since his appointment in January of 2005, he has markedly enhanced the trade association’s capacity—increasing both its staff and budget by nearly 50 percent.

Mr. Greenwood represented Pennsylvania’s Eighth District in the U.S. House of Representatives from January 1993 through January 2005. A senior member of the Energy and Commerce Committee, he was widely viewed as a leader on health care and the environment. From 2001 to 2004, Mr. Greenwood served as Chairman of the Energy and Commerce Committee Subcommittee on Oversight and Investigation with oversight authority over issues in the full Committee’s vast jurisdiction. He led hard-hitting investigations into corporate governance at Enron, Global Crossing and WorldCom; terrorist threats to our nation’s infrastructure; and waste and fraud in federal government agencies.

Prior to his election to Congress, Mr. Greenwood served six years in the Pennsylvania General Assembly (1981-86) and six years in the Pennsylvania Senate (1987-1992). Mr. Greenwood graduated from Dickinson College in 1973 with a B.A. in Sociology. From 1977 until 1980, he worked as a caseworker with abused and neglected children at the Bucks County Children and Youth Social Service Agency.
**SUMMIT CHAIRS**

**Scott McGoohan, J.D.**  
*Director, Science and Regulatory Affairs*  
**Biotechnology Industry Organization**

Scott McGoohan, J.D., joined the Biotechnology Industry Organization (BIO) in 2015, and serves as Director of Science and Regulatory Affairs. Scott has both an extensive scientific and legal background. A published scientist, he received his Bachelors of Science from Boston College, specializing in molecular biology, and then went on to serve as a lab manager and research scientist at Harvard Medical School, where he studied renal fibrosis and epigenetics in the Division of Matrix Biology. Scott earned his J.D. from the University of Wisconsin Law School, and subsequently worked as a consultant and lobbyist, representing various pharmaceutical and device companies and their interests on Capitol Hill. Most recently, he served as Vice President of Reimbursement and Scientific Affairs for the American Clinical Laboratory Association, where his primary responsibilities included diagnostics reimbursement, coding, and regulatory affairs.

A frequent speaker on health care issues, his areas of expertise include molecular diagnostics, personalized medicine, Medicare reimbursement, coding, coverage, and regulatory issues.

**Daryl Pritchard, Ph.D.**  
*Vice President, Science Policy*  
**Personalized Medicine Coalition**

Daryl Pritchard, Ph.D., is the Vice President of Science Policy at PMC, where he leads PMC's efforts to develop and promote optimal science-related policies and to increase awareness and understanding of personalized medicine amongst health care providers, patients, policy decision-makers and other stakeholders. This includes working to identify and address barriers to the adoption of personalized medicine into the health care system, including the development and promotion of appropriate clinical, health care infrastructure, regulatory and payment policies.

Before coming to PMC, Dr. Pritchard served as the Director of Policy Research at the National Pharmaceutical Council (NPC), where he directed NPC's policy research efforts in the areas of personalized medicine, the heterogeneity of treatment effects and the value of specialty biopharmaceuticals, and helped to advance NPC's outreach, alliance development and government relations activities. Prior to joining NPC, Dr. Pritchard served as the Director of Research Programs Advocacy and Personalized Medicine at the Biotechnology Industry Organization (BIO), where he led the organization's policy and research efforts regarding diagnostics and personalized therapies and coordinated BIO's activities involving federal biomedical research programs. He also spent three years as the Director of Government Affairs for the American Association for Dental Research (AADR), and as the primary research policy coordinator for the American Dental Education Association (ADEA).
PANELISTS – KEYNOTES

J. Carl Barrett, Ph.D.
Vice President of Translational Sciences
AstraZeneca

DR. J. CARL BARRETT is Vice President of Translational Science in the Oncology Innovative Medicines Division at AstraZeneca. His responsibility is to develop and execute biomarker strategy and translational sciences efforts to support compound development from research through early and full development in oncology. From 2005-2011, he was Global Head of Oncology Biomarkers and Imaging at Novartis.

