

Increasing Accessing to Nonprescription Drugs

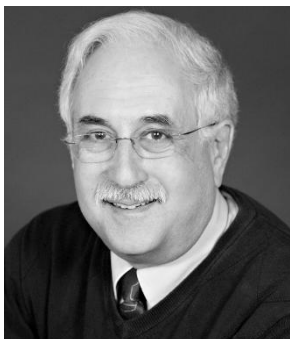
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Speaker Biographies



Russell D. Bradford is Senior Vice President at PEGUS Research, a CRO specializing in consumer behavior research supporting prescription-to-nonprescription and direct-to-nonprescription drug development programs. He partners with sponsors to design, implement, and interpret studies intended to inform FDA regulatory decision-making, including label comprehension, self-selection, actual-use, and real-world evidence studies, as well as programs incorporating Additional Conditions for Nonprescription Use. Dr. Bradford received his medical degree from the University of Utah and completed residency training in internal medicine and pediatrics followed by a fellowship in pediatric infectious diseases at the University of Alabama at Birmingham, where he also earned a Master of Science in Public Health and later served on the faculty in the Departments of Pediatrics and Medicine. He left academia in 2011 to join PEGUS Research, where he has contributed to the strategic and scientific leadership of dozens of nonprescription drug development programs across therapeutic areas, while continuing to provide inpatient pediatric care to children in his local community. Disclosure Statement: Russell Bradford is employed by a company that contracts with medical product sponsor companies, he individually has no direct relationships with sponsor companies.



Eric Brass received his M.D. and Ph.D. (Pharmacology) degrees from Case Western Reserve University. He completed an internal medicine residency and clinical pharmacology fellowship at the University of Washington. After holding faculty positions at the University of Colorado and Case Western Reserve University, Dr. Brass moved to the UCLA School of Medicine where he was Chair of the Department of Medicine at the Harbor-UCLA Medical Center from 1994-2000. He is currently Professor Emeritus of Medicine, David Geffen School of Medicine at UCLA. Dr. Brass has long-standing interests in drug discovery, development and regulation, with a particular focus on the challenges of prescription to OTC switches. He served as a member, and then as Chair, of the FDA's Nonprescription Drugs Advisory Committee. Subsequently he has served as a consultant to a number of companies on nonprescription drug development strategies. Disclosures Statement: Dr. Brass has authored over 200 scientific papers, including several related

to nonprescription drug development and regulatory issues. In the past 36 months Dr. Brass has served as a consultant to Leadiant Biosciences, Novo Nordisk, Kenvue, 3D Communications, Bayer Pharmaceuticals, HRA Pharma/Perrigo, Alimentiv, Consumer Healthcare Products Association, and Lexicon Pharmaceuticals. Dr. Brass has an ownership position in ExBaq LLC.



Brian Canter is an Assistant Policy Research Director on the Biomedical Innovation team working on policy solutions to improve development, regulatory review, and evidence generation for broadening access and availability to medical products. He manages one of the Biomedical Innovation team's cooperative agreements with the U.S. Food and Drug Administration (FDA). Brian's portfolio of work spans several key areas within the biomedical innovation space. As the lead researcher on regulatory considerations to enable greater competition for biologics, he has evaluated the value of the interchangeability designation and derived strategies to foster future biosimilar development for cell and gene therapies. Supporting the Institute's thought leadership to modernize clinical trials, Brian guides the policy work for the Coalition for Advancing Clinical Trials at the Point of Care. Brian has also managed several projects within the Institute's regulatory science work, including public meetings convened with FDA to advance clinical trial innovation and premarket safety analytics. In addition to biomedical innovation, Brian has done extensive work within the Institute's 21st Century Public Health and Population Health portfolio. He oversaw a project focused on addressing the burden of respiratory viruses through reduction of disease transmission. During the COVID-19 pandemic, Brian led the Institute's work to maximize adoption of therapeutics, with a focus on Test-to-Treat pathways. Prior to joining Duke-Margolis, Brian completed a PhD in Biomedical Sciences with a focus in Biomedical Engineering from Rutgers University. His thesis research focused on utilizing radiation therapy systemically to treat metastatic breast cancer that spread to bone. Brian also graduated with a Bachelor of Science in Biomedical Engineering from Tufts University. Disclosure Statement: Brian Canter has no conflicts of interest to disclose.



