NATIONAL HEALTH RESEARCH FORUM

2019 STRAIGHT TALK

NEW THINKING ON PERSISTENT CHALLENGES

RESEARCH!AMERICA 30 YEARS

September 5, 2019
9:00 a.m. to 2:45 p.m.

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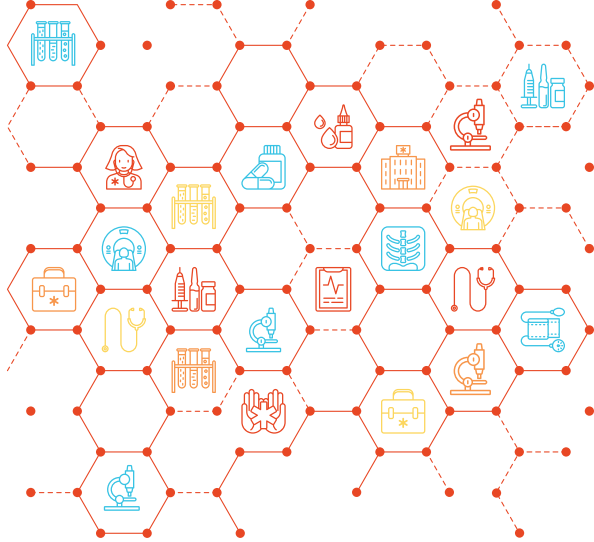


NATIONAL HEALTH RESEARCH FORUM

2019 STRAIGHT TALK

NEW THINKING ON PERSISTENT CHALLENGES

Breakfast Speaker

Robert R. Redfield, MD
Director, Centers for Disease Control and Prevention
Administrator, Agency for Toxic Substances and Disease Registry

Robert R. Redfield, MD, is the 18th director of the Centers for Disease Control and Prevention and administrator of the Agency for Toxic Substances and Disease Registry. He has been a public health leader actively engaged in clinical research and clinical care of chronic human viral infections and infectious diseases, especially HIV, for more than 30 years. He served as the founding director of the Department of Retroviral Research within the U.S. Military's HIV Research Program, and retired after 20 years of service in the U.S. Army Medical Corps. He is a past member of the Office of AIDS Research Advisory Council at the National Institutes of Health, the Fogarty International Center Advisory Board at the National Institutes of Health, and the Advisory Anti-Infective Agent Committee of the Food and Drug Administration.

PANEL 1

Women Researchers Leading Discovery

MODERATOR

Lucinda L. Maine, PhD, RPh
Executive Vice President and CEO, American Association of Colleges of Pharmacy

Lucinda L. Maine serves as executive vice president and CEO of the American Association of Colleges of Pharmacy. As the leading advocate for high quality pharmacy education, AACP works to develop strong academic scholars and leaders, to support excellent professional doctoral and postgraduate degree programs and to build relations with key constituency groups both inside and external to the profession of pharmacy. Prior to assuming her current role in 2002, Maine served as senior vice president for policy, planning and communications with the American Pharmacists Association (APhA). She currently serves on the Board of Directors for Research!America and is an Executive Committee member of the American Foundation for Pharmaceutical Education.

Janine Austin Clayton, MD
NIH Associate Director for Research on Women's Health
Director, NIH Office of Research on Women's Health

Janine Austin Clayton is the architect of the NIH policy requiring scientists to consider sex as a biological variable across the research spectrum. This policy is part of NIH's initiative to enhance reproducibility through rigor and transparency. As co-chair of the NIH Working Group on Women in Biomedical Careers with NIH Director Francis Collins, Dr. Clayton also leads NIH's efforts to advance women in science careers. Prior to joining the ORWH, Dr. Clayton was the deputy clinical director of the National Eye Institute (NEI) for seven years. A board-certified ophthalmologist, Clayton's research interests include autoimmune ocular diseases and the role of sex and gender in health and disease.

Jenny Colombo, PharmD
Vice President of Global Patients and Scientific Affairs,
Takeda Pharmaceutical Company Limited

In her role as vice president of Global Patients and Scientific Affairs, Jenny Colombo works across Research and Development to understand the global health community and prepare for tomorrow's challenges by unlocking connections and partnerships that advance science; move from developing medicines for patients to developing medicines with patients; ensure early and continued, sustainable access to innovative medicines, and assure Takeda's knowledge and leadership relevance for tomorrow. Dr. Columbo has served for the past 22 years in various leadership roles within medical affairs at Roche, Johnson & Johnson, and Takeda. At Takeda, Dr. Colombo also serves as a leader for volunteer and community initiatives to rebuild communities and advance science education, and she is committed to mentoring women in the healthcare industry and has served as a mentor, advisor and leader for the Healthcare Business Women's Association (HBA).