Prior to joining Novartis, Dr. Barrett was the founding Director of the NCI Center for Cancer Research (CCR), which is the NCI intramural center for translation medicine and novel technologies. He was also the Scientific Director at the National Institute of Environmental Health Sciences where his efforts focused on integrating new approaches to toxicogenomics, molecular toxicology, and the Environmental Genome Project.

Dr. Barrett’s research focused on the discovery of the critical genetic and epigenetic changes in the cancer cell, in particular the discovery of genes involved in breast cancer (BRCA1).

Trained as a chemist at the College of William and Mary, he received his Ph.D. degree in Biophysical Chemistry from Johns Hopkins University. He has published over 600 research articles and reviews. He is a member of the Johns Hopkins University Society of Scholars, an elected member of the Ramazini Foundation, an honorary member of the Japanese Cancer Association, and a recipient of multiple NIH awards and Keynote lectures.

Richard Klausner, M.D.
Senior Vice President & Chief Medical Officer
Illumina

RICHARD (RICK) KLAUSNER joined Illumina as Chief Medical Officer in September 2013. Rick is responsible for Illumina’s strategies for advancing genomics into clinical medicine and public health. He is also part of Illumina’s executive management team, which is responsible for directing all aspects of company strategy, planning and operations.

Prior to joining Illumina, Rick was managing partner of the venture capital firm, The Column Group. Previously, he held roles as Executive Director for Global Health at the Bill and Melinda Gates Foundation and as the eleventh director of the National Cancer Institute between 1995 and 2001. He has served as chief of the cell biology and metabolism branch of the National Institute of Child Health and Human Development, and president of the American Society of Clinical Investigation. He also has been Chairman of the National Science Education Standards Projects of the National Academy of Sciences.

Rick currently chairs the International Advisory Board for Samsung, is the Chairman of Audax Health, and previously chaired the Strategic Oversight Council of Sanofi. He is a member of the National Academy of Sciences, the Institute of Medicine, and the American Academy of Arts and Sciences. Rick holds an M.D. from Duke Medical School.
Turna Ray
Editor
GenomeWeb

Turna Ray is an editor at GenomeWeb where she writes about the personalized medicine and molecular diagnostics industries. She closely tracks the evolving regulatory, reimbursement and business environment for precision medicine products.

Turna has been a reporter for ten years and has spent most of her time writing about how advancing knowledge about genomics is changing the way we see ourselves and each other, understand disease, develop medicines and deliver healthcare.

In addition to GenomeWeb, she has also written for Genome Magazine, the Al Jazeera English digital monthly magazine, Science Friday and a number of overseas publications. Occasionally, she moderates panels and speaks at genomics conferences.

When science and passion connect, innovation happens.

Connecting with patients as individuals with unique needs helps us transform the way people live with cancer. This connection energizes us to accelerate the development of medicines with potential for greater patient benefit.
Bonnie J. Addario  
Chair and Founder  
**Bonnie J. Addario Lung Cancer Foundation**

BONNIE J. ADDARIO, Founder and Chair of the Bonnie J. Addario Lung Cancer Foundation (ALCF) and a Lung Cancer Survivor, has been an activist, advocate, educator and change agent empowering patients and giving them a strong voice in the fight against lung cancer since receiving a stage 3B diagnosis more than a decade ago. Although thrust into a role that she had never envisioned for herself, she embraced it and now considers it to be her second career and a personal calling, driven by the goal of making lung cancer a chronically managed disease by 2023.

Recognizing the critical need for education, empowerment, advocacy and research to help patients and families, especially those without resources and support, Bonnie and her family founded the Bonnie J. Addario Lung Cancer Foundation (ALCF) in 2006, and then went on to found the Addario Lung Cancer Medical Institute (ALCMI) with her husband, Tony Addario, in 2008. Since its founding, ALCF and Bonnie have raised over $25 million to support free patient education programs/services, research, community outreach, awareness, advocacy. Through ALCMI, an international research consortium of 20 academic and community medical centers in the US and Europe, Bonnie is helping to drive scientific and clinical research advancements through innovative projects, including: CASTLE (Collaborative Advanced Stage Tissue Lung Cancer Network); INHERIT EGFR T790M; and GENOMICS OF YOUNG LUNG CANCER Study.

