The National Biomarker Development Alliance (NBDA) Forum

March 25, 2013
The Biodesign Institute Auditorium
Arizona State University
Tempe, AZ
The mission of the NBDA is to enable the creation of a standards-based ‘end-to-end’ pipeline for biomarker development.

Although at an early stage, molecularly based (precision or personalized medicine) is a paradigm shifting, potentially transformative, approach to diagnosing, treating and preventing disease. Biomarkers, specific indicators (markers) of normal or disease-related processes – or measures of pharmacologic response to therapy – promise to enable this transformation. However, biomarker development is expensive, unpredictable and fraught with failure. This uncertain and expensive process results in the failure of most biomarkers in late stage clinical trials. For example, despite the submission of over 1500 protein biomarkers for regulatory review since the mid 1990’s, the FDA has approved only 1.5 per year. Although a number of factors contribute to this lack of success, one of the critical reasons for failure is a lack of a standards-based, predictable end-to-end system for biomarker development.

The NBDA will attack this complex problem through the creation and evaluation of level-of-evidence standards at each modular stage of the biomarker pipeline. Over the past 18 months the NBDA has moved from concept – to design through a process that is currently gathering and aggregating data and knowledge from the broad array of communities that discover, develop, commercialize – and benefit from – biomarkers. In parallel, the NBDA is creating an unprecedented knowledge network that will be comprised of local founding partners, (Arizona State University, International Genome Consortium, Critical Path Institute collaborative partners T-Gen and Mayo Clinic) and national and international members of the academic and private sectors and advocacy communities. This is a daunting challenge, but one that can and must be met. For to fail means that biomarker development will continue to be uncertain and unpredictable; failure of late stage clinical trials of new molecularly targeted drugs will continue; the molecular diagnostics industry will remain an unattractive target for investors; and precision medicine will remain an attractive but unattainable vision.

All of the NBDA’s work flows, processes, data and standards will be made publically available. We welcome collaborative national and international partners who bring knowledge, high quality data and/or financial resources to enable the NBDA’s mission. As our guest speaker, FDA’s Dr. Janet Woodcock, has stated, “this job has to be done by the communities.” Thank you for your participation in this Forum and in our workshops. Please join us as we work together to eliminate the uncertainty of biomarker development through the creation of a rational standards-based end-to-end approach – that will ultimately save lives.

Finally we express our sincere appreciation and thanks to the Flinn Foundation and Arizona State University for their grants to support the start up of the NBDA; and to the Piper Foundation for support of the NBDA workshops.
Forum Agenda

1:00 – 1:15 p.m.
“The NBDA Concept – Current Status – Future Plans”
Today’s Agenda
Anna D. Barker, Ph.D.
Chairman, NBDA Leadership Team
Co-Director, Complex Adaptive Systems Initiative
Professor, School of Life Sciences
Arizona State University

1:15 – 1:30 p.m.
ASU, Personalized Medicine and the NBDA
Michael Crow, Ph.D.
President, Arizona State University

1:30 – 2:00 p.m.
“Are Biomarkers the Path to Personalized Medicine?”
If So, What will it Take from the FDA’s Perspective?
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
(Via Video Feed)

2:00 – 2:15 p.m.
Discussion
Meeting facilitator – Robert Mittman, M.S.
Founder of Facilitation, Foresight, and Strategy
Robert Mittman Consulting

2:15 – 2:30 p.m.
Coffee/Tea Break

2:30 – 3:45 p.m.
“Advancing Biomarkers:
The Best of Times and the Worst of Times”
A Facilitated Panel Discussion

Steven D. Averbuch, M.D.
Vice President, Early Global Clinical
Research Oncology; Head Pharmacodiagnostics,
Bristol-Myers Squibb Company

Laura Esserman, M.D., M.B.A.
Director, Carol Franc
Buck Breast Cancer Center;
Professor, Surgery and Radiation;
University of California, San Francisco