Barbara Cohen served as a social science reviewer in FDA's Division of Nonprescription Drugs for nearly fifteen years. She reviewed hundreds of industry meeting packages representing a wide array of therapeutic categories for Rx-OTC switch (including within the ACNU paradigm), and presented at eight public meetings of FDA Advisory Committees. Ms. Cohen's role was to advise on consumer studies that would address FDA clinical concerns regarding appropriate self-selection and use. Ms. Cohen's review expertise in label comprehension and self-selection was

integral to the NDA approvals for both Opill and Narcan, and she was the social scientist of record in the earlier nonprescription approvals of Oxytrol, Nasacort, and Differin, and Sklice. In addition to her ongoing portfolio, Ms. Cohen led a high-profile FDA sponsored innovative label comprehension study to explore whether a novel FDA developed OTC Drug Facts Label was adequately understood by potential users. She and her co-authors published the results in the May 27, 2020 New England Journal of Medicine, and she was a recipient of the 2019 FDA Behavioral and Social Science Research Award for this initiative. Agency Announcement.

Prior to joining FDA, Ms. Cohen served as a federal social scientist at CMS and SSA, and in the earlier years of her career, she held a series of increasingly responsible positions in the pharmaceutical industry as a corporate marketing researcher. She holds a BA magna cum laude from the University of Rochester and an MPA from Princeton University's School of Public and International Affairs. Ms. Cohen retired from FDA in December 2024. She is currently the President of Cohen Nonprescription Consulting LLC. Disclosure Statement: Barbara Cohen is a consultant to companies developing nonprescription drugs.



Michelle Cope is Director of Federal and State Pharmacy and Regulatory Affairs at the National Association of Chain Drug Stores (NACDS). In this role, she works to advance NACDS's health and wellness agenda at the federal and state levels. Over the years, Michelle has supported the advancement of policy initiatives that expand patient access to essential pharmacy services, enhance pharmacy operations, and support pharmacies' ability to serve the public's growing health care needs. Michelle joined NACDS in 1998 and, since that time, has held various positions within the government affairs and policy departments. Her deep institutional knowledge and decades of experience in pharmacy related policy enable her to advise on matters related to strengthening patient access to high quality, community-based care. Disclosures Statement: Michelle Cope has no disclosures to share for this meeting.



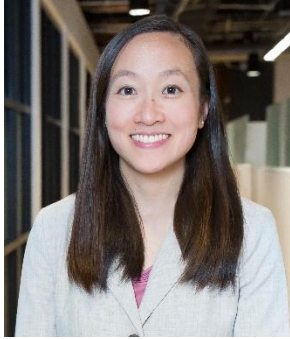
Ruth S. Day is the Director of the Medical Cognition Lab at Duke University. She is a professor in Psychology & Neuroscience and in Linguistics, Senior Fellow at the Duke Center for Aging, and Affiliated Faculty in the Trent Center for Bioethics, Humanities, and Medicine. She has a PhD in cognitive science from Stanford and was on the faculty at Stanford and Yale Universities. Other previous appointments include Visiting Scholar at Carnegie-Mellon University, Faculty at the Linguistics Society of America Institute, and Fellow at the Center for Advanced Study in the Behavioral Sciences. Dr. Day's research focuses on Basic Cognition (attention, memory,

comprehension, problem solving, decision making) and on Medical Cognition (how healthcare professionals, patients, and the general public understand, remember, and use information about health conditions and treatments, especially drugs and medical devices). She was a charter member of the FDA Drug Safety and Risk Management Advisory Committee and has served as a voting member on many other FDA Advisory Committees concerning drugs to treat a wide variety of health conditions, such as arthritis, gastrointestinal, dermatology, endocrine, metabolic, cardiac, renal, oncology, psychiatric, and nervous system conditions. Professor Day has many teaching awards, including “Ten Best Teachers” at Yale and “Distinguished Teacher” at Duke. She taught a National Science Foundation course on “Cognition and Teaching” to faculty across the U.S. in all academic disciplines for many years and has given hundreds of presentations to academic, professional, and government organizations. Her last presentation to the U.S. Congress was on “Cognitive Accessibility of Patient Medication Information.” Disclosure Statement: Ruth Day has no disclosures to share.