Jane Binger, Ed.D., R.N.  
Senior Research Officer, Education, Research & Philanthropy  
**Sutter Health**

DR. BINGER began working with Physician Leaders at the age of 8 when she earned 10¢ a day sorting the mail in her Mother's medical group. Now, she leads strategy development and execution for system-wide research for Sutter Health. Sutter serves 3,000,000 patients in California. In 2014, Jane led the Sutter Individualized & Precision Medicine Strategy Task Force and now leads the multi-disciplinary Task Force planning Sutter’s individualized medicine approach.

Previously, Dr. Binger led PACKARD BASICS, leadership development and education for Physician Leaders, research education for the Board, and the annual strategic goals process at Lucile Packard Children’s Hospital, Stanford University. More than 150 health organizations and associations in the US and Canada have requested results of PACKARD BASICS. As Staff Associate to the CEO, California Pacific Medical Center, she led executive and board education, and a multi-million dollar patient education initiative solely funded by one donor. Jane has served on numerous national committees on physician leadership education. Currently, she serves on PMC’s Integrating Personalized Medicine into Health Care Practice Committee, as a Senior Advisor, Center of Excellence in Diversity in Medical Education, Stanford School of Medicine, and as a Diplomat, University of California Merced Foundation Board.
Kenneth J. Bloom, M.D., F.C.A.P.

Chief Medical Officer

CLARIANT

KENNETH J. BLOOM, M.D., has been the Chief Medical Officer since 2005 and was the original Medical Director of Clarient Diagnostic Services. Dr. Bloom's career spans more than 30 years including key positions in start-up companies, University-based Medical Centers and commercial laboratories. As an early adopter of information technology, Dr. Bloom developed the Pathology Information System at Rush Medical Center and helped design the hospital’s Tumor Registry and Surgical Information System. Using this technology, Dr. Bloom co-founded Initiate Systems, which just prior to its sale to IBM, was estimated to hold an 80% share of the software market that linked individual patient records across various healthcare databases. During his residency, Dr. Bloom developed the first commercial Telepathology system and co-authored the key technical papers. He was an invited speaker at the First International Conference on Clinical Application of Telemedicine in Tromso, Norway in 1993.

Dr. Bloom came to Clarient from Irvine, CA-based US Labs, where he served as Senior Medical Director since 2002. Dr. Bloom’s academic posts have included Clinical Professor of Pathology at USC, Keck School of Medicine, Associate Professor of Pathology at Rush Medical College and one year as a visiting Professor in the Department of Computer Science at DePaul University. Over the past 15 years, Dr. Bloom has held more than 10 appointed positions at Chicago-based Rush Presbyterian-St. Luke’s Medical Center, one of the leading cancer research hospitals in the US.

Andrea Ferreira-Gonzalez, Ph.D.

Chair, Molecular Diagnostics Division

VIRGINIA COMMONWEALTH UNIVERSITY

DR. ANDREA FERREIRA-GONZALEZ is the Chair of the Division of Molecular Diagnostics and director of the Molecular Diagnostics Laboratory at Virginia Commonwealth University Health System. She is an internationally recognized expert in the field of molecular diagnostics and has played a major role in shaping national policy regarding the practice, reimbursement, and guideline development for molecular diagnostics. Dr. Ferreira-Gonzalez is a consultant for the FDA’s Clinical Genetics Panel of the Medical Devices Advisory Committee, CDRH. She was a member of the Secretary of HHS Advisory Committee on Genetics, Health and Society and she was the Chair of the Task Force on Genetic Testing Oversight. She served as a member of Clinical Laboratory Improvement Advisory Committee to HHS. She has been involved in the development of clinical guidelines with CLSI and the Association for Molecular Pathology (AMP). Dr. Ferreira-Gonzalez was President of AMP and Chair of the Professional Relations Committee for the same organization. She is currently the Chair of the Laboratory Developed Test working group.