3:45 – 4:00 p.m.
Discussion

4:00 – 5:15 p.m.
Addressing the Biomarker Conundrum:
“Creating an End-to-End, Standards-Based Critical
Path for Biomarkers”
A Facilitated Panel Discussion

Carolyn Compton, M.D., Ph.D.
Professor, School of Life Sciences
Arizona State University

Michael Berens, Ph.D.
Deputy Director, Research Resources
Translational Genomic Research Institute (TGEN)

Robert J. Penny, M.D., Ph.D.
CEO, International Genomics Consortium
CEO, Paradigm Diagnostics

Raymond DuBois, M.D., Ph.D.
Executive Director, Biodesign Institute
Arizona State University
Co-Leader, Prevention Program, Mayo Clinic

5:15 – 5:30 p.m.
Closing Remarks – Anna D. Barker, Ph.D.

5:30 – 7:00 p.m.
Reception – Directly Adjacent to the Biodesign Auditorium
National Biomarker Development Alliance
“An Inaugural Public Scientific Forum”

Opening Speakers

Anna D. Barker, Ph.D.
Michael Crow, Ph.D.
Janet Woodcock, M.D.
Dr. Barker directs efforts in transformative knowledge networks – specifically directed toward addressing major problems in healthcare as a major focus of Complex Adaptive Systems (CAS) at ASU. These multi-sector networks serve as a foundation for the development of new research models that leverage convergent knowledge, innovative teams and novel funding approaches to better prevent and treat acute and chronic disease. Using CAS as an organizing construct, with an emphasis on computational models, enables understanding and solving multi-dimensional problems in the biomedical and social and sciences. Several initiatives are underway including a national effort in biomarker development and a new consortium focused on in silico molecularly-based medicine. Prior to joining ASU, Dr. Barker served as the Deputy Director of the National Cancer Institute (NCI) and as Deputy Director for Strategic Scientific Initiatives for several years where she developed and led or co-led a number of transdisciplinary programs including the: Nanotechnology Alliance for Cancer; The Cancer Genome Atlas (TCGA); Clinical Proteomics Technologies Initiative for Cancer; Physical Sciences-Oncology Centers – PS-OCs; and foundational programs in biospecimen science and bioinformatics. She served as a senior scientist and subsequently as a senior executive at Battelle Memorial Institute for 18 years; and co-founded and served as the CEO of a public biotechnology drug development company. She has published both in her areas of scientific interest and biomedicine and received a number of awards for her research leadership and advocacy. Her research interests include complex systems, experimental therapeutics and free-radical biochemistry in cancer etiology and treatment. Dr. Barker completed her M.A. and Ph.D. at the Ohio State University, where she trained in immunology and microbiology.

Michael M. Crow became the 16th president of Arizona State University on July 1, 2002. He is guiding the transformation of ASU into one of the nation’s leading public metropolitan research universities, an institution that combines the highest levels of academic excellence, inclusiveness to a broad demographic, and maximum societal impact — a model he designed known as the “New American University.” Under his leadership ASU has established major interdisciplinary research initiatives such as the Biodesign Institute, Global Institute of Sustainability (GIOS), and more than a dozen new transdisciplinary schools, and witnessed an unprecedented academic infrastructure expansion, tripling of research expenditures, and attainment of record levels of diversity in the student body. Dr. Crow was previously professor of science and technology policy and executive vice provost of Columbia University, where he served as chief strategist of Columbia’s research enterprise and technology transfer operations. He has been an advisor to the U.S. Departments of State, Commerce, and Energy, as well as defense and intelligence agencies, on matters of science and technology policy in areas related to intelligence and national security. He is a fellow of the American Association for the Advancement of Science (AAAS) and National Academy of Public Administration, and member of the Council on Foreign Relations and U.S. Department of Commerce National Advisory Council on Innovation and Entrepreneurship. The author of books and articles analyzing science and technology policy and the design of knowledge enterprises, Crow received his Ph.D. in Public Administration (Science and Technology Policy) from the Maxwell School of Citizenship and Public Affairs, Syracuse University.
As Director of CDER, Dr. Woodcock has close interactions with diverse constituencies, including the clinical and scientific communities, members of Congress and the Administration, national media, patient and consumer advocacy groups, the international drug regulatory community, the regulated industry, and representatives of the federal and state agencies. She frequently appears in or is quoted by the national media and has testified repeatedly before Congress. She also previously served as FDA Deputy Commissioner and Chief Medical Officer.