Margaret (Peggy) Hamburg, MD
Foreign Secretary, National Academy of Medicine

Dr. Hamburg is an internationally recognized leader in public health, medicine, and science. She currently serves as foreign secretary for the National Academy of Medicine and chairs the board of the American Association for the Advancement of Science. Dr. Hamburg was the 21st Commissioner of the U.S. Food and Drug Administration, known for advancing regulatory science, modernizing regulatory pathways, and globalization of the agency. Before this, she was founding vice president and senior scientist at the Nuclear Threat Initiative, a foundation dedicated to reducing nuclear, chemical, and biological threats.

Michele Oshman
Director of Federal Advocacy & Alliance Development, Eli Lilly and Company

Michele M. Oshman, director of Federal Advocacy & Alliance Development for Eli Lilly and Company, works in Lilly's Government Affairs office, in Washington, D.C. Ms. Oshman joined Lilly in 2002 as a clinical neuroscience researcher and has served in multiple clinical development and corporate leadership roles. She earned a Six Sigma Black Belt in 2005 and led multiple transformational efforts across the company. She joined the Advocacy team in 2007 and now leads Lilly's federal advocacy engagement with a large portfolio of patient and consumer advocacy organizations, trade associations and coalitions.

Gwen Nichols, MD
Chief Medical Officer, The Leukemia & Lymphoma Society

As LLS's chief medical officer, Gwen Nichols, MD, plays a critical role in advancing cures through a unique combination of clinical, academic and pharmaceutical experience. She oversees LLS's scientific research portfolio, patient services and policy and advocacy initiatives. A physician and scientific researcher, she has dedicated her career to advancing cures for cancers. Most recently, Dr. Nichols was oncology site head of the Roche Translational Clinical Research Center, where she worked to develop new cancer therapies, translating them from the laboratory to clinical trials. Prior to joining Roche in 2007, Dr. Nichols was at Columbia University for more than ten years, where she served as the director of the Hematologic Malignancies Program.

Erin O'Shea, PhD
President, Howard Hughes Medical Institute (HHMI)

Erin O'Shea is president of the Howard Hughes Medical Institute, one of the world's largest biomedical philanthropies. Prior to becoming president in 2016, O'Shea served as HHMI's chief scientific officer. O'Shea maintains a lab at HHMI's Janelia Research Campus. She has been an HHMI investigator since 2000 and is the Paul C. Mangelsdorf Professor of molecular and cellular biology and chemistry and chemical biology at Harvard University. Previously, she served on the faculties of Harvard and the University of California, San Francisco. She serves on the boards of the Albert and Mary Lasker Foundation and Rescuing Biomedical Research and on the scientific advisory board of the Francis Crick Institute. In 2017, *Washingtonian* magazine named O'Shea "one of Washington's 100 most powerful women."

PANEL 2

Collaboration is Key: Exploring the evolving role of cross-sector partnerships as a catalyst to lifesaving progress

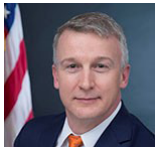
MODERATOR

Jeannie Baumann
Reporter, Bloomberg Law

Jeannie Baumann has covered health policy for *Bloomberg Law* since 2005. She focuses on the intersection of medical research and policy, regulations and law. Jeannie covers the latest developments from the NIH, FDA and Capitol Hill, as well research funding, clinical trial policies, and bioethical issues.

Christopher P. Austin, MD
Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

Christopher P. Austin has served as director of the National Center for Advancing Translational Sciences at the National Institutes of Health since 2012. Prior to this role, Dr. Austin was NCATS' scientific director, focusing on translating basic science discoveries into new treatments and technologies to improve the efficiency of therapeutic/diagnostic development. He founded several initiatives, including the NIH Chemical Genomics Center, the Therapeutics for Rare and Neglected Diseases program, and the Toxicology in the 21st Century program. Before joining NIH in 2002, he led genomic-based target discovery, pharmacogenomic, and neuropsychiatric drug-development programs at Merck. From 2016 to 2018, he served as chair of the International Rare Disease Research Consortium (IRDiRC); Dr. Austin is a member of National Academy of Medicine.