Dr. Ferreira-Gonzalez was the recipient of the AMP Leadership Award for her major contributions to the field. At the international level, Ferreira-Gonzalez is a member of the Molecular Biology Education Committee for the International Federation of Clinical Chemistry, where she has participated over the last four years in developing educational standards for genetic testing for developing countries.
Marc Hartstein
Acting Director, Hospital and Ambulatory Policy Group
CMS

MARC HARTSTEIN has been with the Centers for Medicare and Medicaid Services for more than 25 years. He worked on the original Medicare physician fee schedule and later as a hospital payment policy analyst where he assisted the Department of Justice in successfully defending the Department of Health and Human Services in Regions Hospital v. Shalala before the United States Supreme Court.

From 2004 to 2007, Marc was Deputy Director of the Division of Acute Care where he led several IPPS reforms including development of the MS-DRGs. Marc was the Deputy Director of the Hospital and Ambulatory Policy Group from 2008 through 2012 and is currently the group’s Director. He manages four Divisions that set payments for over $260 billion in Medicare expenditures that affect over 900,000 Medicare providers of hospital care, physician, laboratory and other services. He has a Masters Degree in public policy from the University of Minnesota’s Hubert H. Humphrey Institute of Public Affairs and a bachelor’s degree in political science and economics from the University of Vermont.

Jonathan Hirsch
Founder and President
SYAPSE

JONATHAN HIRSCH is the Founder and President of Syapse, a software company enabling healthcare providers to deploy precision medicine programs. At Syapse, Jonathan works closely with healthcare providers, creating software that integrates complex genomic and clinical data to provide clinicians with actionable insights at point of care. Jonathan is a member of the Global Alliance for Genomics and Health Clinical Working Group, an Advisory Board member of the SXSW Accelerator, a member of the UCSF Technology Advisory Group, and a member of the Steering Committee of Free the Data!, an effort started by Genetic Alliance to crowdsource the interpretation of cancer genes.

Earlier in his career, Jonathan worked in Neuroscience Commercial Development at Abbott Laboratories, where he developed strategies to fund drug development through partnerships and private equity financing. His research at the Center for Molecular Neurobiology at the University of Chicago helped establish the effect of exercise on promoting hippocampal neurogenesis and combating Alzheimer’s disease. Jonathan received an M.Sci. in Neuroscience from Stanford University, and an A.B. in Biology and Political Philosophy from the University of Chicago.
Kay Holcombe
Senior Vice President, Science Policy
Biotechnology Industry Organization

KAY HOLCOMBE is currently Senior Vice President for Health Policy at BIO, the Biotechnology Industry Organization. She works with the BIO CEO and Board, BIO's health policy, reimbursement, government affairs, and alliance development staff to formulate, develop, and advance BIO principles, programs, and strategies related to health policy matters that are of interest to and affect BIO member companies.

Prior to this, as Senior Policy Advisor and Vice President for Government Relations at Genzyme, a Sanofi Company, Kay worked with government relations and regulatory affairs staff, and with principals of Genzyme and Sanofi, to develop and implement corporate policies and appropriate responses to government initiatives in the regulatory and health policy arenas. She worked with members of Congress and their staffs as well as with officials in the Food and Drug Administration and other agencies whose actions had impact on the corporation and the biopharmaceutical industry.

Before joining Genzyme in 2006, Kay spent 8 years as Executive Vice President of Policy Directions Inc., a government relations firm specializing in strategic planning and legislative and regulatory advocacy regarding health care and related issues.
Laura Housman, M.P.H., M.B.A.
Global Head, Pharmaceutical Business & Senior Vice President, Commercial Development
Molecular Health

MS. HOUSMAN joined Molecular Health in October 2013 as Senior Vice President, Chief Commercial Officer. In that role, Ms. Housman was responsible for the commercialization of Molecular Health’s suite of treatment decision support tools for enhanced oncology clinical care, successfully launching its first product, TreatmentMAP™.

Beginning April 2015, Ms. Housman now has responsibility, as Global Head, Pharmaceutical Business and Senior Vice President, Commercial Development, for developing the strategic and commercialization plans for Molecular Health’s pharmaceutical business, beginning with commercializing intellectual property associated with a novel erythropoietin receptor discovered by Molecular Health’s computational software platform, Nucleus™.