Dr. Woodcock has led many cross-Agency initiatives while at FDA. She introduced the concept of pharmaceutical risk management in 2000 as a new approach to drug safety and has led the “Pharmaceutical Quality for the 21st Century Initiative” since 2002. This effort, to modernize pharmaceutical manufacturing and its regulation through the application of modern science and quality management techniques, has been highly successful. She has spearheaded an initiative on pharmacogenomics that has led to unprecedented agency-industry interactions on pharmacogenomics use in drug development. In 2004, she introduced FDA’s “Critical Path” Initiative, which is designed to improve the scientific basis for medical product development. Most recently, she launched the “Safety First” and “Safe Use” initiatives to improve drug safety management within and outside the FDA, respectively.

Dr. Woodcock was previously director of CDER from 1994-2005. During this period, review processes for new and generic drugs were streamlined, and standards for quality, safety and effectiveness were improved. She also oversaw initiatives to automate submission and review of applications and adverse event reports. Under her leadership, CDER’s regulatory decision-making was made more transparent to the public, including publishing CDER’s regulatory procedures and policies, developing over 100 technical “guidances” that describe regulatory standards, providing an unprecedented degree of participation of consumer and patient representatives in FDA processes, and a Center web site inclusive of drug reviews and consumer information. Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER) where she oversaw approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis.

Dr. Woodcock has received numerous awards, including: a Presidential Rank Meritorious Executive Award, the Nathan Davis Award from the American Medical Association (1999), Roger W. Jones Award for Executive Leadership from American University (2000); Public Health Leadership Award (2004) from the National Organization for Rare Disorders; VIDA Award from The National Alliance for Hispanic Health (2005), Leadership Award in Personalized Medicine (Personalized Medicine Coalition, 2005); Public Service Award (American Association for Cancer Research, 2006); the “indispensable person of the year award” (Alliance for Aging Research, 2007), Distinguished Service and Leadership Award (Food and Drug Law Institute, 2008); Distinguished Career Award (Drug Information Association, 2008); Neal Prize for Innovation in Drug Development (ASCPT, 2009); three HHS Secretary’s Distinguished Service Awards; HHS Asian-Pacific Network achievement award, 2001; six FDA Commissioner’s Special Citations; and authored a number of publications. Dr. Woodcock received her M.D. from Northwestern University Medical School.
In his current role, Robert Mittman works with groups of organizations to discover and implement shared approaches to complex and intractable problems. He engages audiences in a lively exchange of perspectives to turn meetings into forums that allow diverse individuals to work productively together - to effect transition to knowledge. Mr. Mittman specializes as a scientific strategist. He helps large groups of scientists from diverse disciplines articulate shared areas of interest, frame significant and innovative research questions, and identify opportunities for new partnerships and collaborations to advance the development of new fields of science. He engages broadly with non-profit health organizations, government agencies, and the for-profit health care industry, including the National Cancer Institute; the Centers for Disease Control and Prevention, the American Association for Cancer Research; the University of California, San Francisco’s School of Medicine; Health Level 7; the Leukemia and Lymphoma Society; the Angiogenesis Foundation; the California HealthCare Foundation; Johnson and Johnson; Ascension Health; and Kaiser-Permanente. Examples of recent strategic facilitation include: integrating the disciplines of biophysics, physical chemistry, and mathematics into biological research; developing a vision of how information technology can improve quality and safety in a range of health care settings from research to the clinic to the home; and crafting a vision for personalized health care. Prior to founding Facilitation, Foresight and Strategy, he advised health care organizations as a director for the Institute for the Future. Robert holds graduate degrees in computer science and public policy analysis, and a Bachelor of Science degree in electrical engineering from the University of California at Berkeley.
LAURA JEAN ESSERMAN, M.D., M.B.A.
Director, Carol Franc Buck Breast Care Center
Professor of Surgery and Radiology, UCSF
University of California, San Francisco