Rick A. Bright, PhD
Deputy Assistant Secretary for Preparedness and Response Director of the Biomedical Advanced Research and Development Authority (BARDA), U.S. Department of Health and Human Services

Rick Bright is the Deputy Assistant Secretary for Preparedness and Response and the director of the Biomedical Advanced Research and Development Authority, a component of the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services. At BARDA, he oversees innovation, development and procurement of medical countermeasures against an array of threats to national security and public health, including chemical, biological, radiological, nuclear threats and pandemic influenza, and emerging infectious diseases. Dr. Bright serves as an international subject matter expert in biodefense, emergency preparedness and response, vaccine, drug and diagnostics development and serves as an advisor to the World Health Organization and the United States Department of Defense.

Gopal Khanna, MBA
Director, Agency for Healthcare Research and Quality (AHRQ)

Appointed in 2017, Director Gopal Khanna leads AHRQ's efforts to meet the Agency's mission of producing evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and working within the U.S. Department of Health and Human Services and with other federal, state, and local partners to make sure that the evidence is understood and used. He came to AHRQ from Illinois, where he was director of the FRAMEWORK Project that developed the vision for Illinois' Healthcare and Human Services Innovation Incubator (HHSi2). Mr. Khanna was also named as a Doer, Dreamer, and Driver in Government Technology's listing of Top 25 public sector innovators.

Richard Loomis, MD
Chief Informatics Officer, Elsevier Clinical Solutions

Dr. Richard Loomis is an industry leader in healthcare IT and informatics with a background in medicine, technology, and business. He recently joined the Clinical Solutions division of Elsevier as the chief informatics officer where he is leading the development of clinical decision support and pathways that span the patient journey. Dr. Loomis completed a fellowship in biomedical informatics at Harvard Medical School and trained in anesthesiology at Beth Israel Deaconess Medical Center. He has served as vice chair of the Healthcare Information and Management Systems Society Electronic Health Record Association and has participated in policy and regulatory initiatives in interoperability and public health.

Melinda Richter
Global Head of Johnson & Johnson Innovation, JLABS

Melinda Richter fosters the Johnson & Johnson Family of Companies external R&D engine and supports the innovation community by creating capital-efficient commercialization models that give early stage companies a big company advantage. By providing infrastructure, services, educational programs and networks in global hotspots, JLABS is the best place to start a company working in healthcare, with a specific emphasis on Johnson & Johnson's sectors: consumer, medical device and pharmaceuticals. Prior to joining JLABS, Melinda was Founder and CEO of Prescience International, an award-winning firm dedicated to accelerating research to the patient. Melinda founded Prescience after she had a medical emergency that left her questioning the efficiency and efficacy of the healthcare system. With the tenacity and resolve of a patient looking for a better solution, she set out to create a better model, which now forms the basis for JLABS' operational infrastructure.

Lynn O'Connor Vos
President & CEO, Muscular Dystrophy Association

Lynn Vos is the president and CEO of the Muscular Dystrophy Association (MDA), dedicated to transforming the lives of people affected by muscular dystrophy, ALS and related neuromuscular disease. She is focused on asserting MDA's leadership in research and care and establishing MDA as the preeminent advocate and provider of services to families affected by neuromuscular disease. Lynn is leading MDA in the development of a comprehensive data hub, MOVR, which will drive the advancement of research, new technologies and care strategies and galvanize both the industry and research arenas to pioneer better care and more cures. She was named Woman of the Year by the Healthcare Business Women's Association in 2005, was nominated by the YWCA to the Academy of Women Achievers in 1999 and received the Corporate Achievement Award from The Jed Foundation in 2006.

PANEL 3

Then, Now, Imagine

MODERATOR

Steve Clemons
Editor at Large, The Hill

Steve Clemons is editor at large of *The Hill*, America's most read political media platform. Previously, Clemons served as editor at large of *The Atlantic*. Clemons is also a foreign policy and politics contributor to MSNBC and is proprietor of a popular political blog, *The Washington Note*. He also founded and serves as senior fellow of the American Strategy Program at the New America Foundation where he previously served as executive vice president. Prior to this, Clemons served as executive vice president of the Economic Strategy Institute, was senior economic & international affairs advisor to Senator Jeff Bingaman, and was the founding executive director of the Nixon Center, now re-named the Center for National Interest.

Tracey D. Brown, MBA, BChE
Chief Executive Officer, American Diabetes Association (ADA)

Tracey D. Brown is chief executive officer of the American Diabetes Association, the nation's largest voluntary health organization and a global authority on diabetes. Brown herself has been thriving while living with type 2 diabetes for over 15 years. She is the first CEO in the organization's almost 80-year history that is living with type 2 diabetes and is committed to stopping the diabetes epidemic. Brown joined the ADA in 2018 after her tenure as senior vice president of operations and chief experience officer at Sam's Club, a division of Walmart, Inc., where she was responsible for creating meaningful member experiences, directing member strategy, marketing and branding, go-to market execution, data and analytics and membership operations.