Prior to joining Molecular Health, Ms. Housman led the Market Access, Pricing and HE&OR group within Novartis’ Pharmaceutical Corporation’s Molecular Diagnostics unit. Following her efforts as part of the Novartis due diligence, acquisition and integration team for Genoptix Medical Laboratory, now a business unit within Novartis Pharmaceutical Corporation, Ms. Housman was promoted to Vice President Global Market Access, Pricing and HE&OR.

Previously, Ms. Housman was Executive Director of Marketing for Charles River Laboratories, focused on worldwide Preclinical, First in Human and Biopharmaceutical Services. Prior to Charles River, Ms. Housman led marketing and commercialization strategies in support of managed care outreach as Director of Marketing for Genzyme Genetics, a business unit of Genzyme Corporation.

Gary D. Koch, M.D, J.D.
Partner, Health Industry Team
Foley & Lardner LLP

GARY D. KOCH is a partner with Foley & Lardner LLP. A member of the firm’s Health Care and Life Sciences Industry Teams, his practice focuses on provider operations, compliance, fraud and abuse, hospital-physician relationships and alignment, and reimbursement matters.

Prior to beginning his career in law, Dr. Koch completed an internal medicine residency at Pacific Medical Center in San Francisco, California. He is a Diplomate of the American Board of Internal Medicine, a Fellow of the American College of Legal Medicine, and a member of the American Health Lawyers Association. He was selected by his peers for inclusion in the 2013, 2014, and 2015 editions of The Best Lawyers in America® in the field of health care. He was also recognized in Chambers USA: America’s Leading Business Lawyers as a leading health care lawyer (2013, 2014, and 2015).

Dr. Koch is a graduate of the University of California Los Angeles, School of Law (J.D., 1989), where he was elected to the Order of the Coif, and Thomas Jefferson University (M.D., 1982) and Pennsylvania State University (B.S., 1980) where he was enrolled in a cooperative five (5) year Premedical-Medical Program.
MICHAEL KOLODZIEJ, M.D., is the National Medical Director, Oncology Solutions, Office of the Chief Medical Officer, Aetna. Dr. Kolodziej attended college and medical school at Washington University in St. Louis where he was Phi Beta Kappa and Alpha Omega Alpha. He completed internal medicine and hematology-oncology training at the University of Pennsylvania in Philadelphia.

After completing training, Dr. Kolodziej joined the faculty at the University of Oklahoma School of Medicine where he was an associate professor. He joined New York Oncology in the winter of 1998, and was a partner in the practice until December 2012. He was an active member of the US Oncology Pharmacy and Therapeutics committee, on the executive committee from 2002-2011, and chairman from 2004-2011. He served as Medical Director for Oncology Services for US Oncology from 2007 -2011. In this role, he helped direct the implementation of the USON clinical pathways initiative, the integration of the USON EMR into this program, and the development of the USON disease management and advanced care planning programs, now known as Innovent Oncology. He has published several manuscripts and given several presentations on oncology care delivery and reimbursement reform, use of evidence based treatment to enhance value, and personalized medicine.

Since joining Aetna in January, 2013, he has been active in Aetna’s oncology delivery reform pilots, pharmacy policy, condition analysis, and genetics subcommittee.

DR. MAAG has over 20 years of executive management experience in the pharmaceutical and diagnostic industries. Prior to joining CareDx, Dr. Maag was President of Novartis Diagnostics based in Emeryville, California. He headed the expansion of the unit with worldwide growth in its blood screening business and established new ventures in molecular diagnostics. Dr. Maag also led one of Novartis’ key affiliates as Country President, Germany, and lived in a dynamically-growing and emerging market as Country President, Korea.

At Novartis headquarters in Switzerland, he helped launch the Infectious Diseases franchise and served as the Head of Strategy for Novartis Pharmaceuticals. Prior to joining Novartis, Dr. Maag worked for 6 years at McKinsey & Company in New Jersey and Germany, focusing on pharmaceuticals and globalization strategies. Supporting various healthcare and high tech companies in their growth efforts, he holds board and advisory positions at Phoenix, MolecularMD, and Cobaltix. Dr. Maag studied pharmaceutical sciences in Heidelberg and London, and received his PhD from the University of Berlin, Germany.
PANELISTS