Dr. Esserman is a surgeon and breast cancer oncology specialist, and is the Director of the Carol Franc Buck Breast Care Center at the University of California, San Francisco (UCSF). She is founder and faculty leader of the program in Translational Informatics spanning the disciplines of bioinformatics, medical and clinical informatics, systems integration, and clinical care delivery. In 1996, she started the Center of Excellence for Breast Cancer Care to integrate clinical care and research, automate tools for the capture of patient and clinical data, and develop systems to tailor care to biology, patient preference, and performance. She is nationally and internationally recognized leader in the field of breast cancer and has published over 150 peer reviewed publications. She is the Principle Investigator of the I-SPY TRIAL program, a multi-site neoadjuvant clinical trial that has evolved into a model for translational research and innovation in clinical trial design. Dr. Esserman has recently launched a University of California-wide breast cancer initiative called the Athena Breast Health Network, designed to follow 150,000 women from screening through treatment and outcomes, incorporating the latest in molecular testing and web-based tools into the course of care. She is a member of President Obama’s council of advisors on science and technology (PCAST) Working Group on Advancing Innovation in Drug Development and Evaluation that is exploring ways that the federal government can optimize support for science-based innovation in drug development and regulatory evaluation processes. Dr. Esserman received her A.B. from Harvard University, and her M.D. and M.B.A. from Stanford University.

STEVEN D. AVERBUCH, M.D.
Vice President, Translational Clinical Development & Pharmacodiagnostics
Bristol-Myers Squibb Company

In his current role(s) of Vice President for Translational Clinical Development and Pharmacodiagnostics, Dr. Averbuch serves as the Executive Sponsor of the BMS translational R&D teams across the full development and life cycle management pipeline; while working to optimize knowledge sharing and biomarker tools across all of R&D to achieve stratified medicine development. He also leads the Pharmacodiagnostics Center of Excellence with its mission to drive strategy and execute on the integrated co-development and co-commercialization of diagnostic tests as companions to BMS products. Dr. Averbuch joined BMS in 2006, co-led the Oncology early strategy team and was the executive sponsor for Oncology Transition Teams for the execution of Phase 2 Oncology programs. He has made significant Global Clinical Research contributions to business development and participated in seven successful acquisitions. He previously held positions at Merck Research Laboratories, AstraZeneca, and Mount Sinai School of Medicine. Dr. Averbuch has authored over 60 peer reviewed publications and book chapters and he is a co-author on one patent. He is currently on the Advisory Board for the University of Kansas Institute for Advancing Medical Innovation. He is a member of the American Society of Clinical Oncology and the American Association for Cancer Research having served on multiple committees for both organizations. He received his M.D. and Internal Medicine training from the University of Illinois, Chicago, and his Medical Oncology training at the National Cancer Institute, National Institutes of Health in Bethesda, Maryland.
Dr. Poste is a Regent’s Professor and Del E. Webb Chair of Health Innovation at Arizona State University (ASU). He founded and built The Bioscience Institute at ASU and served as its Director from 2003 to 2009. In 2009 he launched the Complex Adaptive Systems at ASU (CAS@ASU) which integrates research across disciplines to study the altered regulation of molecular networks in human diseases to provide a contemporary basis for the development of targeted disease interventions, inclusive of remote monitoring of health status using miniaturized body sensors and mobile devices. He is a Fellow of the U.K. Royal Society, the Royal College of Pathologists and the U.K. Academy of Medicine, a Distinguished Fellow at the Hoover Institution, Stanford University, a member of the Council for Foreign Relations and the U.S. Institute of Medicine Board on Global Health. He has served as a member of the Defense Science Board of the U.S. Department of Defense and currently serves on advisory committees for several U.S. government agencies in defense, intelligence, national security and healthcare. He has published extensively on pharmaceutical technologies, cancer and infectious diseases. He was honored in 1999 by Her Majesty, Queen Elizabeth II as a Commander of the British Empire for his contributions to international healthcare and security. He serves on the Board of Directors of Monsanto, Exelixis, Caris Life Sciences, and the Scientific Advisory Boards of Burrill and Company and Synthetic Genomics. From 1992 to 1999, he was Chief Science and Technology Officer and President, R&D, of SmithKline Beecham (SB) where he was associated with the registration of 31 drug, vaccine and diagnostic products. He has received a number of awards including Scientist of the Year by R&D Magazine, the Einstein Award from the Global Business Leadership Council, 2006; and the Scrip Lifetime Achievement Award, 2009.