Alankar Gupta is a physician–executive with over two decades of leadership experience spanning pharmaceutical innovation, consumer health, and digital therapeutics. He currently serves as Vice President and Head of NA Medical Affairs & Safety Sciences at Kenvue, where he leads integrated medical strategy, evidence generation, and scientific engagement across North America. Dr. Gupta is widely recognized for his expertise in Global Rx-to-OTC switch strategy, having led and contributed to multiple high-impact regulatory Rx-to-OTC switch programs across the U.S., Europe, Canada, and Japan. His work has supported the transition of well-known therapies to nonprescription status, advancing consumer access while maintaining strong safety and efficacy standards. He has deep experience engaging with global regulatory authorities, including the FDA, Health Canada, MHRA, and other agencies, and has played a pivotal role in shaping evidence frameworks that support responsible self-care. Prior to Kenvue, Dr. Gupta held senior leadership roles at Click Therapeutics, Sanofi, Merck & Co., and Novartis, where he led global medical affairs, clinical development, and digital health initiatives. His work includes advancing late-stage clinical programs, pioneering decentralized trial designs, and integrating real-world evidence into regulatory and payer strategies. Dr. Gupta holds an MD, an MS, and an MBA, and has authored multiple peer-reviewed publications. He is passionate about advancing patient access to novel, safe, effective, and evidence-based nonprescription therapies, and about leveraging innovation—including digital health, RWE and AI—to transform the future of self-care. Disclosure Statement: Alankar Gupta is an employee of Kenvue and may hold stock or stock options in the company. Kenvue is engaged in the development and commercialization of consumer health products, including nonprescription medicines. Dr. Gupta reports no other

financial relationships, consulting roles, advisory positions, or funding sources relevant to the content of this workshop. The views expressed are his own and do not necessarily reflect the views of Kenvue or its affiliates.



Anna Hung is a pharmacist and health services researcher interested in payer and patient decision making related to pharmacy benefits. Previously, she collaborated with the Defense Health Agency to evaluate the budgetary impact of their antidiabetic drug formulary changes. She has also worked with a variety of managed care organizations to assess their drug utilization and clinical management programs. Her methodological research interests include health care cost evaluations, quasi-experimental study designs, and stated preference research. Dr. Hung received her Doctor of Pharmacy, Master of Science, and Doctor of Philosophy from the University of Maryland. Her PhD is in pharmaceutical health services research, with concentrations in pharmacoeconomics, comparative effectiveness research, and patient-centered outcomes research. Prior to joining the Department of Population Health Sciences, she completed a post-doctoral fellowship at the Duke Clinical Research Institute and served as Co-Chief Fellow. Disclosure Statement: Anna Hung has a parent employed as a statistician at U.S. FDA. She receives honoraria from the American Medical Association as an Editorial Fellow for JAMA Internal Medicine and in 2025 received honoraria from the Academy of Managed Care Pharmacy. She also receives research funding from AstraZeneca, and prior to July 1, 2025, she received consulting fees from Genentech/Roche to advise on a research study.



Irene Laurora is a senior pharmaceutical executive with more than 30 years of leadership experience across Medical Affairs, Clinical Development, Regulatory Strategy, and Consumer Healthcare. She currently serves as Senior Director, Medical and Regulatory Affairs at Perrigo, where she leads global development and medical strategy and implementation for Rx-to-OTC switches. A recognized industry leader in switch science, Dr. Laurora played a pivotal role in the historic Rx-to-OTC approval of Opill, the first daily oral contraceptive available over the counter in the United States. She led the overall clinical program and risk–benefit assessments, and the scientific preparation for the FDA Advisory Committee, culminating in a unanimous vote in favor of approval—a milestone for women’s reproductive autonomy and public health. Throughout her career, she has held senior roles at Pfizer Consumer Healthcare, Bayer, and HRA Pharma, driving major new product launches and serving as a company spokesperson for safety, efficacy, and benefit–risk matters. Her leadership spans therapeutic areas including analgesics,

sleep, cardiovascular health, and contraception. She holds a Doctor of Pharmacy from the Medical College of Virginia and completed a post-doctoral fellowship at Rutgers University. She is also widely recognized for her leadership in advancing women and supporting families with disabilities—honored as Working Mother of the Year (2012) and serving on the Executive Board of Autism NJ from 2017–2022. Disclosure Statement: Irene Laurora is an employee of a Consumer Healthcare Products Company, Perrigo.