Funda Meric-Bernstam, M.D.
*Medical Director*
KhaliFa Institute for Personalized Cancer Therapy, MD Anderson Cancer Center

**FUNDA MERIC-BERNSTAM**
is the Chair of the Department of Investigational Cancer Therapeutics, the Medical Director of the Institute for Personalized Cancer Therapy (IPCT), and a Professor in the Divisions of Cancer Medicine and Surgery at MD Anderson Cancer Center. She has a basic and translational research program focused on molecular therapeutics, predominantly on PI3K/Akt/mTOR signaling, to delineate the mechanism of action of each agent targeting this pathway and the molecular alterations useful to prospectively identify patients who will benefit most from each agent, and optimal combination therapies.

As the Medical Director of the Institute of Personalized Cancer Therapy at MD Anderson, she has not only led large efforts of genomic testing within the institution, but has a) helped build a framework for rapid assessment of actionability of genomic alterations; b) established a Precision Oncology Decision Support Team who can provide point of care input for actionability; c) launched the public website "www.personalizedcancertherapy.org" providing access to expert curation of information on therapeutic relevance of specific genes/variants; d) created databases and clinical trial alert systems to facilitate accrual to genotype-selected trials across the institution; and e) monitors trial enrollment after genomic testing to identify approaches to obstacles to trial enrollment.

Amy M. Miller, Ph.D.
*Executive Vice President*
Personalized Medicine Coalition

**AMY M. MILLER, PH.D.**, has worked with innovators, scientists, providers and payers to overcome barriers impacting personalized medicine for nearly a decade.

Before joining PMC, Miller worked in the Office of the Director of the National Institute of Mental Health, where she served as a liaison among the scientific community, the legislative branch, and the consumers of mental health care and their families. A former American Association for the Advancement of Science (AAAS) fellow, she also served as a domestic policy advisor to Senator Jay Rockefeller.

She began her career as an intramural researcher at National Institutes of Health. Miller received a B.A. from the University of New Orleans and holds a doctorate from the University of Connecticut.
BRUCE QUINN, M.D., PH.D., is a national leader on Medicare policy, the impact of health reform on innovation and the crafting of successful business strategies within the U.S. health care reimbursement system. He is a member of FaegreBD Consulting’s health and biosciences team and leads the reimbursement consulting practice. But with a unique set of skills, Dr. Quinn also provides significant synergies with the firm’s health care, intellectual property, life sciences and government advocacy groups.

With a nationwide client base, Dr. Quinn has worked successfully with both large and small companies in overcoming hurdles to commercialization through negotiation, understanding insightful ways to use the existing system to advantage and the mechanisms of policy change. Since 2008, he has been a full-time business strategist working with attorney and policy teams for both health care and life sciences clients.

Dr. Quinn travels nationwide to speak on health reform issues and publishes actively, most recently writing several peer-reviewed policy articles on advanced diagnostics and a series of authoritative white papers on the 2012-2014 coding reform process for genomic tests.

Before joining FaegreBD Consulting, Dr. Quinn was a senior health policy advisor with Foley Hoag after serving as the regional Medicare medical director for the California Part B program, where he had authority for final coverage decisions on approximately 15 percent of the U.S. Medicare program.
Integrating Personalized Medicine into Health Care

PANELISTS

Jeffrey Ross, M.D.
Medical Director
FOUNDATION MEDICINE

JEFFREY S. ROSS, M.D., is a graduate of Oberlin College, Oberlin, Ohio and The State University of New York at Buffalo School of Medicine in Buffalo, New York. He served as an intern resident and fellow in Anatomic and Clinical Pathology at the Massachusetts General Hospital in Boston, Massachusetts. He was certified by the American Board of Pathology in Anatomic and Clinical Pathology in 1974.

Following his training, Dr. Ross served as Chief of Pathology at the Moncrief United States Army Hospital in Fort Jackson, South Carolina. From 1977 until 1989 he was a member of the faculty of the University of Massachusetts Medical School reaching the rank of Professor and Assistant Dean while continuing as research Assistant Professor at Harvard Medical School and the Massachusetts General Hospital. In 1989 he became the Cyrus Strong Merrill Professor and Chairman of the Department of Pathology and Laboratory Medicine at the Albany Medical College and Pathologist-in-Chief at the Albany Medical Center Hospital in Albany, New York.