Mikael Dolsten, MD, PhD
Chief Scientific Officer and President, Worldwide Research, Development and Medical, Pfizer

Dr. Dolsten is the chief scientific officer and president of worldwide research, development and medical at Pfizer, promoting the company's global scientific leadership in small molecules, biologics and vaccines. In this role, he oversees a variety of research units, including Oncology, Internal Medicine, Inflammation & Immunology, Vaccines, Rare Disease, as well as the Centers for Therapeutic Innovation. Prior to joining Pfizer in 2009, Mikael was president of Wyeth Research. Before that, Mikael served as EVP and head of worldwide research for Boehringer Ingelheim. He is a governor of the New York Academy of Sciences and a fellow of the New York Academy of Medicine, and serves on the Science and Regulatory Executive Committee of The Pharmaceutical Research and Manufacturers of America (PhRMA) as well as the PhRMA Foundation Board of Directors.

Gary H. Gibbons, MD
Director, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health

Gary H. Gibbons, MD, is director of the National Heart, Lung, and Blood Institute at the National Institutes of Health, where he oversees the third largest institute, with an annual budget of approximately $3 billion and nearly 1,000 employees. Dr. Gibbons has enhanced NHLBI's investment in discovery science by steadily increasing the payline and number of awards for early and established investigators. He has provided leadership on key NIH initiatives such as precision medicine and biomedical research workforce diversity. Dr. Gibbons is a member of the Institute of Medicine of the National Academies of Sciences, a Robert Wood Johnson Foundation Minority Faculty Development Awardee, a Pew Foundation Biomedical Scholar, and an Established Investigator of the American Heart Association.

Gary J. Nabel, MD, PhD
Chief Scientific Officer, Global Research and Development, and Head of the North American R&D Hub, Sanofi

Dr. Gary Nabel is chief scientific officer, Global Research and Development, and head of the North American R&D Hub at Sanofi. In addition to serving as senior vice president for the company, Dr. Nabel also oversees the Breakthrough Lab, which developed the first trispecific antibodies now in development for HIV as published in *Science*, as well as cancer immunotherapies and novel vaccines. The Chief Scientific Office sponsors the iAwards, the Postdoctoral and Innovation Fellows Programs, and the Global Science Awards. Dr. Nabel joined Sanofi in 2012 from the National Institutes of Health, where he served as director of the Vaccine Research Center since 1999.

David Skorton, MD
President and CEO of AAMC (Association of American Medical Colleges)

Dr. Skorton began his leadership of the AAMC, which represents the nation's medical schools, teaching hospitals, and academic societies, in 2019 after a distinguished career in government, higher education, and medicine. Most recently, Dr. Skorton served as the 13th secretary of the Smithsonian Institution, where he oversaw 19 museums, 21 libraries, the National Zoo, numerous research centers, and education programs. Prior to that, he served as president of two universities: Cornell University (2006 to 2015) and the University of Iowa (2003 to 2006), where he also served on the faculty for 26 years and specialized in the treatment of adolescents and adults with congenital heart disease. A pioneer of cardiac imaging and computer processing techniques, he also was co-director and co-founder of the University of Iowa Adolescent and Adult Congenital Heart Disease Clinic.

PANEL 4

Leveraging Data to Accelerate Medical Progress

MODERATOR

Jenny Luray, MPA
Senior Advisor, Research!America

As senior advisor, Jenny Luray works across Research!America's policy, development and communications departments to build partnerships and enhance capacity. Previously, Ms. Luray directed U.S. policy and government affairs for BD and Abbott, where she partnered with internal and external stakeholders to address regulatory, payment and public health issues related to diagnostics, medication safety, antibiotic stewardship and insulin monitoring among other issues. In addition, Ms. Luray served as chief of staff to former Senator Barbara Mikulski, and legislative director to Congresswoman Nita Lowey. Ms. Luray currently serves on the Governing Committee of National Evaluation System for health Technology Coordinating Center (NESTcc), an FDA-funded effort to develop the use of real-world data in medical device oversight.

Jeff Andrews, MD, FRCSC
Worldwide Medical Director for Women's Health and Cancer, BD Life Sciences

A board-certified obstetrician & gynecologist, Dr. Andrews has provided women with healthcare in community settings in both metropolitan Toronto, Ontario, Canada, and Washington, D.C., and as associate professor at Duke University Medical Center and Vanderbilt University Medical Center. Jeff held several administrative roles at academic centers, including medical director of the Women's Services, and director of quality improvement and patient safety, director of the Vulvar Diseases Clinic, and lead physician of the Colposcopy Clinic. Before joining BD, Dr. Andrews was the chief medical research advisor for the American Society for Colposcopy and Cervical Pathology.