Mary Alice Lawless is Chief Executive Officer of Biograph Inc., where she leads a Center of Excellence focused on expanding access to healthcare and improving the patient and consumer experience through disciplined strategy, technology systems, and cross-sector collaboration. She is recognized for helping organizations address complex access challenges in ways that align public health objectives, operational feasibility, and institutional accountability. Mary Alice is a chief architect of the Biograph by Amwell Solution for Additional Conditions for Nonprescription Use, or ACNU, an emerging framework developed in response to the evidence-based public health challenge of undertreatment. Her work has centered on building scalable, credible approaches that connect trusted participants across the healthcare ecosystem to support responsible and consistent expansion of nonprescription access. Over the course of her career, Mary Alice has worked with drug and device manufacturers, providers, payers, health systems, pharmacies, and consumer healthcare. She is especially respected for operating at the complex intersection of health policy, regulatory design, market adoption, and care delivery, helping organizations translate innovation into models that can withstand scrutiny and will deliver outcomes. Most recently, she has focused on digital care and the delivery of interventions that balance clinical rigor with patient experience. She also led a coalition of thought leaders, technology partners, and data system participants in providing strategic and process input to the FDA as the agency developed the ACNU pathway, including engagement through a Pre-RFD, Pre-IND activity, and multiple listening sessions. Her leadership reflects a sustained commitment to public-private collaboration and the advancement of access innovation. Mary Alice is a frequent contributor to industry publications, a speaker at major healthcare forums, and an active participant in professional organizations. Her honors include IBM’s Creative Use of Technology Award and the Healthcare Businesswomen’s Association Rising Star Award. Earlier in her career, she worked in national broadcast journalism and pursued advanced study at the University of South Carolina Graduate School of Journalism and the University of Notre Dame, Stayer Center for Executive Education. Disclosure Statement: Mary Alice Lawless has financial interests in Biograph Inc.



Henry W. Lim is the former Clarence S. Livingood chair and chairman of the Department of Dermatology (1997-2017), Henry Ford Health, Detroit, Michigan, USA. Dr. Lim has served as president of the American Academy of Dermatology (AAD), American Board of Dermatology, American Dermatological Association, American Society for Photobiology, and International Union of Photobiology. In 2023, he was elected as president of the International League of Dermatological Societies, which consists of over 200 international societies from over 100 countries as members, representing over 180,000 dermatologists. He was bestowed an Honorary Membership of the AAD in 2020, and in March 2026, he was awarded the AAD Gold Medal, the highest honor given by the AAD. He has published more than 700 articles and edited 11 textbooks (with over 43,000 citations in Google Scholar with an h-index of 105). Disclosure Statement: Henry W. Lim has served as an investigator for Incyte, La Roche Posay, Pfizer, and PCORI; as a consultant for ISDIN, Beiersdorf, L’Oreal, Eli Lilly Zerigo Health, Skinosive, Kenvue, Cantabria Labs, NAOS, and Boehringer Ingelheim; and as a speaker on general education session for La Roche Posay, Cantabria Labs, NAOS, Pfizer, ISIN, Clinuvel, and Rxilient.



Dustin Little is a nephrologist and global clinical head in late cardiovascular, renal, and metabolism in biopharmaceuticals research and development for AstraZeneca, located in Gaithersburg, MD. He joined AstraZeneca in 2016 after serving for 9-years as a physician in the United States Army. Dustin has provided clinical leadership for multiple first-in-class or potential first-in-class novel treatments for cardio-kidney disease and participates in several consortia aimed at developing and validating patient-relevant clinical trial endpoints to improve trial feasibility and drive innovation. Passionate about improving outcomes for individuals living with cardio-kidney-metabolic disease, Dustin continues to see patients as a volunteer at a Washington, DC-area nephrology clinic. Disclosure Statement: Dustin Little is an AstraZeneca full-time employee and shareholder.