Dr. Ross has received numerous academic awards, four patents in molecular diagnostics (including HER2 gene amplification detected by fluorescence in situ hybridization) and is the author of more than 810 peer-reviewed scientific articles and abstracts, 4 textbooks and numerous book chapters in the fields of pathology, molecular diagnostics, oncology and translational cancer research.

Wendy K.D. Selig
Founder and Chief Executive Officer
WSCollaborative

WENDY K.D. SELIG is Founder and CEO of WSCollaborative, a firm that focuses on defining and implementing strategies for establishing winning cross-sector collaborations in the health care arena. Selig is known for her collaborative approach to engagement, with a record of “connecting the dots” and fostering novel partnerships.

From 2009-2015, Selig served as President and CEO of the Melanoma Research Alliance (MRA), where she led and managed MRA’s strategic priorities, research portfolio, engagement with more than 90 corporate and non-profit Allies, and day-to-day operations. MRA, founded by Debra and Leon Black under the auspices of the Milken Institute, is the largest private funder of melanoma research.

Throughout her career, Selig has held leadership roles in numerous coalitions, including serving as founding President of United for Medical Research (UMR) and chair of One Voice Against Cancer (OVAC). She has served on the National Cancer Institute (NCI) Director’s Consumer Liaison Group (DCLG) and is currently President of the National Coalition of Cancer Research (NCCR). She has served on the Patient Leadership Council of the Clinical Trials Transformation Initiative (CTTI) and the Government Affairs Committee of the Prostate Cancer Foundation (PCF), as well as the National Comprehensive Cancer Network’s (NCCN) Tissue Allocation Subcommittee.

A native of Princeton, NJ, Selig is a Magna Cum Laude graduate of Princeton University and holds a Masters in Science (With Distinction) from Northwestern University’s Medill School of Journalism.
Shefali Shah, M.P.H.
Health Policy Advisor

**SHEFALI SHAH** is a highly experienced biopharma industry professional specializing in the areas of reimbursement, pricing and commercial development. Shefali started her career at The Lewin Group, where she supported various pharmaceutical clients on a range of healthcare policy and pricing issues. She then spent a number of years at Genentech, where she managed the home office Government Affairs group and led reimbursement policy and pricing strategy across the portfolio, including for key Genentech products notably Avastin, Tarceva and Lucentis. Shefali also played a critical role in assessing Genentech's commercial response to key legislative and policy initiatives such as the Medicare Modernization Act (MMA).

Most recently, Shefali was a Senior Director at Seattle Genetics where she played a key role in building the commercial organization. During her tenure in senior leadership roles at Seattle Genetics, Shefali was responsible for launch pricing of Adcetris as well as the commercial lead for clinical development and all market forecasting for Adcetris and pipeline agents across a number of different indications.

Shefali currently serves as an advisor to executives at various biotech and pharmaceutical companies on pricing and policy related matters.

Shefali holds a Bachelor of Arts degree from Dartmouth College and a Masters in Public Health with a concentration in Epidemiology and Biostatistics from Boston University.

Jonathan Sheldon, Ph.D.
Global Vice President, Health Sciences
Oracle Corporation

**JONATHAN SHELDON, PH.D.**
Global Vice President, Oracle Health Sciences, is responsible for healthcare analytics platform and solutions. Previously, Dr. Sheldon was Chief Scientific Officer at InforSense, where he was responsible for the company’s strategic direction in the health sciences market, as well as leading the consulting group. Prior to InforSense, he was Chief Technology Officer for Confirmant Ltd, where he was responsible for developing the company’s proteomics products and services. He also established the first bioinformatics group and was Head of Bioinformatics for five years at Roche Welwyn, UK.

Dr. Sheldon holds a Ph.D. in Molecular Biology/Biochemistry from the University of Cambridge.
ERIN SMITH, Senior Manager at Avalere Health, provides strategic insights into Medicare fee-for-service reimbursement and innovative payment policies, with particular insight into the development and operationalization of alternative payment models such as Accountable Care Organizations and bundled payments. She helps life sciences companies, providers, and other healthcare industry stakeholders understand and manage evolving market dynamics related to payment and delivery reform initiatives.