David R. Parkinson is a Venture Partner at New Enterprise Associates (NEA). From 2007 until 2012, Dr. Parkinson served as President and CEO of Nodality, a South San Francisco-based biotechnology company focused on the biological characterization of signaling pathways in patients with malignancy to enable more effective therapeutics development and clinical decision-making. Prior to leading Nodality, Dr. Parkinson served in several leadership roles in the pharmaceutical industry, including; Senior Vice President, Oncology Research and Development, at Biogen Idec where he oversaw all oncology discovery research efforts and the development; Vice President, Oncology Development, at Amgen; and Vice President, Global Clinical Oncology Development, at Novartis. During his tenures at Amgen and Novartis, Dr. Parkinson was responsible for clinical development activities leading to a series of successful global drug registrations for important cancer therapeutics, including Gleevec, Femara, Zometa, Kepivance, and Vectibix. Prior to joining industry, Dr. Parkinson worked at the National Cancer Institute from 1990 to 1997, serving as Chief of the Investigational Drug Branch, then as Acting Associate Director of the Cancer Therapy Evaluation Program. He is a past Chairman of the Food & Drug Administration (FDA) Biologics Advisory Committee and is a recipient of the FDA’s Cody Medal. He currently serves as: a member of the National Cancer Policy Forum of the Institute of Medicine; co-chair of the Cancer Steering Committee of the NIH Foundation Biomarkers Consortium; Chairman of the AACR Finance Committee. Dr. Parkinson received his M.D. from the University of Toronto and completed a Hematology Fellowship at Royal Victoria Hospital at McGill University and was a Research Fellow at the New England Medical Center at Tufts University. He has held academic positions both at Tufts and at the University of Texas MD Anderson Cancer Center.
Dr. Compton is an internationally recognized academic pathologist specializing in gastrointestinal disease and is board certified in both anatomic and clinical pathology. She holds professorships at both Arizona State University and the University of Arizona and serves as an adjunct Professor of Pathology at Johns Hopkins. She is a former Professor of Pathology at Harvard Medical School, Chief of gastrointestinal Pathology at Massachusetts General Hospital and Pathologist-in-Chief of the Boston Shriners Children’s Hospital. Most recently she served as the CEO and President of the Critical Path Institute (C-Path). Prior to joining C-Path, Dr. Compton served as the Director of Biorepositories and Biospecimen Research at the National Cancer Institute (NCI), National Institutes of Health for over six years where she built capabilities in biospecimen science and developed national best practices standards for all aspects of biospecimen acquisition, policy, stewardship and access. These standards currently serve as the basis for sample acquisition across the field of precision (personalized) medicine. Prior to joining the NCI she was the Strathcona Professor and Chair of the Department of Pathology at McGill University and Pathologist-in-Chief of the McGill University Health Center for over five years. She currently serves on a number of national committees, including the Chairmanship of the American Joint Committee on Cancer and is a frequent international speaker on the topics of biospecimen and data standards, and personalized medicine. She has authored more than 500 scientific manuscripts, review articles, books and chapters.