Karen Minerve Murry is Acting Director of the Office of Nonprescription Drugs (ONPD) at FDA. In her role, she works on multiple innovative and strategic initiatives with the goal of improving self-care for Americans through expanded availability of safe, effective, and affordable nonprescription medicines. She is an endocrinologist who received her medical degree from the University of Texas Southwestern Medical School, and her postgraduate medical training and fellowship at Walter

Reed Army Medical Center. After Army service as Chief of Endocrinology at Eisenhower Army Medical Center, she began her FDA career in the Division of Metabolism and Endocrinology Products, where she served as Diabetes Team Leader. She has served as Deputy Director for Nonprescription Drugs since 2014. She has served as clinical lead on multiple landmark projects, including the rule for an Additional Condition for Nonprescription Use, which harnesses the power of technology to make possible wider nonprescription drug availability; the Naloxone Model Drug Facts Label project that made possible the first nonprescription naloxone product, which was followed by a 30% decrease in opioid overdose deaths; and multiple areas of implementation of the monograph reform provisions of the CARES Act. Disclosure Statement: Karen Murry has no personal or financial relationships to disclose.



Valerie J. Parker is an Assistant Policy Research Director at Duke-Margolis, managing one of the institute's cooperative agreements with the US Food and Drug Administration as well as overseeing a core workstream of the institute's Real-World Evidence Collaborative, focused on international regulatory efforts to harmonize real-world data and real-world evidence standards. During her time at Duke-Margolis, Valerie has collaborated and led projects on a range of topics including artificial Intelligence; digital health and data; rare diseases; and pharmacology. In addition to her work with the institute, Valerie has worked with Amgen Inc. as a manager on their Global Regulatory and R&D team, where she assessed and collated international regulator responses to COVID-19 clinical trial standards and laboratory developed tests. She began her career at Epic Systems Corporation where she worked as an implementation project manager. In this capacity, she was able to see first-hand health systems in action and how health care data is collected and stored. Valerie holds a Master of Science in Global Health and a Bachelor of Arts in Cultural Anthropology from Duke University, and she is an active member of the Duke alumni community.



Sue Peschin serves as President and CEO of the Alliance for Aging Research, the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. Since 2012, Ms. Peschin has led the Alliance team on efforts to increase federal investment in aging research; develop Talk NERDY (Nurturing Engagement in Research and Development with You), a research engagement network; and advocate for equitable Medicare affordability and access. Sue is an accomplished speaker and thought leader, whose writing has been published in peer-reviewed journals and top-tier newspapers. Ms. Peschin serves on the Boards of Directors for the Association of Black Cardiologists; the National Health

Council; and the U.S. Pharmacopeia (USP). She also serves as a member of the Science Advisory Board for the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation and on the UMD Claude D. Pepper Older Americans Independence Center Community Advisory Board. Previously, Sue served in senior roles at the Alzheimer's Foundation of America, Consumer Federation of America, Hadassah, and the Violence Policy Center. Disclosure Statement: Sue Peschin has no disclosures to share.



Thomas Rodes is a Policy Research Associate at the Duke-Margolis Institute for Health Policy. He co-leads the Duke-Margolis ReVAMP Drug Supply Chain Consortium, working to generate effective policy solutions that promote a reliable drug supply chain and reduce the frequency and severity of drug shortages. His work on Duke-Margolis' Biomedical Innovation portfolio has also included a wide range of issues in FDA regulatory science and policy, as well as public health and pandemic preparedness. Prior to joining Duke-Margolis, he received his Master's degree in Public Policy from the University of Virginia. Disclosure Statement: Thomas Rodes has no conflicts of interest to disclose.



Mariana Social is an associate professor of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health, with a joint appointment at the Johns Hopkins Carey Business School. Prof. Social researches ways to improve access and affordability of prescription drugs. Specific topics include the global pharmaceutical supply chain, gene therapies, generics and biosimilar markets, and ways to control spending without restricting access to prescription drugs. Dr. Social has authored over 100 peer-reviewed studies and has frequent engagements in printed media, radio, and TV. Dr. Social routinely advises states, Congress, and the US government on biopharmaceutical pricing, regulation and supply chains, having provided testimony before the US Congress, the FDA, and various states on such issues. Dr. Social has been a member of the World Health Organization Technical Advisory Group on Pricing Policies for Medicines since 2023. Dr. Social is a physician trained in adult neurology. She holds a master's in public policy from Princeton University and a PhD in Public Health/Health Systems from Johns Hopkins University. Disclosure Statement: Mariana Social receives research grants to Johns Hopkins Bloomberg School of Public Health from the following institutions: Arnold Ventures, California Department of Health Care Access and Information, ERIC The ERISA Industry Committee, U.S. Department of War. In addition, Prof. Social receives internal research funds from Johns Hopkins University.