Ned Braunstein, MD
Senior Vice President, Regulatory Affairs, Pharmacovigilance and Risk Management, Regeneron

Ned Braunstein joined Regeneron in 2009, and serves as senior vice president, Regulatory Affairs, Pharmacovigilance and Risk Management. Prior to Regeneron, he worked at Columbia University College of Physicians and Surgeons for 13 years as assistant and then associate professor of Medicine and at Merck & Co., Inc, for nine years in positions of increasing responsibility in Clinical Research, Regulatory Affairs and Global Human Health.

Peter Marks, MD, PhD
Director of the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration

Dr. Marks joined the FDA in 2012 as deputy center director for CBER and became center director in 2016. Dr. Marks is board certified in internal medicine, hematology and medical oncology, and is a Fellow of the American College of Physicians. CBER is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies. Dr. Marks and center staff are committed to facilitating the development of biological products and providing oversight throughout the product life cycle.

Eleanor M. Perfetto, PhD, MS
Executive Vice President, Strategic Initiatives, National Health Council (NHC)

Dr. Eleanor M. Perfetto was named senior vice president of Strategic Initiatives for the National Health Council in 2015 and was promoted to executive vice president in 2019. She also holds a part-time faculty appointment at the University of Maryland, Baltimore School of Pharmacy where she is professor of Pharmaceutical Health Service Research. Her research and policy work primarily focus on patient engagement in comparative effectiveness and patient centered-outcomes research, medical product development; patient-reported outcome selection and development; and health care quality.

Joe V. Selby, MD, MPH
Executive Director, Patient-Centered Outcomes Research Institute (PCORI)

A family physician, clinical epidemiologist, and health services researcher, Selby has more than 35 years of experience in patient care, research, and administration. He is responsible for identifying strategic issues and opportunities for PCORI and implementing and administering programs authorized by the PCORI Board of Governors. Selby joined PCORI from Kaiser Permanente, Northern California, where he was director of the Division of Research for 13 years. Selby was elected to membership in the Institute of Medicine in 2009 and was a member of the Agency for Healthcare Research and Quality study section for Health Care Quality and Effectiveness from 1999 to 2003.

Keith Yamamoto, PhD
Professor; Vice Chancellor for Science Policy and Strategy; Director, UCSF Precision Medicine

Dr. Keith R. Yamamoto is UCSF vice chancellor for science policy and strategy, director of precision medicine for UCSF, and professor of cellular and molecular pharmacology at UCSF. He is a leading researcher investigating transcriptional regulation by nuclear receptors. He has led or served on numerous national committees focused on public and scientific policy, public understanding and support of biological research, and science education; he chairs the Coalition for the Life Sciences, and sits on the National Academy of Medicine Council and the National Academy of Sciences Division of Earth and Life Studies Advisory Committee. He is a member of the advisory board for Lawrence Berkeley National Laboratory and the Board of Directors of Research!America.

CLOSING REMARKS

Ned Sharpless, MD
Acting Commissioner, Food and Drug Administration

Norman E. "Ned" Sharpless, MD, became Acting Commissioner of Food and Drugs on the afternoon of April 5, 2019. Previously, he was confirmed as the 15th director of the National Cancer Institute (NCI) on October 17, 2017. Prior to his NCI appointment, Dr. Sharpless served as the director of the University of North Carolina (UNC) Lineberger Comprehensive Cancer Center, a position he held since January 2014. Dr. Sharpless was a Morehead Scholar at UNC–Chapel Hill and received his undergraduate degree in mathematics. He went on to pursue his medical degree from the UNC School of Medicine, graduating with honors and distinction in 1993. He then completed his internal medicine residency at the Massachusetts General Hospital and a hematology/oncology fellowship at Dana-Farber/Partners Cancer Care, both of Harvard Medical School in Boston. After two years on the faculty at Harvard Medical School, he joined the faculty of the UNC School of Medicine in the Departments of Medicine and Genetics in 2002. He became the Wellcome Professor of Cancer Research at UNC in 2012.

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Visit our Student Advocacy webpage to apply!
Application deadline is September 20.

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In addition, Research!America is introducing the new **Science Meets Science** initiative, which will fund activities creating partnerships between social and STEM scientists.

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