Before joining Avalere, Erin served as the Director of the Division of Technical Model Support at CMS in the Center for Medicare and Medicaid Innovation, where she led the team that implements the Bundled Payments for Care Improvement initiative and developed new bundled payments models. She also worked as an analyst focused on payment under Medicare’s Physician Fee Schedule. Prior to CMS, Erin was a regulatory and policy analyst specializing in tobacco control at the World Health Organization in Geneva, Switzerland.

Erin graduated from the University of Maryland School of Law with a Health Law and Policy Concentration and holds BAs in Political Science and Psychology from the University of New Mexico.

RALPH SNYDERMAN, M.D., is Chancellor Emeritus, Duke University and James B. Duke Professor of Medicine in the Duke University School of Medicine. He served as Chancellor for Health Affairs and Dean of the School of Medicine at Duke University from 1989 to July 2004 and led the transition of this excellent medical center into an internationally recognized leader of academic medicine. He oversaw the development of the Duke University Health System, one of the most successful integrated academic health systems in the country, and served as its first President and Chief Executive Officer.

Dr. Snyderman has played a leading role in the conception and development of Personalized Health Care, an evolving model of national health care delivery. He was amongst the first to envision and articulate the need to move the current focus of health care from the treatment of disease-events to personalized, predictive, preventive, and participatory care that is focused on the patient. In 2012, he received the David E. Rogers Award from the Association of American Medical Colleges who referred to Snyderman as the “father of personalized medicine.” Dr. Snyderman is the recipient of numerous scientific and leadership awards for developing more rational models of health care.
Phi D. Vu  
*Director, Diagnostics and Personalized Medicine Policy  
*Biotechnology Industry Organization*

**PHI D. VU, J.D.,** has spent the past decade utilizing his background in biotechnology, public health, and national security to serve the U.S. government, private industry, and academic research organizations. Prior to joining BIO as the Director for Diagnostics and Personalized Medicine Policy, Phi served as a Next Generation Diagnostics Program Manager supporting the U.S. Army’s Medical Countermeasure Systems Joint Program Management Office where he collaborated with a team of scientists, industry partners, and Federal interagency partners in the development, acquisition, and the fielding of FDA-approved medical diagnostics systems.

Phi also served at the DOD’s Joint Program Executive Office for Chemical and Biological Defense providing policy development, portfolio assessment, and program management support to the DOD’s Chemical and Biological Defense Programs. Prior to that, he was an Analyst at ANSER/Analytic Service, Inc. focusing on projects pertaining to issues of global health security and the role of the public health sector in national affairs. He has also worked at Georgetown University Medical Center’s Imaging Science and Information Systems Center developing a biosurveillance and disease monitoring system and served as a researcher at the Virginia Bioinformatics Institute.

Phi received his Juris Doctorate from the University of Maryland School of Law, a Master of Science in Microbiology from Georgetown University, and a Bachelor of Science in Biology from Virginia Tech.
The Personalized Medicine Coalition (PMC) and Biotechnology Industry Organization (BIO) would like to extend a special thank you to the sponsors for their generous support of this summit. As a result of each sponsor’s kind contributions, we are one step closer to bringing personalized medicine to the mainstream. By facilitating the collaboration of payers, patients, health care workers and industry representatives to explore solutions to the challenges involved with the integration of personalized medicine into the health care system, these sponsors are at the forefront of advancing policies to improve patient care.
A PMC/BIO Solutions Summit
ABOUT THE SUMMIT

The Personalized Medicine Coalition (PMC) and Biotechnology Industry Organization (BIO) welcome you to the second in a series of summits that explore solutions to challenges facing the advancement of personalized medicine. Today’s summit will identify the best practices for speeding the integration of personalized medicine into clinical care.

This full-day conference will bring together representatives from industry, patient groups and payers as well as the increasing number of academic health centers and community health care systems that are already delivering personalized care to discuss their work and highlight lessons that may be applicable to the entire health care system. These deliberations will inform future discussions on the advancement of the field.

Notes