David Spangler is Senior Vice President, Legal, Government Affairs and Policy with the Consumer Healthcare Products Association, and leads the association's team of eight across legal, government affairs, and policy functions. He has particular expertise in regulatory matters. Spangler joined CHPA in 1984 as a legislative analyst. He subsequently served in a number of roles for the association in the president's office, project management, international affairs, and, after completing law school in 1995, the association's legal department. Spangler was named a vice president in 1997, and a senior vice president in 2006. His responsibilities were expanded to his current role in 2019. Spangler is a member of the District of Columbia Bar as well as the American Society of Association Executives. He authored the chapter on OTC medicines in "Modern Pharmaceutical Industry: A Primer" (Jacobsen and Wertheimer, eds., 2009) and has served on a range of committees and working groups for the Food and Drug Law Institute and the Global Self-Care Federation. Spangler earned his Certificate in Organizational Management in 1991 from the U.S. Chamber of Commerce's Institute for Organization Management. Disclosure Statement: David Spangler is participating in this public workshop on behalf of CHPA, which represents and is funded by over 70 manufacturers of nonprescription medicines, dietary supplements, and OTC medical devices, including medicines switched from prescription to nonprescription status.



Michael Wolf is the James R. Webster Jr. Professor of Medicine within the Feinberg School of Medicine at Northwestern University. He also serves as Associate Division Chief (General Internal Medicine), Associate Vice Chair (Medicine), and Director of both Northwestern's Center for Applied Health Research on Aging and Claude D. Pepper Older Americans Independence Center. As a cognitive-behavioral scientist and health services researcher, he has specific expertise in cognitive aging, health literacy, medication safety and adherence. For the past two decades, Dr. Wolf has led: 1) observational studies investigating individual, care team, healthcare system, and community-level determinants of health services use, health status, clinical and treatment outcomes; and 2) multi-site pragmatic clinical trials testing both the effectiveness and fidelity of community and healthcare system-based interventions that leverage health and consumer technologies to improve care quality and medication safety through improved patient engagement and care management. Disclosure Statement: Michael Wolf is engaged in activities such as speaking, advising, consulting, or providing education programs for Luto Research, Ltd. and the Patient-Centered Outcomes Research Institute (PCORI).



H. Shonna Yin is a general academic pediatrician and an Associate Professor of Pediatrics and Population Health at the NYU Grossman School of Medicine. She is a federally funded researcher who has spent 15+ years examining strategies to improve pediatric healthcare quality and safety, using a health literacy lens. A large focus of her research centers on the intersection between health literacy and medication safety, including the development and evaluation of low literacy interventions to improve parent understanding of medication instructions. Dr. Yin's NIH/NICHD-funded research supported the identification of best practices in the labeling/dosing of pediatric prescription medication labels and dosing tools, informing clinical practice and policy change. This has included AAP Policy Statements, as well as pharmacy standards-setting guidances from the US Pharmacopoeia and NCPDP. Dr. Yin is also funded via the FDA's Safe Use Initiative to examine how EHRs can be leveraged to promote pharmacy adoption of dosing best practices. Her work using a health literacy-informed approach to improve provider-parent communication of medication instructions was the focus of her research as a RWJ Foundation Physician Faculty Scholar and a Pfizer Fellow in Clear Health Communication. Dr. Yin has been a key member of the CDC-initiated PrOTECT (Prevention of Overdoses & Treatment Errors in Children Taskforce) initiative to reduce medication overdoses in children since it was formed in 2008, and served as the AAP's representative to this group. For 6 years, she served as an Executive Committee Member of the AAP's Council on Quality Improvement and Patient Safety. Her contributions to pediatric medication safety led her to be selected to receive the 2017 Institute for Safe Medication Practices Cheers Award in recognition for outstanding research on strategies to prevent parent medication administration errors. Dr. Yin is a graduate of MIT and the University of Rochester School of Medicine. She completed residency training in Pediatrics and a Masters of Science degree in Clinical Investigation at the NYU School of Medicine. Disclosure Statement: Shonna Yin reports research funding from NIH/NICHD, FDA, CDC, PCORI, RWJF, Pfizer.