In addition to his roles as Deputy Director for Research Resources, Dr. Berens serves as Director of the Cancer and Cell Biology Division and Professor and Head of the Brain Tumor Laboratory Unit. He was a member of Governor Jane Dee Hull’s 2002 Taskforce on Genomics, which developed strategies for the funding, partnerships, and recruitment that launched TGen. Dr. Berens’ academic career has included appointments at the University of Zurich, the Bowman Gray School of Medicine of Wake Forest University, the University of California at San Francisco, and the Barrow Neurological Institute. At the Barrows Institute, he served for 12 years as Senior Investigator and Director of Neurology Research. He currently is pursuing a translational research program in brain tumor research that includes preclinical therapy development, novel treatment target discovery, and the study of malignant cell motility. His research program includes collaborations with Barrow Neurological Institute, Mayo Clinic, multi-institutional consortia and international laboratories in Seoul, Tokyo, Sydney and Bergen (Norway). Dr. Berens current research is funded by the National Institutes of Health and private medical Foundations. He holds four patents, and is founder of two for-profit ventures: Creative Scientific Methods Inc, and Avolix Pharmaceuticals, Inc. He serves on editorial boards for scientific journals and committees that support governmental agencies, professional societies, and non-profit organizations. He is also active in the technology and public policy sectors, and is a past Chairman of the Arizona Technology Council. Dr. Berens received his Ph.D. from the University of Arizona.
Dr. Penny is the CEO of the International Genomics Consortium (IGC) and also serves as a Founder and CEO of Paradigm Diagnostics. Paradigm is a new company dedicated to bringing genomics technologies to personalized medicine. While at the IGC, he founded the Molecular Profiling Institute and served as its CEO and Board Chairman and led its successful merger into Caris Life Sciences. Dr. Penny is a recognized expert in the translation of diagnostics into patient care as well as in biorepositories and biospecimen research and has established two national reference medical laboratories. He also served as the Principal Investigator for the founding Biospecimen Core Resource that supported The Cancer Genome Atlas (TCGA) cosponsored by the NCI and the NHGRI. Dr. Penny received the College of American Pathologists’ 2012 Distinguished Patient Care Award for his extensive scientific translational research to accelerate the adoption of molecular pathways and associated therapies into the field of pathology and oncology to improve the lives of cancer patients. In 2011, he received the AZ BioIndustry Association Jon W. McGarity Leadership Award for vision in advancing personalized medicine and industry leadership. He received his B.S., M.S., Ph.D. (Genetics) and M.D. from the University of Arizona and pathology training at Harvard’s Brigham & Women’s Hospital in Boston, Massachusetts, where he served as Chief Resident and completed fellowships in hematopathology and surgical pathology. Dr. Penny has published extensively including a textbook in oncology.

As Executive Director of the Biodesign Institute, Dr. Dubois leads a large group of faculty and staff dedicated to addressing critical global challenges in health care, sustainability and security through the development of solutions inspired from natural systems. In addition he serves as the Dalton Chair; School of Health Solutions; and Professor, Department of Chemistry and Biochemistry at ASU and as Co-leader of the Cancer Prevention Program at the Mayo Clinic. In this latter role, he is actively engaged in enabling the active partnership between ASU and the Mayo Clinic, including the development of a medical school campus. Dr. DuBois is an internationally renowned expert in the molecular and genetic basis for colorectal cancer and continues his research work at Biodesign. Before joining ASU, he served as provost and executive vice president and professor of cancer medicine and cancer biology at the University of Texas MD Anderson Cancer Center in Houston. He also served in various roles at Vanderbilt University including the Division of Gastroenterology, Hepatology and Nutrition. His research work led to the discovery of COX-2 inhibitors for the treatment of selected inflammatory diseases. Dr. Dubois has published extensively and received a numerous awards including the: Ellen F. Knisely Distinguished Chair in Colon Cancer Research; Johns Hopkins Society of Scholars; Dorothy P. Landon Cancer Research Prize; and Richard and Hinda Rosenthal Foundation Cancer Research Award, among others. He is a Fellow of the American Association for the Advancement of Science, and is past president of the American Association for Cancer Research. He received his Ph.D. from the University of Texas Southwestern Medical Center and his M.D. from the University of Texas Health Science Center at San Antonio, and completed a residency and gastroenterology fellowship at Johns Hopkins.
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